ASCLS Mission/Vision Statement

The American Society for Clinical Laboratory Science serves as the voice of all clinical laboratory professionals, creating a vision for the advancement of the clinical laboratory practice field, and advocating the value and role of the profession ensuring safe, effective, efficient, equitable, and patient-centered healthcare.

ASCLS Core Values

Core Values include enhancing quality standards and patient safety; providing professional development opportunities; promoting expanded roles and contributions of clinical laboratory professionals to the healthcare team; increasing the diversity in the profession; and expanding the voice and role of under-represented individuals and groups.

ADDRESS CHANGES
Postmaster: Send address changes to Clinical Laboratory Science 6701 Democracy Blvd, Suite 300 Bethesda MD 20817

ASCLS MEMBER EDITORS
Editor-in-Chief
David G Fowler PhDCLS(NCA)
Office of the Associate Vice Chancellor for Academic Affairs University of Mississippi Medical Center 2500 North State Street Jackson MS 39216 601-815-1149; fax 601-984-2970 dfowler@acadaff.umsmed.edu

Continuing Education Editor
George A Fritsma MS MT(ASCP)
The Fritsma Factor http://www.fritsmafactor.com 153 Redwood Drive Trussville AL 35173 205-821-5641, fax 205-975-7302 george@fritsmafactor.com

Clinical Practice Editor
Bernadette Rodak MS CLSpH(NCA)
Clinical Laboratory Science Program Indiana University Clarian Pathology Laboratory 350 West 11th Street, 6002F Indianapolis IN 46202 317-491-6163 broidak@iuui.edu

Research and Reports Editor
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59th Clinical Research Division/SGRL 2200 Berquist Dr., Bldg. 4430 Lackland AFB TX 78236-9908 210-292-6555, fax 210-292-6053 david.mcglasson@lackland.af.mil

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ASCLS Continues Collaborative Efforts to Address Laboratory Reimbursement and Workforce Issues

PAULA GARROTT

The theme of recent Washington Beat articles has been the Medicare Clinical Laboratory Competitive Bidding Project. This issue continues to “top” the list of legislative and regulatory issues as implementation of the demonstration project in the San Diego Metropolitan Statistical Area continues. Three San Diego-area laboratories have filed a lawsuit seeking to block the demonstration project on the grounds that the US Department of Health and Human Services failed to comply with the federal Administrative Procedure Act, failed to protect small businesses, and established a program that threatened irreparable injury to laboratories in the designated area (Sharp Healthcare v. Leavitt, S.D.Cal. No. 08 CV 0170, filed 1/29/08). The American Society for Clinical Laboratory Science (ASCLS), along with the other members of the Clinical Laboratory Coalition (CLC), are supporting this lawsuit. In addition, ASCLS and other CLC member organizations continue to lobby for the passage of HR 3453 and S. 2099, bills that have been introduced to repeal the Medicare competitive bidding project for laboratory services.

As efforts continue in Washington DC to address the ongoing threats to appropriate reimbursement for clinical laboratory services, another critical issue is impacting the practice of clinical laboratory science—the increasing shortage of qualified practitioners. Although the criticality of the shortage varies geographically, there is increasing concern among employers, educators, professional associations, and policy makers that the shortage will continue to worsen. The US Bureau of Labor and Statistics projects a need of approximately 150,000 new practitioners per year through 2014. Accredited educational programs are currently graduating only about 5000 annually.

A variety of factors have been suggested as contributing to the shortage including a decline in educational programs, an increasing shortage of qualified faculty, competing opportunities for “science-minded” students, less than optimal working conditions and salaries, and the retirement of the baby boomers who represent the largest number of current practitioners.

Legislative support to address the workforce shortage (Medical Personnel Shortage Act and the Allied Health Reinvestment Act) has been largely unsuccessful. Although we will likely continue to seek legislative action, ASCLS, along with other laboratory professional organizations and stakeholders, is working collaboratively through the Coordinating Council on the Clinical Laboratory Workforce (CCCLW) to address these workforce issues.

The Coordinating Council on the Clinical Laboratory Workforce (CCCLW) is a coalition of clinical laboratory organizations, governmental and regulatory agencies, and industry partners. The CCCLW developed as a result of a summit that was held in June 2000. The summit was organized by ASCLS to address the growing clinical laboratory personnel shortage and to share and coordinate the efforts of all the participating organizations. Attendees worked to identify the issues impacting the shortage of laboratory personnel and recognized that to begin to address these issues would require an ongoing and collaborative effort.

Recently the CCCLW held a strategic planning session led by a professional facilitator to re-focus its efforts. Twenty-eight individuals representing fourteen organizations participated. The strategic planning session was guided by the following focus question: “How will the CCCLW focus our collective efforts to:

• increase the number of qualified practitioners;
• increase healthcare and public awareness of our value in achieving positive patient outcomes; and
• contribute to our reputation as a forum for key workforce issues?”

The meeting involved brainstorming and large and small group work to identify industry trends, articulate and document a practical vision, identify any underlying contradictions, and develop possible actions and strategic directions. Consensus was reached on the following key vision elements:
1. Enhanced community awareness and professional prestige
2. Improved total rewards
3. Established and uniform credentials and levels of practice
4. Defined career advancement
5. Unified voice
6. Expanded collaborative and consultative roles for practitioners
7. Optimized recruitment and retention

Based on these seven elements of the CCCLW vision, the following four strategic action directions were identified:
1. Driving the business case internally and externally
2. Improving our professional profile
3. Aligning the scope of practice
4. Creating effective recruitment and retention

Four workgroups were established to address the four strategic action directions. Each workgroup identified key action areas and developed a five-quarter strategic planning implementation calendar. The progress of the workgroups will be reported at the CCCLW meetings and shared with the member organizations. One important CCCLW initiative that should be implemented soon is a website that will serve to coordinate and facilitate communication of workforce initiatives.

Reimbursement and workforce shortage issues are interrelated. It is essential that we work together as an industry to address these issues. ASCLS has long been a leader and a team player in these collaborative initiatives. However, success is dependent on each individual practitioner becoming involved and advocating on behalf of the profession in the legislative and regulatory arenas, in our workplaces, and in our communities.
The following white paper was presented to the ASCLS House of Delegates on July 21, 2007. The white paper represents the work of an inter-agency task force commissioned by ASCLS to address issues related to the education and practice roles of clinical laboratory professionals. A white paper is an expository paper to initiate an awareness of an issue and/or to educate regarding the elements of an issue or problem. It does not include a statement of policy or infer action taken by the Society.

The task force was chaired by Mary Briden, a past president of ASCLS. Other task force members were: Susan Beck, ASCLS (CLS educator); Bernie Bekken, ASCLS (immediate past president – ex-officio); Dana Duzan, ASCLS (manager); Paul Epner, industry (Abbott Diagnostics); Linda Fell, ASCP (educator); Frankie Harris-Lyne, ASCLS (CLT educator); Shirlyn McKenzie, ASCLS president (ex-officio); Susan Morris, ASCLS (manager); Bob Newberry, AMT (manager); Rick Panning, ASCLS (facilitator, manager); Elissa Passiment, ASCLS executive vice president (task force staff support); Dana Procsal, CLMA (CEO); Deb Rodahl, ASCLS (manager); and Randy Vandevander, ASCLS (manager).

ABBREVIATIONS: AMT = American Medical Technologists; ASCLS = American Society for Clinical Laboratory Science; ASCP = American Society for Clinical Pathology; CLMA = Clinical Laboratory Management Association; DMAIC = Define, Measure, Analyze, Implement, and Control.

INDEX TERMS: certification; clinical laboratory science; clinical laboratory staffing; education; medical technology; personnel standards; practice levels.

Clin Lab Sci 2008;21(2):68

The Dialogue and Discussion Section is a forum for editorials, short articles, commentaries, and letters to the editor on clinical laboratory science topics and professional issues of general interest to readers including ASCLS activities and position papers. For more information about submissions to the Dialogue and Discussion section contact: Margaret LeMay-Lewis, Managing Editor, Clinical Laboratory Science Editorial Office, IC Ink, 858 Saint Anne’s Drive, Iowa City, IA 52245. (319) 354-3861. ic.ink@mchsi.com

The task force was a collaborative project that included representatives from ASCLS, Clinical Laboratory Manage-
ment Association (CLMA), American Medical Technologists (AMT), American Society for Clinical Pathology (ASCP) and industry (Abbott Diagnostics). The task force membership included CLT/MLT and CLS/MT educators and laboratory managers from diverse laboratory environments and geographic locations.

The task force used the 6 Sigma / DMAIC (Define, Measure, Analyze, Implement, and Control) process improvement methodology as a roadmap. In October 2005, the task force met to “Define” the major problems facing the profession and establish the project goals. The task force then began the “Measure” phase of the process which involved collecting data in order to validate the problems defined by the task force, identify additional important problems, and solicit creative ideas for solutions. Measurement included:

- a review of literature related to clinical laboratory levels of practice.
- a review of scopes of practice in several health professions.
- focus groups of laboratory educators and managers conducted at national professional meetings.
- a national survey used to collect quantitative data as well as comments on a proposed model.

In July 2006, the task force met again to review the information from the literature review, the comparisons with other health professions, and the focus groups. The literature review and focus groups confirmed that the current system was not working and did not meet the current needs of the profession.

Problems that were identified include the fact that associate degree and baccalaureate degree personnel are often used interchangeably, that non-certified employees are hired to perform laboratory tests, that employees lack the communication skills needed for today’s workplace, and that laboratory practitioners are leaving the profession because there are limited opportunities for advancement. Based on that information, the task force developed a model that defined the educational and certification requirements for laboratory practitioners at each level of practice. The task force designed a web-based survey to collect feedback on the model from as many laboratory professionals as possible. To ensure that the survey data would be meaningful, a pilot version was distributed in early November 2006. Following analysis of the pilot study results, additional changes were made to the survey document. The web-based survey was widely disseminated in January 2007 through the cooperation of laboratory professional associations as well as the National Accrediting Agency for Clinical Laboratory Sciences.

The task force met in February of 2007 and began the “Analyze” phase of the process which included a review of the responses to the survey. Based on this analysis, the model was revised. Following this meeting, the task force met by teleconference to discuss the implications of this new model and to make recommendations for laboratory educators, managers, practitioners, and professional organizations. In this white paper, the task force presents the information collected in the measurement phase of the process, the revised model, and a discussion of the implications of this model for the laboratory profession.

Review of levels of practice literature

The task force reviewed publications on the knowledge and skills expected of clinical laboratory practitioners at different levels of practice and with increasing years of experience. The ASCLS and ASCP Levels of Practice documents and the 2005 report on “The Clinical Laboratory Workforce” by the Bureau of Health Professions were also reviewed. Key findings included:

- There is considerable overlap in the scope of practice between CLT/MLT and CLS/MT practitioners.
- CLS/MT practitioners perform more complex technical tasks, management tasks, and more communication tasks than CLT/MLT practitioners; however many of the CLT/MLT tasks require problem solving and high-level reasoning.
- At entry level, the CLS/MT practitioners perform core tasks more frequently than advanced tasks or management skills. Five years later, the core task responsibilities remain at a high level and advanced technical and management tasks increase (without additional education). These tasks are primarily in laboratory operations and communication/consultation areas.
- Sixty-four percent of CLS/MT practitioners perform routine tests “frequently” and the same percentage reported that they “never or rarely” perform specialized tests.
- The percentage of workers who reported being “very satisfied” with the level of challenge in their jobs declined from 37% to 17% between 1993 and 2002. Job satisfaction does not differ for CLT/MLT or CLS/MT practitioners.
- CLT/ MLT programs have a higher number of new students and a higher attrition rate than CLS/MT programs.
Fifty-five percent of educational programs have changed curricula during the past year but only five percent have eliminated any content.

Scope of practice reviews
The task force reviewed the scopes of practice in the professions of pharmacy, physical therapy, and occupational therapy. Information was collected through interviews and from websites. Only occupational therapy has true articulation and a “career ladder” beginning with the assistant level. In each profession, the scope of practice differentiating the entry level and the baccalaureate or masters level is well defined. The difference in the scope of practice between baccalaureate/masters and the doctoral level is not clearly defined in any of these professions. Due to state licensure, the scope of practice for the disciplines varies from state to state. All the disciplines are struggling with many of the same issues as the clinical laboratory profession.

Focus groups
Two focus groups were conducted in the first quarter of 2006. The first was conducted at the Clinical Laboratory Educators’ Conference (CLEC) and the second was at the CLMA ThinkLab ’06. The former group was largely made up of educators and the latter group was made up of administrators from hospital laboratories. Because the focus groups were small in size (average size of six), and the sample was not random, the task force could not draw conclusions about laboratory practice in all settings. However, the results of the focus groups were used in combination with other data to inform the task force and guide the survey development. Key findings from the focus groups include:

- There is little difference in the scope of practice between associate degree and baccalaureate degree personnel.
- The skill mix in laboratories is driven by a few key factors including state laws, laboratory budgets, CLT/CLS availability, and relationships with educational programs.
- The lack of clear distinctions between levels of practice serves to reduce the externally perceived professionalism of laboratory practitioners.
- The lack of differentiation of job scope combined with unclear career paths, low wages, and increasing alternatives is demoralizing and seems to increase retention problems among younger laboratory professionals.
- Curricula in educational programs are viewed as reflecting “the way it has always been” with some specific additions as a result of new technology.
- More automation and greater use of software with clinical algorithms will increase the need for associate degree level practitioners.
- More baccalaureate degree practitioners will be needed to develop clinical algorithms, for test utilization consultation especially in the area of molecular testing, for troubleshooting automated methods, and for the expanded technological skills for areas such as molecular testing.
- The advanced practitioner or clinical doctorate is seen by some as providing a career ladder beyond the baccalaureate degree.

Survey
The task force determined that it needed to survey a large population of laboratory educators, managers, and laboratory practitioners in order to validate the findings of the literature review and the focus groups and also to provide an opportunity for the profession to comment on the task force’s preliminary proposal for a new model. To ensure a robust survey instrument, a pilot survey was first developed, the results of which were used to identify possible ambiguities in the wording of the questions and to identify appropriate choices to include as objective responses to the survey questions. A non-random solicitation to laboratory leaders and select educators occurred. Fifty-two respondents completed the survey. The task force then analyzed the results and modified the survey as deemed appropriate.

The final survey was deployed in January of 2006 and opened for web-based responses for approximately 30 days. Over 2500 responses were received. An analysis of the survey method and responder demographics identified specific limitations on the ability to generalize the data.

Key methodology and respondent demographic limitations:
- Respondents formed a convenience sample (self-selected, not random) which attracted largely CLS/MT certified respondents from metropolitan areas with more than 20 years experience (nearly 11% met all three criteria; CLS/MT respondents were more than six times more common than CLT respondents).
- The CLT respondents were skewed towards smaller facilities (38% were in small hospitals).
- Fifty-eight percent of rural respondents were associated with smaller facilities.

Notwithstanding these limitations, the large number of respondents and the consistency of responses gave the task force confidence that important perspectives were being brought forward. Since this survey was always described as advisory in
nature, conclusions were drawn based on subgroup analysis as opposed to relying only on analysis of the total sample. Key findings from the survey:

- The consensus was that the current clinical laboratory work environment is not appropriate. More than 95% of respondents indicated that there was a need for change (some need, great need, or critical need) based on the presented rationale and their own experience. Approximately two-thirds of the respondents indicated that there was a great or critical need for change.
- Approximately two-thirds of respondents indicated that neither certification level nor educational attainment level significantly defined job differentiation in practice.
- When asked if the proposed change that would limit microbiology and blood banking skills performed by associate degree practitioners was justified, 30% of the respondents thought that there was minimal or no justification for this change and over 40% thought that there was good or great justification for the change.
- When asked whether or not the model should be adopted, 55.4% of the respondents said yes and 44.6% said no. The percent of respondents who did not want the model implemented was highest in the following groups; respondents with an associate degree (55.6%), educators of that population (78.9%), laboratory managers (50.4%), and laboratory directors (52.15).
- Over 1000 respondents provided written comments describing objections or suggestions for changes in the model.

THE PROPOSED MODEL FOR LEVELS OF PRACTICE IN CLS

Based on the data collected in the literature review, focus groups, and national surveys, the task force revised the model to reflect a new vision and new standards for the levels of practice in the clinical laboratory science (see Table 1). The model attempts to make the educational process more realistic, attainable, and differentiated. The model represents “what should be” rather than “what is”. It differs from “what is” in several important ways. First, the model more clearly differentiates levels of practice based on education, certification, and experience. Second, the model affirms the importance of certification and verified competency at all levels of practice. Third, the model defines the practice skills that should be taught and can be expected of new practitioners at each level. In some areas that are not currently well differentiated, the model includes a description of specific practice skills to better differentiate the levels (e.g., associate degree practice skills in blood bank and microbiology). Finally, the model represents a true career ladder from entry level positions through the clinical doctorate. This model will not work with today’s curriculum, availability of certificate and associate degree candidates, and possibly some state licensure requirements. However, the model is compliant with and exceeds the current CLIA requirements.

The model assumes that:
- practitioners receive national certification at each level.
- practitioners at each level are responsible for performing and/or supervising the duties performed at lower levels.
- skills needed at all levels include, but are not limited to: communication, troubleshooting, quality control, patient safety, basic laboratory safety (OSHA/EPA), ethics, interpersonal skills, cultural awareness, information technology/computer skills, terminology, basic laboratory operations.
- competency must be verified at all levels of practice.
- systems for documenting continued competence and recertification would be available at each level of practice.
- an individual could enter at the certificate, associate degree level, baccalaureate degree, or masters degree level.
- once graduates of educational programs enter the workforce, additional education would be available and required for those who wish to advance their knowledge, skills, and level of practice.

Definitions used in the model:
- Training = structured instructional program leading to competence in a practice skill prior to independent practice. This could be offered by an employer, formal educational institution, or professional society.
- Additional education = continuing education programs, formal coursework, or programs leading to additional certification or an advanced degree.
- Certificate = certificate indicating completion of a structured or defined educational program.
- Relevant experience = supervised experience in the practice skill.

IMPLICATIONS AND RECOMMENDATIONS

The proposed model was developed after extensive data collection and analysis to address problems in the laboratory profession identified by educators, managers, and practitioners. The model describes what laboratory practice would look like if the profession were able to start from scratch and design a system that ensured patient safety, encouraged practitioners’ professional development, and facilitated the effective use of laboratory personnel at all levels. Of course,
<table>
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<tr>
<th>Level</th>
<th>Practice skills</th>
<th>Education</th>
<th>Relevant experience</th>
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<tbody>
<tr>
<td>I</td>
<td>Phlebotomy</td>
<td>HS/GED + training</td>
<td>No</td>
<td>CLA or certificate</td>
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<td></td>
<td>Specimen processing</td>
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<td>Order entry—accessioning</td>
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<td>Culture set-up</td>
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<td>Specimen processing (histo/micro/cyto)</td>
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<td></td>
<td>Waived testing</td>
<td>HS/GED + additional education</td>
<td>Yes</td>
<td>CLA or certificate</td>
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<td>II</td>
<td>Automated chemistry, immuno-chemistry, coagulation, hematology, urinalysis</td>
<td>Associate</td>
<td>No</td>
<td>CLT / MLT</td>
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<td>Less complex microbiology (procedure/media selection and culture inoculation; specimen preparation and inoculation/loading of automated ID/Sensitivity instrumentation, direct microscopic procedures, i.e. gram stain; recognition of potential organisms, likely sources and significance of culture findings; confirmatory testing and sub-culturing; non-waived antigen kit tests; macroscopic screening for parasites; urine cultures)</td>
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<td>Less complex blood banking (ABO, Rh, antibody screen, crossmatch, direct antiglobulin testing, blood and component release)</td>
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<td>Manual differentials with higher review of abnormal results</td>
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<td>Urine microscopy</td>
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<td>Less complex body fluids (cell count, automated chemistries, gram stain)</td>
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<td>III</td>
<td>Body fluid microscopy with higher level review of abnormal results</td>
<td>Associate</td>
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<td>CLT / MLT</td>
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<td>Blood bank</td>
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<td>CLS / MT</td>
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<td>Molecular testing that follows established protocols</td>
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<td>Advanced techniques in hematology/bone marrows</td>
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<td>Advanced techniques in coagulation</td>
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<td>Advanced techniques in chemistry (electrophoresis, etc.)</td>
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<td>Advanced techniques in immunochemistry and drug testing (HPLC, etc.)</td>
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<th>Level</th>
<th>Practice skills</th>
<th>Education</th>
<th>Relevant experience</th>
<th>Certification</th>
</tr>
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</table>
| V     | Infection control/epidemiology  
|       | Method evaluation/test development  
|       | Patient education  
|       | POC oversight  
|       | Front line supervision  
|       | Research protocols  
|       | Safety officer  
|       | Student/staff education and training oversight  
|       | Technical consultation  
|       | Informatics  
|       | Cellular therapy—stem cell transplantation | Baccalaureate + additional education | Yes | CLS / MT |
|       | Cytogenetics  
|       | Advanced molecular / PCR (Modify existing, tests, troubleshooting, method evaluation, research and development)  
|       | Advanced flow cytometry  
|       | Histocompatibility  
|       | Specialist in (blood bank, chemistry, hematology, coagulation, etc) | Baccalaureate + additional education | Yes | Specialty certification |
| VI    | Compliance/coding/regulatory  
|       | Quality management  
|       | Risk/patient safety management  
|       | Operations/business management (Overall management of the laboratory, regulatory affairs / compliance, quality assurance, process improvement, information management, personnel management, productivity and performance monitoring, inter- and interdisciplinary management, financial management (capital, operating, and personnel), projecting and monitoring, contractual agreements/business planning)  
|       | Technical management (Coordinates, plans, manages and monitors testing activities and R & D, data management and problem solving, instrument selection, test development and method evaluation)  
|       | Educational program director | Masters degree in relevant area | Yes | CLS / MT plus other relevant certification |
| VII   | Clinical assessment  
|       | Evidence-based practice/research  
|       | Grand Rounds  
|       | Laboratory services clinical consultation  
|       | Patient counseling  
|       | Grant-funded research P.I.  
|       | Test utilization/assessment/protocol development  
|       | Test ordering | DCLS or PhD | No | CLS / MT plus other relevant certification |

(Table 1 continued from previous page)
it is not possible to start from scratch, so moving from “what is” to “what should be” will be a complicated and lengthy process. The first step in this process is seeking consensus from laboratory professionals on this model as the vision of “what should be”. This will involve discussions on the implications of the model among educators, managers, and practitioners.

**Implications for educators and students**
The model provides educators with a clear guide for curricula at each level of practice. Using this model as a guide, educators can focus on the theory and technical skills that graduates need to function in their professional careers and avoid teaching topics that will not be needed for entry level practice. Often educators struggle to fit more content into their programs in order to accommodate advances in science and technology. The model can serve as a means to limit the breadth of material covered and allow educators to emphasize the depth of understanding in those areas needed for clinical competence at a given level. Clinical laboratory students should find curricula more meaningful and relevant to the expectations in their entry level jobs. Well defined curricula should also facilitate progression from one educational level to the next.

The model may raise concerns for educators if it is viewed as requiring fewer credits and courses for some programs. However, the model does not necessarily suggest that the length or number of credits in educational programs be reduced, rather that the content of the courses be focused on the specific knowledge, skills, and attitudes needed for competence at that level of practice. It is likely that, by limiting the material that must be covered at a given level, educators could devote more time to higher level skills such as troubleshooting, problem solving, and communication.

This model will only work if there are sufficient educational programs and those programs are accessible to students and meet the needs of rural and/or underserved areas. New programs will be needed and new methods of education will be required to enable practitioners to advance from one level of practice to the next. The model will also require more partnerships between educational institutions and clinical affiliates in order to provide the necessary clinical education.

**Implications for laboratory managers**
At each level of practice, the proposed model would have an impact on clinical laboratory management. The first level of practice includes new standards for training and certification and this should result in higher skill levels in these important areas of clinical laboratory practice. The ability to advance along a career ladder should also lead to a higher level of professionalism and decreased turnover among Level I practitioners. The educational preparation and practice skills of the Levels II and III practitioners would be appropriate for physician office labs, for most small rural hospitals, and for routine testing in the majority of clinical laboratories. By assigning advanced procedures to the Levels IV and V practitioners, managers can make better use of laboratory professionals with baccalaureate degrees and more clearly distinguish between the CLS/MT and CLT/MLT levels of practice. The fifth level of this model provides new recognition for baccalaureate level practitioners who obtain specialized experience, education, and certification. The requirement for a masters degree for Level VI practitioners recognizes the need for higher degrees for these advanced leadership roles. At the highest level of practice, a new clinical role for laboratory practitioners is defined that would improve laboratory services and patient care through clinical consultation to mid-level practitioners and physicians. Using this model, laboratory managers could assign work responsibilities based on the practice skills that can be expected from a practitioner at each level of practice. Employee morale should improve as a result of the well defined career ladder through which motivated individuals at all levels of practice can advance.

As laboratory managers study this model, they may be concerned about implementing this system in their current laboratories with today’s workforce and educational options. The model assumes an adequate supply of practitioners and accessible educational programs and this does not exist today. Recruitment, education, and retention of laboratory professionals are essential, not only for the success of this proposed model, but also for the future of the laboratory profession. A strategy for ensuring an adequate supply of practitioners and educational programs must be included in the implementation plan and will require a commitment of resources from all stakeholders in the laboratory profession.

**Implications for laboratory practitioners**
In focus groups and surveys conducted by the task force, laboratory practitioners expressed a great deal of frustration with the lack of differentiation between the current levels of practice. This model addresses that concern by providing a well defined career path for laboratory professionals. The model makes it possible for individuals to enter at one level, gain employment, and move up the ladder through additional education, certification, and experience. The emphasis on education and certification should increase laboratory
practitioners’ sense of professionalism and progress in their careers. At the higher levels of practice, the model describes roles for clinical laboratory professionals that recognize their expertise and ability to contribute to the health care system. Young laboratory practitioners may be more likely to stay in the profession when they see opportunities for advancement through education, experience, and advanced certification.

Setting out defined job functions at each level helps differentiate the levels of practice, but it also places limitations on practice at all levels. There are many practitioners who are currently performing laboratory tests that would not be included in their scope of practice in the proposed model. Any strategy of implementation for this new model must recognize the value of current laboratory practitioners and protect their jobs. The transition from current practice to the proposed model will be difficult, but without a vision and a plan for change, the frustrations of the present will continue.

Recommendations
For this model to be successfully implemented, laboratory educators, managers, practitioners, certification agencies, accreditation agencies, and professional organizations will all need to work together to plan the transition from “what is” to “what should be”. In order to implement this model, laboratory educators must:

- revise current curricula to match the model.
- develop new educational programs that are accessible and allow for an uncomplicated progression from level to level.
- work with managers to identify mechanisms for Level I training.
- work with certification and accrediting agencies to ensure that the model is reflected in examination content and accreditation standards.

Laboratory managers must:

- educate administrators and human resource departments on the new model and update job descriptions to reflect the new levels of practice.
- work with human resources departments to ensure that pay scales are commensurate with practitioners’ education and experience at all levels of practice.
- revise staffing plans based upon the new levels of practice to maximize the use of practitioners at each level of practice.
- ensure that their employees only perform the practice skills that are within their scope of practice.
- support educational programs by providing the clinical affiliations needed for practice skill development.

Laboratory practitioners must:

- plan their careers using the model as a guide.
- seek the education and experience needed to move up the career ladder.
- maintain and document continued clinical competence.

Laboratory certification agencies must:

- revise or develop examinations for all levels described in the model.
- work with their sponsoring organizations and their accrediting agencies (e.g., NCCA) to develop a plan for defensible certification examinations in the transition time between the old and new standards for laboratory practice.
- provide affordable and accessible methods for documenting continued competence.

Laboratory accrediting agencies must:

- work with their sponsoring organizations to develop standards and guidelines based on the model levels of practice.
- educate program directors, paper reviewers, and site visitors on new standards.
- develop standards and guidelines for new programs that may be developed.

Laboratory professional organizations must:

- inform members about the proposed model and provide opportunities for members to be involved in discussions and recommendations.
- identify champions to speak at conferences, publish papers, and promote the new model.
- revise the Body of Knowledge to match the model.
- provide membership opportunities for practitioners at all levels of practice.
- provide the continuing education needed for each level of practice.
- work with educators to develop educational materials and programs for new levels of practice.
- work with certification and accrediting agencies to ensure that the model is reflected in examination content and accreditation standards.
- promote evidence-based research to validate the need for and effectiveness of the model.
- lobby state and national legislative bodies for increased funding for clinical laboratory educational programs and students.
Next steps
The task force used the 6 Sigma DMAIC (Define, Measure, Analyze, Implement, Control) process to address problems with the current levels of practice in the laboratory profession. The task force proceeded through the “Define” phase in several meetings that resulted in goals, objectives, and a research plan. In the “Measure” phase, the task force collected data from literature, interviews, focus groups, and surveys. The proposed model and recommendations are the result of the “Analyze” phase and it is now time to move to the “Implement” and “Control” phases of the process. This will require a continued commitment from all the organizations represented on this task force and the additional involvement of other stakeholders such as certification agencies and accrediting agencies.

Given the complexity of the laboratory profession, the path forward will not be easy. However, after listening to the concerns of so many, the task force came to believe that a new vision for the laboratory profession is necessary. Without a change in the status quo, problems such as student attrition, blurred lines of responsibility and compensation among laboratory personnel with different education levels, attrition of talented laboratory professionals due to ineffective use of their skills, and lack of advancement opportunities will continue. In addition, the professional status of clinical laboratory practice and laboratory practitioners suffers when professional organizations fail to agree on the common and appropriate scopes of practice for laboratory personnel at all levels. A necessary first step will be to share the proposed model with all members of the laboratory profession for discussion and input. Feedback from these discussions will be used to finalize the model before it is presented to participating organizations for approval. Therefore, the task force recommends the following.

1. The participating organizations should accept the white paper with the proposed model for levels of practice.

2. ASCLS should create a new inter-organizational task force to move the new model through the steps necessary for implementation and validation. This task force should:
   • work with participating organizations to develop a process for distribution of the white paper and new model that includes a method for obtaining support from members.
   • study the impact of this model on state licensure.
   • determine the number of laboratory practitioners needed at each level of practice and determine the ability of the educational programs to meet that demand.
   • consider developing a strategy for validating the model through evidence-based research.
   • Suggested timeline:
     • January 2008: Develop a plan and process for dissemination that includes a PowerPoint presentation for on-line distribution with accompanying script and Q&A component to promote review, dialogue, and input from all participating organizations’ members.
     • February 2008: Present model for discussion at the Clinical Laboratory Educators’ Conference.
     • March 2008: Submit the model to all participating organizations.
     • Spring 2008: Seek membership support of new model.
     • Summer 2008: Submit the model to all participating organizations for final review, support, and approval.

Clin Lab Sci encourages readers to respond with thoughts, questions, or comments regarding this article. Email responses to ic.ink@mchsi.com. In the subject line, please type “CLIN LAB SCI 21(2) DD BECK”. Selected responses will appear in the Dialogue and Discussion section in a future issue. Responses may be edited for length and clarity. We look forward to hearing from you.

BIBLIOGRAPHY
The Doctorate in Clinical Laboratory Science: CLS Education beyond the Baccalaureate

ELIZABETH KENIMER LEIBACH

ABBREVIATIONS: ASCLS = American Society for Clinical Laboratory Science; CLS = clinical laboratory science; DCLS = doctorate in clinical laboratory science; NAACLS = National Accrediting Agency for Clinical Laboratory Sciences.

INDEX TERMS: clinical doctorate; clinical laboratory science; evidence-based practice; professional doctorate.

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Elizabeth Kenimer Leibach is chair and associate professor in the Department of Biomedical and Radiological Technologies, Medical College of Georgia, Augusta GA.

Address for correspondence: Elizabeth Kenimer Leibach EdD MS CLS MT(SBB), chair and associate professor, Department of Biomedical and Radiological Technologies, EC 2437 Medical College of Georgia, Augusta GA 30912-0500. (706) 721-3046, (706) 721-7631 (fax), ekenimer@mcg.edu.

The American Society for Clinical Laboratory Science (ASCLS) has clearly articulated the responsibilities of the Doctorate in Clinical Laboratory Science (DCLS):

“Missing within the continuity of healthcare are enough scientists and physicians within the clinical laboratory or elsewhere on the healthcare team, who are totally dedicated to and who have the breadth of knowledge and assigned authority essential to the ordering of appropriate laboratory tests, the effective use of laboratory test information, effective consultation with other healthcare team members, direct communication with patients, review of patient records, and interpretation/application of laboratory generated information in reference to clinical signs and symptoms. A clinical laboratory science professional holding a doctoral degree (DCLS) is needed to provide the critical interface across the healthcare system in order to assure improved patient outcomes and cost effective patient care.”

At some level, all who have needed healthcare recognize the need for an individual to function in our healthcare system as described above. In fact, the need for interpretation of laboratory information related to appropriate patient assessment is a growing need worldwide. In a recent publication in an online global news service, the point was made and supported with survey data that confusion over test-ordering practices in Great Britain places patients at risk. Blame for the confusion was attributed to lack of clinical pathology education in the medical curriculum.

With the design and implementation of the DCLS, the clinical laboratory science profession has claimed and accepted responsibility for the quality of the information provided by the clinical laboratory and for assuring its effective use in patient care. We have recognized that ours is the profession best prepared, by education and practice, to speak to total quality and advancement for the clinical laboratory. With this step, the profession has also completed its “career ladder” with positions identified to address all areas of the laboratory industry including its leadership.

Believing CLS to be the profession best suited to lead the clinical laboratory is just the first step toward meeting the growing needs of patients worldwide. Obviously if medical education is assessed to be inadequate in clinical pathology, much more content must be added to the baccalaureate CLS curriculum in preparation for the burgeoning need for quality leadership and patient care roles. DCLS leadership groups have approached the definition of the required additional education in several ways.

First, task forces of the ASCLS and the National Accrediting Agency for Clinical Laboratory Sciences (NAACLS) developed competencies in an iterative process referencing an extensive review of competency requirements of other doctoral-level healthcare practitioners. These competencies
were validated by a qualitative process involving thematic analysis of interviews with current practitioners self-identifying as “advanced practitioners” functioning in patient care roles for which they were prepared by experience and formal education.

Standards for accreditation of DCLS programs were then written by NAACLS and reviewed by the profession in open hearings throughout the country. Considering the scope of the DCLS competencies as well as doctoral curricula from other healthcare disciplines and biomedical science programs of comparable rigor, the DCLS program of study was set at a minimum of 90 semester credit hours beyond the baccalaureate CLS degree. Additional admissions requirements, e.g., minimum scores on standardized proficiency examinations, minimum grade point averages, and prerequisite course work, are not specified but are to be addressed by individual institutions and their program admissions committees. Practice and expertise areas addressed by the competencies are given in Table 1.

An ASCLS task force concurrently developed the DCLS model curriculum comprised of course descriptions, instructional objectives, and a course sequence based on the baccalaureate CLS foundation. The DCLS curriculum is not technical in the traditional CLS interpretation. Rather, the doctoral curriculum is based on new competencies related to post-graduate biomedical sciences; patient interactions, communication, and patient case management; CLS diagnosis and therapies; evidence-based practice; and clinical services delivery as shown in Table 2.\(^4\)

Together, the five curricular areas describe content designed to prepare practitioners with an educational base of science, technology, communication skills, diagnostic decision-making tools, and research applied to practice (evidence-based practice). Tables 3 through 7 summarize examples of content addressing DCLS competencies and curricular areas.

The model curriculum materials developed by the ASCLS task force were disseminated for review and comment by a sample of individuals in other healthcare professions with knowledge of clinical laboratory science responsibilities in healthcare delivery, interest in furthering the quality of the clinical laboratory, and expertise in clinical healthcare education. A total of 22 sets of curricular materials were distributed with a response from 12 reviewers (55% response rate). Table 8 summarizes reviewer response categories.

Some general observations can be made from preliminary data analysis of the reviews. The PhD/MD reviewers’ comments expressed different perceptions. One reviewer suggested more services delivery and clinical content, the other consistently commented that curricular content was outside the scope of practice of the CLS. Comments from the PhD reviewers were consistently favorable with one suggesting more public health exposure and another (PhD, RN) suggesting more interdisciplinary team interactions. All MD comments were favorable but inconsistent in the nature of suggestions for improvement. One MD found the curriculum lacking traditional CLS technical content while the other suggested more clinical (patient-related) content. The PharmD (also MT-credentialed), while assessing the DCLS curriculum favorably overall, commented that the objectives related to pharmacology overlapped those in the pharmacy curriculum. The physician assistants (PA-C, both BS and MS prepared) shared detailed suggestions for more clinical experiences. One PA-C in particular, who is also CLS-credentialed, was able to suggest specific clinical experiences to teach competencies directly applicable to the CLS practice and knowledge base. These clinical experiences were tailored for CLS practice having been modified from the more gen-

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**Table 1.** DCLS competency areas

<table>
<thead>
<tr>
<th>Area I</th>
<th>Scientific/medical knowledge</th>
</tr>
</thead>
<tbody>
<tr>
<td>Area II</td>
<td>Patient care (assessment, management)</td>
</tr>
<tr>
<td>Area III</td>
<td>Interpersonal/communication skills</td>
</tr>
<tr>
<td>Area IV</td>
<td>Professionalism (ethics, regulatory)</td>
</tr>
<tr>
<td>Area V</td>
<td>Outreach (professional promotion)</td>
</tr>
<tr>
<td>Area VI</td>
<td>Continuous practice improvement</td>
</tr>
<tr>
<td>Area VII</td>
<td>Services delivery (administration, financial)</td>
</tr>
</tbody>
</table>

**Table 2.** DCLS curriculum content areas

<table>
<thead>
<tr>
<th>Group I</th>
<th>Advanced basic sciences</th>
</tr>
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<tbody>
<tr>
<td>Group II</td>
<td>Patient interactions</td>
</tr>
<tr>
<td>Group III</td>
<td>Clinical laboratory diagnosis and therapies</td>
</tr>
<tr>
<td>Group IV</td>
<td>Statistics, research methods, evidence-based practice</td>
</tr>
<tr>
<td>Group V</td>
<td>Ethics, policy, and clinical services delivery</td>
</tr>
</tbody>
</table>
eral (non-CLS related) clinical curriculum of the PA. These comments will undoubtedly prove valuable in structuring educational clinical experiences for the DCLS.

The CLS profession has known from the inception of the DCLS that it represents a new healthcare practitioner. In fact the competencies of DCLS practice are designed to address existing specific needs in the clinical laboratory industry and the CLS profession. As such, it was recognized that aspects of some clinical competencies in the DCLS curriculum (and needed in practice) might be shared by other health professions and thus taught by representatives of non-CLS health professions. The primary purpose of the curriculum review process was to garner the input and educational strategies of those non-CLS health professions vested in the quality of clinical laboratory information who could contribute to the education of the DCLS. More extensive analysis of data from DCLS curriculum reviews continues and will be

Table 3. DCLS biomedical science content

- Clinical pharmacology and therapeutics (drug classes and delivery)
- Integrated systems biology (genetics, anatomy, physiology)
- Cancer biology and immunology (epidemiology, chemotherapy)
- Molecular and cell biology (genomics, gene regulation, drug discovery)
- Disease mechanisms (immunology, microbiology, pathophysiology)

Table 4. DCLS patient interactions content

- Patient interactions
- Healthcare communications
- Healthcare education principles
- Health assessment
- Clinical patient management

Table 5. DCLS diagnosis and therapies content

- Disease processes (symptoms/laboratory findings)
- Hematopathology
- Immunohematology/transfusion services
- Issues in public health
- Health informatics/epidemiology

Table 6. DCLS research content

- Biostatistics/research design
- Evidence-based practice
- Scientific communications/research ethics
- Grant writing
- Final scholarly treatise

Table 7. Clinical services delivery content

- Healthcare policy
- Licensure/ethics
- Professional advocacy
- Administration (private/government/education)
- Human resource management/finance

Table 8. Curricular review response categories

<table>
<thead>
<tr>
<th>Degree/Credential</th>
<th>Contacted</th>
<th>Responded</th>
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<td>PhD, MD</td>
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<td>2</td>
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<tr>
<td>PhD (2 MT*)</td>
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<td>3</td>
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<tr>
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<tr>
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<td>PharmD</td>
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<tr>
<td>Masters, PA-C (2 CLS*)</td>
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<tr>
<td>Bachelors, PA-C</td>
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</tr>
<tr>
<td><strong>TOTAL</strong></td>
<td><strong>22</strong></td>
<td><strong>12</strong></td>
</tr>
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</table>

* Number of respondents with clinical laboratory science degree and credential
reported when completed. However, even from the preliminary review some guiding tenets for curriculum development have emerged.

First, other healthcare disciplines are not necessarily able to identify clinical competencies from their scopes of practice that relate to the proposed scope of practice of the DCLS. Though the reviewers, in the main, saw a need for the DCLS, the clinical competencies they prescribed for the practitioner are in general the ones they teach their own practitioners. Extrapolating from the sample of responses, one can conclude that other health professions would, without specific guidance, train DCLS students clinically in a manner similar to their own professions. This conclusion is supported by the comments from physicians and the pharmacist that the education of the DCLS infringed upon their professional scopes of education and practice. Therefore, even though other disciplines may participate in the DCLS educational process, the CLS profession will, in the end, be responsible for identifying specific clinical experiences necessary to meet clinical competencies we have defined in the DCLS scope of practice. The CLS-relevant comments of the one PA-C who is also CLS-educated and credentialed corroborated this notion. While other practitioners recognize that there are needs specific to clinical laboratory services delivery, only CLS has defined these needs and can fashion appropriate clinical experiences to address them.

The continuing task of CLS educators involved in DCLS program implementation, therefore, is to identify content and instructional methodologies in the curricula of other health professions that must be modified for and incorporated into the DCLS curriculum in order to adequately enable our keystone practitioner to maximize benefits of laboratory services to our client groups. Continue to monitor our professional literature and the ASCLS website (www.ascls.org) for progress updates on the latest developments. Please post general comments to the ASCLS Forums. (You can find the Forums from the “About” link on the title bar of the ASCLS homepage). Your comments can help shape the future of our profession!

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REFERENCES
Strongyloidiasis: A Review and Update by Case Example

KATHERINE GREINER, JOSEPH BETTENCOURT, CAROLE SEMOLIC

A 77-year-old female immigrant from South America presented with epigastric pain, diarrhea, gastrointestinal bleeding, malabsorption, and acid reflux disorder. A gastroduodenoscopy, performed to assess for peptic ulcer disease, revealed parasitic larvae in the duodenal mucosa which were subsequently identified as *Strongyloides stercoralis* rhabditiform larvae. Anti-helminthic therapy was initiated to resolve infection.

OBJECTIVES: Review the pathogenesis, diagnosis and treatment of strongyloidiasis; alert laboratory professionals to the importance of early detection of *Strongyloides stercoralis* in specimens from immigrants at risk and immunodeficient patients to reduce morbidity and mortality.

ABBREVIATIONS: AIDS = acquired immunodeficiency syndrome; EIA = enzyme immunoassay; HIV = human immunodeficiency virus; HTLV-1 = human T-cell lymphotropic virus type 1; IgE = immunoglobulin E; IgG = immunoglobulin G.

INDEX TERMS: hyperinfection; immunodeficiency disorders; rhabditiform larvae; strongyloidiasis.

**CASE HISTORY**

A 77-year-old female immigrant from South America sought medical attention at a hospital clinic due to epigastric pain and diarrhea. She was diagnosed with gastrointestinal bleeding, malabsorption, and acid reflux disorder coupled with possible ulceration of the esophagus. A gastroduodenoscopy was performed to determine if she had peptic ulcer disease. Recommendations for stool analysis were made based on the histopathology findings.

**LABORATORY RESULTS**

Biopsies of the small intestine and esophageal-gastric junction were taken. The mucosa of the small intestine was hyperemic and characterized by areas of acute or chronic inflammation. The gastric mucosa of the fundus also was hyperemic and had focal areas of mild, nonspecific, chronic inflammation. Focal metaplasia, suggestive of Barrett’s esophagus, was seen in the esophageal mucosa. There was no evidence of ulceration, granuloma formation, or malignancy.

Cross-sections of structures resembling parasitic larvae were prominent in the duodenal histologic preparations. Subsequent stool analysis confirmed that these forms in sectioned tissue were *Strongyloides stercoralis* larvae. The larvae were observed in the mucosal region of the duodenum, within the lumen of the crypts of Lieberkuhn (Figure 1). Typically, the crypts are invaded by juvenile or adult forms of *Strongyloides stercoralis*.
Three stools for ova and parasite studies were submitted to the laboratory the following week. Trichrome stains on smears prepared from stool concentrates on all three specimens were negative for protozoa but revealed *Strongyloides stercoralis* rhabditiform larvae. Two fecal smears had many larvae present while the third showed only a few.

A diagnosis of strongyloidiasis was made on the basis of rhabditiform larval morphology. Larvae were characterized by a short buccal cavity, a sharply pointed tail, and the presence of a noticeable midsection genital primordium. *Strongyloides* ova are a rare finding in fecal smears and were not seen on the slides reviewed.

**LIFE CYCLE**

*Strongyloides stercoralis* is a member of the order Rhabditida which includes tiny round worms which bridge the gap between free-living and parasitic modes of life. Within this order, *Strongyloides stercoralis* is the most common, widespread species of medical importance in humans and other primates but also infects other mammals like dogs and cats.

Humans acquire strongyloidiasis through soil, food, or water contaminated with infectious larvae. Invasive third-stage, filariform larvae (490 μm-630 μm) can directly penetrate skin from soil or be ingested in contaminated food or water (Figure 2). The site of skin entry is usually exposed areas on the hands, feet, and buttocks. Invasive juveniles that burrow into the skin are transported to the lungs by the bloodstream, where they migrate from pulmonary capillaries to alveolar spaces. Upward movement from the lungs to the respiratory airways causes irritation. Juveniles are coughed up to the pharynx and then swallowed, eventually lodging in the intestine. Lung migration is unnecessary if juveniles in food or water are directly swallowed and conveyed to the small intestine.

In the small intestine filariform larvae molt twice, developing into adult female parasites (2 mm-3 mm). Females anchor into the intestinal mucosa with their mouths or thread their anterior ends into the submucosa. They produce several dozen, thin-shelled eggs per day through parthenogenesis.

Eggs are released into the intestinal lumen or submucosa and hatch during transit through the gut or while in the submucosa. Juveniles escaping from the eggs develop into first stage larvae called rhabditiform larvae (300 μm -380 μm) which are passed from feces to soil. The rhabditiform larvae become infective third-stage filariform larvae after two more stages of development in soil and are capable of infecting a new host if directly contacted or ingested.

Autoinfection can occur and represents a permutation of the life cycle. If first stage juveniles molt twice during transit down the intestinal tract, they become infective filariform larvae that can penetrate the lower gut mucosa (internal autoinfection) or perianal skin (external autoinfection) and begin migration to the lungs and up the respiratory tree to the pharynx, ultimately returning to the small intestine. Autoinfection occurs at a significant rate in states of immunosuppression and appears to contribute to the life-threatening hyperinfections seen in individuals with immunocompromising illness. Whether by continuance of adult worms in the small intestine or by autoinfection, some cases of strongyloidiasis have resulted in persistent infection lasting for decades.

In the free-living life cycle of *Strongyloides stercoralis*, rhabditiform larvae can molt to the fourth stage of development in soil, maturing into free-living adult males and females. Adult worms mate, resulting in egg release from which new rhabditiform larvae emerge. These hatched larvae then either develop into free-living adult worms or into filariform larvae that infect humans.

**SYMPTOMS**

Disease severity varies in strongyloidiasis. Numerous cases originating in endemic areas are chronic and asymptomatic when immunocompetency exists. Some individuals are evaluated for parasitosis on the basis of unexplained eosinophilia

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**Figure 1.** *Strongyloides stercoralis* rhabditiform larva in the lumen of a crypt of Lieberkuhn. 430X
only. The more complex cases are characterized by symptomatology resulting from higher numbers of parasites in skin, lung, and gastrointestinal tissue.

Dermatologic involvement at filariform points of entry is manifested by a migrating, urticarial, erythematous rash, termed larva currens. Larva currens occurs more often in the skin of the buttocks, groin, and trunk than that of the extremities. Eruptions may be particularly prominent in perianal sites where the external autoinfection cycle begins.

Pulmonary migration phases are associated with coughing, wheezing, and shortness of breath, symptoms which may lead to a diagnosis of asthma and treatment with steroid-based medications that potentiate more extensive parasite invasion.

Epigastric pain and abdominal tenderness, along with bloating, nausea, anorexia, and diarrhea are general signs of gastrointestinal invasion. A potentially fatal outcome is associated with massive hyperinfection due to autoinfection cycles. Compli-

Figure 2. Life cycle of *Strongyloides stercoralis*

cated strongyloidiasis is associated with colitis and ulceration of the intestinal mucosa with resulting bowel perforation.

LABORATORY DIAGNOSIS
The primary detection method for *Strongyloides stercoralis* remains stool examination whereby first-stage rhabditiform larvae can be demonstrated in freshly passed specimens. A direct fecal exam, preferably done with saline-Lugol iodine stain, is effective in diagnosing the less frequent cases of massive infection. However, in uncomplicated infection the parasite load in specimens is usually low, requiring examination of stool that has been concentrated by the formalin-ethyl acetate technique. Mild to moderate eosinophilia\(^1,2\) may be the only clue that parasite infection exists when stools are negative, indicating that further testing on stool should be done. Low worm loads and day-to-day variability in the shedding pattern of juveniles raise the level of difficulty in detecting larvae in most cases of strongyloidiasis. Multiple examinations of stool significantly improve diagnostic sensitivity.\(^3,4\) Rarely, embryonated eggs can be seen in stools from patients who are experiencing severe diarrhea or from whom specimens have been collected with purgation.

The inherent difficulty in identifying *Strongyloides stercoralis* in stool specimens relates to the morphologic similarities that exist between the ova and rhabditiform larvae of *Strongyloides* and the ova and rhabditiform larvae of hookworms. The hookworms, *Necatur americanus* and *Ancylostoma duodenale*, also are nematodes which parasitize the small intestine. Their impact on humans is generally more severe because they feed on blood and tissue fluids after invading the mucosal lining, causing iron deficiency anemia and hypoproteinemia.

*Strongyloides* infection is diagnosed by detection of rhabditiform larvae in fecal material. In contrast, hookworm infection is diagnosed by demonstrating ova in stool, which are routinely excreted, or the adult male and female worms which can be recovered after antihelminthic treatment. In hookworm infection, however, eggs can hatch in stool as a result of constipation or delayed examination, yielding rhabditiform larvae which bear close resemblance to *Strongyloides* rhabditiform larvae and are confused with them. Detection of *Strongyloides* larvae can be further complicated if patients are dually infected with both *Strongyloides* and hookworms.

While the ova of *Strongyloides stercoralis* and hookworms are too similar to practically differentiate, the rhabditiform larvae of the two nematodes can be distinguished from each other. The buccal cavity of *Strongyloides stercoralis* larvae is short, being one-third to one-half the width of the head (Figure 3) while the buccal cavity of hookworm larvae is slightly longer than the width of the head. The genital primordium is large and usually visible in *Strongyloides* rhabditiform larvae but not readily apparent in hookworm rhabditiform larvae. In addition, the esophagus of *Strongyloides* rhabditiform larvae is hourglass-shaped and characterized by a posterior esophageal bulb.

In addition to histologic examination of duodenal tissue, duodenal aspirate evaluation increases the probability of detecting rhabditiform larvae to 60%-70%.\(^5\) Wet mount preparations of centrifuged duodenal fluid without preservative are examined within one hour of collection. Due to the invasive nature of duodenal aspiration, collection of duodenal fluid is generally reserved for rapid diagnosis in children suspected of heavy worm infestation or immunocompromised patients.

Pulmonary strongyloidiasis is often diagnosed with examination of wet preparations of sputum, bronchial washings and brushings, bronchoalveolar lavage fluid, or pleural fluid. Gram, acid-fast, and Papanicolaou stains all enhance detection of *Strongyloides* larvae.\(^3,6,7\)

A few other techniques can be used to detect *Strongyloides* larvae but are not typically done in diagnostic laboratories. The Baermann method and the Harada-Mori filter paper technique are based on larval migration during incubation.\(^3,8\) In the Baermann method, larvae migrate from fecal material

Figure 3. *Strongyloides stercoralis* rhabditiform larva in a fecal smear with the short buccal cavity evident. 430X
on gauze that lines a funnel containing warm water. Larvae move into the warm water and are collected by centrifugation. The Harada-Mori technique employs filter paper inoculated with fecal material which absorbs water in a test tube by capillary action during 30°C incubation. Larvae can be discerned at the sides of the filter paper after migration during incubation.

Agar plate culture is particularly effective in detecting Strongyloides larvae. 3,8,9,10 Agar plates are inoculated with stool or duodenal fluid and incubated for two days at room temperature. Larvae crawl on the agar and spread bacteria in their paths, creating bacterial growth patterns on the agar surface. Larvae can be seen with microscopic examination of the plates and their presence confirmed with formalin washing of the plate surface and examination of the sediment from the washing.

Diagnosis of strongyloidiasis by enzyme immunoassay (EIA) serology has proven somewhat useful in immunocompetent individuals. 3 The EIA for detecting Strongyloides stercoralis infection detects immunoglobulin G (IgG) to filariform larvae. A major drawback to EIA evaluation for infection is that specificity is compromised when cross-reactive antibodies are present from other helminth infections like hookworm infection, filariasis, Ascaris lumbricoides infection, and acute schistosomiasis. 3,11 As with many infections, antibodies can be detectable for years after treatment and it is often difficult to differentiate between past and current infection. The EIA can be of value, however, as a screening test. Negative test results in immunocompetent individuals suggest infection is unlikely while positive results warrant further assessment for parasites.

TREATMENT
The anthelmintic agents thiabendazole, albendazole, and ivermectin are used to treat strongyloidiasis. Thiabendazole has been associated with a relapse of infection and gastrointestinal side effects. Albendazole is a broad-spectrum anthelmintic drug which is safe and effective in treating Strongyloides stercoralis infection. Research indicates that it would be a useful, low-cost, medication to presumptively administer to immigrants at risk for parasitosis to reduce overall healthcare costs due to parasitic infection, annually, in the United States. 3 Ivermectin is a favored drug for treatment of strongyloidiasis because it is fairly well tolerated and associated with a high cure rate. It is very effective in treating both uncomplicated and complicated strongyloidiasis but more costly and limited in its range of activity against helminths than albendazole.

DISCUSSION
Strongyloidiasis is one of the most difficult parasitic diseases to diagnose due to a general absence of distinctive ova in stool specimens and a rarity of larval forms, particularly in uncomplicated cases. The life cycle of Strongyloides stercoralis also is one of the most complex of the helminthic cycles due to both parasitic and free-living forms and parthenogenic and autoinfection factors.

The ability to recognize Strongyloides stercoralis rhabditiform larvae in specimens is particularly important now due to increased immigration from areas of the world endemic for strongyloidiasis and the impact that immunodeficiency states have on Strongyloides stercoralis infection. Immunodeficiency predisposes the host to potentially massive, fatal infection with both parasites and bacteria. Heavy worm infestation of the intestinal wall causes ulceration of the mucosa producing symptoms suggestive of a duodenal ulcer or ulcerative colitis. Mucosal perforation can produce secondary, widespread bacterial sepsis that often causes fatality. Hyperinfection, which involves the gastrointestinal tract and lungs, can progress to disseminated or fulminant strongyloidiasis with parasite infestation of the liver, heart, adrenals, pancreas, kidneys and central nervous system.

Strongyloidiasis affects more than 30 million people worldwide. 3 It is endemic in tropical regions and found under the same climatic and sanitary conditions favorable to hookworm infection. With immigration to the US reaching record highs over the past century, hundreds of thousands of immigrants have come to the US each year from such regions. 12 Those at higher risk for strongyloidiasis have immigrated from countries in Central and South America, the Caribbean, sub-Saharan Africa, Asia, Southeast Asia and the Middle East, many of which are experiencing an explosive spread of acquired immunodeficiency syndrome (AIDS). In the US strongyloidiasis is endemic in the southeast and has been well documented in the mentally disabled, many of whom are institutionalized. 13,14,15 International travel poses a risk for Americans with immunosuppression who tour countries endemic for strongyloidiasis.

Strongyloidiasis is one of the primary causes of death in the US due to helminths. 3 Complicated infection typically affects those with altered immune responses and occurs with malnutrition, high dose corticosteroid therapy, anti-cancer therapy, transplant therapy, malignancies, congenital immunodeficiencies and infections with human T-cell lymphotropic virus type 1 (HTLV-1), and human immunodeficiency virus (HIV).
The immune response to *Strongyloides stercoralis* is poorly understood but eosinophils and immunoglobulin E (IgE) seem to help limit infection with it to the intestine. Eosinophilia is a useful marker for infection and eosinopenia is correlated with a poor clinical outcome in fulminant infection.\(^{16}\) Defective T-cell responses coupled with autoinfection cycles account for heavy worm burdens in some immunosuppressed individuals and lead to hyperinfection syndrome and disseminated strongyloidiasis.

There is a strong correlation between *Strongyloides stercoralis* hyperinfection and HTLV-1 where both cause endemic infection, such as in southern Japan and the Caribbean.\(^{17}\) Co-infection with *Strongyloides stercoralis* and HTLV-1 is associated with treatment failure related to dysfunctional immune responses.\(^{18,19}\) A high level of interferon gamma is produced, and little interleukin 4, causing a reduction in IgE\(^{20}\) which is needed for vasoactive effects in the intestine to assist in the expulsion of helminths. The immunomodulatory effect caused by HTLV-1 thus potentiates hyperinfection with *Strongyloides*.* Testing for HTLV-1 is sometimes recommended for patients hyperinfected with *Strongyloides* who are refractory to standard anthelminthic treatment.

Diarrhea caused by intestinal parasitosis is prominent in AIDS and is related to impaired immunologic defense mechanisms along the intestinal mucosa. The prevalence of specific parasites appears to vary from country to country.\(^{21}\) While strongyloidiasis is not considered to be one of the more significant presenting opportunistic infections in AIDS\(^{22,23}\) HIV positive patients affected by it are at high risk for dissemination of infection and treatment failure.\(^{24}\) It can be transmitted through anal sex and via oral contact and is associated with a lack of eosinophilia and poor IgE response.\(^{23,24,25}\) Individuals with AIDS often have additional risk factors which intensify *Strongyloides* infection such as treatment with corticosteroids, mycobacterial disease, malignancy and malnutrition.

**CONCLUSION**

This patient was treated with anthelminthic agents to relieve her gastrointestinal symptoms. Long-term follow-up was not possible due to a treatment plan offered through outpatient services at the hospital clinic.

In the majority of cases, a diagnosis of strongyloidiasis can be made in the clinical laboratory by microscopic examination of stool, tissue, and body fluids. The special tests that provide supplemental information about *Strongyloides stercoralis* infection are economically impractical to perform even in the best of laboratories. They are sporadically needed and their overall use does not justify their cost and the additional personnel training required in order to perform them.

Molecular-based tests would facilitate the detection of strongyloidiasis and other parasitic infections by increasing sensitivity and specificity levels in testing but are currently not well-developed for clinical parasitology. They are used for a small number of parasite infections like *Trichomonas vaginalis* infection, babesiosis, and toxoplasmosis.\(^{8}\) Immunodiagnostic tests continue to be used as primary back-up assays to confirm parasitosis. However, mailing specimens with medical histories to the limited number of reference laboratories that perform them and obtaining test results can be a lengthy process.

Immigration from developing countries and a prevailing increase in immunodeficiency disorders throughout the world, particularly AIDS, has heightened an awareness of parasitic diseases that were once considered relatively uncommon in the US. Standard fecal exams on individuals at risk for intestinal parasitosis could help avoid delay in diagnosis and treatment of infections. Clinical laboratory scientists are faced with the continued challenge of maintaining their proficiency in the microscopic identification of parasites since they can potentially alter the clinical outcome of parasite infections, like strongyloidiasis, with good detection skills.

**REFERENCES**


CLINICAL PRACTICE

Clinical Laboratory Educators’ Conference 2008 Abstracts

POSTER PRESENTATIONS
Presenters are listed in bold face type.

Deborah Fox PhD, Our Lady of the Lake College, Baton Rouge LA

The purpose of this study was the development and testing of a novel method for assessment of white blood cell (WBC) identification skills used in the field of clinical laboratory sciences (CLS). A dual format exam was administered to both novices (students) and experts (laboratory professionals). Format 1 was similar to current assessment formats, simply presenting a series of single WBC images for identification. Format 2 applied principles of visual cognition, grouping WBCs for identification by patient and presenting multiple example images from the patient before requesting identification of individual cells. This novel exam format was intended to: (a) provide a contextualized visual background for single cell identifications, (b) mirror the process of WBC identification used in clinical practice, and (c) promote improved performance on difficult/ atypical WBC identifications. Statistical analyses did suggest that expert performance levels were significantly improved by the novel exam presentation format. Novice performance, however, was not significantly altered by exam format. Overall results indicated that the novel exam format invited experts to implement similarity-based processing, allowing some identifications to be made at the level of the patient case, rather than simply at the feature identification level. Implications of this study include possible alterations to current certification/ proficiency exam formats for questions requiring the visual identification of white blood cells. This study also suggests that using patient image sets as instructional stimuli may encourage the development of advanced cognitive processing skills in students.

Comparison of Registry Scores between an Online and On-campus Clinical Laboratory Sciences Degree Program
Kara Hansen-Suchy MEd MT(ASCP)SH, Weber State University (WSU), Ogden UT

In recent years online courses have been increasing in availability to meet the needs of students unable to attend college in a more traditional setting. Another topical development has been the ability to earn a degree granted entirely through online delivery at both the MLT/CLT and MT/CLS level. Lingering doubts have been expressed with regard to the quality of online instruction as compared to the more conventional classroom method as it relates specifically to overall student performance, especially in a scientific curriculum. Since the number of graduates from a completely online delivery system has thus far been limited, the question has not been thoroughly deliberated. This study examined the performance outcome of an online-delivered degree versus the traditional classroom and is comprised of 73 online and 213 on-campus graduates in clinical laboratory sciences from WSU during the years 2002 to 2007 at both the MLT/CLT and MT/CLS level. Outcomes were assessed by comparing categorical and total test scores, in addition to first time pass rates on the ASCP Board of Registry Exam. The two groups (campus vs. online) remained statistically indistinguishable in the majority of categories when analyzed with an unpaired t-test at $p=0.05$. Surprisingly, those categories demonstrating statistical differences displayed divergence in both directions. Categories that exhibited a statistical difference were scrutinized for possible explanations, as well as feasible solutions to improve curriculum and narrow disparity.

Coping with Additional Upper Division Requirements: A Case Study
Linda J McCown MS CLS(NCA), University of Illinois at Springfield, Springfield IL

Core professional courses, service learning, diversity, and collaboration are some initiatives emphasized at universities today to ensure that the graduates have knowledge and skills that will help them as persons, professionals, and citizens. Clinical laboratory science (CLS) programs, however, have little space in the curriculum to add new courses or activities. This qualitative case study examines how a CLS program dealt with the mandate to add upper division general education requirements to the curriculum. With the vision of becoming a top five public liberal arts university, a new general education curriculum was implemented at the University of Illinois at Springfield which required the addition of new upper division courses. Questions which guided the research were: “What strategies are used” and “What barriers exist” when dealing with such a curricular challenge. Ongoing and simultaneous data collections and analysis were performed using interviews and artifacts such as emails, web postings, and minutes. Analysis and categorization of the data revealed the importance of communication and compromise between the
administration, the curriculum committee, and the CLS program. These compromises were accomplished by such strategies as visits with the administrator very early in the process, meeting with the science representative to the curriculum committee, and adding content suggested by the most resistant members of the committee. Examples of revisions to the CLS curriculum are conversion of the education/management course to a general education course, and addition of “engagement” competencies, and daily reflective journals to the clinical rotation courses.

Designing a 21st Century Molecular Pathology Degree Program

Ericka Hendrix, Lori Rice-Spearman MS, Texas Tech Health Sciences Center, School of Allied Health Sciences, Lubbock TX

Since the inception of the Texas Tech Health Sciences Center graduate program in molecular pathology in 2003, the development of the curriculum has been a fluid and dynamic process to meet the demands of this developing profession. The curriculum is assessed annually by the following methods: advisory committee, input from faculty retreat, feedback from clinical preceptorship sites, surveys from employers, survey from graduates, and outcome measures. The evaluation process over the past four years has led to the development of a curriculum that has moved from a research emphasis to a practice management emphasis. The clinical research component has been redefined to comprehensively address start-up testing and assay validation. In addition, a course has been developed that specifically concentrates on the unique challenges of the operational issues involved with accreditation, personnel development, and external communication with clinicians. A human genetics course was added in place of an introductory molecular diagnostics course, which has deepened the level of graduate study. A redeveloped statistics course now includes relevant human genetic statistics and, finally, adding a cell biology course has acted as leveler to the diverse student enrollment. Currently, we are working to integrate the courses to provide the students a more congruent experience. The design of the curriculum for the 21st century molecular pathology degree program must include components that prepare graduates for the demands of start-up testing and assay validation as well as unique management issues related to the diagnostic molecular laboratory.

The Effects of Peer Tutoring on Outcomes Measures

Eunice Lee, Lori Rice-Spearman MS, Texas Tech Health Sciences Center, School of Allied Health Sciences, Lubbock TX

Success among first year clinical laboratory science (FYCLS) students in a 2+2 program can be compromised due to transitioning from a traditional academic campus to a professional program. Peer tutoring was initiated to assist FYCLS students in developing study skills that support comprehensive learning and acclimation into a professional program. Peer tutoring was developed by recruiting second year CLS (SYCLS) students who had demonstrated strong study habits and professional conduct. Initially a group review was offered for the FYCLS prior to the first exam. Afterwards, those who scored below 75% in any of the subjects were encouraged to seek individual tutoring with a SYCLS. Periodic group reviews were conducted for all students regardless of performance on weekly exams. Exam scores were monitored on a spreadsheet to determine the impact of tutoring on performance and a survey was completed by FYCLS and SYCLS addressing expectations of the tutoring. Of the FYCLS, 67% participated in the first group review session and 33% in individual tutoring. Thirty percent of the individuals who consistently utilized individual tutoring experienced an increase in exam scores (12 points). One hundred percent of the FYCLS would recommend utilizing the resources of the tutoring initiative to fellow classmates. Amongst the SYCLS, all stated that tutoring was an opportunity for review of first year material in preparation for the national certification exam.

Emergency Preparedness Instruction: Use of a Global Bioterror Scenario in a CLS Curriculum

Karen Golemboski PhD MT(ASCP), Michelle Draper MBA MT(ASCP), Bellarmine University, Louisville KY

The public health community recognizes the importance of preparing allied health professionals for response to emergencies. The Center for Public Health Preparedness has developed core competencies for laboratory professionals, including the application of “creative problem-solving and flexible thinking”. Emergency-preparedness education is a suitable topic for the application of problem-based learning, which encourages creativity and flexibility in the context of a situation. Atlantic Storm is a global bioterror scenario developed by the Center for Biosecurity (University of Pittsburgh Medical Center) involving an intentional multi-national smallpox attack, originally executed as a cabinet-level tabletop exercise in January of 2005. The Atlantic Storm scenario was incorporated into a CLS seminar class, which was designed to address, among other outcomes, current topics of professional interest. Students were assigned roles as political and institutional leaders during the scenario, over four one-hour class periods. Interdisciplinary issues covered during the scenario included international approaches to civil liberties during a crisis, the structure of existing international organizations, and appropriate roles for these entities in response to a bioterror incident. Public health concerns, national response to disease, distribution of resources, and outcomes of actions taken were discussed. Students were also asked to compare events of the scenario with other possibilities such as pandemic influenza. Student evaluations were favorable and indicated that,
after the exercise, there was an increased recognition of the need for emergency planning, not only on an institutional basis but also nationally and internationally.

**Integrating Cultural Competence Awareness into Allied Health Education**

*Linda J. Graeter PhD MT(ASCP), Charity Einhaus Accurso PhD MT(ASCP), Gideon H Labiner MS MT(ASCP) CLS(NCA), Melanie J Giusti MT(ASCP), Lara N Kolar MT(ASCP), Ryan D McGough MS MT(ASCP), Erin C. Rumpke MT(ASCP), Alan Vespie MEd CNMT RT(N), Nancy Steinberg Warren MS CGC, University of Cincinnati, Cincinnati OH*

The faculty in three allied health educational programs – Advanced Imaging Technology, Clinical Laboratory Science, and Genetic Counseling – developed a project with the goal of enhancing cultural competence amongst campus and distance learning students and core, adjunct, and clinical faculty. The CLS Program’s ultimate goals included developing cultural competence training units that could be delivered to campus and distance learning students and developing training materials that would assist the program’s various faculty groups in serving a diverse student population. Following a series of faculty training sessions with cultural competence experts, the core faculty in the programs drafted discipline-specific cultural competence curricular maps to identify curricular units that contained cultural competence elements. The curricular maps and concomitant learning activities were evaluated against benchmark practices that were described by the consultants. The CLS curricular review showed that the existing cultural diversity units in our capstone courses included the required fundamental training elements and that key cultural competence elements were appropriately included in existing courses. However, because our goal was to develop innovative and enriching means by which to address cultural competence, additional course activities were developed. Examples of those learning activities include an interactive self-assessment tool that also serves to foster critical thinking, a simulation style assignment that addresses the numerous aspects of cultural diversity, and the inclusion of an enhanced unit that addressed the socioeconomic factors of infectious diseases. Additionally, to increase cultural competence awareness, a portfolio of materials was developed and utilized as a required faculty training tool.

**Medical Decision Making and Critical Pathways in Laboratory Science Education**

*Eileen Carreiro-Leuwanowski MS CLS, University of Massachusetts Dartmouth, North Dartmouth MA*

Critical or clinical pathways generally involve diagnostic algorithms as a mechanism to improve patient care. Recent updates to NAACLS accreditation standards for clinical laboratory science (CLS) curriculum includes instruction in both critical pathways and medical decision making. To address this need, during a senior Medical Laboratory Science (MLS) clinical chemistry course, each student was assigned four unique but interrelated clinical case studies, the data for which they derived from “mock” patient samples used during their assigned laboratory sessions. At the end of their lecture series, including guest speakers from other related healthcare professions, half of the class was asked to identify the primary diagnosis for each of their cases and provide an algorithm showing the interrelationship between the diagnosis and any anticipated laboratory data outcomes. This activity was followed by written case study reports justifying how their experimental laboratory data supported their proposed patient diagnosis for each case. The remaining half of the class simply submitted the written case study reports for each case. The case study reports for both groups were graded based on a predetermined rubric. Results showed that the group that initially generated an algorithm had report grades that were 22% higher. Instructors also noted that those students in the algorithm group were more likely to request additional instructor help and feedback and to ask more in-depth questions during algorithm development.

**Professionalism: Making the Grade**

*Elizabeth E Correiro, MAT, CLS(NCA), Brenda Berube MS, University of Massachusetts Dartmouth, North Dartmouth MA*

A crucial demand for highly qualified healthcare practitioners exists, mostly in the areas of technical, professional, and operational improvements. In response, the University of Massachusetts Dartmouth Department of Medical Laboratory Science seeks to better prepare students for a career in the clinical laboratory by actively engaging students in the development of professional competency along with technical skills. Skills such as attention to detail, approachability, attitude, and attendance have been incorporated into the curriculum in an effort to meet the demands of future employers. Teaching strategies make use of well-designed course objectives and specific, measurable learning outcomes based on a survey of professional attributes. Data was collected from fifty New England area hospitals and more than one hundred MLS college students. The instrument requested the respondent to rank, by importance, ten pre-selected qualities of a laboratory professional. Survey results indicate that although employers and students rank knowledge in the field and attention to detail as “most important”, discrepancies exist in the importance of the following skills: adaptability, approachability, attitude, and attire. Instructional strategies focusing on narrowing the gap between the workplace and students will be reviewed. Such strategies include introducing first year students to professional organizations and requiring
Student Performance Outcomes on Molecular Diagnostics Laboratory Modules Incorporated into CLS Program Senior Clinical Chemistry Course
Barbara Kraj MS MT(ASCP), Lester Pretlow PhD CLS(C) NRCC(CC), Barbara Russell EdD MT(ASCP)SH, Medical College of Georgia, Augusta GA

As new molecular assays are being developed in basic research laboratories and the Food and Drug Administration (FDA) approves more tests for diagnostic applications in clinical laboratories, a new CLS discipline is being established: molecular diagnostics. The current NAACLS accreditation standards require that the CLS educational programs incorporate molecular diagnostics into the curriculum “including performance of assays”. Molecular diagnostic course content was added to our CLS program in fall 2005. Student laboratories consisted of online virtual laboratories of PCR (polymerase chain reaction) and DNA fingerprinting of subjects of kinship and crime investigations. In fall 2006 and 2007, students began performing PCR and DNA electrophoresis as part of their student laboratory experience. We evaluated student learning by written examination of lecture and laboratory content. We found a statistically significant difference between the groups’ examination performance that had a “hands-on” experience and the one that had a virtual experience only. Additionally, we found that the statistical analysis of the upper 25th percentile of students showed no significant difference in the student performance when either virtual or hands-on laboratories were used. There was no statistically significant difference in the performance of students in the lowest 25th percentile either. The data suggests that the hands-on laboratory experience has no effect on the highest performing students or the lowest performing students. However, since there was a statistically significant difference in student performance for the whole group, the data suggests that hands-on experiential laboratories have the greatest effect on students who perform in the middle percentiles.

Surveys of Support for the Doctorate in Clinical Laboratory Science
Kathy Doig PhD CLS(NCA) CLSp(H), Michigan State University, East Lansing MI; Susan Beck, PhD CLS(NCA), The University of North Carolina at Chapel Hill, Chapel Hill NC

Two recent surveys of clinical laboratory professionals shed light on the interest in and support for the Doctorate in Clinical Laboratory Science (DCLS). One survey conducted by Beck and Doig in 2005 inquired about the career preparedness and plans of early career professionals. A randomly selected sample of 972 laboratory practitioners with one to three years of experience was asked about their interest in pursuing the DCLS. Of the 299 respondents, 65% expressed interest in following this career path. Another 28% thought it would be good option instead of pursuing a medical or physician assistant career. In open ended questions, 35% of respondents were enthusiastic, with some eager for more information. A second survey with implications for the DCLS was conducted in 2007 by an inter-agency task force charged to rethink the levels of practice in CLS. A non-random sample of over 2500 laboratory professionals responded to questions about a proposed model which included the DCLS level of practice. Only 7.5% of respondents thought that laboratory professionals would not be good at consultation. Over one-third (36.5%) thought that hospitals would not hire a DCLS. Responses to these questions differed based on the respondents’ employment. For both questions, pathologists appeared to be more supportive of the DCLS than some other laboratory groups. These two surveys demonstrate substantial interest in the DCLS from early career laboratory professionals and support for this career path from laboratory professionals.

TECHNOLOGY DEMONSTRATIONS

Educating the Educator: Teaching Students How to Teach
Yasmen Simonian PhD CLS(NCA) MT(ASCP), Weber State University, Ogden UT

Constant changes in providing healthcare, budgetary constraints, and the shortage of clinical laboratory personnel have all greatly impacted the employment opportunities and job descriptions of clinical laboratory scientists. Baccalaureate degree laboratory technicians are replacing bench work with more administrative roles and responsibilities. One such responsibility is that of an educator. Recently hired personnel require quality training. Residents and interns in hospitals and clinics need information on newly developed laboratory tests; and our veteran colleagues are required to complete certain continuing education credits by attending in-service refreshers, workshops, and presentations. The objective of this technology demonstration is to provide a design for quality teaching methodologies included in a senior capstone course for a clinical laboratory sciences (CLS) BS-de-
gree programs. The new technologists need to be able to teach others; therefore the capstone project was developed giving students an opportunity to learn how to teach and to develop teaching materials. The design includes projects analyzing needs, target populations, tasks, objectives, and current training and resources. In addition, implementation plans, course design documents and evaluation plans will be demonstrated.

Examples of teaching projects on PowerPoint presentations developed by senior CLS students both from online and on campus, will also be demonstrated. These projects have been presented to laboratory personnel, interns, and residents in various hospitals and clinics. The presentations have been a great avenue to introduce the students early on to the entire healthcare team and review the role and the value of clinical laboratory scientists in providing quality healthcare.

Let's See That One More Time!
Linda A Smith PhD, Shirlyn B McKenzie PhD, University of Texas Health Science Center, San Antonio TX

The clinical laboratory science (CLS) curriculum continues to expand and educators struggle to fit basic and new concepts into limited course time. Complex topics such as antibody panel ‘cross-off’, identification of fungal agents, and the coagulation cascade, that normally would have been taught in extended lecture times are compressed. While students struggle to master these concepts in shortened classroom presentations, some clinical affiliates take students for less time in practicums or have ceased to perform certain types of testing. This, in turn, reduces time for application or reinforcement of the concepts. Interactive learning modules requiring input by students and providing them with direct feedback are a good adjunct to traditional lecture presentations and provide an opportunity for repetition until the concept is learned. While faculty have the content expertise, few have time or expertise to develop these modules. CLS faculty at the University of Texas Health Science Center hired a high school student with exceptional computer skills in several different program applications to help develop learning modules that could be incorporated into lecture or provided to students via computer access. Faculty provided the creative concepts and flow while the student incorporated these into computer format. These practice or reinforcement modules use a variety of interactive methods including immediate feedback to student responses. This technology demonstration will include several completed modules including one for the coagulation cascade, one for antibody panel workups, and a fungal identification module under development.

National Tuberculosis Curriculum Consortium Technology Products
Sandra Latshaw MA, University of Nebraska Medical Center, Omaha NE; Kathleen Mugan MEd, University of Arkansas for Medical Sciences, Little Rock AR; Maribeth Flaws PhD, Rush University Medical Center, Indian Head Park IL

Tuberculosis (TB) is currently on the decline in the US, however, it is imperative that all medical disciplines remain alert to the detection, identification, and treatment of this deadly disease. Therefore, the National Tuberculosis Curriculum Consortium (NTCC) was established in October 2003 under a contract from the National Heart, Lung and Blood Institute of the National Institutes of Health (N01-HR-36157). One mission of the NTCC is to create access to educational and training opportunities for CLS/CLT students. This technology demonstration will highlight curricular products created by the NTCC for TB education in CLS/CLT programs. A sampling of all completed or preliminary work products will be demonstrated including test questions, competencies, computer-based learning objects, PowerPoint presentations, and computerized case studies. These educational products are available to all CLS/CLT programs at no cost through the NTCC website (http://ntcc.ucsd.edu/) as they are developed. Although TB testing may be sent to reference laboratories, it remains important content for clinical laboratory students. The NTCC technology products can supplement and or update current TB teaching materials. By developing active learning modules to enhance current TB curriculum for CLS/CLT students, it is the hope that TB infection rates will remain low in the US.
## Program at a Glance

**Tuesday, July 29, 2008**

<table>
<thead>
<tr>
<th>Time</th>
<th>Event</th>
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<tbody>
<tr>
<td>8:30 - 12:00</td>
<td>ASCLS Board of Directors Meeting - all are welcome</td>
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<tr>
<td>8:30 - 4:30</td>
<td>ASCP Sponsored Workshop: Immunochemical Methods in the Clinical Laboratory</td>
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<td>8:30 - 5:00</td>
<td>ASCP Sponsored Workshop: Update in Hemostasis and Thrombosis</td>
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<td>9:30 - 5:00</td>
<td>Clinical Lab Expo</td>
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<td>Incoming Committee Chairs Orientation</td>
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<td>Session Moderator Orientation</td>
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<td>1:00 - 2:30</td>
<td>State Presidents’ Seminar (Out-going State Presidents)</td>
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<td>1:00 - 2:30</td>
<td>Clinical Laboratory Science Editors</td>
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<td>Abstract Review Committee</td>
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<td>Clinical Laboratory Science Consulting Editors</td>
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<td>Continuing Education Advisory Committee (CEAC)</td>
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<td>2:45 - 4:15</td>
<td>Student Forum Orientation - all students invited</td>
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<td>Scientific Assembly Chairs Planning</td>
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<td>2:45 - 6:00</td>
<td>Presidents-Elect Seminar (Incoming State Presidents)</td>
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<td>Product Development Committee</td>
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<td>6:00 - 7:30</td>
<td>NCA/NAACLS Update</td>
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<td>7:00 - 8:00</td>
<td>First Timer’s Reception (for all Annual Meeting first time attendees)</td>
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<td>7:00 - 9:30</td>
<td>Alpha Mu Tau Fraternity Board Meeting</td>
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Wednesday, July 30, 2008

8:00 - 9:15 a.m.  ASCLS Award Ceremony...............................Hotel
9:15 - 10:15 a.m.  Patient Safety and the Clinical Laboratory............................Michael Astion
10:15 - 10:45 a.m.  Shuttles to convention center

SCIENTIFIC SESSIONS  Convention Center, Renaissance Hotel
10:45 – 12:15 pm  Are Your Point of Care Testing Personnel Competent.......Peter J. Howanitz & James H. Nichols
                    DNA Analysis as a Tool in Immunohematology..........................Christine Lomas-Francis
                    Meeting the Laboratory Testing Needs of an Aging Population........Allan S. Jaffe
                    Personnel Licensure: Progress, Pitfalls, and Perseverance...............Panel
Noon - 1:30 p.m.  Student Forum Business Meeting ......................................Hotel
                    Shuttle to convention center available following Student Forum
12:15 - 2:00 pm  Dedicated Exhibit Hours (Exhibits open 9:30 a.m. - 5:00 p.m.)
                    Poster Presentations (12:30 - 1:30 p.m.)
12:30 - 2:00 p.m.  CLEC 2009 Planning Committee ........................................Convention Center

SCIENTIFIC SESSIONS  Convention Center
2:00 - 3:30 p.m.  Clinical Outcomes of Obesity from a Laboratory and Behavioral Point of View.........Sarah Colby
                    Nutrigenomics-the Connection
                    Between Nutrition and Genes......................................... John A. Milner, Mary Frances Picciano
                    Are You Smarter Than a Laboratory Director- Case Studies in Microbiology....Joseph M. Campos
                    Current Strategies in Anticoagulant Monitoring................................Dorothy Adcock
2:30 - 5:00 p.m.  Health Care Forum..........................................................Panel
3:45 - 5:15 p.m.  Chromogenic or Clottable Assays for Monitoring
                    Subjects on Heparins or Oral Anticoagulant Therapy ....................David L. McGlasson
                    Blood Donor Testing: Successes and Future Threats........................Richard J. Benjamin
                    The Emerging Importance of Molecular Clinical Microbiology.............Joseph M. Campos
                    Personalized Medicine: Tools for Optimization of Pharmacotherapy........William Clarke
5:15 – 6:00 pm  Shuttles to Hotel from Convention Center
6:00 - 7:30 p.m.  ASCLS Issues Update ........................................................Hotel
8:00 - 11:00 p.m.  Welcome Reception and Education and Research Silent Auction.....................Hotel
Thursday July 31, 2008

7:00 – 8:00 a.m.  Regions I-V Caucuses..........................................................Hotel

8:00 a.m.  Shuttles to Convention Center begin

SCIENTIFIC SESSIONS  Convention Center

8:30–10:00a.m  Glycated Hemoglobin Standardization (The NGSP/IFCC Dilemma) ......................David B. Sacks
Classroom Assessment or How Are We Doing......................................................Karen S. Chandler
Cost Does Matter ...............................................................................................Caroline A. Ambrose
Professional Issues: Open Forum .......................................................................Rick Panning

10:15–11:45 a.m.
Blood Transfusion Safety: Where’s the Risk? ......................................Jeanne A. Lumadue
Thinking Outside of the Box: Creative Techniques to Help Recruit and Engage Members ........Sharon Bobryk & Linda Goossen
Going Somewhere? Infections in Travel Medicine ........................................Louis M. Weiss
Managing Low Level Troponin Results:
The Cardiologist’s and Laboratory Perspective ............................................Allan S. Jaffe

11:45 – 1:30 p.m.  Lunch Break– on own Exhibits 9:30 a.m. – 2:00 p.m. ............Last Opportunity to see exhibits

Noon – 1:15 p.m.  Midday Sessions  Bring your own lunch
Must register, may purchase box lunch on registration form

Humor in the Workplace ....................................................................................Cheryl R. Caskey
Case Studies of the Rich and Famous: Autoimmune Diseases .........................Patsy Jarreau
Autoimmune Diseases East Meets West:
An Integrative Approach to Solving a Medical Mystery ......................................Cindy Johnson
Emotional Intelligence: IQ Doesn’t Cut It Anymore ...........................................Glen McDaniel

Noon – 1:15 p.m.  Roundtables  Must register – Lunch Included

Dealing with Difficult Employees ........................................................................Edward J. Peterson, Jr.
Clinical Chemistry Case Studies from the Consumer Website ......................Linda S. Gorman & John Koenig
Faculty Recruitment and Development in University-Based Programs ...........Susan Beck
Yeast Susceptibility Testing: Should We or Shouldn’t We?..............................Lynda A. Britton
How to Be a State Society Treasurer ................................................................Bobbi Kochvar
Online-Assisted Learning ....................................................................................Kimberly P. Murray
Current Issues in Laboratory Information Systems Operations ......................Suzanne H. Butch
Implementation and Inventory Management of 7 Day Single Donor Platelets ......Donna Strauss
Personnel Licensure ............................................................................................Paula Garrett
Red, White, Blue & Science Too!

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<td>Tick, Tick... BOOM! Tick &amp; Arthropod-borne Diseases..............................Louis M. Weiss</td>
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<td>Managing, Teaching, and Working with Echo-Boomers..................................Linda Laatsch</td>
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<td>New Directions for Laboratory Accreditation Surveys..............................Margaret Peck</td>
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<td>Morphology or Flow Cytometry-Who Makes the Diagnosis..............................Kathleen Finnegan</td>
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<td>Helping to Build Laboratory Capacity and ...............................................Vicki S. Freeman &amp; Wendy L. Arneson</td>
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<td>Improving Utilization of Laboratory Tests................................................Brian Jackson</td>
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<td>Bylaws Committee .........................................................................................Hotel</td>
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<td>Student Forum Elections .............................................................................Hotel</td>
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<td>T'nT Bash (social event) Hosted by the Tennessee &amp; Texas State Societies ....Hotel</td>
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Friday, August 1, 2008

7:50 – 8:30 am     | Regions VI –X Caucuses .............................................................Hotel |

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<td>Advanced Immunohematology Case Studies.............................................Michelle S. Kanuth &amp; Linda A. Smith</td>
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<td>Physician Office Laboratory Start-Up..................................................Tim Dumas</td>
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<td>Evidence-Based Clinical Chemistry Cases.............................................Mary Ann McLane</td>
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<td>11:00 – Noon</td>
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## Scientific Sessions

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| 12:30 – 2:00 p.m. | Scientific Assembly Meetings & Luncheons  
                    Lab Administrators  
                    Consultants  
                    Hematology/Hemostasis  
                    Industry  
                    Molecular/Genetics  
                    Quality/Regulatory Affairs  
                    All welcome  |
| 2:00 – 3:45 p.m. | Minority Forum Board Meeting |
| 2:15 – 3:45 p.m. | Career Opportunities for the Clinical Laboratory Scientist Part II  
                    Molecular Genetic Analysis in Leukemia & Lymphoma: Advantages & Limitations  
                    Drug Induced Immune Hemolytic Anemia: A New Paradigm  
                    Ensuring Quality Blood Specimen Collection  
                    Adam Bagg  
                    Susan T. Johnson  
                    Cathee M. Tankersley & Ruth E. McCall |
| 4:00 – 5:30 p.m. | Student Jeopardy  
                    Member Submitted Papers  
                    Leading with Authority Rather than Power  
                    Multiple Platforms for Undergraduate Research  
                    Kyle Riding  
                    TBA  
                    Chérie V. Peterson  
                    David M. Falleur & Rodney E. Rohde |
| 6:30 – 10:30 p.m. | Alpha Mu Tau Honorary Fraternity Dinner (ticket required) |

## Social Events

### Saturday, August 2, 2008

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<td>8:30 – 9:30 a.m.</td>
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<td>10:00 – 1:30 p.m.</td>
<td>House of Delegates – State delegates seated; all others welcome in gallery seating</td>
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| 1:30 – 3:00 p.m. | Lunch – on your own  
                    Past ASMT/ASCLS National Presidents’ Luncheon (by invitation)  
                    New Board Orientation-Including Student Forum (bring lunch)  
                    Leadership Development Committee |
| 3:00 – 4:30 p.m. | 2009 Annual Meeting Steering Committee  
                    PAC Board  
                    Education & Research Fund Board  
                    Alpha Mu Tau Board  
                    Consumer Response Team |
| 5:00 – 6:00 p.m. | President’s Reception (by invitation) |
Antimicrobial Resistance of Uncomplicated Urinary Tract Infections in Northern Utah

MICHAEL MCQUILKIN, ALEXANDER LUND, WYATT PALMER

OBJECTIVE: To evaluate antimicrobial resistance in uropathogenic bacteria in northern Utah.

DESIGN: One hundred twenty bacterial isolates from community-acquired UTI in the northern Utah area (Davis and Weber Counties) were tested. Samples were taken from otherwise healthy women, ages 18 to 50. Antimicrobial susceptibility testing for sulfamethoxazole/trimethoprim (SXT/TMP), ciprofloxacin, and nitrofurantoin comprised the process.

SETTING: The Clinical Laboratory Science Department at Weber State University, with samples coming from clinics in the northern Utah area (Davis and Weber Counties).

PARTICIPANTS: Urine samples were taken from otherwise healthy women, ages 18 to 50, who suffered from uncomplicated urinary tract infections.

MAIN OUTCOME MEASURE: Antimicrobial resistance was measured using antimicrobial susceptibility testing and shown with other national resistance rates.

RESULTS: Of bacterial isolates, 21.3% were resistant to SXT/TMP, 14.4% were resistant to ciprofloxacin, and 13.9% were resistant to nitrofurantoin. The resistance rates for ciprofloxacin and nitrofurantoin were acceptable for empirical UTI treatment (< 20% resistance), but local bacterial populations were found to demonstrate an increase in resistance to these two drugs as compared to previously observed national data. SXT/TMP resistance was above the recommended resistance threshold of 20% for effective empirical treatment, as advised by the IDSA.

CONCLUSION: Results suggest that uncomplicated community-acquired UTI be treated with nitrofurantoin. Other recommendations include continued monitoring of local uropathogenic antimicrobial resistance.

ABBREVIATIONS: ATCC = American Type Culture Collection; IDSA = Infectious Disease Society of America; NCCLS = National Committee for Clinical Laboratory Standards; SXT/TMP = sulfamethoxazole/trimethoprim; UTI = urinary tract infections.

INDEX TERMS: infection; pathogen; resistance; urology; Utah.


Michael McQuilkin MT(ASCP) is a cytogeneticist for the Mayo Clinic, Rochester MN.

Alexander Lund MT(ASCP) is a generalist for Intermountain Healthcare at the McKay Dee Hospital Laboratory, Ogden UT.

Wyatt Palmer MT(ASCP) works in Special Chemistry at the Mayo Clinic, Rochester MN.

Address for correspondence: Alex Lund MT(ASCP), 1206 22nd Street, Ogden UT 84401. (801)710-7243. AlexLund@mail.weber.edu

Sources of research support: This project was funded via the Phyllis Crosby Gardner Undergraduate Research Scholarship. Special thanks to the McKay-Dee Hospital Microbiology Department, the Student Health Center at Weber State University, and other Intermountain Health locations for their participation.

The study was presented in poster form at the Weber State University Undergraduate Spring Symposium (Ogden UT, March 2007) and the National Conference for Undergraduate Research (San Francisco CA, April 2007).

Urinary tract infections (UTI) cause millions of clinical visits every year in the US, with over half of all women reporting at least one UTI in their lifetime. The organisms that cause these infections typically react well to a wide range of antibiotics, thus culture and antimicrobial sensitivity testing are rarely performed for patients with UTI. The preference for empirical antimicrobial therapy is due, primarily, to the predictability of the etiological agents that cause infection; namely Escherichia coli which accounts for 75%-90% of bacterial isolates. Recently, there has been an alarming increase in the occurrence of resistance to the drugs commonly prescribed, namely sulfamethoxazole/trimethoprim (SXT/TMP), ciprofloxacin, and nitrofurantoin. This resistance can cause...
a number of healthcare related issues ranging from problems with antibiotic dosage to patient hospitalization. While national trends of antimicrobial UTI resistance have been tracked, actual patterns of resistance vary by locale.\textsuperscript{1,5,6}

The antimicrobial susceptibility of bacterial organisms isolated from patients with known UTI in northern Utah (primarily Davis and Weber Counties) was the primary focus of this study. The isolated bacteria were subjected to each of the three aforementioned antibiotics. These antimicrobials were chosen due to their high prescription and efficacy rates.\textsuperscript{5} Measurement of resistance and susceptibility was accomplished by Kirby-Bauer disc diffusion antimicrobial susceptibility testing.

**MATERIALS AND METHODS**

This study included 108 bacterial isolates from the urine of 120 patients ages 18 to 50 with diagnosed uncomplicated community-acquired UTI from northern Utah during November 2006 to January 2007 (12 samples resulted in no growth). Specimens were received from 17 area clinics and hospitals, and all 120 patient records were reviewed by the primary care giver in order to verify that the UTI were community-acquired and uncomplicated, with uncomplicated defined as only structurally and neurologically normal female urinary tracts without pregnancy or urinary catheter involvement. Urine samples were collected in BD Vacutainer Culture and Sensitivity urine transfer kits with preservative and kept in a monitored refrigerator at four degrees Celsius for no more than 24 hours. Bacterial identification was performed on 62 samples using the Dade Microscan Walkaway instrument (Dade International Inc., West Sacramento CA).

Resistance of the bacterial isolates to SXT/TMP, ciprofloxacin, and nitrofurantoin was determined by comparing the zones of inhibition around each antibiotic coated sensitivity disc, obtained by measuring the diameter of the area which lacked bacterial growth in millimeters two ways and averaged, as according to the National Committee for Clinical Laboratory Standards (NCCLS) and the Infectious Disease Society of America (IDSA) Kirby-Bauer disc diffusion standards.\textsuperscript{5,7,8} The bacterial measurements were then classified as susceptible or resistant as stated by NCCLS cut-off points.\textsuperscript{8} Kirby-Bauer growth media was inoculated using 0.5 MacFarland standards as measured by BD Crystal Spec Nephelometer\textsuperscript{™} (Becton Dickinson Diagnostic Systems, Franklin Lakes NJ) in Hardy Diagnostic 10 mL clear tubes, in conformance with the previously mentioned guidelines. Hardy Diagnostic Antimicrobial Sensitivity discs were aseptically placed on the Kirby Bauer growth media. Bacterial inhibition zones were measured after overnight incubation. Three America Type Culture Collection (ATCC) bacterial control strains were continuously grown and measured throughout the experimental phase of the study, with all controls giving acceptable results.

**RESULTS**

The 108 microbial isolates tested were from 120 women with uncomplicated community-acquired UTI. Of the 120 samples collected, 12 resulted in no growth and therefore could not be tested. Results of bacterial identification were obtained from the clinical facility for 62 samples, which included the following organisms: 41 *E. coli*, eight *K. pneumoniae*, three *E. faecalis*, two *E. cloacae*, two *K. aerogenes*, one *C. freundii*, one *P. mirabilis*, one *P. aeruginosa*, one *E. aerogenes*, one *K. oxytoica*, and one *R. ornithinolyt*. Only a portion of the bacterial isolates were identified because overall resistance determines empiric treatment efficacy and the scope of this study did not warrant the identification of all samples. Of the 108 isolates tested, 21.3% were resistant to SXT/TMP, 14.4% were resistant to ciprofloxacin, and 13.9% were resistant to nitrofurantoin.

As a subgroup of UTI in general, *E. coli* infections were also analyzed in order to detect the resistance rate, as *E. coli* represents the primary uropathogen.\textsuperscript{5} Analysis of patient data concerning only infections in which *E. coli* was the known causative agent showed that SXT/TMP had exceeded the IDSA’s advised resistance rate of 20%. Of *E. coli* strains, 21.95% were resistant to SXT/TMP, thus exceeding the IDSA acceptable level of resistance.\textsuperscript{7}

**DISCUSSION**

Antimicrobial resistance is a nationwide problem, which requires constant surveillance in order to prevent a systemic breakdown in viable treatment due to widespread resistance. Other national studies have shown increasing uropathogenic resistance rates, but local studies are recommended so physicians and other primary care givers can be apprised of the resistance patterns in their regions and treat patients accordingly. As no data tracking resistant uropathogenic bacteria in northern Utah is available, comparisons have been drawn between local and national data. Data collected on the national level from 1995 to 2001 showed a small increase in the rate of resistance in three prominent drugs used to treat uncomplicated UTI as plotted with this current data (Figure 1). Although we cannot make a valid conclusion as to whether Utah is following a national trend due to the lack of published information, the results of this study showed that
the uropathogenic bacteria in northern Utah have become sufficiently resistant to treatment with SXT/TMP as to render its use contraindicated. A ten-year resistance comparison is shown in Figure 2.

In order to prevent the propagation of SXT/TMP resistance traits, it is no longer advisable to use SXT/TMP for the treatment of uncomplicated UTI. An alternative to SXT/TMP, ciprofloxacin is an inadvisable option. Ciprofloxacin has been associated with tendinopathies, including spontaneous Achilles tendon detachment. Nitrofurantoin, relatively free of major side effects and with the lowest demonstrated incidence of resistance, presents the most viable option for treatment. One hundred mg twice daily for 7 to 10 days is the appropriate UTI management course.  

The clear increase in antimicrobial resistance warrants continuing study of not only the local bacterial population in Utah but elsewhere. It is therefore recommended that further surveillance be undertaken in order to monitor local resistance rates. The importance of accurate local resistance information behooves institutions to monitor future changes and make the data public in order to prevent further resistance and possible antimicrobial impotence.

Clin Lab Sci encourages readers to respond with thoughts, questions, or comments regarding this article. Email responses to ic.ink@mchsi.com. In the subject line, please type “CLIN LAB SCI 21(2) RR LUND”. Selected responses will appear in the Dialogue and Discussion section in a future issue. Responses may be edited for length and clarity. We look forward to hearing from you.

REFERENCES
Evaluation of Disinfectants on Military NATO and DECON Litters

DONNA M HENSLEY

OBJECTIVE: This study evaluated the effectiveness of five disinfectants: A33, 10% bleach, 1% bleach, SPOROX, and 3% H₂O₂, on military NATO and DECON litters.

DESIGN: Suspensions of Acinetobacter baumannii, Staphylococcus aureus, and spore-enhanced Bacillus subtilis, with five percent albumin, were inoculated onto litters and dried overnight. The litters were saturated with disinfectant solutions and sampled after 10 minutes. The Log₁₀ reduction in the number of bacteria recovered was calculated.

SETTING: 59th Medical Wing, 59th Clinical Research Division, Lackland AFB TX.

MAIN OUTCOME MEASURES: A reduction of ≥3 Log₁₀ in the number of bacteria recovered from the test squares compared to the control squares was considered effective disinfection.

RESULTS: On the NATO litter 10% bleach and SPOROX were effective against vegetative cells. On the DECON litter A33, 10% bleach, and SPOROX were effective against vegetative cells. After the 10 minute exposure none of the disinfectants evaluated were effective against spore-enhanced B. subtilis.

CONCLUSION: When contaminated with vegetative cells military NATO and DECON litters can be effectively disinfected with a 10 minute exposure to some disinfectants. Further research is needed to find an effective disinfectant for spore contamination.

ABBREVIATIONS: AFB = Air Force Base; ATCC = American Type Culture Collection; BAMC = Brooke Army Medical Center; BSA = bovine serum albumin; CFU = colony forming units; D/E = Dey/Engley; DECON = decontamination; H₂O₂ = hydrogen peroxide; NAM = nutrient agar with manganese sulfate (50 µg/mL); NATO = North Atlantic Treaty Organization; QAC = quaternary ammonium compound; SBA = Trypticase soy agar with five percent sheep’s blood.

INDEX TERMS: A. baumannii; disinfection; infection control; surface disinfection.
at the time of injury sampled 61 separate acute traumatic injury wounds from 49 casualties upon arrival at the 31st Combat Support Hospital in Baghdad. The study revealed a predominance of gram positive organisms of low virulence and pathogenicity. No multi-drug resistant gram negative organisms were recovered. A study conducted in Iraq and Kuwait by the Walter Reed Army Institute of Research found skin colonization in only 1 of 160 patients who were screened and in only 1 of 49 soil samples, but *A. baumannii-calcoaceticus* complex isolates were recovered from treatment areas in all seven of seven field hospitals sampled.

Bacteria, including *Acinetobacter* spp., have been shown to survive for long periods of time, greater than four months, on dry inanimate surfaces. Some of these surfaces, such as beds, tables, hygroscopic bandages, a stretcher, and infusion pumps, have been implicated as reservoirs for transmission of disease in hospital settings. Surface disinfection has been cited as a contributing factor in controlling and eliminating the transmission of disease from inanimate objects. Many factors can influence surface survival of bacteria and the effectiveness of surface disinfection: type of disinfectant used, type of organisms present, concentration of organisms present, porosity of the material, type of material, and presence of bioload. Additionally, it has been reported that the bacterial binding capacity of a fabric varies with organism and type of fabric. For example, *Staphylococcus aureus* and *Pseudomonas aeruginosa* bind more efficiently to polyester, acrylic, and wool than to cotton. Standard North Atlantic Treaty Organization (NATO) litters are made of loosely woven plastic and nylon. There are few reports in the literature of bacterial disinfection studies performed on porous surfaces and none that address the presence of bioload. This study was undertaken to evaluate the effectiveness of various disinfectants on military NATO and DECON litters in the presence of simulated bioload.

**METHODS**

*Staphylococcus aureus* American Type Culture Collection (ATCC) 29213 and *Bacillus subtilis* ATCC 6633 were obtained in lyophilized form from MicroBioLogics, St. Cloud MN. *A. baumannii* was isolated in the Wilford Hall Medical Center clinical microbiology laboratory from a patient who had served in Iraq. The isolate was stored at -70°C in trypticase soy broth with 20% glycerol until used. These organisms were chosen for the study due to their relevance to current events and as characteristic organisms to represent gram positive cocci, gram negative rods, and spore forming gram positive rods. All cultures for this study were incubated at 37±2°C in ambient air and each isolate was subcultured twice before testing. *S. aureus* and *A. baumannii* were grown on trypticase soy agar with five percent sheep’s blood (SBA). To enhance spore production *B. subtilis* was grown on nutrient agar with manganese sulfate (50 µg/mL) (NAM) and incubated for five days before use to achieve >90% spores. Spore production was confirmed by spore stain. Bacterial suspensions were prepared by harvesting cells from 18 hour to 24 hour growth of *A. baumannii* and *S. aureus* on SBA or five day growth of *B. subtilis* on NAM and transferring the cells to 0.9% sterile saline. To simulate bioload bovine serum albumin (BSA) was added to the bacterial suspensions to achieve a five percent BSA concentration. The suspensions were adjusted spectrophotometrically to an absorbance at 600 nm of 0.15 for *S. aureus* and *A. baumannii* and 0.5 for *B. subtilis*. Absorbance was determined on a Beckman DU Series 600 spectrophotometer. The resulting suspensions contained approximately 1 x 10⁶ colony forming units per milliliter (CFU/mL). The concentrations of the inoculation suspensions were verified by preparing 1:10 serial dilutions of the suspensions in sterile saline and plating the dilutions on SBA. The resulting colony counts were used to calculate the suspension concentrations.

To create a simulated bacterial reservoir 100 µL aliquots of the suspensions, a total inoculation of approximately 1 x 10⁷ CFU, were transferred onto 1.5 inch test squares (n=3 positive control and n=3 test) on clean litters and allowed to dry overnight. The test squares were saturated with the disinfectant solutions: A33 (a quaternary ammonium compound (QAC) disinfectant, Airkem Professional Products, Division of Ecolab, Inc), prepared according to manufacturer’s instructions; 10% solution of 6.0% household bleach in sterile deionized water (1% bleach); SPOROX (7.5% hydrogen peroxide (H₂O₂) plus 0.85% phosphoric acid, Sultan Chemicals), supplied ready to use; or 3% H₂O₂, prepared by diluting 30% H₂O₂ (Sigma-Aldrich) with sterile deionized water. The disinfectants were prepared fresh each day of use. The control squares were saturated with sterile deionized water. After a 10 minute contact time the tip of a sterile cotton tipped swab, moistened with sterile water, was placed in one of the corners of the square. The swab was moved over the surface of the litter, spiraling inward until the entire surface area of the square had been sampled. The sampling time was approximately 15 seconds per square. The swabs were placed in one mL of saline (for A33, SPOROX, and H₂O₂) or Dey/Engley (D/E) neutralizing broth (for bleach) and vortex mixed vigorously for three
to five seconds. The excess moisture was expressed from the swab by rolling it against the side of the tube and then the swab was discarded. The samples were serially diluted, 1:10, in sterile saline and plated on SBA for quantitation. The mean CFU/mL recovered was calculated for each test and control group. The Log$_{10}$ reduction in the number of bacteria recovered from the disinfectant test squares compared to the water control squares was calculated. The organism/disinfectant combinations were set up as separate experiments and each set of test squares was compared to the control squares from the same experiment. A minimum of $1 \times 10^4$ CFU/mL had to be recovered from the control squares for the results to be accepted. A reduction of $\geq 3$ Log$_{10}$ (99.9%) in the number of bacteria recovered was considered effective disinfection.

RESULTS
As shown in Table 1, the mean number of CFU/mL recovered from the control squares for all test runs on the NATO litter was slightly lower than the number recovered from the DECON litter. The day to day variability in the CFU/mL recovered from the control squares was greater on the NATO litter than on the DECON litter (Table 2). The mean CFU/mL recovered from each set of test and control squares was used to calculate the Log$_{10}$ reduction for each disinfectant/organism/litter combination (Table 3).

In this study none of the disinfectants tested were effective against the spore-enhanced *B. subtilis* on either litter, but A33, 10% bleach, and SPOROX were effective against *A. baumannii* and *S. aureus* on the DECON litter and 10% bleach and SPOROX were effective against *A. baumannii* and *S. aureus* on the NATO litter. Under these test conditions 1% bleach and 3% $\text{H}_2\text{O}_2$ were not effective against *A. baumannii* or *S. aureus* on either litter.

DISCUSSION
Finding and eliminating reservoirs and routes of transmission for nosocomial infections remains a high priority for healthcare workers. The increase in the number of multi-resistant organisms and the volume of international travel add to the urgency of this problem. Disinfection of porous surfaces is an area that is largely unexplored. This study evaluated the effect of five disinfectants on selected bacteria inoculated on military NATO and DECON litters. The 10% bleach and 3% $\text{H}_2\text{O}_2$ were included as disinfectants commonly used by healthcare workers. The 1% bleach was evaluated to determine if a lower concentration of bleach could be substituted as a safer and less costly alternative for the 10% bleach. Under the test conditions in our study the 1% bleach was not acceptable as an alternative to 10% bleach. A33 is currently in use as a disinfectant in some military deployment settings. To our knowledge there are no published reports in the literature addressing the effectiveness of A33 or other QACs on porous material. SPOROX is marketed for use as a high level disinfecting solution for heat-sensitive dental instruments. We chose to include SPOROX in the study for several reasons. The high concentration of $\text{H}_2\text{O}_2$ in SPOROX (7.5%) results in oxidation of biological debris, an important consideration for use in trauma settings, which may result in more effective disinfection. SPOROX is commercially available and comes ready to use. If shown to be effective SPOROX could provide an easy, effective means of disinfection in deployment settings. In our study SPOROX was more effective than the 3% $\text{H}_2\text{O}_2$. To achieve effective disinfection the manufacturer of A33 recommends a contact time of 10 minutes. We chose to use the same contact time for each disinfectant challenge. It is probable that increasing contact time would result in effective disinfection for some of the disinfectant/organism/litter combinations that were ineffective at the 10 minute contact time. The amount of time that could be allotted for disinfection of litters would vary greatly in real world situations, from little or no time in a mass casualty situation to hours in low demand situations. It was not within the scope of this study to evaluate multiple contact times.

The NATO litter is made of a tightly woven cotton duck material and the DECON litter is a loosely woven plastic and nylon mesh. Both types of litters are currently in use by our military forces deployed throughout the world though the NATO litters are gradually being phased out in favor of the newer DECON litter. In this study both litter types were inoculated with equal numbers of bacteria but we recovered a greater number of CFUs from test squares on the DECON litter than those on the NATO litter for each of the three bacteria used. Possible explanations for this are: 1) the bacteria bind better to the NATO litter (cotton) than to the DECON litter (plastic and nylon), making recovery harder; or 2) the material construction, tightly woven (NATO) versus loosely woven (DECON), contributed to recovery differences.

| Table 1. Mean colony forming units per milliliter recovered from control squares |
|-----------------------------------|------|------|------|
| Litter                            | A. baumannii | S. aureus | B. subtilis |
| NATO                             | 4.91E+05 | 3.52E+05 | 1.63E+05 |
| DECON                            | 1.32E+06 | 2.91E+06 | 3.16E+06 |
by allowing increased access to bacteria on the more loosely woven material of the DECON litter. Previous reports in the literature indicate that *S. aureus* binds more strongly to polyester than cotton, supporting the theory that construction of the material being disinfected plays an important role in determining recovery. There was greater between run variability in the CFU/mL recovered from the control squares on the NATO litter than on the DECON litter. This could also be explained by the differences in the construction of the litters. It is interesting to note that on the NATO litter the tests that were determined to be ineffective resulted in $\log_{10}$ reductions ranging from 0.32 to 2.92 but on the DECON litter the reductions for the ineffective tests were all $\leq 0.73 \log_{10}$, indicating an “all or nothing” type of result. It is possible that the more loosely woven fabric allows a more even distribution of the disinfectant or a more reproducible access for recovery. The same question (material composition or construction?) can be asked for the disinfection results. If the data is classified as either “effective” or “non effective” disinfection, the only difference between the two litters is the A33 with the vegetative cells. A33 was effective against vegetative cells, i.e., *A. baumannii* and *S. aureus*, on the DECON litter but not on the NATO litter. The activity of quaternary ammonium compounds may be reduced by materials such as cotton indicating that material composition may have played a role in the effectiveness of disinfection by A33.

There are many variables that affect disinfection. Scrubbing before or during disinfection and rinsing after disinfection were not evaluated as part of this study, but these and other mechanical procedures that may be part of a routine disinfection procedure could influence the total reduction in the number of CFU/mL recovered from a porous surface. It is also important to mention that the actual state of litters in use, especially in a trauma setting, will vary dramatically. The overall cleanliness of the litter, the presence or absence of blood, the amount of time that could be dedicated to disinfection procedures before the litter is needed again, and other variables would all influence the effectiveness of any disinfection procedure. It would not be possible to reconstruct every disinfection situation. We limited this study to disinfection of litters contaminated with bacterial suspensions containing a simulated bioload of five percent bovine serum albumin with application of the disinfectants for 10 minutes. With the continuing problem of hospital acquired infections, the rising incidence of community acquired infections, and the growing number of multi-resistant organisms, infection control is gaining in importance. Additional research into surface disinfection of porous materials is needed to fully answer the questions that arise concerning protection of the public from infectious disease transmission.

**Table 2.** Mean colony forming units per milliliter recovered from test and control squares

<table>
<thead>
<tr>
<th>NATO litter</th>
<th>A. baumannii</th>
<th>S. aureus</th>
<th>B. subtilis</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Control</td>
<td>Test</td>
<td>Control</td>
</tr>
<tr>
<td>A33</td>
<td>1.2E+05</td>
<td>5.3E+03</td>
<td>7.5E+04</td>
</tr>
<tr>
<td>10% bleach</td>
<td>5.23E+04</td>
<td>0</td>
<td>4.7E+04</td>
</tr>
<tr>
<td>1% bleach</td>
<td>5.23E+04</td>
<td>2.5E+02</td>
<td>4.7E+04</td>
</tr>
<tr>
<td>SPOROX</td>
<td>1.3E+06</td>
<td>0</td>
<td>9.33E+05</td>
</tr>
<tr>
<td>3% $\text{H}_2\text{O}_2$</td>
<td>1.3E+06</td>
<td>5.23E+03</td>
<td>9.33E+05</td>
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</tbody>
</table>

<table>
<thead>
<tr>
<th>DECON litter</th>
<th>A. baumannii</th>
<th>S. aureus</th>
<th>B. subtilis</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Control</td>
<td>Test</td>
<td>Control</td>
</tr>
<tr>
<td>A33</td>
<td>1.1E+06</td>
<td>0</td>
<td>1.6E+06</td>
</tr>
<tr>
<td>10% bleach</td>
<td>1.6E+06</td>
<td>0</td>
<td>5.9E+06</td>
</tr>
<tr>
<td>1% bleach</td>
<td>1.6E+06</td>
<td>7.76E+05</td>
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</tr>
<tr>
<td>SPOROX</td>
<td>1.27E+06</td>
<td>0</td>
<td>1.23E+06</td>
</tr>
<tr>
<td>3% $\text{H}_2\text{O}_2$</td>
<td>1.27E+06</td>
<td>7.63E+05</td>
<td>1.23E+06</td>
</tr>
</tbody>
</table>
ACKNOWLEDGEMENTS: This research was performed under the authority of the Department of Defense and the 59th Medical Wing, 59th Clinical Research Division, Lackland AFB TX, Institutional Review Board. The author would like to acknowledge Lt. Col Theresa Dremsa, director of nursing research, and Maj Luci Perri, infection control nurse, for their assistance in the design of this protocol. The author wishes to thank the men and women of the United States Armed Forces who have deployed in support of international military operations.

REFERENCES


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Table 3. Log reduction after 10 minute exposure to disinfectant

<table>
<thead>
<tr>
<th>Disinfectant</th>
<th>A. baumannii</th>
<th>S. aureus</th>
<th>B. subtilis</th>
</tr>
</thead>
<tbody>
<tr>
<td>A33</td>
<td>6.04</td>
<td>4.00</td>
<td>0.00</td>
</tr>
<tr>
<td>10% Bleach</td>
<td>2.00</td>
<td>1.00</td>
<td>0.00</td>
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<tr>
<td>1% Bleach</td>
<td>0.00</td>
<td>0.00</td>
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</tr>
<tr>
<td>SPOROX</td>
<td>6.10</td>
<td>5.57</td>
<td>0.00</td>
</tr>
<tr>
<td>3% H₂O₂</td>
<td>0.22</td>
<td>0.44</td>
<td>0.00</td>
</tr>
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</table>

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Table 3. Log reduction after 10 minute exposure to disinfectant
The Effect of Ozone on Common Environmental Fungi

WILLIAM KORZUN, JEFFREY HALL, RONALD SAUER

OBJECTIVE: To determine if gaseous ozone can effectively kill common environmental fungi.

DESIGN: This study was designed to test the null hypothesis that there is no significant difference in viability between fungal conidia treated with ozone and fungal conidia not treated with ozone. A single control group design was utilized.

SETTING: Academic research laboratory.

INTERVENTIONS: Freshly prepared suspensions of Cladosporium spp., Stachybotrys spp., and Aspergillus niger conidia were diluted and plated onto the surface of solid agar plates. The plates were exposed to room air or to different concentrations of ozone for up to four hours, as were uninoculated plates. All plates were then incubated at 25°C until quantitative colony counts could be performed.

MAIN OUTCOME MEASURE: The effect of ozone on fungal conidia viability was assessed by comparing quantitative colony counts from conidia exposed to ozone to quantitative colony counts from conidia exposed only to room air.

RESULTS: There was a significant ($p < 0.05$) decrease in viable conidia of all three fungi, at ozone concentrations of 5.0 – 12.8 parts per million, by four hours of exposure. However, in every case, some conidia remained viable even at the highest level of exposure.

CONCLUSIONS: These data suggest that ozone must be used in conjunction with other methods of remediation or for more prolonged exposure times in order to eliminate fungal contamination of buildings.

ABBREVIATIONS: BRI = Building Related Illness; ppm = parts per million; SBS = Sick Building Syndrome.

INDEX TERMS: Building Related Illness; fungi; ozone; Sick Building Syndrome.


William Korzun PhD DABCC MT(ASCP) is associate professor, Department of Clinical Laboratory Sciences, Virginia Commonwealth University, Richmond VA.

Jeffery Hall MS MT(ASCP) is laboratory manager, Mary Washington Hospital, Fredricksburg VA.

Ronald Sauer MA CLS(NCA), SM(NRM), SM(ASCP) is associate professor, Department of Clinical Laboratory Sciences, Virginia Commonwealth University, Richmond VA.

Address for correspondence: William Korzun PhD DABCC MT(ASCP), associate professor, Department of Clinical Laboratory Sciences, 301 College Street, Virginia Commonwealth University, PO Box 980583, Richmond VA, 23298-0583, (804) 828-9469, (804) 828-1911 (fax). wjkorzun@vcu.edu

Portions of this manuscript were presented as a poster at the annual meeting of the American Society for Clinical Laboratory Science, Chicago IL, July 2006. Portions of this manuscript were submitted in partial fulfillment of the requirements for the Master of Science degree in Clinical Laboratory Sciences at Virginia Commonwealth University.

Air and moisture-related problems in buildings have been on the rise since the early 1970s, contributing to a phenomenon termed Sick Building Syndrome (SBS). As a result of humidity, reduced air exchange rates, and the composition of most building materials, a variety of saprophytic and potentially harmful fungal species have been isolated in cases of SBS. These fungi are relatively harmless to healthy individuals at low levels; however they can pose risks for immuno-compromised individuals or for healthy hosts when present in elevated numbers. Although the cause-and-effect relationship is controversial, these fungi, as well as other...
microbial pathogens, have also been implicated in the more serious situation termed Building Related Illness (BRI). For example, hypersensitivity to Aspergillus may be manifested as allergic bronchopulmonary aspergillosis and/or allergic fungal sinusitis. Sensitization to Cladosporium has been associated with severe cases of asthma. Furthermore, cases of BRI have been alleged to involve mycotoxins released from Stachybotrys found in water-damaged buildings.

A potential remediation for buildings contaminated with fungi is exposure to ozone, O$_3$. In the stratosphere, the formation of ozone from diatomic oxygen and the decomposition of ozone to diatomic oxygen both absorb potentially harmful ultraviolet and cosmic radiation. In the lower troposphere, ozone can be generated by gamma irradiation, ultraviolet lights, lightning, high voltage electrical equipment, and sunlight-induced reactions involving volatile organic compounds in smog and NO$_2$. The strong oxidation potential of ozone makes it fairly toxic to living cells by a variety of mechanisms including free radical formation, lipid peroxidation, oxidation of sulfhydryl and other functional groups in proteins, and alteration of membrane permeability. According to the Clean Air Act, ozone exposure for humans should not exceed 0.12 parts per million (ppm) at a daily one-hour average.

Several studies have shown ozone to be effective at killing a variety of bacteria and fungi. Castillo and others reported that an aqueous solution of ozone sprayed on beef carcasses significantly reduced the load of *Escherichia coli* and *Salmonella typhimurium* on the smooth surfaces of the carcasses. Serra and others demonstrated a 10-fold decrease in viable airborne mold conidia in cheese ripening rooms after treatment with gaseous ozone. Dyas and others reported 95% killing of *Pseudomonas aeruginosa*, *Staphylococcus aureus*, *Aspergillus fumigatus*, and *Candida albicans* after exposure to gaseous ozone, with the fungi requiring higher concentrations of ozone for longer periods of time (1.0-1.5 ppm for six hours) than the bacteria to achieve the same level of killing. Kowalski and others showed that *Escherichia coli* and *Staphylococcus aureus* could be killed with 99.99% efficiency with gaseous ozone. However, ozone concentrations as high as 1500 ppm were required to achieve that level of killing.

There is a dearth of quantitative data on the efficacy of ozone to reduce the fungal burden in contaminated building environments. We investigated the effect of different ozone concentrations in the air and different exposure intervals on the viability of freshly prepared conidia of common environmental fungi.

**Materials and Methods**

**Preparation of fungal conidia**

Samples of *Cladosporium* spp., *Stachybotrys* spp., and *Aspergillus niger* were cultured from buildings suspected of mold contamination. These fungi were utilized in this study because they were isolated in high numbers from the respective buildings, and because they are easily distinguishable from each other and from potential laboratory contaminants on the basis of colonial morphology and microscopic appearance. Cultures were grown on Sabouraud’s dextrose agar in the dark at 25°C for seven days. Each culture was passed at least twice before use to ensure that the cultures were pure and that the isolates were viable. Conidia were harvested by agitating the agar with 1 mL of sterile water. The conidia suspensions were then diluted 1/5 with sterile water and allowed to settle for several minutes to remove larger fungal particles. Conidia suspensions were then adjusted by visual comparison to the turbidity of a 0.5 McFarland standard. Each suspension was examined microscopically to ensure that conidia were present. The suspensions of *Cladosporium* spp. and *Aspergillus niger* were then diluted 1/10 and the suspensions of *Stachybotrys* spp. were diluted 1/100 with sterile water. These dilutions were selected after preliminary experiments revealed that these dilutions would lead to colony counts between 50 and 500 colony-forming units per plate inoculated with 10 μL of conidia suspension. The difference in the dilution required for *Stachybotrys* spp. was undoubtedly due to differences in the size and refractive index of its conidia, compared to those from the other two fungi. Ten μL of supension was spread uniformly across the surface of a fresh Sabouraud’s dextrose agar plate for exposure to ozone or control conditions.

For each day’s experiment with each organism, three plates were inoculated for each ozone concentration and each time of exposure. Each experiment was performed in triplicate with each organism, on three different days with fresh conidia suspensions each day.

**Ozonation Conditions**

Plates were exposed to ozone in a clean 2’ x 4’ x 2’ chamber constructed of plywood and plexiglass. All joints were sealed with silicone caulking. An Air-Zone XT-800 ozonator was centrally located on the exterior of the top panel of the chamber, expressing ozone to the interior of the chamber. Inoculated test and control plates were evenly spaced throughout the interior floor of the chamber and exposed to ozone from one to four hours in one hour increments. Preliminary experiments revealed that ozone concentrations...
of <5 ppm had no effect on the viability of conidia from any of the three fungi. Ozone concentrations of 5.0-7.0 ppm and 11.0-12.8 ppm were achievable inside the chamber with the ozonator set to the two highest settings; and these two concentrations were tested over the selected times. Ozone concentration was monitored using a Model A-21ZX Ozone Sensor manufactured by Eco Sensors, Inc. The chamber was equilibrated to the appropriate ozone concentration for approximately 15 minutes prior to introducing the inoculated plates. Baseline atmospheric ozone readings using the Model A-21ZX Ozone Sensor of the ozonation chamber were taken prior to application of ozone to each test set. All baseline atmospheric ozone readings were 0.04 ppm or less.

**Controls**

For each experiment with each organism, five control plates were set up. One control plate was inoculated with 10 μL of the water used to prepare the conidia suspensions, and incubated without ozonation, to verify the sterility of the agar and the water. The second control was an uninoculated plate that was ozonated for the same time interval as the inoculated plates, to verify that the air in the chamber did not contribute to the number of viable conidia observed on a plate after ozonation. Three control plates were inoculated with the same conidia suspension as the rest of the plates in that experiment, but were not exposed to ozone prior to incubation.

**Quantitation of viability**

After ozonation for a prescribed time interval, inoculated plates and controls were removed from the chamber, incubated at 25°C in the dark, and examined daily for fungal growth. Colony counts were determined by manually counting colonies when they were first visible. In most instances, immature colonies could be observed with the naked eye within 48 hours to 72 hours; but plates were held until colonial characteristics could be distinguished to verify that there were no contaminants and that the appropriate organism was growing. The identity and purity of the organisms on the plates for colony counts was confirmed by microscopic examination with a lactophenol cotton blue stain.

**Statistical analysis**

The colony counts for each organism, exposed to each level of ozone, for each time interval, were compared to the colony counts obtained from the same conidia suspensions on the control plates that were not exposed to ozone, using the t-test for independent samples. A $p < 0.05$ was considered a statistically significant difference in viability.

**RESULTS**

The graphs in Figures 1 through 3 illustrate the effect of ozone on the viability of conidia of *Aspergillus niger*, *Cladosporium* spp., and *Stachybotrys* spp., respectively. All three experienced statistically significant reductions in viability after exposure to 11.0-12.8 ppm of ozone, while *Aspergillus niger* and *Stachybotrys* spp. were also significantly affected at a level of 5.0-7.0 ppm. However, some conidia from all three fungi survived, even after four hours of exposure to the higher dose.

The data also reveals differences between the three fungi and between levels of exposure in the kinetics of the effect of ozone on the viability of their conidia. Although there are not enough time points to make quantitative comparisons, it appears that exposure to the higher level of ozone led to a more rapid decline in viability of the conidia of the three fungi than did exposure to the lower level of ozone. Furthermore, it appeared that with the higher level of ozone, there was a more dramatic decrease in viability of the conidia of *Aspergillus niger* and *Cladosporium* spp. after only one hour, whereas the most dramatic decrease in viability of the conidia of *Stachybotrys* spp. occurred after two hours of exposure.

There was also a qualitative difference in the effect that ozone had on *Cladosporium* spp. compared to the other two fungi. Colonies of *Aspergillus niger*, *Stachybotrys* spp., and *Cladosporium* spp. were typically visible within 48 hours of inoculation of a Sabouraud’s dextrose agar plate with their respective conidia. Following exposure to ≥5 ppm ozone, however, colonies of *Cladosporium* spp. were not visible until 72 hours after inoculation, and the colonies were smaller and less pigmented than those from conidia exposed only to room air. This finding suggests that even though some conidia of *Cladosporium* spp. were able to survive ozonation, the gas causes damage to the metabolic and/or biosynthetic capabilities of the conidia that do survive.

**DISCUSSION**

The results of our study show that ozone is toxic to three environmental fungi commonly isolated from buildings contaminated with mold. We were able to demonstrate significant reductions in the viability of conidia from *Aspergillus niger*, *Cladosporium* spp., and *Stachybotrys* spp. following exposure to ozone at a concentration of 11.0-12.8 ppm for one to four hours. A potential limitation of our study design was that the conidia from these fungi were tested after the organisms had been cultured in a laboratory...
environment, with each culture passed at least twice. It cannot be determined from our study whether these fungi would be more or less susceptible to ozone-mediated damage in their natural environment.

Our results are consistent with earlier investigations into the efficacy of ozone to kill certain bacteria and fungi in two respects. First, while significant killing was achieved with ozone, the killing was not complete under the conditions of the experiments. Second, the concentrations of ozone required to achieve significant killing were well above the level that is considered safe for human exposure. In our study, we used ozone concentrations that were approximately 40 times to 100 times higher than what is considered safe for human exposure. Even though the half-life of ozone in a confined space is reportedly less than ten minutes, a building treated with ozone at that level would be uninhabitable for at least two hours after treatment.

The results of our study reveal several limitations to the potential remediation of mold-contaminated buildings by ozonation. First, the level of killing we observed was significant but not complete, even after four hours of exposure. This suggests that ozonation would provide only a transient reduction in the total mold burden in a contaminated building. Second, the level of killing we observed was with the conidia exposed to gaseous ozone on the surface of agar plates. In contaminated buildings, molds frequently grow into or even behind materials such as sheetrock, plaster, or tiles that would present a diffusion barrier and protect the fungi from gaseous ozone generated in a room or other building spaces. Third, we were able to achieve an ozone concentration of 11.0–12.8 ppm with a commercial ozone generator operating on the “high” setting and discharging the ozone into a closed chamber with only 16 ft³ of total volume. This,
along with the first two limitations, suggests that it would be difficult to achieve effective fungicidal concentrations of ozone inside large buildings.

Given the results of this study, further research is indicated to identify the specific macromolecules in fungal conidia that are oxidatively damaged by ozone, in order to elucidate the mechanisms whereby ozone is toxic to each of the species of mold that commonly contaminate buildings. An understanding of these mechanisms will facilitate future research into what other agents may be combined with ozone to potentiate its fungicidal activity and to overcome the physical barriers to its successful application to the process of building remediation.

In conclusion, gaseous ozone in high enough concentrations can significantly reduce the number of viable conidia from Aspergillus niger, Cladosporium spp., and Stachybotrys spp., but not completely eliminate them. Ozonation may be useful as one component of a multifaceted strategy for treating mold-contaminated buildings; however, it is unlikely to be effective by itself for building remediation.

Clin Lab Sci encourages readers to respond with thoughts, questions, or comments regarding this article. Email responses to ic.ink@mchsi.com. In the subject line, please type “CLIN LAB SCI 21(2) RR KORZUN”. Selected responses will appear in the Dialogue and Discussion section in a future issue. Responses may be edited for length and clarity. We look forward to hearing from you.

REFERENCES
FOCUS: BIOETHICS

Bioethics—Problems for Today

SUSAN J LECLAIR

LEARNING OBJECTIVES
After completing the articles in Focus: Bioethics, the reader should be able to:
1. compare the Kantian view of ethics and utilitarianism as tools for medically-related decision-making.
2. compare and contrast autonomy and beneficence as tools for medically-related decision-making.
3. justify the use of these ethical theories in each of the three settings.
4. assess the philosophical theory used by a facility in situations concerning decision making.
5. assess the philosophical theories used by a facility in situations concerning informed consent.

Before there was treatment for serious diseases, there was no need for a discussion about the side effects of that treatment. Before there was life after certain diagnoses, there was no need for a discussion about the quality of that life. Before there was large scale experimentation on humans, there was no need for informed consent. Before there was laboratory or medical imaging studies to provide scientific support for diagnosis, there was no need for a discussion of the role of those practitioners in the ethical decision-making process. Before there were medically or scientifically based ethical dilemmas, there was no need to consider the effect of compromising one’s ethical belief.

But, we now live in times that demand these discussions as we deal with our own or family decision-making, with issues in our professional environment and with policies at all levels of government. So how do we face ethical dilemmas?

It is possible to simply rely on the moral teachings of one’s religion. But different religions have different teachings regarding some situations and are silent regarding other situations. No one willingly follows a religion that does not claim to have the correct answers. Since the answers do not agree, at least some must be incorrect. How does one determine this? The answer “Mine is correct and yours is not” is not intellectually satisfying.

It is possible to simply ignore these dilemmas. After all, they only involve a small number of people in highly circumscribed, perhaps even contrived, relationships. As long as these situations do not involve one personally, then not having an opinion is an option. But is it a satisfying choice? To quote Socrates, “The unexamined life is not worth living.” Are we not as humans required to grapple with thought and to exercise free will? If so, then failing to confront the issues of the day makes us less human.

It is possible to evaluate the basic assumptions through which we live our lives. A philosophical approach is difficult, for many assumptions are ingrained in a complex web of belief systems, cultural expectations, education, and experience. What is moral in one culture might not be in another. What was correct at one time might not be in another.
bias and tradition are at the heart of many disputes today. Are ethics a constant or does they too change with time or place? If they change, then what need is there for profound thought? If they do not change, then why do we not find them as constants throughout history or cultures?

Ethical dilemmas that face the medical and scientific communities will only increase as we move forward into this century. Whether as patients or caregivers, laboratorians will be involved in them at many different levels. If a person does not support a particular action, how can they continue to work for an organization or institution that does? If a person does support a particular action, how can they continue to work for an organization or institution that refuses to act in this manner?

The scenarios presented here do not at first glance impact the clinical laboratory directly. Yet, each of us has faced a patient who has refused to provide a blood specimen. How hard should we try to convince another that having a specimen collected is a good thing? Each of us expects that our wishes concerning our own medical care will be honored. What impact will our knowledge and influence have as we serve as health proxies to others?

There is a worldwide debate over the utilization of personal information by unknown numbers of agencies and groups. As we are responsible for the generation of the data, are we responsible for how that data is used? Or are we just following orders? Or do we have multiple (perhaps contradictory) views as individuals, as parents, as health proxies, as professionals?

This Focus section is not intended to provide definitive answers. It is the intent to provide a framework for people to clarify their own views, particularly on informed consent. While there are many different frameworks for these discussions, we chose those that differ most dramatically. We hope that they will encourage lunchtime discussions, after dinner musings, and spirited conversations at professional meetings.

Susan J Leclair PhD CLS(NCA) is the Focus: Bioethics guest editor. She is chancellor professor, Department of Medical Laboratory Science, University of Massachusetts Dartmouth, 285 Old Westport Road, Dartmouth MA 02747-2300. (508) 999-8786. sleclair@umassd.edu.

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ENDNOTES
FOCUS: BIOETHICS

Case One: Patient Autonomy and the Freedom to Act against One’s Self-interest

JENNIFER WILSON MULNIX

A 16-year-old Hodgkin lymphoma patient refuses to have his blood specimen drawn, thus canceling his scheduled oncologic treatment. As a 16-year-old, he has no legal standing as an adult. His parents are split over his decision. One supports his right to choose; the other wishes the specimen to be drawn and the chemotherapy reinstated. The physicians at the hospital are seeking legal redress to have the court order the blood specimens to be taken.

INDEX TERMS: autonomy; bioethics; informed consent; Kant; Mill; utilitarianism.

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Jennifer Wilson Mulnix PhD is assistant professor, Department of Philosophy, University of Massachusetts Dartmouth, Dartmouth MA.

Address for correspondence: Jennifer Wilson Mulnix PhD, assistant professor, Department of Philosophy, University of Massachusetts Dartmouth, 285 Old Westport Road, North Dartmouth MA 02747 (508) 910-6869, (508) 990-9674 (fax). jmulnix@umassd.edu.

Susan J Leclair PhD CLS(NCA) is the Focus: Bioethics guest editor.

Are people uniquely qualified to decide what is in their best interest? At what age? This case raises compelling questions concerning the role of paternalism in healthcare, and the asymmetrical nature of the physician-patient relationship. A patient often willingly surrenders some autonomy to the physician who, as an expert, may be in a better position to recognize what is in the patient’s best interest. Moreover, one of the legitimate aims of government is ensuring the well-being of its citizens. When we apply these positions to circumstances in which a patient does not have the ability to deliberate, such as small children and mental illness, the case for restricting patient choice seems straightforward.

However, one can advance an argument in favor of patient autonomy when the patient meets the minimum standards of rationality. This argument does not defend patient autonomy by reference to the intrinsic value of the individual. Rather, one can argue that it is the quality, not length of life that is important. Further, it should be up to each individual to decide what minimum quality of life is acceptable.

Some argue a patient is never in a position to give informed consent because he or she cannot appropriately judge the advice of the physician. To achieve informed consent the patient must be competent to understand the details of his or her situation; must be provided all the relevant information; and must be free from coercion. In our case, the patient has refused to have a blood specimen collected. Furthermore, the parents have not decided what is in his best interest. Absent a decision, the 16-year-old’s autonomy should be protected. To impose a minimum age requirement on when an individual is capable of rationally deliberating for him or herself is arbitrary. In the case under consideration, while the 16-year-old patient does not have legal status as an adult, presuming he is a “normal” 16-year-old, he may meet minimum standards of rationality necessary for informed consent. United States law considers a person who is at least 14 years old to be eligible for legal emancipation so it could be construed that a 16-year-old is capable of judging self-interest, regardless of legal standing as a minor.

Is it ever legitimate for a government or physician to restrict the actions of citizens or patients for their own good, even when the citizen is capable of acting rationally? Many argue that the individual freedom of a rational adult should never be restricted unless it interferes with the freedom of another. This is the harm principle. In fact, a basic feature of individual autonomy is the ability for people to choose things that are
not good for themselves. So, while the physician may in fact be the only one qualified to determine what is in the patient’s best interest, it is still up to the patient to decide whether he will act in self-interest.

Key to assessing this issue is the recognition that it is the quality, not the length, of life that is important. Sometimes the pain of an illness or its treatment creates more suffering than a patient is willing to endure, even for a promise of a better life in the future. Moreover, it is up to the individual to decide what minimum quality of life is acceptable. And no one is in a better position to make this judgment than the individual. Thus, even if a physician is in a better position to know the patient’s best interest, it is still the choice of the patient to refuse treatment if he views the harm as too great. Autonomy means the ability to choose things that are not in one’s self-interest. Compelling people to act in ways for their own good is never legitimate. Thus, the issue is not who is in a better position to judge what is in the patient’s best interest, but for even conceding the role of expertise to the physician a patient should be allowed to choose to act against his self-interest.

One might advance further arguments that the individual, barring irrationality, is always in a position to judge what is in his self-interest, but this is unnecessary. What needs to be demonstrated is not what is in the best interest of the patient, but whether the patient meets the minimum standards for informed consent.

ENDNOTES
2. This refers to a Kantian deontological argument, where it would violate the intrinsic worth of an individual to treat him or her as a means instead of an end. See Kant I. Groundwork of the metaphysics of morals [1785]. Cambridge: Cambridge University Press; 1997.
3. This is essentially a consequentialist argument, wherein life only has value insofar as it brings the person happiness. I am also alluding here to Mill’s distinction between the quality and quantity of life. See Mill JS. Utilitarianism [1863]. Crisp R, editor. New York: Oxford University Press; 1998.
5. For a further explanation of the conditions for informed consent, see the Principles of the Nuremberg Code [1946-1949]. Available from http://www.cirp.org/library/ethics/nuremberg/. Accessed 2008 Jan 15. Though these principles are immediately concerned with the conditions of legitimate use of human subjects in medical experiments, the conditions for informed consent can be applied to consent to medical treatment.
FOCUS: BIOETHICS

Case One: Patient Interests and Medical Paternalism

MJ MULNIX

A 16-year-old Hodgkin lymphoma patient refuses to have his blood specimen drawn, thus canceling his scheduled oncologic treatment. As a 16-year-old, he has no legal standing as an adult. His parents are split over his decision. One supports his right to choose; the other wishes the specimen to be drawn and the chemotherapy reinstated. The physicians at the hospital are seeking legal redress to have the court order the blood specimens to be taken.

INDEX TERMS: autonomy; bioethics; informed consent; Kant; Mill; utilitarianism.


Michael J Mulnix PhD is assistant professor, Dean College, Department of Philosophy, Franklin MA.

Address for correspondence: Michael J Mulnix PhD, assistant professor, Dean College, Department of Philosophy, 99 Main Street, Franklin MA 02038. (508) 541-1755. mmulnix@dean.edu.

Susan J Leclair PhD CLS(NCA) is the Focus: Bioethics guest editor.

The most fundamental question presented by this case is, “Who is in position to judge what is in the patient's best interest?” To many, the answer seems clear. Respect for the autonomy of the patient requires that he have the power to make decisions regarding his medical treatment. That is, there is a presumptive case in favor of allowing patients the right to determine for themselves the course their lives will take, and this includes the course their medical treatment or non-treatment will take. This rests on the assumption that patients are capable of exercising autonomy. But, what is required for a person to be in a position to exercise genuine autonomy?

In order to make autonomous decisions two conditions must be satisfied. First, the agent must be minimally rationally capable. In other words, a patient must be capable of recognizing and weighing differences between diverse treatment options, and then be able to reach a reasoned conclusion. In this case, the issue is complicated by the fact that the patient is a minor. Nevertheless, that we have chosen the age of 18 to be the ‘age of reason’ seems arbitrary, and certainly there is a case to be made that many persons under the age of 18 meet the condition of minimal rationality. The second condition for autonomous action is that the individual must have knowledge relevant to making informed decisions. Though one may have the rational abilities to make decisions with respect to investing money in the stock market, he might lack the knowledge to make informed choices. Hence, he should rely on others with knowledge to make decisions on his behalf. Likewise, we may wonder whether patients can make informed choices regarding their medical care.

So, does the young patient meet these two conditions? Actually, he fails on both counts. With respect to the first condition: acting according to our perceived interests is insufficient to guarantee that we have exercised autonomy, since we can, and often do, act in ways that we want but which are counter to our actual interests. In order to make an autonomous decision we must at least be able to disambiguate our true from our perceived interests (even if, in the end, we choose against them). However, this requires us to take an objective and emotionally detached stance with respect to our own desires. This is difficult when we are confronted with life circumstances that hinder objectivity relative to our presently perceived interests. In such circumstances, it would be in our interest to trust those who are capable of making emotionally detached judgments.

Often patients are so deeply invested in the circumstances of their lives it is a real question whether they can achieve the sort of objectivity necessary for rational choice. Patients, therefore, are unreliable authorities with regard to their best
interests. Obviously, people make mistakes adjudicating between what is or is not a genuine interest in many situations. But, certain life circumstances make it more likely (and sometimes even probable) that a person will err. Confronting a medical condition is one among these life circumstances that make it more difficult for a person to make rational, sound, and determinate judgments. Consequently, our patient is not the final authority regarding his own medical interests, and neither are his parents, as they also are too emotionally invested to be objective.

Moreover, patients rarely have access to the relevant knowledge requisite for making informed decisions. The complex medical data affecting even the most mundane of medical procedures is often accessible only to those who have spent their life specializing in such knowledge. Thus, even if the patient is somehow able to detach himself from his own life circumstances in order to make an objective determination of his interests, he is not necessarily in a position to make an informed decision since he may not have access to all of the relevant information. Some might argue that physicians and medical staff have a moral duty to inform the patient so that he can make the decision. But is that even possible, let alone desirable? Given the haste with which many medical decisions must be made, and given the years of experience that guide physicians and medical staff in making decisions, it is implausible to suppose that physicians can ever adequately inform patients about all the relevant medical information necessary for informed choices. It takes years of intense schooling and focus to gain such knowledge, and in the context of immediate patient care it seems irresponsible to expect patients to be able to gather, synthesize, and understand everything relevant to their condition when doing so took their specialized physicians years.

Thus, it appears that neither the patient nor his parents are positioned to make informed and accurate choices. Rather, physicians are those positioned best. Certainly, physicians can make mistakes, so we need to ensure that decisions are informed by medical standards. Physicians are not infallible, but they are less fallible than their patients. Giving authority to the persons most aptly situated to make accurate judgments concerning patient medical needs is the most rational course of action. Therefore, we should adopt a policy of limited medical paternalism, whereby physicians are considered final authorities regarding patient healthcare interests.

Hence, if the physicians believe it will serve the patient’s medical interests to continue his chemotherapy by having his blood specimen drawn, they should be granted the authority. The patient and his medical proxy are incapable of making autonomous decisions. So, we should rely on those who are in the best position, all things considered, to make judgments regarding the medical needs of the patient: we should trust our physicians.

ENDNOTES

2. For an interesting discussion concerning how certain medical conditions can hinder a person’s ability to distinguish their genuine interests from presently perceived interests, see: Groarke L. Paternalism and egregious harm: Prader-Willi syndrome and the importance of care. Public Affairs Quarterly 2002;(16):3.

3. Arguments that detail the conditions necessary to be a final authority with regard to one’s interests can be found in: Taylor C. What’s wrong with negative liberty? In: Ryan A, editor. The idea of freedom. Oxford: Oxford University Press; 1979. Taylor makes a claim stronger than the one above, in that he argues that an individual is never a final authority with respect to his interests due to the inescapability of his emotional investment in his own life. Though, for the argument of this paper, the weaker claim that an individual can sometimes be so emotionally invested in present circumstance that he can be disqualified as a final authority with regard to his interests is all that is required.

4. For a discussion concerning possible responses to this question see: Lipkin M. On telling patients the truth. Newsweek, 1979 Jul 4.

Clinical trials in a number of countries are now underway to evaluate experimental, non-human blood substitute.\(^1\) One scenario calls for the blood substitute to be available on board emergency vehicles. This allows first responders the opportunity to provide transfusion support at an accident site and on the way to the hospital. However, many of the patients who would most benefit from the use of this material may be unconscious and unable to comprehend or sign an informed consent. One possible solution would be to eliminate the need for informed consent.

INDEX TERMS: autonomy; bioethics; informed consent; Kant; Mill; utilitarianism.

Clinical trials in a number of countries are now underway to evaluate experimental, non-human blood substitute.\(^1\) One scenario calls for the blood substitute to be available on board emergency vehicles. This allows first responders the opportunity to provide transfusion support at an accident site and on the way to the hospital. However, many of the patients who would most benefit from the use of this material may be unconscious and unable to comprehend or sign an informed consent. One possible solution would be to eliminate the need for informed consent.

The infamous Tuskegee experiments in Alabama began in 1932, some 10 years before the Nazi experiments. They continued 25 years after the 1947 creation of the Nuremberg Code. The experiments documented the progression of syphilis in African American males. The men were not told they had syphilis, nor were they told they were subjects of an experiment. Ten years after the initiation of the study, it was discovered that penicillin cured the disease; however, the men were not treated, and the experiment continued. Many subjects died, and those who did not suffer the debilitating effects of the untreated disease. Wives were infected by their unsuspecting husbands, and children were infected by their mothers. The experiments were finally put to an end in 1972, as a result of front page articles featured in the Washington Star and The New York Times.\(^4\) The Tuskegee experiments prompted Congress to impose federal regulations on human experimentation, requiring voluntary, informed consent of human subjects involved in federally funded experiments.\(^5\)

To avoid the horrors of the past, informed consent is required for experiments involving humans. However, federal regulations allow for a narrowly tailored exception which permits research in emergency settings without informed consent. To fall within the exception, the research must meet the following criteria: (a) informed consent is not feasible; (b) the human subjects must be in a life-threatening situation; (c) available treatments are unproven or proven unsatisfactory; (d) participation in the research carries the prospect of direct benefit to the subjects; (e) the collection of valid scientific evidence is necessary to determine the safety and effectiveness of the particular intervention; and (f) the clinical investigation could not practicably be carried out without the waiver.\(^6\) Allowing first responders to administer blood substitute to unconscious patients when blood loss is critical...
and there is no legal representative to consent for the patient meets these criteria.

In emergency cases informed consent may not be feasible if the patient is unconscious and there is no legal representative. Moreover, there is no way for researchers to prospectively identify who in the community will suffer massive blood loss at an emergency site. When first responders determine that blood loss is life-threatening, blood transfusion is necessary to ensure patient survival during transportation. Currently, first responders administer volume expanders to increase the patient’s blood volume. However, these do not support tissue oxygenation. Administering a blood substitute may benefit the patient by simulating the properties of a blood transfusion. The safety and effectiveness of the blood substitute can only be assessed without a waiver because patients suffering massive blood loss would not be able to comprehend the information being supplied to them even if they were conscious.

Of course, the fact that the law allows an exception to the informed consent requirement does not mean waiving the requirement is the right thing to do, but waiving informed consent in emergency cases is consistent with the principles underlying the requirement. Given the unthinkable treatment of human beings during the Nazi and Tuskegee experiments, the world cannot trust that all of humanity will view fellow human beings as ends in themselves, that is, as autonomous individuals who innately possess value and natural rights. Instead, history has proven that at least some researchers view their subjects as means to gain scientific knowledge, or as expendable for the greater good of society. However, in the case of unconscious patients who will die without a first response transfusion, administering the blood substitute affirms the patient’s value as a human being. Unlike the Nazi and Tuskegee experiments, waiving informed consent in these emergency cases attempts to benefit the patient and acknowledges his/her welfare as the most important objective.

Exceptions to informed consent are dangerous, no matter how narrowly tailored. Still, in first response situations where death is imminent due to blood loss, the humane course of action is to administer the blood substitute. To safeguard against abuses, the experimental protocol should detail the conditions under which informed consent is waived. The institutional review board (IRB) should discuss the proposed clinical trial with members of the participating communities. These discussions should include the risks and benefits of the trial, identifying groups that should be excluded from the trial, including community consultants on the IRB, and discussing other mechanisms for ensuring community involvement. The IRB should also publicly disclose information about the clinical trial to the communities involved before the trials begin. Lastly, an independent data monitoring committee should be established to oversee the clinical trials.

ENDNOTES
1. In addition to the Nazi and Tuskegee experiments discussed in the comment, controversial experiments continue. Three examples include the gene therapy experiment at the University of Pennsylvania, the skin cancer vaccine experiment at the University of Oklahoma, and the AZT experiment in Africa. See: Charrow R, Bramlage JC. Biomedical research: human subjects protection. The National Law Journal. Oct. 30, 2000:B10. This reports the FDA found that researchers at the University of Pennsylvania failed to fully comply with informed consent requirements and that researchers at the University of Oklahoma misled subjects into thinking the experimental skin cancer vaccine would shrink their tumors. Also see: Lurie P, Wolfe S. Unethical trials of interventions to reduce the transmission of the human immunodeficiency virus in developing countries. New Eng J Med 1997;337:853. This explains ethical violations in fifteen of sixteen studies on AZT performed in third world countries.
FOCUS: BIOETHICS

Case Two: A Kantian Approach to the Morality of Blood Substitute Clinical Trials Without Informed Consent

KEOTA FIELDS

Clinical trials in a number of countries are now underway to evaluate experimental, non-human blood substitute. One scenario calls for the blood substitute to be available on board emergency vehicles. This allows first responders the opportunity to provide transfusion support at an accident site and on the way to the hospital. However, many of the patients who would most benefit from the use of this material may be unconscious and unable to comprehend or sign an informed consent. One possible solution would be to eliminate the need for informed consent.

INDEX TERMS: autonomy; bioethics; informed consent; Kant; Mill; utilitarianism.

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Keota Fields PhD is assistant professor, Department of Philosophy, University of Massachusetts Dartmouth, Dartmouth MA.

Address for correspondence: Keota Fields PhD, assistant professor, Department of Philosophy, University of Massachusetts Dartmouth, 285 Old Westport Road, Dartmouth MA 02747. (508) 999-8506. Kfields@umassd.edu.

Susan J Leclair PhD CLS(NCA) is the Focus: Bioethics guest editor.

The ethical question posed by this scenario is penetrating: Is it moral to use an experimental, non-human blood substitute to provide on-site transfusions without the patient’s informed consent? At first blush, assuming the blood substitute is effective, commonsense morality might uphold its moral permissibility both because the patient’s life could be saved and because the knowledge gained from such trials may save lives. This view fits a position in normative ethics called consequentialism; the view that the only factors relevant to an action’s moral worth are its consequences. As Shelly Kagan puts it, “If an act will have bad results, that is a reason not to perform it; if, on the other hand, it will have good results, then that is a reason to perform it.”

However, since a requirement forcing medical personnel to obtain informed consent could have negative consequences with no obvious countervailing benefits, the consequentialist appears committed to the claim that medical personnel have an obligation not to require informed consent—that such a requirement would be immoral. That’s because consequentialism claims that we are morally required to perform the act with the best outcome in a given situation. Since performing the transfusion without the obstacle of obtaining informed consent could produce the best outcome compared to the alternative of seeking informed consent (even in the case where it can plausibly be obtained), we are morally required to do so and any other act is morally forbidden. But this seems too strong. Shouldn’t we at least seek informed consent whenever we can? It’s also worth noting that consequentialism is consistent with the claim that the transfusion is morally required even if those performing it know beforehand that the patient will die—if the blood substitute is known to be toxic—so long as the death of this patient results in medical knowledge that can save lives in the future. This places consequentialism outside the realm of commonsense morality. What seemed to be an obvious and unproblematic method for determining one’s moral obligations in this case is revealed on analysis to require substantial and controversial moral commitments.

At this point, the reader sympathetic to the moral value of the consequences of performing these transfusions but unwilling to accept consequentialism’s more severe implications might want to argue that there is a middle ground. We could construe the moral value of the outcome in this case in conditional terms. We could say, for instance, that if informed consent can be obtained, then one has a moral obligation to do so; but if informed consent cannot be obtained, then one
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has a moral obligation to promote a procedure that could save lives now and in the future. However, it should be noted that this principle does not follow from consequentialism. Recall that for the consequentialist an action’s consequences are its only morally relevant factor. Since obtaining informed consent has no influence on whether or not the experimental transfusion is successful, it does not factor at all into the consequentialist’s moral calculus except negatively in the case where obtaining informed consent would forestall the procedure’s benefits. So there is no room within consequentialism for the construction of conditional moral principles like the one above.

Where does the consequentialist go wrong? Kant gives us an incisive analysis. The problem, according to Kant, is that the consequentialist allows the patient’s value to be determined solely by the outcomes she can be used to produce, for instance whether she can be used to promote life saving treatments. Commonsense morality does not value people to be contingent on outcomes. Commonsense morality claims using a person as an instrument for the sole purpose of securing a favorable outcome is immoral—particularly without consent. Kant supports commonsense morality and offers an explanation as to why such actions are immoral.

While Kant’s full theory is large and complex it seems clear that the consequentialist approach to this case would violate a version of Kant’s fundamental moral principle: the categorical imperative. The version of the categorical imperative at issue is what Kant calls the Formula of Humanity (FoH): “So act that you use humanity, whether in your own person or in the person of any other, always at the same time as an end, never merely as a means” (AK 4: 429). Kant does not claim we should never use people as means, only that we should never treat them exclusively as means. To do so would be to regard a self-directed rational being as little more than a tool. Kant thinks we can, and often do, use the capacities of others for the accomplishment of our own ends without treating them merely as instruments; but this only happens when we behave towards others in ways that they can consent to when they are exercising their reason. Such conditions do not obtain in the case of the non-consensual blood transfusions under discussion, and this is a compelling reason to deem the proposal immoral.

ENDNOTES
5. Kant’s moral theory can be found in: Kant I. Groundwork of the metaphysics of morals. Cambridge: Cambridge University Press; 1997.
6. The standard format for citing passages from Kant’s works is to refer to the volume number and page number of the German Academy (AK) edition of his works where the passage may be found. For instance, (AK 4: 227) refers to volume 4, page 227 in the German Academy edition.
FOCUS: BIOETHICS

Case Three: Ethics of Coercion

ANDREW M SWIFT

A woman is murdered in a small town. At autopsy, the pathologist notes the woman had engaged in sexual relations shortly before her murder. The police department determines the male partner should be considered a person of interest in their investigation. They begin a canvas of the town, asking every male to voluntarily consent to a DNA test. Men refusing to provide the specimen will be publicly listed as potential suspects and perhaps arrested. All 1500 men in the town provide a specimen and none is identified as the sex partner. The DNA results are entered into the FBI’s database and made available to every law enforcement agency in the country.

INDEX TERMS: autonomy; bioethics; informed consent; Kant; Mill; utilitarianism.

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Andrew M Swift PhD is professor, Department of Philosophy, St. Ambrose University, Davenport IA.

Address for correspondence: Andrew M Swift PhD, professor, Department of Philosophy, St. Ambrose University, 518 West Locust Street, Davenport IA 52803. (563) 333-6000. swiftandrewm@sau.edu.

Susan J Leclair PhD CLS(NCA) is the Focus: Bioethics guest editor.

The investigative techniques involved in this case are well within the bounds of acceptable police practice.¹ There is a compelling state interest in apprehending the woman’s killer and the police have an obligation to use all reasonable and legitimate means to solve the crime.² These techniques include a number of methods designed to influence, persuade, and sometimes pressure people to cooperate with criminal investigations.

It could be argued that the police should not have asked the men to submit to DNA testing because some might have felt pressured to comply. This did not appear to be the case. All the men agreed to be tested when they all could have declined participation. Insofar as the testing exonerated them it is reasonable to suppose many agreed to be tested because they knew that the analysis would exclude them as suspects. Most rational individuals when faced with this set of circumstances would agree to assist the investigation even under pressure to comply. That is to say, a decision to submit to DNA testing under pressure is consistent with voluntary participation.³

The police may have asserted undue influence by informing the men that their refusal to participate might result in a public listing and/or possible arrest. Did this play a role in some of the men’s decision to agree to be tested? In all probability, it did. The question is not whether it played a role in the men’s decision to participate, but whether it represented an undue influence.

Influence is not necessarily coercion and police are permitted to attempt to influence people who are cooperating in criminal investigation.⁴ Police routinely withhold information from potential suspects and witnesses to gain their collaboration and in some cases outright deception is recognized as a legitimate investigative method.⁵ Given compelling state interest in apprehending the murderer, it seems reasonable the police would use this technique to get the men to agree to a non-invasive test that would potentially exclude them as suspects.

While it is important to note again that in this case all of the men obliged and none were publicly listed as uncooperative, the question of public listing raises a moral question as it may lead to unjustified sanctions against innocent people. This, in turn, raises an interesting question: can the threat of public listing be justified when the police have no intention of following through?
If the threat of public listing is a deception designed to gain cooperation, then it could be argued that it is a legitimate investigative technique. Many people are reluctant to cooperate with police investigations and it is a common practice for the police to apply pressure to ensure cooperation. This is a problem only if the police act on the threat, and in this case, they did not.

Finally, it might be argued that even though the men did consent to the testing they were not informed the results would be permanently recorded and made available to law enforcement agencies throughout the country. Had the men known the implications of their participation in this investigation would they have still agreed to be tested?

For non-forensic genetic defect testing, the facility conducting the DNA tests has an obligation to inform patients of the risks and benefits. Informed consent is a legal requirement for laboratories performing DNA testing. Personnel are required to explain it fully and answer all questions.

Informed consent, however, is not a requirement for criminal investigation. Consequently, the fact that the men were not completely informed of the full implications of their decision is not itself evidence of wrongdoing on the part of the police.

Even if police have an obligation to inform potential suspects the results would be entered into the FBI’s database, they could solve this problem by simply not sharing the findings. The question of whether or not to share any outcomes is not relevant to the criminal investigation.

This case poses no insurmountable ethical problems. The men regarded as suspects voluntarily agreed to provide DNA for testing. Even if some of the men felt pressured to submit to the DNA testing, the use of pressure is a commonly accepted investigative practice. Even if it could be shown that the public listing of the uncooperative persons is wrong, it doesn’t logically follow that the threat of such a public listing is unethical. Even if it can be shown that the men had the right to know that the results would become part of the FBI database, this could be easily remedied in a way that does not compromise the criminal investigation. The investigative techniques in this case are completely acceptable.

ENDNOTES
FOCUS: BIOETHICS

Case Three: Collection of Evidence in a Murder Investigation

JESSICA GOSNELL

A woman is murdered in a small town. At autopsy, the pathologist notes the woman had engaged in sexual relations shortly before her murder. The police department determines the male partner should be considered a person of interest in their investigation. They begin a canvas of the town, asking every male to voluntarily consent to a DNA test. Men refusing to provide the specimen will be publicly listed as potential suspects and perhaps arrested. All 1500 men in the town provide a specimen and none is identified as the sex partner. The DNA results are entered into the FBI’s database and made available to every law enforcement agency in the country.

INDEX TERMS: autonomy; bioethics; informed consent; Kant; Mill; utilitarianism.

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Jessica Gosnell PhD is assistant professor, Department of Philosophy, Saint Ambrose University.

Address for correspondence: Jessica Gosnell PhD, assistant professor, Department of Philosophy, Saint Ambrose University, 518 West Locust Street, Davenport IA 52803. (563) 333-6088. GosnellJessica@sau.edu.

Susan J Leclair PhD CLS(NCA) is the Focus: Bioethics guest editor.

The case against this investigation rests on the failure to obtain informed consent. Informed implies the subject is provided with information and achieves understanding. Consent must be voluntary because one cannot be said to consent to something if it is against his will.1

A significant challenge to the acquisition of valid informed consent is evaluating to what extent the subject understands the information he has been given. In the case of research subjects, while they may be provided with sufficient information to competently agree to participate, their consent is unlawful if they do not understand.2 The requirement for informed consent has traditionally placed the burden on the party seeking consent; this party is obligated to find a way to adequately explain the information and its implications.

Consent is invalid when information is withheld. In obtaining consent, an agent may choose to manipulate the information to present the most compelling case. The agent attempts to balance the subject’s right to information and the interests of a third party.3

Another threat to informed consent is involuntary consent in which subjects feel coerced. Information manipulation and coercion combine when a subject who does not understand consents because he fears being perceived as foolish or as “holding up” the process with clarifying questions. Subjects remain uninformed about what they are consenting to. Both inadequate information and the sense of pressure nullify the legitimacy of their informed consent.

In this case, all three challenges to valid informed consent are present. First, it is not clear the men understood the implications. They were not told the results would be recorded and made available throughout the country. This could change the subjects’ reactions to the request. The men were not provided essential information.

It may be the information was intentionally withheld or manipulated to avoid resistance. If investigators strategically selected information to coerce their compliance, a further dimension is added to the failure to achieve informed consent. While it may be true the men were more likely to comply if they did not know about the national registry, their compliance as a result of manipulation only stands to demonstrate the critical nature of the information. Not informing the men for this reason could be compared to borrowing money from a friend and deliberately omitting that you have no intention to pay it back on the grounds
that this will make the friend less likely to extend the loan. It may be true, but it certainly does not justify manipulating the friend in this way. In this case the investigators could say that they are acting in the best interest of the victim, or possibly the state, and that this justifies omitting the critical information. Again, while this may be true, it does not change the fact that the consent they elicited could not be accurately described as informed. Though this could not have been known at the time, the fact that the testing revealed that none of these men was the woman's partner only stands to support the point that there was no reason to maintain that the interests of the investigation could outweigh the interests of 1500 innocent men, given that in practice, this infringement produced no useful results. A critic of this point might complain that we legitimately withhold information all the time. We cannot be expected to report all of the truth all of the time because this is simply a cumbersome means of communication. However, in this case, the information about public registration of the DNA results is relevant to each man's decision. Because a reasonable person could have predicted that this would matter to the rational judgment of the men, it is crucial information to communicate to those from whom compliance is requested.4

Finally, consent of these men was likely involuntary. Given that non-compliance would result in public listing as suspects and possibly being arrested, the men under investigation may have agreed to the test as a result of undue coercion and not from deliberation and rational choice. Therefore, because the consent was not voluntary, but arrived at out of fear, the investigation failed to act with valid informed consent.

This is a case of noncausal overdetermination, the philosophical idea that a fact can obtain for multiple sufficient reasons.5 Any one of these three breaches independently compromises the investigation. Because none of the 1500 men were suspects on any other grounds, they were merely subjects being asked to aid in investigation who were no obligated by the law to comply. For this reason, they should have been respected as rational agents and asked for their informed consent to DNA testing. In this case it is not clear that this was acquired.

ENDNOTES
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Continuing Education Questions

SPRING 2008

To receive 1.5 contact hours of basic level P.A.C.E.* credit for the Focus: Bioethics questions, insert your answers in the appropriate spots on the continuing education registration form that follows, then mail a photocopy of the form as directed.

LEARNING OBJECTIVES
After completing the articles in Focus: Bioethics, the reader should be able to:
1. compare the Kantian view of ethics and utilitarianism as tools for medically-related decision-making.
2. compare and contrast autonomy and beneficience as tools for medically-related decision-making.
3. justify the use of these ethical theories in each of the three settings.
4. assess the philosophical theory used by a facility in situations concerning decision-making.
5. assess the philosophical theories used by a facility in situations concerning informed consent.

CONTINUING EDUCATION QUESTIONS
1. Immanuel Kant believed that acts should be judged on the basis of:
   a. the positive outcomes it produced.
   b. the negative outcomes it produced.
   c. the value that the decision has at the time of the deciding.
   d. whether the decision can be applied universally.

2. When viewing a situation through Kant’s ethical principles, using people only as a means to an end:
   a. is never possible.
   b. can be viewed as necessary when there are unusually great benefits to be gained.
   c. could be possible if they were used as both the means and the end.
   d. is always correct.

3. In order for an act to be ethical for a person using Kant’s principles, it:
   a. is judged to be ethical only on the basis of pure motives.
   b. should be the more beneficial choice.
   c. protects the person who is making the decision from unwanted consequences.
   d. can be applied to all people in all circumstances.

4. According to Kant, lying in order to protect a person from hearing some unwanted news would be:
   a. acceptable in all cases.
   b. acceptable when there is a greater good to be gained from the lie.
   c. unacceptable save for situations in which the person is incapable of receiving the truth in a logical fashion.
   d. unacceptable.

5. The determinant element for people who believe in utilitarian ethics is the:
   a. motives of the decision maker.
   b. outcome for the decision maker.
   c. motives for both the decision maker and the maker of the dilemma.
   d. outcomes for all involved.

6. In the assessment of a utilitarian decision, the most important aspect is the:
   a. question of informed consent.
   b. quality of the motives.
   c. seriousness of consequences.
   d. situation in which the decider finds him/herself.

7. The use of scientific information gathered from unwilling participants in scientific experiments such as that gathered from concentration camp prisoners could be:
   a. acceptable by Kant.
   b. acceptable by utilitarians.
   c. unacceptable by Kant because it is a specific situation.
   d. unacceptable by utilitarians because the data is not that valuable.
FOCUS: BIOETHICS

8. Coercion as part of obtaining informed consent is:
   a. totally unacceptable to Kant and his followers under any circumstances.
   b. totally unacceptable to consequentialists.
   c. acceptable to Kant in some circumstances.
   d. acceptable to consequentialists in some circumstances.

9. As a system of thought, beneficence is simply a method to:
   a. allow the person most involved in a situation to make a decision.
   b. use the greatest good as the measure of good decision making.
   c. have the most able person make a beneficial decision.
   d. develop a consensus before making a decision.

10. Is a form asking for permission to perform surgical procedures such as appendectomy, bowel resection, hysterectomy, transurethral resection, or cardiac catheterization an acceptable method of informed consent?
   a. No
   b. Yes
   c. Since the symptoms caused by the conditions are difficult to separate, it is logical to group these together.
   d. These conditions require surgical intervention and, as such, are grouped together under DRGs.

11. When would a person who believes as Kant does view failing to use extraordinary life support as ethical?
   a. Never.
   b. Only if you did not have the legitimate opportunity to do so.
   c. If you believe there is no significant difference in the outcome.
   d. Extraordinary means is not an ethical responsibility, so it doesn’t matter.

12. Recent discussions in the US suggest that paying for organ donations will increase supply. Which of the following would be considered an example of free and informed consent?
   a. A forty-five-year-old attorney who wishes to donate a kidney for a friend
   b. A thirty-two-year-old woman who will use the money to pay off debts
   c. An eighteen-year-old whose mother has asked him to
   d. An Indian father for whom the money is equal to one year’s salary

13. Which of the following statements could be considered coercive?
   a. “If you don’t participate in this action, it could be construed that you are against its principles.”
   b. “If you join this study, you will be paid for all supplies.”
   c. “If you agree with me on this point, you could be eligible for a raise in pay.”
   d. “If you don’t agree with this decision, you will be exercising autonomy.”

14. It could be argued that most patients have no real autonomy over the choice of treatment because they:
   a. do not understand the technical aspects of their treatment.
   b. can not separate themselves from the non-objective more emotional aspects of the situation.
   c. do not understand the entirety of the process they will be experiencing.
   d. surrendered that right when they accepted this particular physician/patient relationship.

15. One socially accepted example of patient autonomy is:
   a. a seventeen year old female requesting birth control pills.
   b. making a choice to forego treatment and enter hospice.
   c. preference of alternative in place of conventional medication.
   d. the use of alternative therapies.

16. The form that is signed by all patients prior to admission into a hospital allows for:
   a. all treatment decisions to be made by physicians.
   b. only those treatments listed in the form to be provided to the patient.
   c. the right of the patient to refuse the treatments that the physicians choose.
   d. decisions to be make by a health proxy as defined by the hospital.

17. An example of an informed consent would be one in which the decision maker is:
   a. thoroughly familiar with ALL of the aspects of the situation.
   b. has some familiarity with most of the aspects and can learn of the others through “full disclosure” of risks, etc.
c. has adequate familiarity with at least one side of the situation.
d. has limited knowledge of the situation but is willing to assume the burden.

18. Physicians are often unwilling to abide by the decisions of patients because they believe:
   a. they will be the ones sued if things go wrong.
   b. patients only hear what they want to hear.
   c. the patient’s emotional state makes informed consent impossible.
   d. patients do not have adequate scientific/medical knowledge to make such decisions.

19. In general, medical decisions for patients under legal age of adulthood are:
   a. always the physician’s right.
   b. always the parents’ right.
   c. the physician’s right in cases of emergency treatment when no parent/guardian is available.
   d. the child’s right if he/she understand the complexities of the situation.

20. The Vulcan axiom “the needs of the many outweigh the needs of the few” is an example of:
   a. Kantian ethics
   b. utilitarianism
   c. beneficence
   d. autonomy
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5. a  b  c  d  15. a  b  c  d
6. a  b  c  d  16. a  b  c  d
7. a  b  c  d  17. a  b  c  d
8. a  b  c  d  18. a  b  c  d
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