



Answering the Call of the Wild: Laboratory Licensure!!

2008 Collaborative Spring Meeting
Wednesday
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Certification

- Definition:
 - "A person has the appropriate qualifications to fulfill the duties of the profession."
 - Usually achieved by passing an examination.
- Certification *does not* regulate the profession.
 - It does not ensure the quality of the person's performance on the job.
 - Examples of agencies that certify laboratory personnel are ASCP, NCA, and AMT.
 - These organizations all now have CMP (certification maintenance programs) that mandate continuing education in order to maintain certification.

Licensure

- Definition:
 - "A process by which an agency of government grants permission to the individual to engage in a given occupation upon finding that the applicant has attained the minimal degree of competency required to ensure that the public health, safety, and welfare will be reasonably well protected". (Simberg, 1978)

Licensure

- Most licensure laws include the following components:
 - Education
 - Entry level requirements
 - Continuing education
 - Examination
 - National or state certification
 - Ethics
 - standards of professional behavior
 - Experience
 - Grandfathering into the field
 - Alternative avenues of qualification

Licensure

- To obtain and maintain a license usually means:
 - Paying a fee
 - Meeting personnel standards
 - Continuing education
- Oversight by a Board of Peers

Coming out of the Jungle

- **Laboratories emerging role in Patient Safety**
 - Institute of Medicine (IOM)
 - 49,000-98,000 Americans die annually as a result of preventable healthcare errors. Leapfrog
 - JCAHO patient safety goals



Coming out of the Jungle

- **Laboratories emerging role in Quality**
 - **National and state patient safety initiatives**
 - IHI
 - Leapfrog/Keystone
 - IHC
 - CDC evolution of NNIS into NSHN



Coming out of the Jungle

- **The laboratories emerging role in Disaster Preparedness**
 - The clinical laboratory professional serves as a first line of surveillance of infectious disease agents and is responsible for the early detection and identification of the etiology of biologic agents.
 - Prevention and control strategies depend on the ability of the clinical laboratory professional to adequately provide and communicate critical information to public health and law enforcement agencies.
 - In the event of a biological or chemical attack, the clinical laboratory professionals will be expected to provide information on proper collection, processing, handling, and/or transport of samples to the appropriate laboratory.
 - During recovery from a national disaster, laboratory professionals are essential for accurate and timely patient triage, diagnosis and treatment

Coming out of the Jungle

Experience in states with licensure:

- No direct correlation between implementation of licensure and increased compensation
- No correlation between implementation and exacerbation of the personnel shortage
- Healthcare is NOT more costly – quality laboratory testing performed by appropriately educated and competent personnel increases patient safety and should result in more cost effective healthcare

Coming out of the Jungle

Patient Safety: :

- No laboratory test is perfect even in the best of hands
- We have gone from 9 waived tests in 1992 to now more than 2,000
- 2005 CDC published "Good Laboratory Practices for Waived Testing"
 - Personnel competency affects quality and reliability of test results

Coming out of the Jungle

Patient Safety: :

- The same test kits may be used in hospitals, reference labs and POLS
- All of these have different personnel requirements
- The test quality should not differ in requirements because of the testing site

Statement of ASCLS position

- ASCLS believes that state personnel licensure provides the best mechanism to assure that clinical laboratory services are performed with an adequate level of professional competence by requiring appropriate entry level qualifications for individuals engaged in the practice of clinical laboratory science in all settings.

Statement of ASCLS position

- ASCLS believes that through the competency requirements established by licensure for clinical laboratory practitioners, the public health and safety is enhanced.

Statement of ASCLS position

- ASCLS believes that state personnel licensure provides the only legal basis to bar incompetent practitioners from providing services to the public.

Statement of ASCLS position

- ASCLS believes that personnel licensure is essential to define in state statute the clinical laboratory science scope of practice and protect it by excluding those who have not acquired the appropriate requisites for licensure.

Statement of ASCLS position

- ASCLS believes that minimum requirements for licensure should include both educational (academic and clinical) requirements and passage of a validated competency-based national certification examination.

Statement of ASCLS position

- ASCLS believes that licensure renewal should require documentation of continuing education as a means of demonstrating continuing competence.

Statement of ASCLS position

- ASCLS believes that licensure will provide for the creation of a much-needed mechanism to identify, collect data on, and provide access to the state's laboratory workforce. This relevant information will facilitate the ability to address manpower shortages and distribution, to effectively respond during a bioterrorism or other public safety threat by mobilizing the appropriate clinical laboratory professionals, and address other specific workforce needs.

Swinging from the vines



- Why should laboratory professionals in Iowa look at licensure?
 - Licensure of laboratory personnel will minimize harmful outcomes due to practitioner error because of inadequate or inappropriate training.
 - There are many examples of harm caused to patients by laboratory errors.
 - Any one of a 1000 tests that a laboratory performs has the potential to be performed incorrectly.

Swinging from the vines



- A wrong laboratory test result can mean:
 - misdiagnosis or death
 - no diagnosis and no treatment when needed
 - incorrect diagnosis and improper treatment with harmful outcomes
 - repeat testing due to questionable results
 - costly follow-up procedures, including unnecessary surgery, worry and anxiety for patients and parents/families
 - additional costs to the healthcare system and financial hardship for the consumer public

Swinging from the vines



- Reduction of escalating cost of healthcare through increased quality and consistency of services.
 - Gives us an opportunity to improve upon the inadequacies of federal regulations (CLIA).
 - Data from the CMS Certification of Waiver and Provider Performed Microscopy Procedures Pilot Project shows that laboratories in states with laboratory licensure programs performed better overall than those states that did not.
 - This project confirmed CMS's concerns about quality problems in these laboratories i.e. identified the dangerous combination of not following instructions and lack of testing personnel training.
 - One of the CMS recommendations is to validate the effectiveness of the educational approach; licensure and continuing education requirements can help achieve this goal.

Fears and Opposition

- "The personnel shortage will get worse!"
- "There is no link between quality and licensure!"
- "Licensure puts limits on the Pathologist/Medical director in selecting employees!"
- "This is money out of the hospital/ or pathologists pocket!"
- "Licensure adds another layer of regulation on top of CLIA!"



Benefits



- Improved image of the profession
- People thinking of entering the field will be part of a licensed profession
- Networking
- Prevents undesirables from working in the field
- Remove individuals who are incompetent

Take a walk on the *wild* side

- We are forming a coalition in Iowa to look into licensure.
 - The following organizations are being contacted to be part of the coalition:
 - AMT
 - ASCLS-IA
 - ASCP
 - CLMA
 - Cytotechs
 - Histotechs
 - Independent hospitals
 - Iowa Public Health Association
 - Rural network affiliates



Take a walk on the *wild* side

- We need subcommittee members
 - Education
 - Finance
 - Legal issues
 - Researching other state bills
 - Researching laboratory errors that have caused patient harm
- We need members help in acquiring a lobbyist
- Other subcommittees as needed!



Take a walk on the *wild* side

- As members of our organization,
 - Go out and talk to co-workers, other healthcare professionals and healthcare consumers about the laboratory and how vital it is to the healthcare system.
 - Listen to ideas and suggestions.
 - If we all work together we can improve healthcare quality for the people of the state of Iowa.

Take a walk on the *wild* side

If we all work together we can improve healthcare quality for the people of the state of Iowa!



References

- 1. ASCLS Role of Clinical Laboratories in Bioterrorism Preparedness Position Paper, 2002.
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- 3. Passiment Elissa, Quality Systems - The Role of People, Laboratory Medicine, September 2005.
- 4. ASCLS Value of the Profession Position Paper, 2005.
- 5. Institute of Medicine. To Err is Human: Building a Safer Health Care System. National Academy Press. 1999.