PROFICIENCY TESTING:

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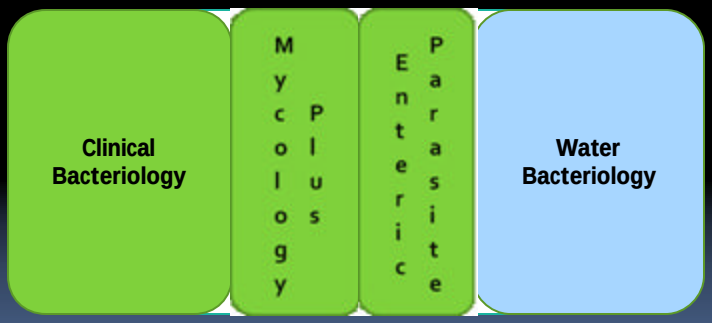
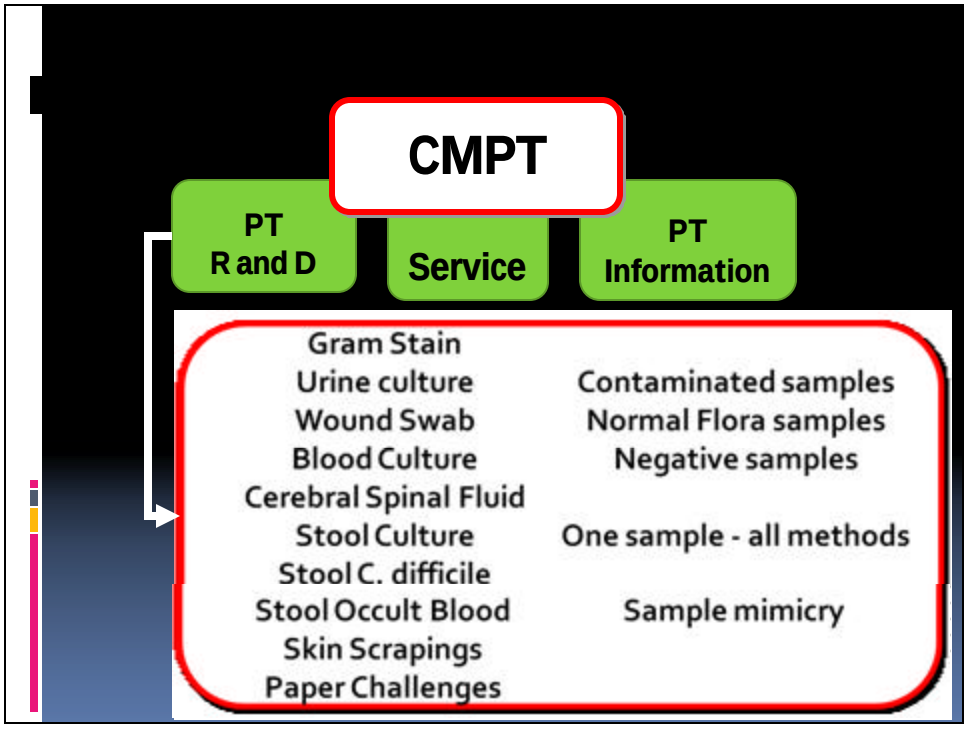
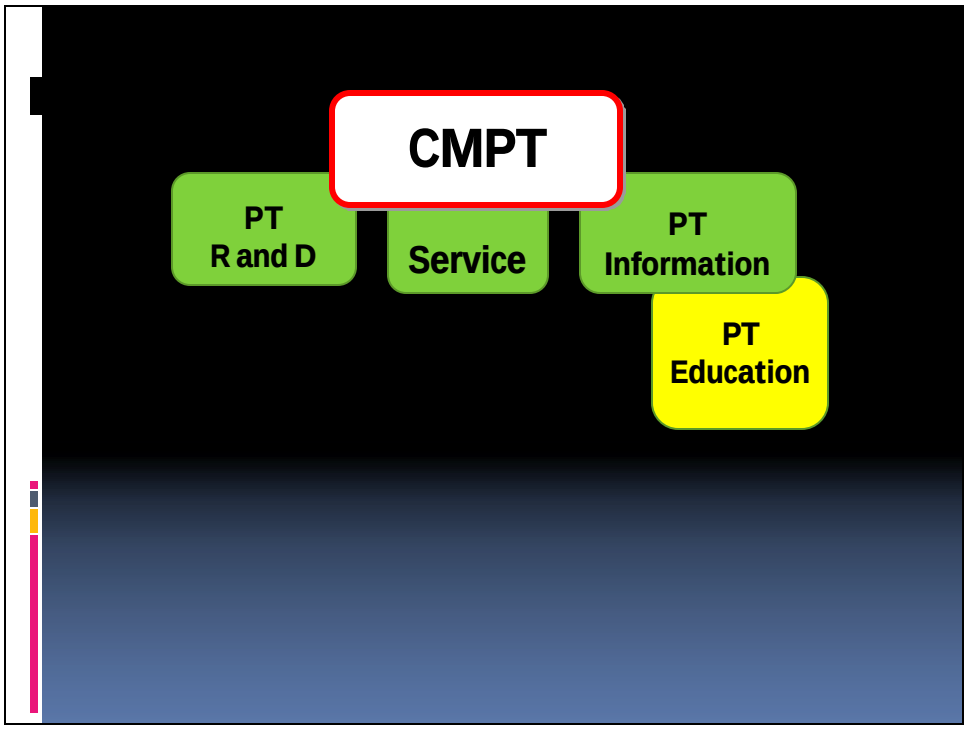
By way of introduction...

CMPT
Pathology and Laboratory Medicine
University of British Columbia
Began 1983
Annually Certified ISO9001:2000
Meet Requirements of ISO Guide 43-1:1999

By way of introduction...




CMPT
PT
R and D
Service
PT
Information
Gram Stain
Urine culture
Wound Swab
Blood Culture
Cerebral Spinal Fluid
Stool Culture
Stool C. difficile
Stool Occult Blood
Skin Scrapings
Paper Challenges
Contaminated samples
Normal Flora samples
Negative samples
One sample - all methods
Sample mimicry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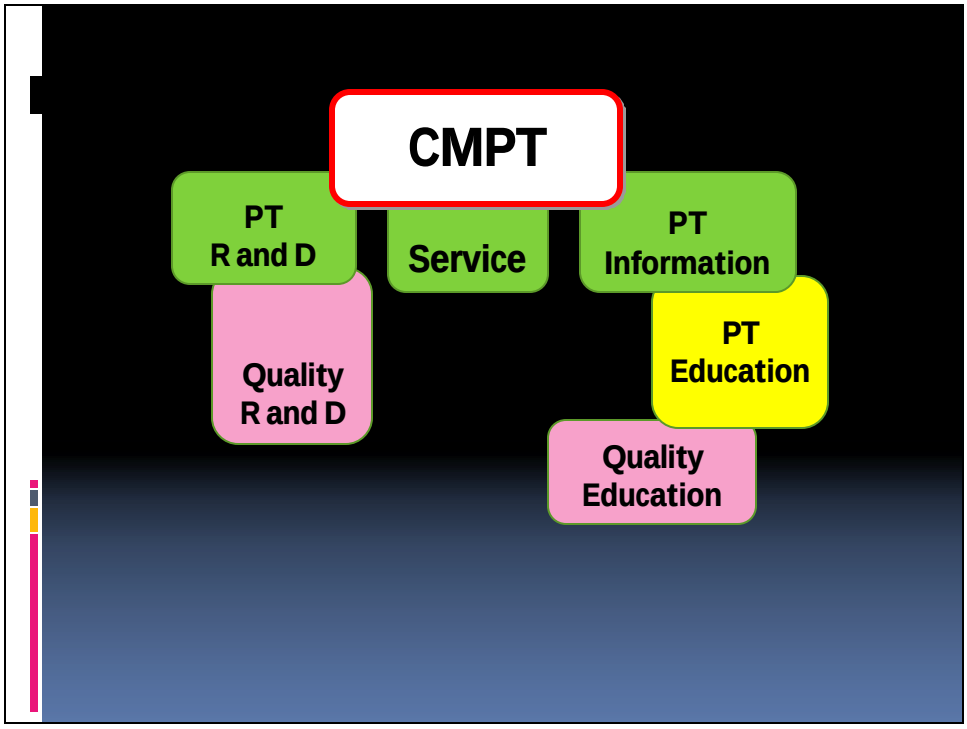
Education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R and D
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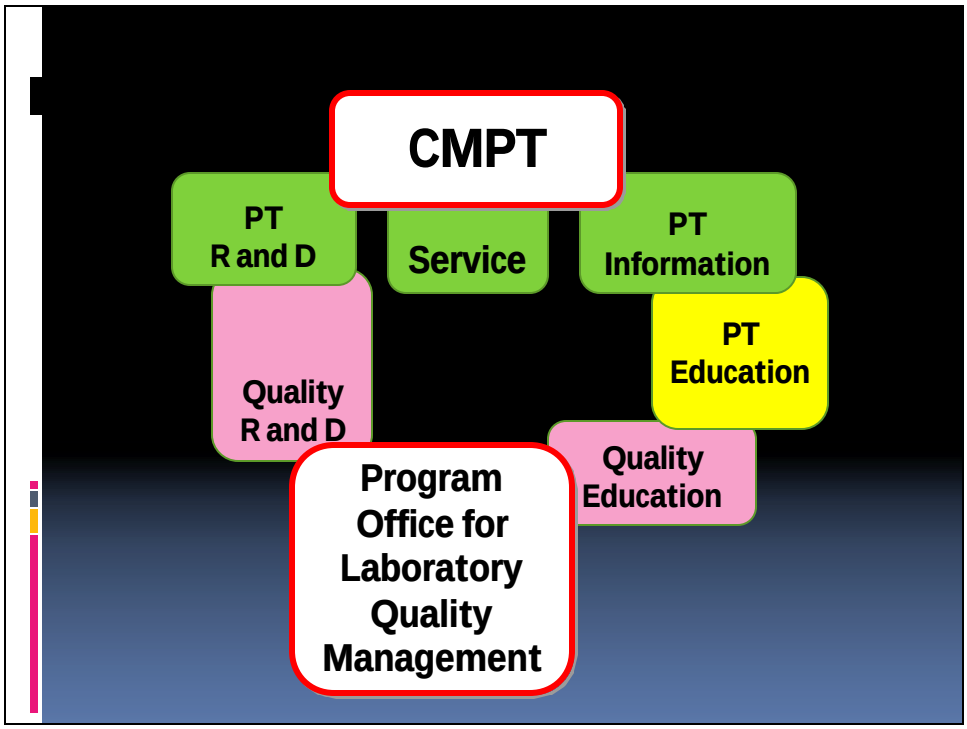
Education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Laboratory
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Management

Proficiency Testing

- A program of externally provided samples of known composition submitted to one or more participant laboratories, with the purpose of demonstrating ability (proficiency or competency)
- Also called External Quality Assessment
- Also called Inter-laboratory Comparison.
- Also called unknowns.

Administrative folks think highly of PT/ EQA

- A **regulatory** requirement of CLIA
- A regulatory requirement of EPA
- A regulatory requirement of CFIA
- A **normative** requirement of ISO 15189:2007
- A **normative** requirement of ISO/IEC 17025:2006

Proficiency Testing has been around for a long time

- Some form of external challenges since 1946.
- Primary focus has been on inter-laboratory comparison.
- Since mid-1980's a shift in philosophy towards, demonstrating an individual laboratory's quality and competence.

Barriers to Effective Proficiency Testing Programs

- Regulatory intrusions and consequences
- Changing laboratory profiles
- Changing laboratory methodologies
- Complex matrix interferences
- Traditional sample production strategies

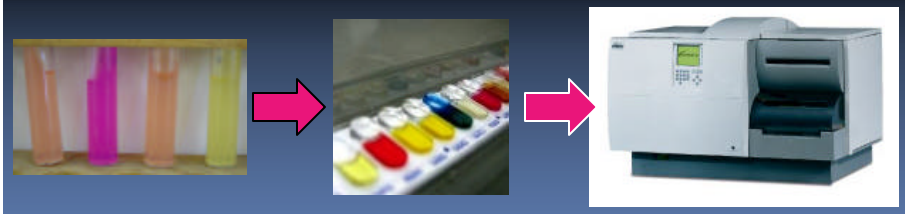
Microbiology Proficiency Testing is showing its age.

- Primary focus tends to be on:
  - Ability to perform microbial identification.
  - Determine antimicrobial susceptibility

Made sense in 1950's 1960's, 1970's. No longer makes sense today.

Most Traditional Proficiency Testing is Obsolete

- When first conceived most tests were individually and manually performed.
- With automated equipment, the proficiency being measured is that of the equipment and equipment maker, not the laboratory or the laboratorian.



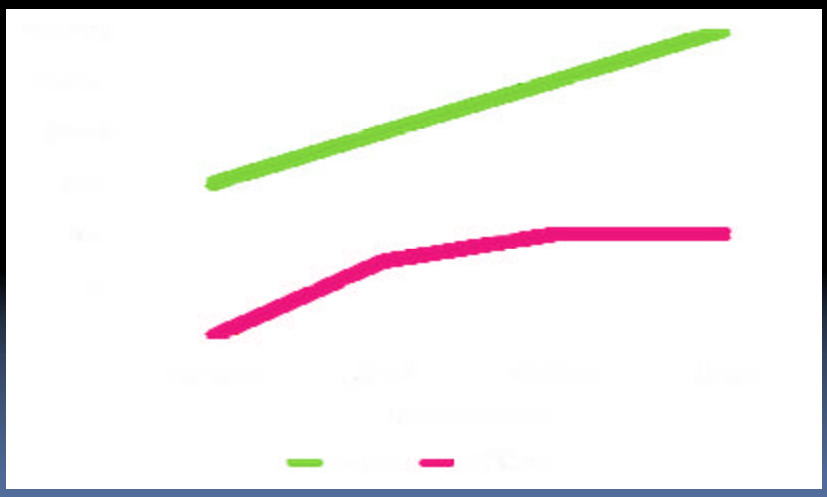
Same is true in other disciplines as well

- Chemistry
- Immunology
- Haematology

Traditional Proficiency Testing is a poor supplement to quality control

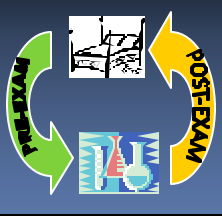
- Most programs provide too few samples too irregularly for error detection.
- Most laboratories sidestep true competency assessment.

PT/Sample Ratio

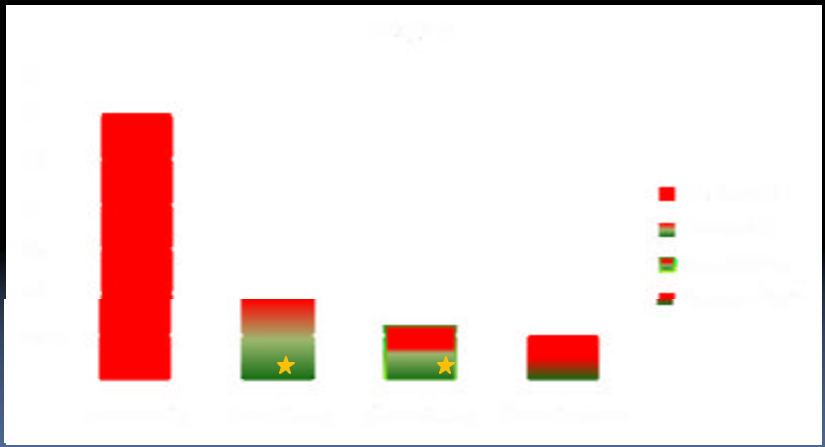


What most proficiency testing does **not** tend to look at:

- Are negative samples reported as negative?
- Are contaminated samples reported as contaminated?
- Are complex samples submitted for referral?
- Are pre-analytic factors addressed?
  - Improper containers and transport
  - Outdated samples.
  - Mislabeled samples.
  - Rejection criteria
- Are post-analytic factors addressed?
  - Interpretive commentary included



Urine Culture Results



PT within the quality management toolbox

- PT as an internal quality alert.
- PT as part of an internal audit.
- PT as a part of inter-technologist comparison.
- PT as part of quality improvement.

PT as a Quality Alert

- If an incorrect or invalid conclusion was reached with a PT sample, could the same outcome occur with a clinical sample?
  - Are PT samples processed identical to clinical samples?
  - Are sufficient samples with sufficient diversity provided?

PT as part of an internal audit.

1. Is there a PT program?
2. Were the samples addressed upon receipt?
3. Are there mechanisms in place to ensure that the PT samples are processed consistent to routine clinical samples?
4. Are the samples reported consistent to the reporting of routine clinical samples?
5. Are the results of PT samples evaluated, and where indicated investigated?

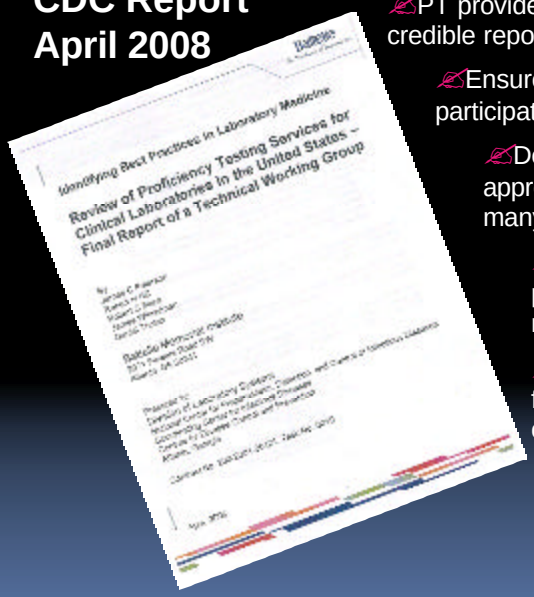
PT as a part of inter-technologist comparison

- Samples where inter-technologist testing is appropriate to consider:
  - Interpretation of Acceptance/Rejection criteria
  - Gram (or other) staining
  - Interpretation and action on culture plates
    - Visual interpretation
    - Interpretation confirmation
  - Selection of reporting mnemonics

Adjusting PT to fit the modern laboratory

- Redefining our programs
  - Increasing collaboration
  - Increasing specialization
  - Sample redistribution
  - New challenge methodologies
  - Increasing total testing cycle challenges
- Ensuring Program Quality through standards and accreditation.

CDC Report April 2008



- PT providers should publish scientifically credible reports in peer-reviewed journals.
- Ensure all clinical laboratories participate in PT, including waved tests.
- Develop a methodology-based approach for PT (one material for many assays).
- Samples should mimic patient samples with a minimum of matrix effect.
- Small adjunct studies with fresh frozen samples in conjunction with "routine" PT.
- Evaluate alternatives to current CLIA requirements for frequency and scoring.
- Develop innovative approaches to PT.

Does PT improve quality?

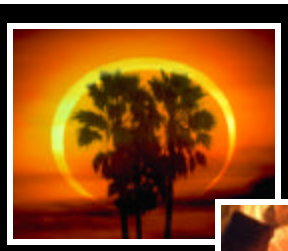
- Probably yes, but hard to prove.
  - Accredited programs do better on PT
  - Laboratories with consistently high PT performance do better with accreditation
- Clinical Error?
- Clinical error detection?
- OFIs and Continual Improvement?

Does PT improve quality?

Even if
quality improvement
and improved patient safety
cannot be demonstrated,
PT is
too valuable,
too much potential
too inexpensive
to be discarded.

in summary…

- Medical laboratory proficiency testing as been around for 60 years
- Respected as a valued monitoring tool
  - Interlaboratory comparisons
  - Internal audit
  - Inter-technologist education
- Starting to show its age.
  - Testing the wrong thing in the wrong way.
  - Falling behind laboratory reality.



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