



Role of PT in Laboratory Quality Management

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FROM A LABORATORY 'S PERSPECTIVE, WHAT ARE STRENGTHS AND WEAKNESSES OF PARTICIPATING IN AN EDUCATIONAL PT/EQ PROGRAM?

- ★ **Advantages** – reaches wider audience than regulatory PT and reduces punitive atmosphere, which encourages discussion:
 - identifies technical needs for new equipment and methods;
 - assesses staff competency and assists in improving staff confidence;
 - improves communication with clinicians;
 - improves the quality of testing, which ultimately improves patient outcomes

FROM A LABORATORY 'S PERSPECTIVE, WHAT ARE STRENGTHS AND WEAKNESSES OF PARTICIPATING IN AN EDUCATIONAL PT/EQA PROGRAM?

★ **Disadvantages** – increased costs for testing and evaluation

- may be difficult to obtain and request validated high quality samples;
- educational objectives are not well understood (communication problems) so may not participate;
- since not mandatory, may not have government support or recognition;
- educational programs may be co-opted for regulatory purposes;
- lab may not follow up if samples are not graded

WHAT PTPROGAME ELEMENTS ARE ESSENTIAL FOR PT/EQATO BE A USEFUL EDUCATIONAL EXPERIENCE?

★ Essential elements:

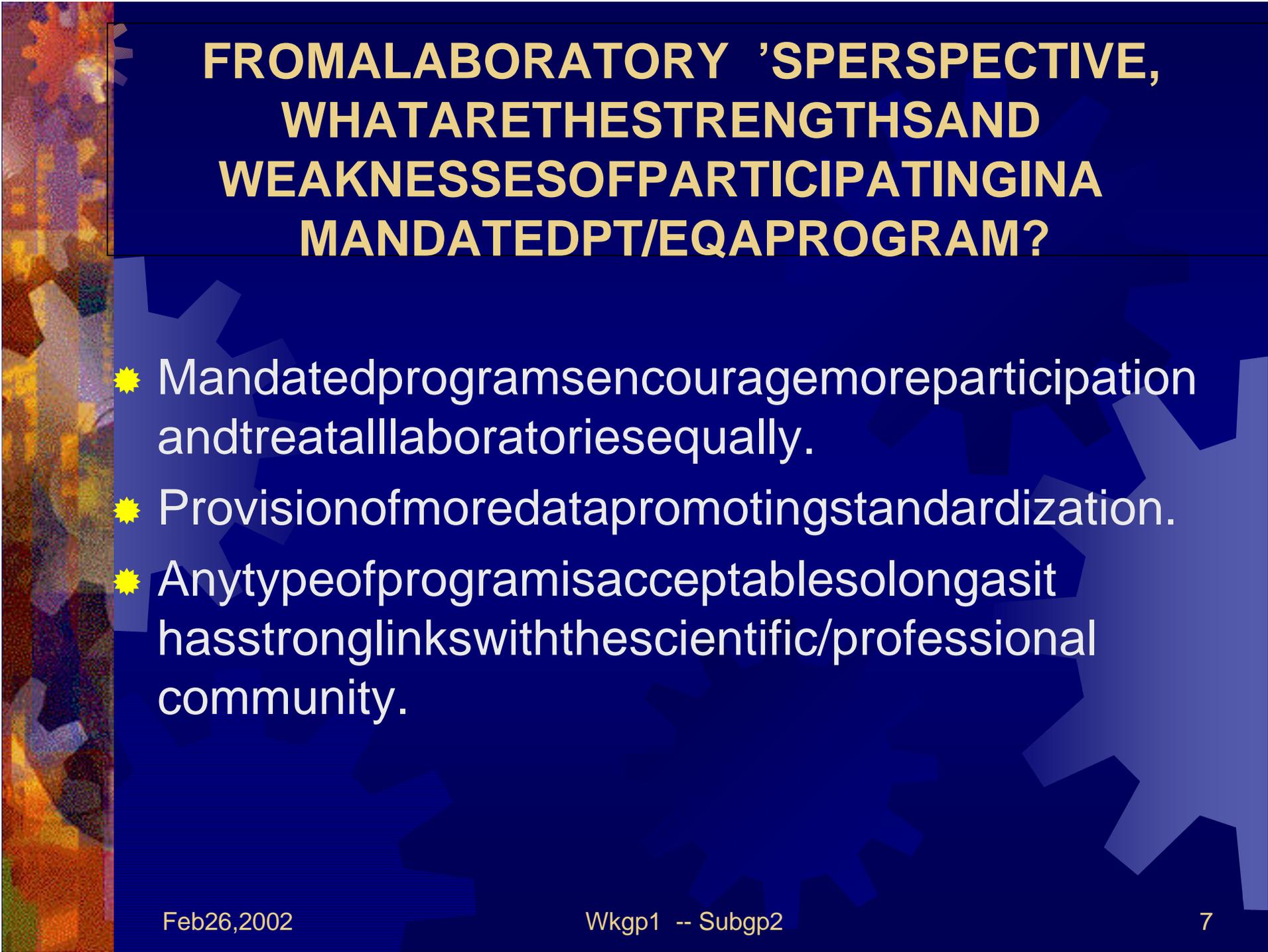
- identify specific target audience;
 - provide focused objectives and clear standardized instructions;
 - provide interlaboratory comparison and timely feedback;
 - recognize differences between disciplines, tests, methodologies, clinical practice patterns;
- ## ★ “Problem-based control” (a problem identified:)
- assist lab in determining how problem occurred;
 - offers new and emerging technology and organismsto increase laboratory awareness

WHAT EDUCATIONAL OPPORTUNITIES SHOULD PROGRAMS BE ENCOURAGED OR REQUIRED TO PROVIDE?

- Data interpretation - include all instrument or all method comparisons, percentile for lab scores, trends, timely turnaround of results (making retesting possible), clear description of target audience, graphical or visual information
- Supplemental information (interpretive guidelines)
- Provide information on commonly misidentified cells or organisms, common errors, feedback on medical relevancy

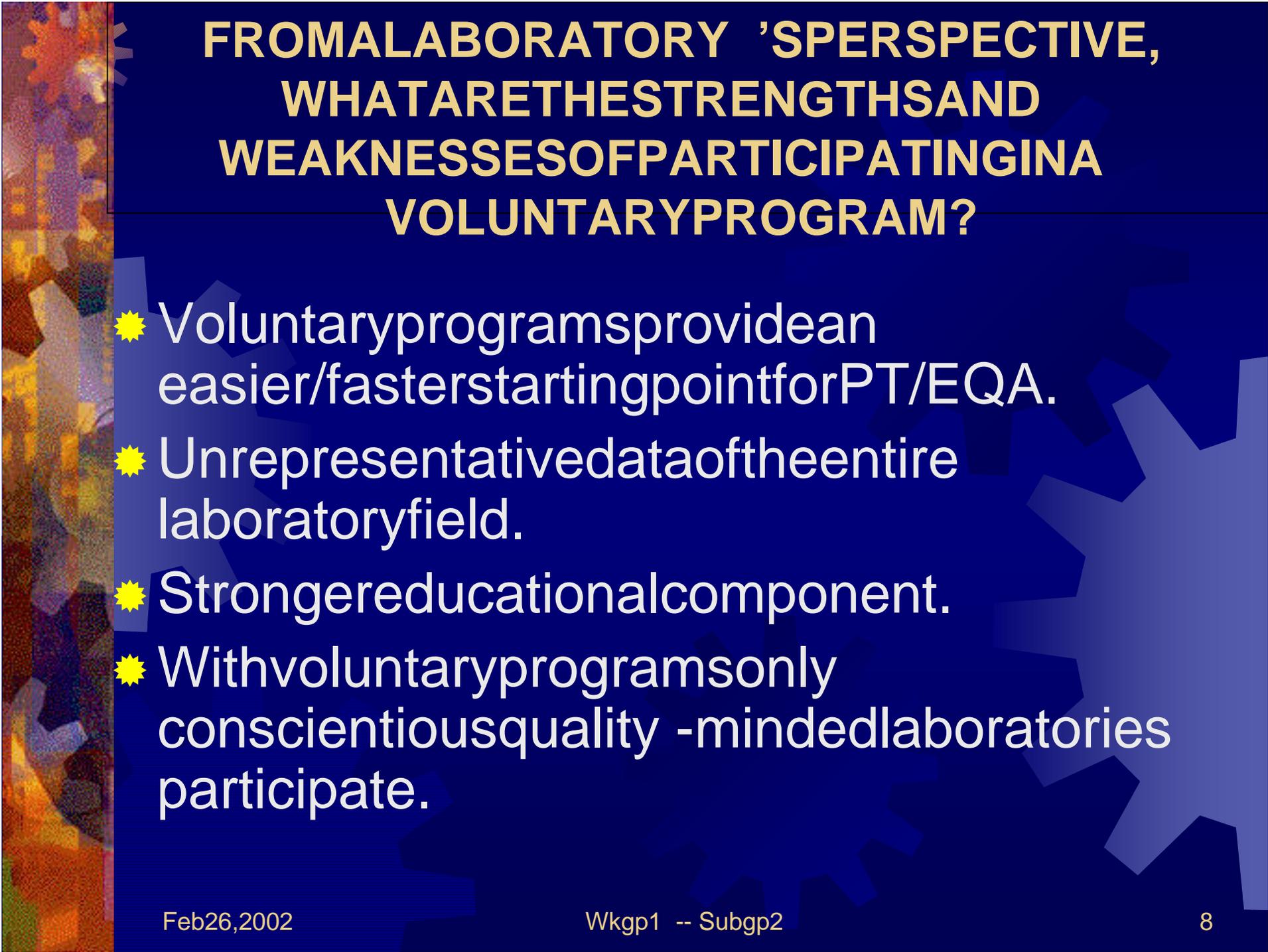
WHAT EDUCATIONAL OPPORTUNITIES SHOULD PROGRAMS BE ENCOURAGED OR REQUIRED TO PROVIDE?

- ★ Communication and training - provide clear description of target audience and educational objectives, program manuals and handbooks, newsletters, summaries from users, face to face customer service, training; information to lab students, interns
- ★ Background information – provide information on how to interpret results, reference to standards and guidelines, structured approach for remedial action



FROM A LABORATORY'S PERSPECTIVE, WHAT ARE THE STRENGTHS AND WEAKNESSES OF PARTICIPATING IN A MANDATED DPT/EQA PROGRAM?

- ★ Mandated programs encourage more participation and treat all laboratories equally.
- ★ Provision of more data promoting standardization.
- ★ Any type of program is acceptable so long as it has strong links with the scientific/professional community.



FROM A LABORATORY 'S PERSPECTIVE, WHAT ARE THE STRENGTHS AND WEAKNESSES OF PARTICIPATING IN A VOLUNTARY PROGRAM?

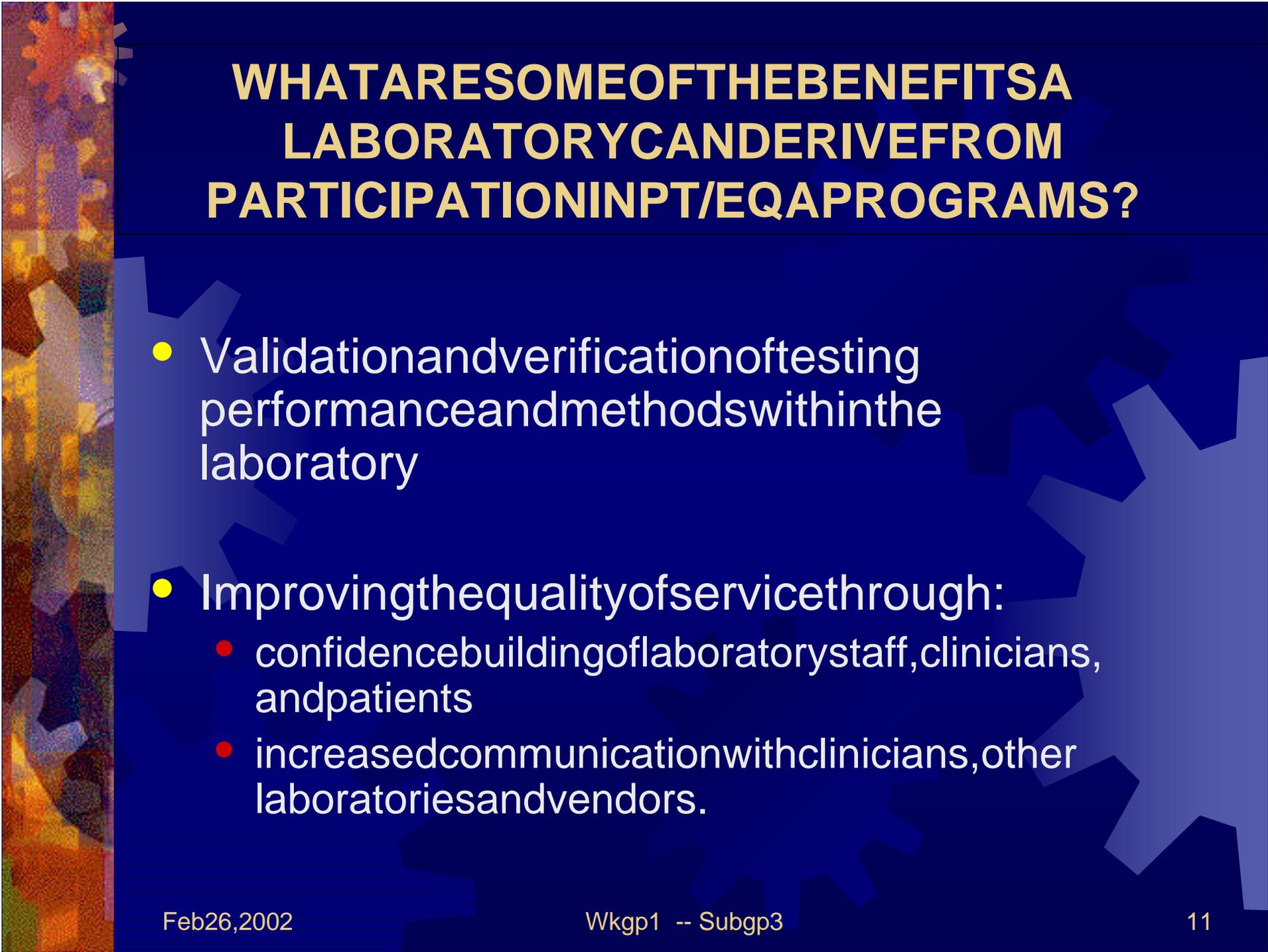
- ★ Voluntary programs provide an easier/faster starting point for PT/EQA.
- ★ Unrepresentative data of the entire laboratory field.
- ★ Stronger educational component.
- ★ With voluntary program only conscientious quality-minded laboratories participate.

WHAT ARE THE DIFFERENCES IN MANDATED PROGRAMS OFFERED BY GOVERNMENT, ACADEMIC, OR COMMERCIAL SPONSORS?

- ★ Governmental schemes usually linked with laboratory license/accreditation
- ★ Academic schemes mostly focus on clinical outcome and education
- ★ Commercial schemes essentially focus on analytical outcome

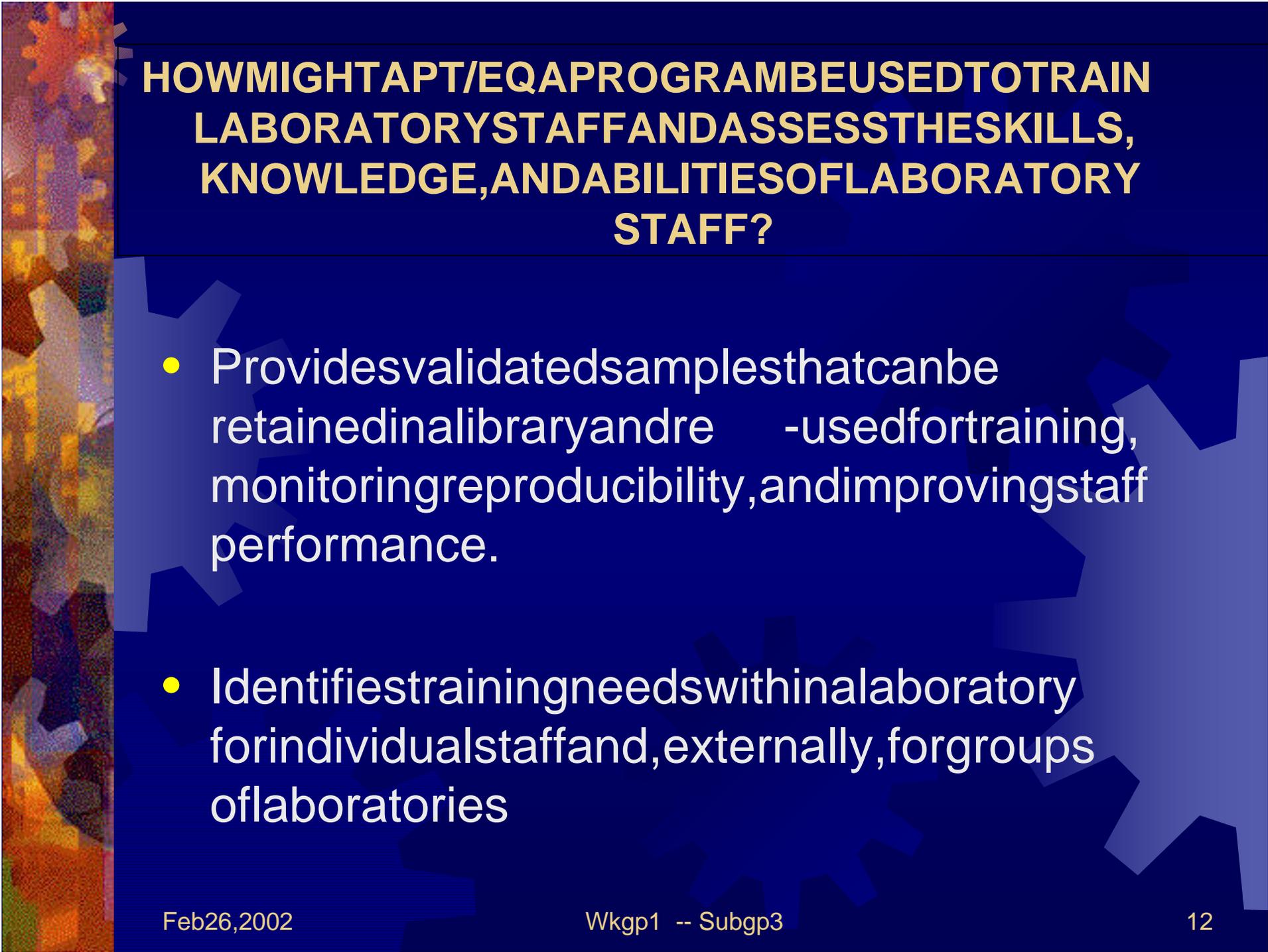
WHAT ARE SOME OF THE BENEFITS A LABORATORY CAN DERIVE FROM PARTICIPATION IN PT/EQA PROGRAMS?

- PT is an important source of education and training
 - may provide the only opportunity for laboratory peer interactions in resource limited countries.
- Identifying problems with the equipment, processing, or other testing component to correct deficiencies
 - also provides support and justification for resources (e.g. new equipment purchases)



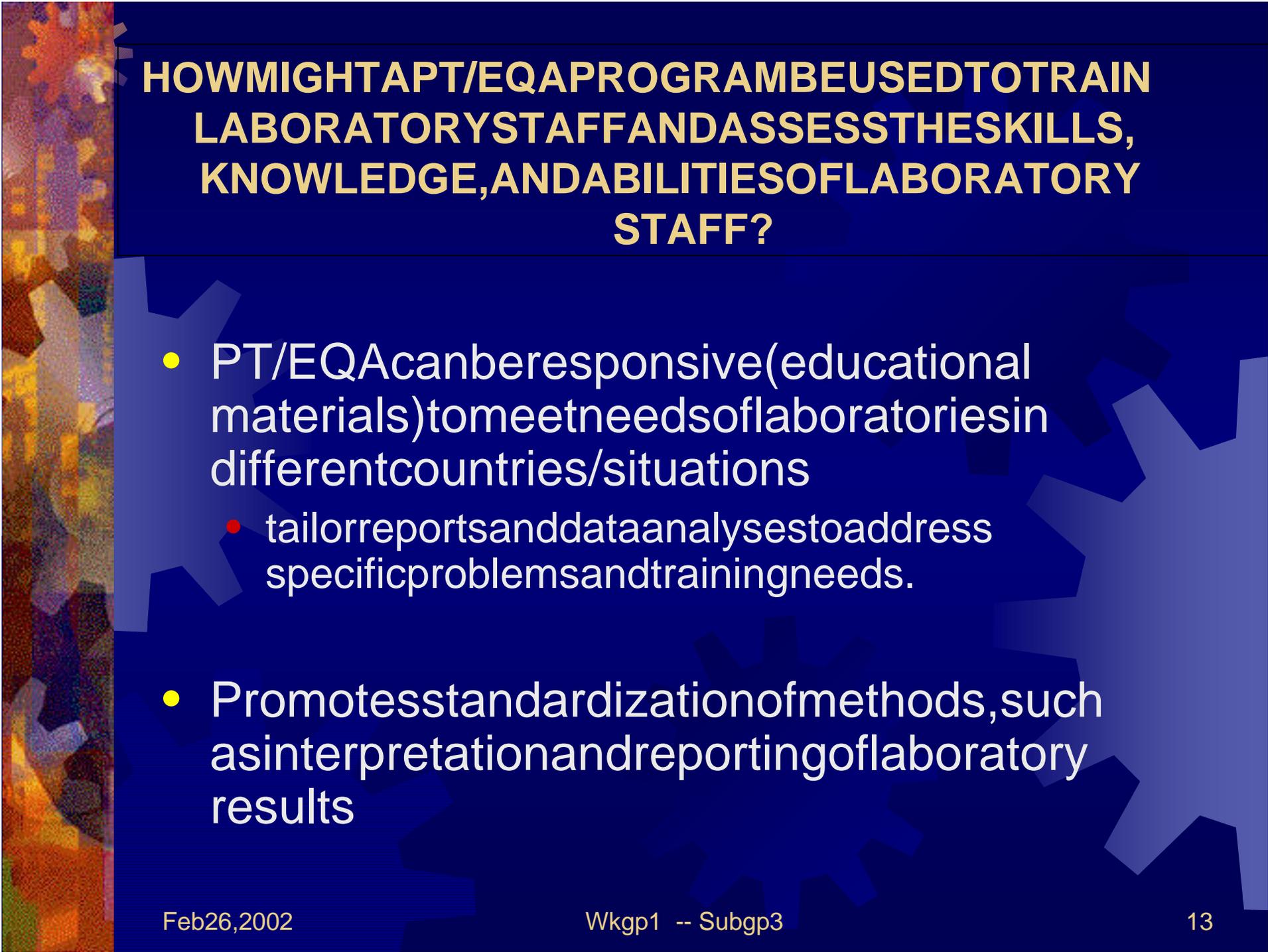
WHAT ARE SOME OF THE BENEFITS A LABORATORY CAN DERIVE FROM PARTICIPATION IN PT/EQA PROGRAMS?

- Validation and verification of testing performance and methods within the laboratory
- Improving the quality of service through:
 - confidence building of laboratory staff, clinicians, and patients
 - increased communication with clinicians, other laboratories and vendors.



HOW MIGHT APT/EQA PROGRAM BE USED TO TRAIN LABORATORY STAFF AND ASSESSTHE SKILLS, KNOWLEDGE, AND ABILITIES OF LABORATORY STAFF?

- Provides validated samples that can be retained in a library and re-used for training, monitoring reproducibility, and improving staff performance.
- Identifies training needs within a laboratory for individual staff and, externally, for groups of laboratories



HOW MIGHT A PT/EQA PROGRAM BE USED TO TRAIN LABORATORY STAFF AND ASSESSTHE SKILLS, KNOWLEDGE, AND ABILITIES OF LABORATORY STAFF?

- PT/EQA can be responsive (educational materials) to meet needs of laboratories in different countries/situations
 - tailor reports and data analyses to address specific problems and training needs.
- Promotes standardization of methods, such as interpretation and reporting of laboratory results

WHAT ARE THE BENEFITS TO A LABORATORY WHEN PT/EQA PROGRAM IS USED AS PART OF THE ACCREDITATION OR LICENSING PROCESS?

- PT/EQA is first step in resource limited countries and may serve to trigger on-site evaluation of lab in addition to identifying priority issues for evaluation.
- Since accreditation provides same measure of process/standards, PT is one measure of outcomes.
- PT may provide a better measure of performance in large laboratories where accreditation may only provide a cursory process check for each testing service

WHAT ARE SOME OF THE CHANGES PT/EQA PROGRAMS NEED TO MAKE IN THEIR PROGRAM TO ENHANCE THEIR USE FOR ACCREDITATION OR LICENSURE?

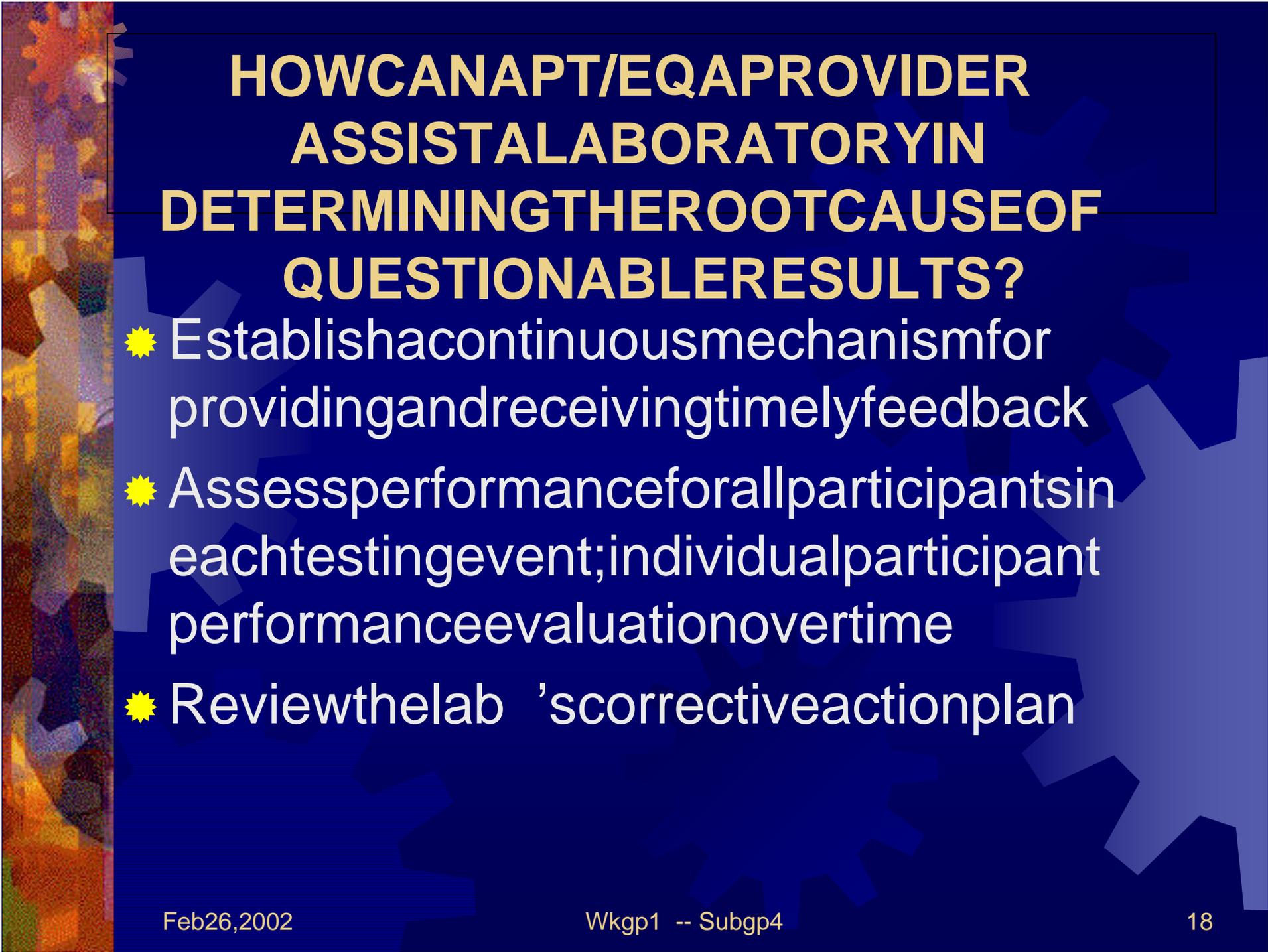
- The data from PT programs may be used to set performance expectations and focus the on-site evaluation/accreditation process.
- The greatest benefit occurs when qualified staff conduct the accreditation process to address PT performance deficiencies.

HOW CAN A LABORATORY ENSURE THAT PT/EQ RESULTS ARE USED TO ENHANCE LABORATORY PERFORMANCE?

- The purpose of PT needs to be understood
 - an external mechanism to monitor, improve test performance
- PT should be considered a positive, not a negative tool
- Labs need to have specific procedures for handling
 - when possible, testing PT samples like patient specimens

HOW CAN A LABORATORY ENSURE THAT PT/EQ RESULTS ARE USED TO ENHANCE LABORATORY PERFORMANCE?

- ★ Use PT samples to evaluate the lab's processes, not to evaluate an individual
 - ★ If problems occur, these should reflect process problems
 - ★ Contact EQA provider and/or manufacturer to ensure problems are not due to sample matrix



HOW CAN APT/EQ A PROVIDER ASSIST A LABORATORY IN DETERMINING THE ROOT CAUSE OF QUESTIONABLE RESULTS?

- ✦ Establish a continuous mechanism for providing and receiving timely feedback
- ✦ Assess performance for all participants in each testing event; individual participant performance evaluation over time
- ✦ Review the lab 's corrective action plan

HOW CAN A PT/EQA PROVIDER ASSIST A LABORATORY IN DETERMINING THE ROOT CAUSE OF QUESTIONABLE RESULTS?

- ★ Consultationsite visits to evaluate processes
- ★ Provide additional samples when needed
- ★ If PT/EQA problem is method dependent, EQA providers should contact the manufacturer.

CAN AND SHOULD PT/EQA PROGRAMS ADDRESS THE ISSUE OF THE UNCERTAINTY ASSOCIATED WITH MEASURING A LABORATORY'S PERFORMANCE ASSESSMENT?

- The credibility and utility of PT/EQA programs are dependent upon the identification, characterization, and, where possible, resolution of sources that introduce uncertainty.
- Design elements and rigor of challenge must consider the education and training of analysts, particularly in resource -restricted countries.

CAN AND SHOULD PT/EQA PROGRAMS ADDRESS THE ISSUE OF THE UNCERTAINTY ASSOCIATED WITH MEASURING A LABORATORY'S PERFORMANCE ASSESSMENT?

Sources of Uncertainty	Responsible Partner	Comment
Specimen Design/Preparation -Matrix -Homogeneity /viability	PT/EQA provider Manufacturer	Behavior should be similar to authentic patient samples; commutability
Value Assignment	PT/EQA provider Calibration lab	Increasing uncertainty from use of CRM to use of participant mean/median
Stability -Timeframe for analysis - Storage conditions -Transportation/handling	PT/EQA Provider/ Manufacturer	

CAN AND SHOULD PT/EQAP PROGRAMS ADDRESS THE ISSUE OF THE UNCERTAINTY ASSOCIATED WITH MEASURING A LABORATORY'S PERFORMANCE ASSESSMENT?

Sources of Uncertainty	Responsible Partner	Comment
Specimen Processing Variables	laboratory	Process as patient specimens; follow provider instructions
Analysis	Laboratory/ Manufacturer	Measurement uncertainty related to bias and imprecision
Reporting Requirements	PT Provider and Laboratory	Unique reporting requirements may not be consistent with routine practices

WHAT WEIGHT SHOULD BE PLACED ON PT/EQA PERFORMANCE COMPARED WITH OTHER MEASURES OF PERFORMANCE MEASURES?

- PT is a significant objective measure (indicator) of laboratory performance.
 - Outcomes are used to drive evaluations of laboratory practices and other measures of laboratory performance.
 - In some instances, e.g., resource restricted countries, PT/EQA may be the only indicator of laboratory performance.
- If PT primarily evaluates the analytic phase of laboratory testing it must not be used as the sole process for measuring laboratory performance.

WHAT WEIGHT SHOULD BE PLACED ON PT/EQA PERFORMANCE COMPARED WITH OTHER MEASURES OF PERFORMANCE MEASURES?

- PT outcomes must be evaluated by the lab regardless of provider assessment of laboratory performance, i.e., successful or unsuccessful performance.
- Not all PT programs are equivalent, e.g., performance evaluation criteria.

HOW COULD PT/EQA PROGRAMS BE USED AS A VEHICLE TO INTRODUCE STANDARDIZED TESTING ALGORITHMS, CRITICAL LIMITS, REPORTING PROTOCOLS, ETC. THROUGHOUT A COUNTRY OR REGION?

EQA is a powerful tool for improving desired testing algorithms, standardized nomenclature and standardized protocols in the following ways:

- ✦ Information can be used to define/describe “state of the art” of lab practice and formulate relevant performance criteria.
- ✦ PT providers should provide PT samples in a clinical context (case histories) when possible.
- ✦ PT providers should require reporting in standardized units and nomenclature



FROM A LABORATORY'S PERSPECTIVE, WHAT WOULD BE THE ADDED VALUE OF PARTICIPATION IN A PROGRAM THAT HAS MET INTERNATIONALLY ACCEPTED REQUIREMENTS TO BE AN ACCREDITED PT/EQA PROGRAM?

- ✦ It provides a higher degree of confidence that the laboratory is being evaluated fairly by defined procedures
- ✦ It is essential for compulsory PT programs to be accredited by a third party.
- ✦ It provides the potential for arbitration by an independent body.

Summary

Role of EQA/PT in laboratory management will depend on:

- Type of EQA organization
- Goals of the schemes
- Resources
- Level of quality desired

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