

**REPORT OF THE POL STUDY REVIEW SUBCOMMITTEE
CLINICAL LABORATORY TECHNOLOGY ADVISORY COMMITTEE
November 8, 1999**

The Subcommittee met in Los Angeles to review the recommendations made by San Diego State University and to advise the Department regarding whether or not the State should pursue an expanded study to address some of the limitations identified in the initial study. **Recommendation: The Subcommittee appreciated SDSU's recommendation to do a new study, but the subcommittee concluded that the magnitude of the task and the lack of clear evidence of clinical relevance of a future study made it difficult to support continuance of efforts using State funds at this time** (Vote: 3 for the recommendation, 1 against).

The Committee understood that the completed study met the legislative mandate but that recommendations were essentially to be guided by whether further evaluation was justified to answer questions and whether these answers would be important to the health and welfare of Californians. To achieve this goal, the Committee divided its deliberations into three phases:

- The extent to which the completed pilot study addressed important concerns regarding differences between POL and non-POL facilities.
- Recommendations for future study, should a study be recommended
- Thoughts about whether the State should consider funding a future study

Point 1 – The extent to which the completed pilot study addressed important concerns regarding differences between POL and non-POL facilities. Limitations acknowledged by the Subcommittee that suggest that the pilot study could not completely answer this question.

1. The completed study did not address medical necessity
2. Other acknowledged AHPs (e.g., registered nurses, respiratory care practitioners) were not specifically addressed in the POL and non-POL classifications
3. Proficiency testing was the only metric used; utilization and inspection data were not included in the analysis. The committee was informed that although inspection data were available for licensed facilities, comparative data were unavailable for other facilities.
4. The unit of analysis in the completed study was the individual analyte. It would have been more appropriate, if quality at this level could be defined, to use the laboratory as the unit of analysis.
5. The completed study, evaluating proficiency testing, examined only one intralaboratory quality metric. A complete assessment of quality must encompass, in addition, the pre and post analytic components of laboratory testing.
6. Proficiency testing providers account for different instrumentation; however, there may be issues related to focusing on instrument peer comparisons.
7. Because the study selected only three challenge points, unsuccessful performance may have been missed if that performance included points outside the window period (i.e., failures in the immediate period before or after the study window).
8. There may be some limitations to statistical methods used
9. Laboratories doing only waived testing would not be captured by this study
10. Evidence suggests that improvements have occurred in POLs over time. This represents a success of the proficiency testing program and of current regulation.

Recommendations for future study, should a study be recommended

1. The data collection instrument proposed by San Diego State University would not address the concerns identified above as limitations to the concluded study. Specifically, the report proposes primarily a prospective study not too different than the one completed. Broader issues would need clear definition and would expand the scope of the data effort.
2. To assess licensed personnel (e.g., MT/CLS, RN) involvement, it will be important to identify the role of the licensed personnel and what functions they perform in the laboratory (e.g. testing personnel, testing only proficiency testing samples, general oversight).

3. There is a clear need to define laboratory “quality” in measurable terms if the intention is to use the laboratory as the unit of analysis. It may be difficult to achieve consensus on what that definition would entail (e.g., preanalytical components, clinical relevance) although it is clear that any definition must encompass the total testing process. Other quality measures might include: inspections/physical assessment, turnaround time, satisfaction, complications, how reference ranges are established,
4. Efforts should be taken to incorporate the impact of laboratory testing on patient outcome. Exploration needs to be given as to whether or not outcome measures could or should be included in future studies.
5. Because of the magnitude of the questions, the scope of this study would probably best be served by partnership with CDC and perhaps other state agencies, specialty societies.
6. The study design to evaluate the impact of personnel on testing quality must be able to isolate this variable from other measures of laboratory structure. Although there may be differences in California personnel standards, personnel definitions may be sufficiently broad to incorporate experienced vs. less experienced laboratory personnel, whether or not these individuals are licensed in other geographic areas.
7. It is likely that a longer longitudinal study period would be necessary to draw valid conclusions.
8. The issue of necessity must be handled separately; however, we do not believe that such a study could be reasonably approached because definitions of necessity and tools to measure it from a laboratory perspective do not presently exist. Necessity, although important, is not a measure of laboratory quality even though it can be considered a measure of quality healthcare systems.
9. Waived and PPM facilities quality should be included in any expanded study. Non-regulated analytes and non-regulated laboratories should be included. Given an increasing utilization of waived testing and the increasing number of tests that are being given waived testing status, this is an increasingly important subset of laboratory results. 74% of laboratories presently perform only waived and PPM testing.
10. The study should be commissioned to a large interdisciplinary organization with the capacity for large scale research projects.
11. An advisory panel should be established to work with any commissioned organization to ensure that there is clinical relevance to the work being conducted.
12. The organization that would conduct the study must have relevant clinical, laboratory, and health services expertise.

Thoughts about recommending a future study

1. This completed study suggests there could be merit in conducting a broader definitive study. The Subcommittee acknowledged that the State did an excellent job with the limited resources they had to perform the statutory mandate.
2. Before a definitive study is conducted, efforts should be taken to first determine the potential magnitude of impact of laboratory quality on patient care. No evidence has been presented that the difference observed has had any adverse impact on the health and safety of Californians.
3. This study should not be conducted unless specific issues related to quality can be definitively addressed. It would not be worthwhile to partially address the questions or to provide funding for another limited study.
4. Funding for a definitive study would be considerable and it may take many years to get the desired results. Some of the underlying considerations, assumptions and technology may change during the time of observation and assessment. This would make statements regarding future relevance more difficult.

While the committee may disagree with the assigned relevance of some of the issues raised in the SD report, a number of factual points have been discussed in our recommendations above.