PERFORMANCE EVALUATION FOR SCREENING LABORATORIES OF THE ASIA-PACIFIC REGION

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Abstract. The Centers for Disease Control and Prevention (CDC) has a long history of involvement in quality assurance (QA) activities for support of newborn screening laboratories. Since 1978, CDC's Newborn Screening Quality Assurance Program (NSQAP), has distributed dried-blood spot (DBS) materials for external QA and has maintained related projects to serve newborn screening laboratories. The first DBS materials were distributed for congenital hypothyroidism screening in 1978 and by 2001, NSQAP had expanded to over 30 disorders and performance monitoring for all filter paper production lots from approved commercial sources. In 2001, there were 250 active NSQAP participants, 167 laboratories from 45 countries and 83 laboratories in the United States. Of these laboratories, 31 are from the Asia Pacific Region representing nine countries primarily for two disorders. In 1999, US laboratories had more errors for Performance Evaluation (PE) specimens than other laboratories; but in 2000, US laboratories had fewer errors. International laboratories reported 0.3% false-negative PE clinical assessments for congenital hypothyroidism and 0.5% for phenylketonuria (0.5%) in 2000. Paperless PE data-reporting operation using an Internet website has recently been implemented.

INTRODUCTION

Newborn screening for detection of treatable, inherited metabolic diseases is a major public health responsibility. Effective screening of newborns using dried-blood spot (DBS) specimens collected at birth, combined with follow-up diagnostic studies and treatment helps prevent mental retardation and premature death. The CDC has a long history of involvement in quality assurance (QA) activities for the support of newborn screening laboratories (National Research Council, 1975). Since 1978, in response to requests from public health laboratories and with the Association of Public Health Laboratories (USA) as a co-sponsor, the Newborn Screening Quality Assurance Program (NSQAP) has distributed dried-blood spot materials for external QA services and has maintained related projects to serve newborn screening laboratories. In 1978, the first blood-spot QA materials were distributed for congenital hypothyroidism screening. NSQAP has now expanded to provide QA services for over 30 disorders. As another QA service, NSQAP for 20 years has routinely assessed and assured that the blood-collection performance parameters are met for all filter paper production lots from approved commercial sources (Hannon *et al*, 1997). Fig 1 shows the activities and partners of NSQAP and a map of countries with at least one participating laboratory.

MATERIALS AND METHODS

The NSQAP consists of two DBS distribution components, quality control (QC) and proficiency testing (PT). The QC materials, which are intended to supplement the participants' method- or kit-control materials, allow participants to monitor the long-term stability of their assays. The PT program provides laboratories with quarterly panels of blind-coded DBS specimens and gives each laboratory an independent external assessment of its performance. All DBS specimens in the PT surveys and QC production lots were prepared from whole blood of 55% hematocrit. Purified analytes or natural donor

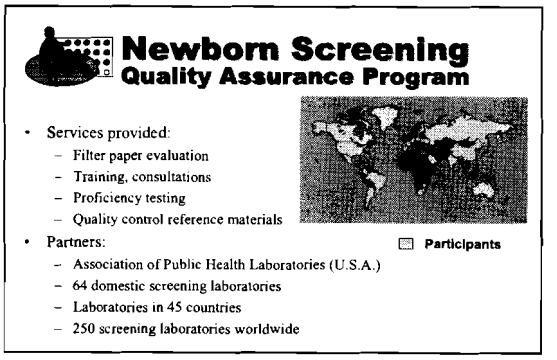

Fig 1. Activities and partners of the newborn screening quality assurance program.

Table 1. Participants from the Asia-Pacific Region.

Country	Number of participants
Australia	5
China	15
Hong Kong	1
New Zealand	1
Philippines	1
South Korea	3
Taiwan	3
Thailand	1

blood were used for all blood enrichments, except for thyroid-stimulating hormone (TSH), which used the Second International Reference Preparation (80/558). DBS materials for QC and PT are certified for homogeneity, accuracy, stability, and suitability for kits from commercial sources. Specimen sets are packaged in a zip-close plastic bag with desiccant, and instructions for analysis and data-report forms are included separately in the shipping package. Both analytic performance and clinical assessments are monitored and evaluated.

RESULTS AND DISCUSSION

In 2001, there were 250 active NSQAP participants, 167 laboratories from 45 countries including 83 laboratories in the United States. Of these laboratories, 30 are from the Asia-Pacific Region and represent the nine countries listed in Table 1. These laboratories primarily participate for two disorders, phenylketonuria and congenital hypothyroidism, but some participate only in the QC component and not in the PT. A few of the Asia-Pacific laboratories participate for 5 or more disorders. Fig 2 and 3 show the 2001 reported PT results for phenylalanine and TSH measurements for one representative quarter for detection of phenylketonuria and congenital hypothyroidism, respectively. These data are representative of the data reported for the other quarters in 2001 and are shown by the analytic method used. Fig 2 shows that the difference among the mean phenylalanine values by method is minimal and that these mean values for the Asia-Pacific Region are similar to those reported for all other participants. Fig 3 shows that the mean TSH values by two methods are higher than the other method group and are also higher than the mean value for all other participants. These data are similar to those observed for these two methods in other regions worldwide.

Participants are requested to report both the analytic values and presumptive clinical assessments and the cutoff values used for presumptive clinical assessments. Laboratory-reported specific cutoff values are applied to the grading algorithm for the clinical assessment. In 1999, the US laboratories had more misclassification errors for PT specimens than did other laboratories (data not shown); but in 2000, these laboratories had fewer errors. Some of the PT specimens fall close to the decision level for classifications and thus rigorously tested the ability of laboratories to make the expected decision. The most serious misclassification error is the false-negative report. Fig 4 shows the

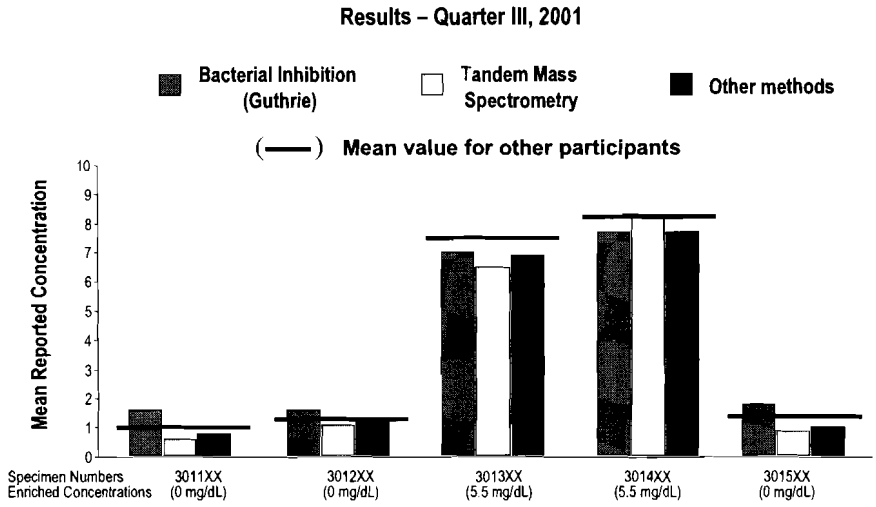

Fig 2. Performance evaluation data for Asia-Pacific Region for phenylalanine.

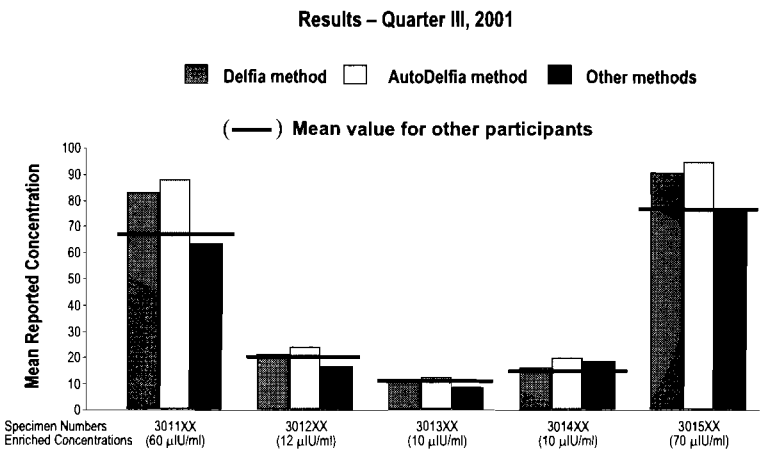

Fig 3. Performance evaluation data for Asia-Pacific Region for thyroid-stimulating hormone.

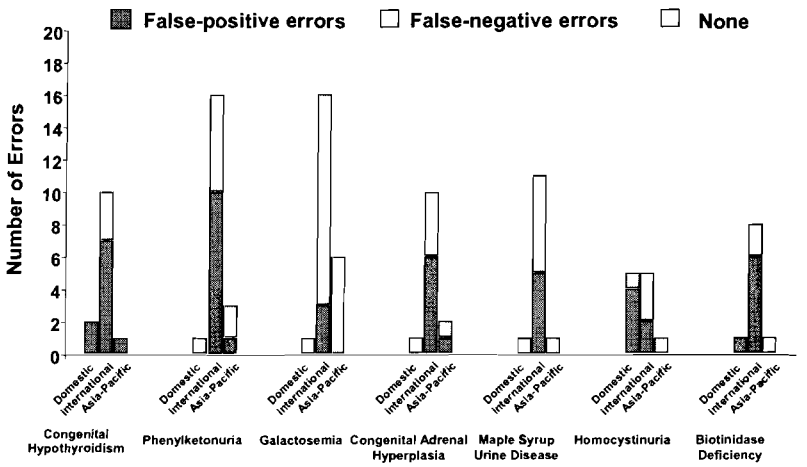

Fig 4. Summary of performance evaluation errors for year 2000 by disorder and region.

misclassification errors reported by region in 2001 for the PT program. The international laboratories reported more false-negative PT clinical assessments than did the other two groups. Fig 4 shows that misclassification errors were reported by the Asia-Pacific laboratories; however, no false-negative results were reported for congenital hypothyroidism, maple syrup urine disease, and biotinidase deficiency.

CONCLUSIONS AND RECOMMENDATIONS

The performance of the Asia-Pacific Region laboratories is similar to that of laboratories worldwide. Rapid interaction with laboratories reporting false-negative results and resolution of this problem (corrective action) are critical to quality performance of the screening laboratories. The proactive response of the quality assurance program should be an essential component for operations. The NSQAP makes immediate contact with laboratories reporting false-negative results and offers consultative services. The capacity to make rapid contact with participating laboratories can be difficult, however, especially with the international participants. NSQAP designed and initiated a paperless PT data-reporting operation using an Internet Website that will permit quicker access to PT data for international participants and a more

timely focus on corrective actions. NSQAP is designed to help screening laboratories achieve excellent technical proficiency and maintain confidence in their performance while daily processing large volumes of specimens.

REFERENCES

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