

reproducibility and linearity. Also, an evaluation of the appropriateness of the reference interval ensures that the test can differentiate a normal result from one suggesting a disease process. It is difficult to estimate the number of mistakes that can be averted by method verification. However, it is considered a hallmark of good laboratory practice to prevent errors when introducing a new test system, by verifying acceptable performance of the new methodology before testing patient specimens.

#### Costs

##### *Number of Tests Needed To Verify Method Performance Specifications (Per Analyte)*

There are no standards of practice established for method verification, and there is great variability in what laboratories currently do to verify performance specifications. The NCCLS has published several guidelines for verification of the elements of acceptable performance. One way to document performance is to use NCCLS protocols, document EP15-P for accuracy and precision, EP6-P for linearity (reportable range), and C28-A for reference intervals. The three separate protocols require a total of 120 assays, at a minimum. Reducing this number can be accomplished by performing some of the analyses

together using the same specimens. Therefore, our estimate using the NCCLS protocol, in which we assumed a range of 120 to 150 assays per analyte or test, may overestimate the number of assays required.

#### Reagent Costs

We estimated the cost for reagents by obtaining price quotes from reagent manufacturers (Beckman-Coulter, Dade-Behring and Roche Diagnostics). Because the price estimates vary with test volumes, we assumed a moderate test volume with an average cost across analyzers to estimate an average reagent cost. We also estimated an average reagent cost to be \$1.79 per test. We did not include costs for calibration or QC materials. However, many manufacturers provide assistance to laboratories for method verification, and this assistance many times includes providing reagents to the laboratory free of charge. Although manufacturers will incur some cost for reagents, the cost is significantly less than the retail sales price we quote.

#### Labor Estimates

Because we do not know the average number of analytes per test system, we assumed a broad range of analyst time (4 to 16 hours) at a rate of \$17.90 per hour (Ward-Cook and Tannar, 2001). We are also assuming 1 hour of laboratory

director time at a rate of \$33.45 per hour (Bureau of Labor Statistics Occupational Outlook Handbook, 2000–2001 edition).

#### Materials

For the NCCLS approach, patient materials would suffice; however, these must be tested on a separate analyzer that serves as a reference for accuracy determinations. In addition, we are assuming that previously tested, stored patient samples would be used; therefore, we included locating previously tested patient materials in labor costs.

#### Total Costs

Based on the incidence of introduction of individual tests reported in the Pacific Northwest Laboratory Medicine Sentinel Monitoring Network survey (LaBeau, *et al* 1999), the cost of the requirement to perform method verification among affected laboratories can range from \$8.3 to \$15.3 million the first year (Table 6). Considering the costs of method verification for replacement analyzers, the costs can range between \$3.0 and \$4.8 million (Table 7). Therefore, the total first year expense for method verification may range from \$11.3 to \$20.1 million. The aggregate impact for method verification, with a discount over the next 5 years, may range from \$49.6 to \$88.0 million.

TABLE 6.—IMPACT OF METHOD VERIFICATION, NEW SINGLE TESTS

Number of tests	Percent adding	Number of laboratories adding	Number of tests added	Med tech labor cost (range) *	Lab director labor cost*	Total labor cost (range)*	Reagent cost (range)*	Total cost methods (range)
0 .....	62	18,353	0	0	0	0	0	0
1 .....	16	4,736	4,736	\$0.34–1.36	\$0.16	\$0.50–\$1.52	\$1.02–1.27	\$1.51–2.79
2 .....	8	2,368	4,736	0.34–1.36	0.16	0.50–1.52	1.02–1.27	1.51–2.79
3 .....	5	1,480	4,440	0.32–1.27	0.15	0.47–1.42	0.95–1.19	1.42–2.61
4 .....	4	1,184	4,736	0.34–1.36	0.16	0.50–1.52	1.02–1.27	1.51–2.79
5 .....	5	1,480	7,400	0.53–2.12	0.25	0.78–2.37	1.59–1.99	2.37–4.38
.....	.....	.....	26,048	1.87–7.47	0.88	2.75–8.35	5.60–6.99	8.32–15.33

\* Millions of dollars

TABLE 7.—IMPACT OF METHOD VERIFICATION, ANALYZER REPLACEMENT

Analyzer type	Number of analyzers	Number of analyzers replaced each year	Medical technologist labor cost*	Laboratory director labor cost*	Total labor cost*	Reagent cost *	Total replacement cost *
TDM .....	3,230	646	\$46.3–185.0	\$21.6	\$67.9–206.6	\$0.45–0.56	\$0.51–0.76
Chemistry .....	7,657	1,531	109.6–438.6	51.2	160.9–489.8	1.10–1.38	1.26–1.87
Hematology .....	12,439	2,488	178.1–712.5	83.2	261.3–795.7	0.27–0.34	0.53–1.13
Ligands .....	3,404	681	48.7–195.0	22.8	71.5–217.7	0.25–0.33	0.32–0.52
Reproduction ....	930	186	13.3–53.3	6.2	19.5–59.5	0.27–0.33	0.29–0.39
Immunology .....	223	45	3.2–12.8	1.5	4.7–14.3	0.06–0.08	0.07–0.09
.....	.....	.....	399.3–1,597.1	\$186.5	585.8–1,783.7	2.18–2.72	2.98–4.77

TDM = Therapeutic drug Monitoring.

\* Thousands of dollars.

\* Millions of dollars.