SUPPLEMENT ARTICLE

Economic Evaluation of Tandem Mass Spectrometry Screening in California

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The authors have indicated they have no financial relationships relevant to this article to disclose.

ABSTRACT

OBJECTIVE. On the basis of California's experience implementing a pilot tandem mass spectrometry (MS/MS) screening program, an economic evaluation was conducted to determine the economic benefits and costs of a statewide MS/MS screening program.

METHODS. Cost-effectiveness, benefit/cost, and cost-utility analyses were conducted with a base-case set of assumptions. The base-case assumptions were varied by using a set of more-favorable and less-favorable assumptions to test the robustness of the analysis findings.

RESULTS. The total estimated, annualized, incremental costs of MS/MS screening of 540 000 births in California were nearly $5.7 million; 83 affected newborns would be identified. Screening would reduce the expected lifetime costs of medical care for affected newborns by $7.2 million ($9.0 million in the best-case scenario and $1.8 million in the worst-case scenario). When all program costs and savings were considered, screening saved $1.5 million ($3.4 million saved in the best-case scenario and $3.8 million additional costs in the worst-case scenario). With only incremental program costs, the cost per life saved was $708 000 and the cost per case detected was $68 000. With consideration of the projected lifetime medical care costs, the total cost per case detected was $132 000. MS/MS screening produced a benefit/cost ratio of $9.32 ($11.67 with the best-case set of assumptions and $4.34 with the worst-case set of assumptions). In this analysis, the benefits of screening exceeded total program costs by $47.1 million (the net incremental benefit). In the worst-case scenario, the net incremental benefit of screening was $18.9 million. Screening saved 949 quality-adjusted life-years (QALYs) and saved $1628 per QALY in the base case analysis. Under the worst-case scenario, the cost per QALY was $14 922.

CONCLUSIONS. We found that the benefits of MS/MS screening outweighed the costs and that the net benefits were significant and robust in various scenarios with various conservative underlying assumptions.

www.pediatrics.org/cgi/doi/10.1542/peds.2005-2633G

doi:10.1542/peds.2005-2633G

Key Words
newborn screening, economics, cost-utility

Abbreviations
MS/MS—tandem mass spectrometry
QALY—quality-adjusted life-year
PKU—phenylketonuria
CDC—Centers for Disease Control and Prevention

Accepted for publication Dec 27, 2005

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PEDIATRICS (ISSN Numbers: Print, 0031-4005; Online, 1098-4275); published in the public domain by the American Academy of Pediatrics

THE California legislature authorized and funded a pilot tandem mass spectrometry (MS/MS) screening program, which was conducted from January 7, 2002, through June 13, 2003. During that period, 755 698 infants were born, 353 894 newborns were screened, and 53 cases of disorders detectable with MS/MS were identified in the screened population (including 2 cases that were missed initially with MS/MS testing but would have been identified with our revised cutoff values). On the basis of this experience, the overall incidence in California is ~1 case per 6700 newborns screened. We did not include phenylketonuria (PKU) because we were evaluating the marginal benefits of MS/MS screening, compared with the incremental cost of adding the new technology to the existing screening program, which already screens for PKU. Using this incidence figure, we project that statewide screening of 540 000 annual births would, on average, identify 83 cases with disorders detectable through MS/MS screening.

Cost-effectiveness, benefit/cost, and cost-utility analyses were conducted to determine whether the benefits achieved through an expanded newborn screening program with MS/MS technology justify the costs of implementing the program. The analyses were conducted from the perspective of the costs of screening to the public (excluding additional costs borne by families), with several sets of assumptions that were varied to test the robustness of the conclusions.

METHODS

Costs of Program Operation

The cost estimate includes the incremental costs associated with implementing MS/MS screening. The costs of the pilot project differ from the costs of a statewide MS/MS screening program because of differences between the limited scope of the pilot program (eg, PKU not included) and the ongoing statewide newborn screening program. However, the costs of the pilot project can be used to develop reasonable estimates of the costs of adding MS/MS technology to the basic newborn screening program. Direct program costs were allocated to the categories of personnel and administration (6 staff positions), equipment (12 MS/MS instruments plus ancillary equipment), supplies ($3.72 per test for 540 000 tests), laboratory contracts (rental of space and labor at $3.46 per test for 540 000 tests), and follow-up centers and were based on the actual experience with the personnel needs for a comprehensive program, including education, testing, interpretation, reporting, follow-up testing of false-positive and diagnosed cases, and quality control for clinical laboratory elements.

Valuing the Benefits of Screening

To estimate the direct medical care cost savings that might be realized through MS/MS screening from a payers' perspective, first we needed to estimate the distribution of clinical outcomes expected with and without screening. We developed a model with the clinical outcome categories used by Insinga et al,[1] ie, death, severe neurologic impairment, mild neurologic impairment, acute complications only, and asymptomatic. With a distribution of clinical outcomes similar to that reported by Schulze et al,[2] we established our base-case scenario of expected outcomes without screening. Then a base-case scenario of outcomes expected with screening was developed with input from a panel of metabolic specialists in California.

For each clinical outcome category, we estimated the expected average lifetime medical care costs of treatment per individual. The total lifetime costs were calculated by multiplying the estimated lifetime medical care costs per newborn by the number of newborns within each clinical outcome category, with and without screening. To establish our base-case estimate of the lifetime medical care costs of MS/MS-detectable disorders with severe neurologic impairment resulting from inborn errors of metabolism that were not diagnosed through screening, we used (as a proxy) the $1 014 000 (2003 dollars) estimate published by the Centers for Disease Control and Prevention (CDC)[3] for the lifetime costs for a person with mental retardation. A 3% inflation rate was applied to adjust this estimate to 2004 dollars as $1 044 420. The lifetime costs of moderate developmental delay ($77 079, in 2004 dollars), as proposed by Carroll and Downs,[4] were used as a proxy for the lifetime medical care costs for a moderately affected individual with a MS/MS-detectable disorder. We estimated the lifetime costs for acute MS/MS-detectable disorder complications only ($40 000) and for asymptomatic individuals ($500). The difference between the total lifetime costs with MS/MS screening and the total lifetime costs without MS/MS screening equals the total lifetime medical care costs avoided.

In calculating the total benefits attributable to saving lives through MS/MS screening, we needed to value the lives saved. For our base-case analysis, we used a value derived from a report by the US Environmental Protection Agency[5] that valued a life at $5.7 million ($5.5 million in 2003 dollars, adjusted to 2004 dollars with a 3% inflation rate).

Valuing the Costs of Screening

The incremental program costs for the annual cohort of births plus the estimated total lifetime costs of medical care for the affected births in the cohort (for each of the 3 scenarios, as described below), as detected through MS/MS screening, equal the total annualized incremental costs of MS/MS screening (the total marginal program costs). The incremental costs per life saved are calculated by dividing the incremental program costs by the number of lives saved. Similarly, the incremental costs per case detected are calculated by dividing the incremental program costs by the number of cases with MS/MS-detectable disorders diagnosed through screening in any given year. The benefit/cost ratio is calculated by dividing the total incremental program benefits by the total incremental program costs.

Cost-Utility Analysis

A cost-utility analysis calculates the incremental cost per quality-adjusted life-year (QALY), with the survival gains being adjusted for the quality of those lives. With this method, outcomes are assigned a relative value called "utility," with perfect health being 1 and death being 0. We assigned utility values of 0.90 to newborns with no symptoms, 0.87 to those with acute complications, 0.65 to those with mild/moderate neurologic complications, and 0.39 to those with severe neurologic complications. The utility values for mild/moderate and severe neurologic complications were based on estimates by Bennett et al.[6] The utility analysis also incorporates estimates of the expected lifespans of individuals with different levels of disability.[7,8] For the utility analysis, we used the $5.7 million value per life saved estimate[5] and not the alternative estimate of $4.5 million.[9]

Sensitivity Analysis

In the sensitivity analysis, we varied multiple sets of assumptions to test the robustness of the base-case analyses. For the estimate of the lifetime medical care costs avoided through screening, we held constant the base-case clinical outcomes expected without screening and calculated the expected costs by using a best-case scenario and then a worst-case scenario. We also varied the estimate of the lifetime medical care costs for a MS/MS-detectable case that was not screened, using the $0.5 million to $1.5 million range suggested by Schulze et al,[2] on the basis of projected expenses for hospitalizations and medications. The middle ($1 million) of this estimate range is consistent with the 2003 CDC estimate[3] that was used in the base-case analysis ($1 014 000). Lastly, an alternative value per life saved of $4.5 million[9] was used in the sensitivity analysis, as a more-conservative estimate than the $5.7 million used in the base-case analysis.

RESULTS

Costs of Program Operations

The first-year program startup costs would be $9.2 million. These costs would include $4 million in initial equipment costs. If the $4 million in equipment costs were depreciated over 8 years, then the ongoing incremental annualized direct costs to the California Newborn Screening Program for MS/MS technology would be almost $5.7 million (Table 1). The costs of collection of specimens, distribution of results, and tracking of cases would not be increased and are not included in the incremental costs.

TABLE 1 **Incremental Annualized Costs of MS/MS Screening in California**

Cost Category	Cost Estimate
Personnel and administration	$540 000
Equipment[a]	$500 000
Supplies	$2 012 500
Laboratory contracts	$1 870 000
Follow-up centers	$742 000
Total	$5 664 500

[a] Costs of $4 million, depreciated over 8 years.

Valuing the Benefits of Screening

Table 2 summarizes the base-case outcomes expected with and without screening. The base-case scenario with no MS/MS screening assumed that 10 deaths would occur. The base-case scenario with screening (scenario A) assumed that 2 deaths would occur. The sensitivity analysis used a best-case scenario with screening (scenario B) that assumed that no deaths would occur and a worst-case scenario (scenario C) that assumed that 6 deaths would occur. Compared with the base-case scenario, the best-case scenario assumed that more cases would be asymptomatic, whereas the worst-case scenario assumed that more cases would involve severe or mild/moderate impairment.

Table 3 presents the estimated total lifetime medical care costs avoided for the base-case analysis and the alternative scenarios. The base-case analysis (with the $1 million lifetime medical care cost estimate) showed that, with screening, more than $7.2 million in medical care costs would be avoided. In contrast, the best-case scenario (with an estimate of $1.5 million in lifetime medical care costs) produced an estimate of $12.7 million in medical care costs avoided, and the worst-case scenario (with an estimate of $0.5 million in lifetime medical care costs) produced an estimate of just more than $713 000 in lifetime costs avoided with screening.

Table 4 presents several MS/MS screening economic outcomes for screening scenarios A, B, and C. In scenario A (the base-case analysis, assuming $1 million in lifetime medical care costs), 8 lives are saved with screening and the total costs saved are $1.5 million for the cohort of 83 cases identified through screening, compared with the estimated costs expected in the absence of screening. With the use of only incremental program costs, the costs per life saved are $708 000 and the costs per case detected are $68 000. With consideration of the projected lifetime medical care costs, the total costs per case detected are $132 000. With the lower and higher estimates of lifetime medical care costs, the costs per case detected are $112 000 and $148 000, respectively.

The same set of economic measures were calculated

TABLE 2 **Expected Distribution of Clinical Outcomes With and Without MS/MS Screening in California**

Screening	MS/MS Available	No.				
		Death	Severe Neurologic Impairment	Mild/Moderate Impairment	Acute Complications Only	Asymptomatic
None, base case	No	10	10	10	25	28
Scenario A, base case	Yes	2	3	3	47	28
Scenario B, best case	Yes	0	2	4	25	52
Scenario C, worst case	Yes	6	8	14	27	28

Results were based on a hypothetical annual sample of 540 000 California newborns and 83 cases with MS/MS detectable disorders.

for scenario B (best-case analysis) and scenario C (worst-case analysis) (Table 4). In scenario B, 10 lives are saved and the total costs saved through screening ranges between −$922 000 (spent) and $3.4 million (saved), depending on which estimate of lifetime medical care costs is used. For scenario C, in which only 6 lives are saved, the total saved costs with screening range between −$2.9 million and −$4.9 million.

Benefit/Cost Analysis

Table 5 presents the total incremental benefits, total incremental program costs, net incremental benefits, and benefit/cost ratio for all 3 scenarios, with 3 estimates of the lifetime medical care costs and 2 estimates of the value of lives saved. In the base-case scenario, the benefits of screening exceed program costs by $47.1 million (the net incremental benefit). In the worst-case scenario, the net incremental benefit of screening is $14.1 million; in the best-case scenario, the net incremental benefit of screening is $60.4 million. The benefit/cost ratio is $9.32 for the base-case scenario and ranges between $8.65 and $9.89 for the lower and higher lifetime medical care cost estimates, respectively (assuming a $5.7 million value of life). If a lower value ($4.5 million) for the lives saved is assumed, then the benefit/cost ratio is reduced, but not by much ($6.96 to $8.19). In the best-case scenario, the lowest benefit/cost ratio is $8.78 and the highest is $12.31; in the worst-case scenario, the benefit/cost ratio is between $3.30 and $4.50.

Cost-Utility Analysis

The results of the cost-utility analysis are shown in Table 6. Scenario A (base-case analysis) produces 949 additional QALYs and saves $1628 per QALY. With the lower estimate of $0.5 million in lifetime medical care costs, the cost per QALY is $2389. Scenario B (best-case analysis) produces 1221 additional QALYs, ranging between a savings of $5797 per QALY and a cost of $755 per QALY. In scenario C (worst-case analysis), 259 QALYs are achieved, at a cost of $11 401 to $19 129 per QALY.

DISCUSSION

The economic analysis presented here is a top-down approach designed for practical program needs. This analysis weighs the benefits of expanding the newborn screening program with MS/MS technology against the additional program costs required to screen all 540 000 California newborns. The value of the analysis is to establish an understanding of how the benefits and costs of screening change with different assumptions of program effectiveness and expected costs.

Because the assignment of a value to a life saved is controversial, we used 2 different estimates, one that values a life saved at $5.7 million and one that values a life saved at $4.5 million. These produce benefit/cost ratios between 3.30 and 12.31 (with different assumptions of lifetime medical care costs). However, even if we assumed a much lower value of life, eg, $1 million, the (base-case) benefit/cost ratio of $2.68 is still quite acceptable.

Many health economists regard the benefit/cost ratio as too subjective, because it is based on the value assigned to lives saved. The cost-utility approach was developed so that all benefits could be presented with respect to QALYs. This analysis is robust even with lower estimates of the value of lives saved. In the worst-case scenario, which produces only 259 QALYs saved, the cost per QALY is between $11 000 and $19 000. This is similar to the results of the Wisconsin economic analysis of MS/MS screening (for the whole spectrum of MS/MS-detectable disorders that can be diagnosed through newborn screening), in which the cost per QALY was estimated to be $15 252.[1] Generally economists have accepted a standard that a cost per QALY of $50 000 or less is considered a cost-effective investment.[10] In this analysis, this threshold is easily met.

The treatment costs avoided through screening are based on the underlying distribution of outcomes expected with MS/MS screening, compared with not having a program. The distributions of possible outcomes were varied in the base-case, best-case, and worst-case scenarios, to account for the lack of certainty regarding the long-term clinical outcomes expected for the cohort of 83 patients with MS/MS-detectable disorders.

The CDC estimate of $1 014 000 in lifetime costs for a mentally retarded person includes a large proportion of indirect costs attributable to lost productivity. However, in this analysis, we used the same estimate to represent

TABLE 3 **Estimated Lifetime Medical Care Costs Avoided With MS/MS Screening in California**

Program Effectiveness Scenarios	Lifetime Medical Care Cost Estimates for an MS/MS-Detected Case With Severe Neurologic Impairment		
Screening scenario A, base case	$1 000 000 (base case)	$1 500 000	$500 000
Without screening (*a*)	$12 530 204	$17 086 004	$7 086 004
With screening (*b*)	$5 321 052	$6 687 792	$3 687 792
Treatment costs avoided ($a - b$)	$7 209 152	$10 398 212	$3 398 212
Screening scenario B, best case			
Without screening	$12 530 204	$17 086 004	$7 086 004
With screening	$3 432 405	$4 343 565	$2 343 565
Treatment costs avoided	$9 097 798	$12 742 438	$4 742 438
Screening scenario C, worst case			
Without screening	$12 530 204	$17 086 004	$7 086 004
With screening	$10 727 693	$14 372 333	$6 372 333
Treatment costs avoided	$1 802 511	$2 713 671	$713 671

TABLE 4 **Summary of Economic Impact of MS/MS Screening in California**

Total Lifetime Medical Care Costs	Scenario A, Base Case	Scenario B, Best Case	Scenario C, Worst Case
$1 000 000			
Lives saved (*a*)	8	10	6
Incremental program costs (*b*)	$5 664 500	$5 664 500	$5 664 500
Lifetime medical care costs with screening (*c*)	$5 321 052	$3 432 405	$10 727 693
Total costs with screening ($d = b + c$)	$10 985 552	$9 096 905	$16 392 193
Total costs without screening (*e*)	$12 530 204	$12 530 204	$12 530 204
Total costs saved with screening ($e - d$)	$1 544 652	$3 433 298	$(3 861 989)
Incremental costs per life saved (*b*/lives saved)	$708 063	$566 450	$944 083
Incremental costs per case detected (*b*/83)	$68 247	$68 247	$68 247
Total costs per case detected (*d*/83)	$132 356	$109 601	$197 496
$500 000			
Lives saved	8	10	6
Incremental program costs	$5 664 500	$5 664 500	$5 664 500
Lifetime medical care costs with screening	$3 687 792	$2 343 565	$6 372 333
Total costs with screening	$9 352 292	$8 008 065	$12 036 833
Total costs without screening	$7 086 004	$7 086 004	$7 086 004
Total costs saved with screening	$(2 266 288)	$(922 062)	$(4 950 829)
Incremental costs per life saved	$708 063	$566 450	$944 083
Incremental costs per case detected	$68 247	$68 247	$68 247
Total costs per case detected	$148 823	$96 483	$145 022
$1 500 000			
Lives saved	8	10	6
Incremental program costs	$5 664 500	$5 664 500	$5 664 500
Lifetime medical care costs with screening	$6 687 792	$4 343 565	$14 372 333
Total costs with screening	$12 352 292	$10 008 065	$20 036 833
Total costs without screening	$17 086 004	$17 086 004	$17 086 004
Total costs saved with screening	$4 733 712	$3 066 144	$(2 950 829)
Incremental costs per life saved	$708 063	$566 450	$944 083
Incremental costs per case detected	$68 247	$68 247	$68 247
Total costs per case detected	$112 678	$120 579	$241 408

Results were calculated per cohort of 83 diagnosed cases.

the expected lifetime medical care costs for a severely affected, neurologically impaired child with a MS/MS-detectable disorder that was not detected through newborn screening. To account for the uncertainty with respect to this estimate, which is by far the largest cost category, we varied the expected lifetime medical care costs within the range of $0.5 million to $1.5 million proposed by Schulze et al,[2] which represents their estimate of the average lifetime costs of hospitalization and medication for an individual affected with a MS/MS-detectable disorder not detected through screening. As expected, the higher estimate ($1.5 million) produced the most favorable cost-effectiveness and benefit/cost ratio values. The higher estimate may be the most realistic one, on the basis of the experiences reported by several California parents of children born with MS/MS-detectable disorders that were not diagnosed through screening. It was not uncommon to have $1 million in

TABLE 5 Benefit/Cost Analysis of MS/MS Screening in California

Lifetime Medical Care Costs	Value of Life					
	Scenario A, Base Case		Scenario B, Best Case		Scenario C, Worst Case	
	$5 700 000	$4 500 000	$5 700 000	$4 500 000	$5 700 000	$4 500 000
$1 000 000						
Lives saved (*a*)	8	8	10	10	4	4
Medical care costs avoided (*b*)	$7 209 152	$7 209 152	$9 097 798	$9 097 798	$1 802 511	$1 802 511
Value of lives saved (*c* = *a* × value of life)	$45 600 000	$36 000 000	$57 000 000	$45 000 000	$22 800 000	$18 000 000
Total incremental benefits (*d* = *b* + *c*)	$52 809 152	$43 209 152	$66 097 798	$54 097 798	$24 602 511	$19 802 511
Incremental program costs (*e*)	$5 664 500	$5 664 500	$5 664 500	$5 664 500	$5 664 500	$5 664 500
Net incremental benefits (*f* = *d* − *e*)	$47 144 652	$37 544 652	$60 433 298	$48 433 298	$18 938 011	$14 138 011
Benefit/cost ratio (*d*/*e*)	$9.32	$7.63	$11.67	$9.55	$4.34	$3.50
$500 000						
Lives saved	8	8	10	10	4	4
Medical care costs avoided	$3 398 212	$3 398 212	$4 742 438	$4 742 438	$713 671	$713 671
Value of lives saved	$45 600 000	$36 000 000	$57 000 000	$45 000 000	$22 800 000	$18 000 000
Incremental program costs	$48 998 212	$39 398 212	$61 742 438	$49 742 438	$23 513 671	$18 713 671
Total incremental program costs	$5 664 500	$5 664 500	$5 664 500	$5 664 500	$5 664 500	$5 664 500
Net incremental benefits	$43 333 712	$33 733 712	$56 077 938	$44 077 938	$17 849 171	$13 049 171
Benefit/cost ratio	$8.65	$6.96	$10.90	$8.78	$4.15	$3.30
$1 500 000						
Lives saved	8	8	10	10	4	4
Medical care costs avoided	$10 398 212	$10 398 212	$12 742 438	$12 742 438	$2 713 671	$2 713 671
Value of lives saved	$45 600 000	$36 000 000	$57 000 000	$45 000 000	$22 800 000	$18 000 000
Incremental program costs	$55 998 212	$46 398 212	$69 742 438	$57 742 438	$25 513 671	$20 713 671
Total incremental program costs	$5 664 500	$5 664 500	$5 664 500	$5 664 500	$5 664 500	$5 664 500
Net incremental benefits	$50 333 712	$40 733 712	$64 077 938	$52 077 938	$19 849 171	$15 049 171
Benefit/cost ratio	$9.89	$8.19	$12.31	$10.19	$4.50	$3.66

TABLE 6 Cost-Utility Analysis of MS/MS Screening in California

Estimates of the Marginal Cost per QALY[a]	Outcomes		
	Scenario A, Base Case	Scenario B, Best Case	Scenario C, Worst Case
QALY saved	949	1221	259
Cost per QALY with $1 million lifetime costs	$(1628)	$(2812)	$14 922
Cost per QALY with $0.5 million lifetime costs	$2389	$755	$19 129
Cost per QALY with $1.5 million lifetime costs	$(4989)	$(5797)	$11 401

[a] Per cohort of 83 diagnosed cases of MS/MS disorders.

medical costs reached within the first few years of life (for very long-chain acyl-CoA dehydrogenase deficiency and glutaric acidemia type 1 disorders).

In the base-case and best-case scenarios, MS/MS screening almost always saved money, compared with the costs that would have been incurred in the absence of screening. The range of benefit/cost ratios calculated with 9 different sets of assumptions showed that MS/MS screening makes sense even with the most conservative assumptions. MS/MS screening leads to sizeable cost savings at best and is a reasonably good value, according to standard health economic benchmarks, at worst.

ACKNOWLEDGMENTS

This work was supported by a grant from the Health Resources and Services Administration (1 H46 MC 00199-03).

Special thanks go to Lisa A. Faulkner, PhD, Martin Kharrazi, PhD, Stephen M. Downs, MD, MS, and Richard Scheffler, PhD, for their valuable review and feedback. Special thanks also go to Bruce Barshop, MD, Susan Winter, MD, and Steven Cedarbaum, MD, who provided input in the development of the program effectiveness scenarios.

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Pediatrics 2006;117;S280
DOI: 10.1542/peds.2005-2633G