

CLIA Waived vs Moderately Complex Rapid HIV Testing: How Much Will It Cost?

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Background

- ❧ Rapid HIV tests are useful in both clinic and outreach settings because more persons learn their results. Some newer rapid tests are simple, accurate, do not require special laboratory equipment, and can be performed in 15 minutes.
- ❧ The Clinical Laboratory Improvement Act (CLIA) could categorize these diagnostic tests as moderately complex or as waived. The two categories require different personnel.

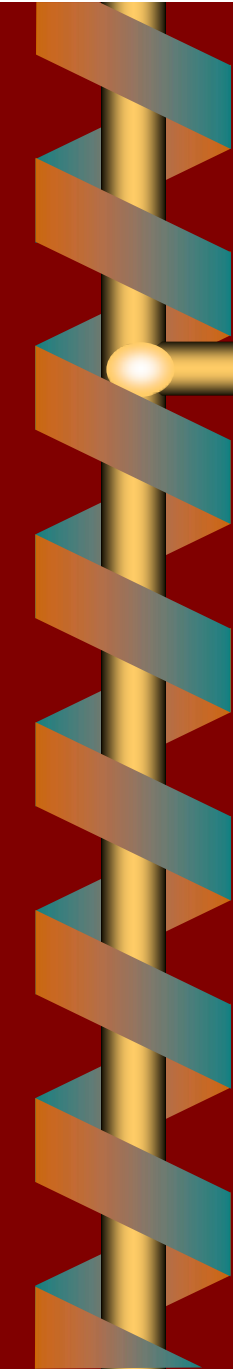


Objective

- Estimate the costs for California's HIV testing program if simple, rapid HIV tests are categorized as waived versus moderately complex.

Methods

- ⌚ We calculated personnel costs for rapid HIV testing under the two CLIA categories. Based on specific qualifications required and the state's personnel classification system, hourly wages to perform rapid tests would be \$9 if waived and \$17 if moderately complex. Counseling times were derived from the counseling and testing database. We estimated that rapid tests would require 15 minutes to perform.



Results

- Of approximately 200,000 annual HIV tests, 1% are positive. Risk assessment (pretest counseling) requires 20 minutes. Disclosure sessions (posttest counseling) average 15 minutes for HIV-negative persons and 45 minutes for HIV-positive.
- For negative results, a single rapid test is performed. Initial positive results require confirmation with two more tests.

Comparison of Personnel Costs - Waived Complexity vs Moderate Complexity

	No. sessions	Mins per session	Total Counseling Hrs	Total Hrs Conducting Rapid Tests	“Waived” Costs @ \$9 /hr	“Moderate” Costs @ \$17 /hr
Risk Assessments	200,000	20	66,667		\$600,000	\$1,133,333
Negative Disclosures	198,000	15	49,500	49,500	\$891,000	\$1,683,000
Positive Disclosures	2,000	45	1,500	1,500	\$27,000	\$51,000
Totals			117,667	51,000	\$1,518,000	\$2,867,333

Costs could almost double...

- Annually, a total of 117,667 hours are required for counseling, and approximately 51,000 hours for rapid testing. If the counselor also performs the test, waived HIV testing would cost California \$1,518,000 per year, and moderately complex, \$2,867,339 (\$1.35 million more.)



Increase would be at least \$400,000

- ⌚ If a person other than the counselor performs the test, additional personnel costs would range from a minimum of \$408,000 to \$867,000 annually if rapid tests were categorized as moderately complex, assuming these persons actually spent all work hours performing tests.



Conclusion

- ❧ Rapid HIV testing will cost substantially more with moderately complex than with waived categorization under CLIA.

Conclusion

- ⌚ A conservative estimate suggests that in California, full implementation of rapid testing under moderately complex categorization would likely cost roughly twice as much as under waived categorization -- an increase of over \$1 million.



Conclusion

- Other methods of estimation resulted in a range of up to a *six million dollar* cost increase to implement moderately complex rapid HIV testing, compared to waived.



Program/Policy Implications

- ⌚ Waived rapid HIV tests will be most cost-effective, but subject to less formal oversight.
- ⌚ Therefore, programs need to develop systems to guarantee quality and proficiency.

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