

Emerging Infectious Diseases and Laboratory Operations

Report No. 96-07 -- Executive Summary

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INTRODUCTION AND BACKGROUND

The management audit of emerging infectious diseases was requested by the Metropolitan King County Council and was included in the 1996 Auditor's Office work program.

The Prevention Services Division of the Seattle-King County Department of Public Health (SKCDPH) administers the Communicable Disease Prevention Section, which includes the Communicable Disease/Epidemiology and Tuberculosis Control Units, and the SKCDPH laboratory, which assists in the detection of infectious diseases. Offices throughout the SKCDPH would be involved in the event of an emerging disease outbreak; however, the sections noted above would provide the primary responses and would serve integral roles in the initial management of an outbreak response.

OBJECTIVE AND SCOPE

The audit objectives were to determine how well prepared the SKCDPH is to identify and respond to potential emerging infectious diseases, some of which may be imported via international air travel to the Seattle-King County area, and to determine how the SKCDPH might improve its preparedness. Specifically, the audit examined:

- current issues and trends in the local, national, and international response systems to emerging infections;
 - SKCDPH preparedness to identify and respond to an emerging disease outbreak;
 - national and international preparedness;
 - local, state, and federal policies, regulations, and guidelines for responding to emerging diseases and SKCDPH compliance with these policies, regulations, and guidelines; and
 - actual and potential benefits and costs of maintaining an extensive SKCDPH laboratory.
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SUMMARY STATEMENT OF FINDINGS

The general conclusions are that the SKCDPH is generally well prepared to respond to infectious disease outbreaks at the local level and is generally in compliance with local, state, and federal regulations for responding to infectious diseases. However, improvements are needed in the management of the SKCDPH laboratory where many of these infectious diseases would be identified. Due to the overlap of service capability with the state Department of Health, Harborview Medical Center, and commercial laboratories, as well as SKCDPH's failure to determine the economic feasibility of providing specific testing services, it is questionable whether the public health benefits achieved by operating a separate SKCDPH laboratory outweigh the economic costs of providing those services in-house.

The audit also concluded that SKCDPH laboratory fees did not reflect the actual costs of conducting the tests as required by the Code of the King County Board of Health, that the SKCDPH laboratory has not performed a cost analysis or developed a cost allocation model for the tests it performs, that SKCDPH laboratory staff should collaborate more with the state Department of Health laboratory staff to ensure that laboratory testing is performed in accordance with WAC requirements, and that the SKCDPH laboratory is conducting some tests that are better suited to being performed in an environmental laboratory.

MAJOR FINDINGS AND RECOMMENDATIONS

Finding III-A. The SKCDPH is generally well prepared to handle infectious disease outbreaks at the local level, although its capabilities may be limited by national and international preparedness that is less than optimal.

The SKCDPH has developed guidelines for responding to infectious disease outbreaks in its "Public Health Emergency Response Manual, and also has established a public information hotline that provides prerecorded messages regarding current public health concerns. The SKCDPH recently demonstrated its ability to respond to an infectious disease outbreak when a student at Denny Middle School in Seattle was diagnosed with meningitis. Although five students were ultimately confirmed as having active cases of meningitis and a sixth potential case was identified, the SKCDPH prevented the disease from spreading by coordinating with school officials, Washington State Department of Health staff, staff from the Centers for Disease Control, and the media to notify and dispense prescriptions to individuals who had been in direct contact with the identified or suspected cases.

The audit noted, however, that regardless of how well prepared the SKCDPH is to respond to an infectious disease outbreak at the local level, weaknesses at the national and international levels could affect the SKCDPH's ability to respond to an outbreak or epidemic occurring over a broader area (e.g., AIDS). For example, because national disease reporting requirements often differ from state reporting requirements, improvements need to be made in the method used to determine what diseases are reportable at both the state and national levels to create a cooperative, national approach toward disease identification and control.

The audit also noted that improvements could be made in the SKCDPH's ability to identify and respond to infectious disease outbreaks through additional cross-training of SKCDPH staff and by using a geographic information system (GIS) for disease surveillance purposes.

The audit recommended that the SKCDPH evaluate the feasibility of using a GIS to improve their disease surveillance, prevention, and control efforts and increase its cross-training efforts to maximize its ability to respond to a disease outbreak.

Finding III-B. The SKCDPH is in compliance with most local, state, and federal regulations; however, its monitoring capabilities are sometimes limited due to the lack of enforcement of disease reporting requirements.

The SKCDPH is governed by various regulations at the local, state, and federal levels, including the King County Code, the Code of the King County Board of Health (BOH), the Washington Administrative Code (WAC), and the Revised Code of Washington (RCW). The audit found that the SKCDPH generally adheres to all applicable regulations but was not fully compliant with the WAC requirement that requires local health departments to establish written policies and procedures for placing staff on leave if they contract an infectious disease. However, the SKCDPH has hired a health and safety coordinator who is in the process of drafting a policy to implement this requirement.

The audit also found that the SKCDPH's disease surveillance efforts are sometimes limited because health care providers do not always fulfill their disease reporting responsibilities. This occurs primarily because there is no policy or procedure at the local or state level for enforcing the reporting requirements.

The audit recommended that the SKCDPH continue its efforts to educate the public about infectious diseases, explore alternative methods for informing health care providers of disease reporting requirements and improving disease identification and reporting rates, and develop a policy regarding placement of staff on leave if they contract an infectious disease.

Finding IV-A. Laboratory service fees did not reflect the actual costs of conducting tests as required by the Code of the King County Board of Health.

Although the SKCDPH performs many of its laboratory tests at no cost to the client, the Code of the King County BOH requires the SKCDPH to charge fees for certain testing services provided to private physicians, private physician clinics, group practices, private laboratories, and hospitals, and that these fees be based upon health department costs. For some tests, the BOH Code listed the actual fee to be charged; however, these fees were determined in 1983 and have not been updated since. In a sample of tests for which fees were charged, the audit found that fees did not reflect the actual cost of performing the tests, and that costs ranged from 53% to 634% more than the established fees. The primary reason for fees being too low was that they did not reflect the time required to perform each type of test. Adjusting fees to reflect actual costs, as required, is likely to reduce the amount of contributions from the county's current expense fund and City of Seattle's general fund.

Finding IV-B. The SKCDPH laboratory has never performed a cost analysis or developed a cost allocation model for the tests it performs.

The audit found that the SKCDPH laboratory has never performed a cost analysis of the tests it performs and has not developed a cost allocation model, although these are done routinely by other public health laboratories. The lack of these basic management systems prevented SKCDPH management from determining the cost of each test and setting fees accordingly, identifying anomalies in laboratory operations, and determining whether it was cost-effective to perform certain tests in-house. For example:

- Although SKCDPH submitted a request to increase laboratory fees in 1995 (which lapsed without approval), it did not perform an analysis to determine the appropriate amount for each fee. Consequently, the requested fee increases would not have covered the cost of performing each respective test.
- Because the SKCDPH did not monitor the factors associated with operating the laboratory, management had not identified that direct testing hours accounted for only 6.5 full-time equivalent (FTE) microbiologists although the laboratory had 7.5 FTE

microbiologists, or that direct testing time accounted for only 86% to 88% of available microbiologist staff time.

- A survey of several commercial laboratories in the Puget Sound region revealed that many of the low-volume tests currently performed by the SKCDPH laboratory could be performed at a much lower cost in a commercial laboratory because SKCDPH's costs were, on average, 122% more than the fees that a commercial laboratory would charge for the tests.

Finding IV-C. The SKCDPH has not been receptive to collaborating with the State Department of Health (DOH) laboratory, and has assumed the DOH laboratory's responsibility for confirmation testing without documented authority to do so.

The audit found that the state DOH laboratory is legally mandated, in accordance with WAC 246-100-231, to perform confirmation tests currently performed by the SKCDPH laboratory. The state DOH laboratory performs these tests for all counties in the state except King County. Although the SKCDPH laboratory is performing these tests, neither the state nor the SKCDPH has any documentation indicating that the SKCDPH has been provided the authority to perform the tests.

The audit found that the state DOH laboratory director has contacted three previous SKCDPH directors about collaborating on tests currently performed by both the DOH and SKCDPH laboratories, citing both specific areas for collaboration and numerous benefits that could be achieved as a result. Although the state laboratory director's recommendations included tests that the state laboratory is already mandated by the WAC to perform, SKCDPH has generally been nonresponsive to these requests.

Finding IV-D. Some tests that the SKCDPH laboratory currently conducts are better suited to being performed in another laboratory environment.

The majority of tests performed in the SKCDPH laboratory are clinical in nature (i.e., testing medical specimens); however, the laboratory also conducts water and meat fat tests, which are environmental tests. The audit found that the SKCDPH laboratory conducts water tests although King County has its own environmental laboratory in the Department of Natural Resources that is both certified and set up to perform the type of water testing conducted by the SKCDPH laboratory. The SKCDPH laboratory also performs meat fat tests, although there is no public health purpose for these tests. Because clinical and environmental laboratories are generally set up quite differently from each other, the water and meat fat tests are better suited to being performed in another laboratory environment.

Finding IV-E. Maintaining a separate laboratory in the SKCDPH may not be the most cost-effective way of serving the community's public health needs.

The audit found that the absence of adequate management systems and controls raises the question of whether it is prudent for SKCDPH to operate its own separate laboratory. Although SKCDPH management has determined that there is a public health purpose for the clinical tests that its laboratory performs, it has never looked at the laboratory from a business perspective to determine whether it is economically feasible to maintain the laboratory, whether it should perform certain tests that it currently performs, or the proximity of the Washington State DOH and Harborview Medical Center laboratories to the SKCDPH laboratory and the overlap of service capabilities among these and other nearby laboratories.

The audit also found that using laboratory guidelines developed by the state DOH laboratory director to evaluate each test performed could assist SKCDPH in determining not only the public health rationale, but also the business rationale (i.e., economic feasibility) of continuing to perform each test.

The audit recommended that the Metropolitan King County Council:

- retain an independent laboratory consultant to evaluate the laboratory services performed by the SKCDPH and make recommendations regarding the continuation of

those services;

- make a decision, based on the consultant's recommendations, regarding the level of services to be provided by the SKCDPH laboratory;

If the Council decides to maintain the SKCDPH laboratory, SKCDPH management should pursue the following recommendations:

- develop management systems for setting laboratory fees and identifying and monitoring anomalies in laboratory performance;
- make a proactive effort to establish a collaborative relationship with the state DOH laboratory which should include determining which laboratory is best suited to performing certain tests;
- establish a laboratory fee structure that reflects the cost of performing each test, as required by the Code of the King County Board of Health;
- establish a budget format that facilitates tracking of laboratory costs; and
- coordinate its influenza surveillance efforts with the state DOH to eliminate duplication.

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