Title
PRESERVING LOCAL PUBLIC HEALTH LABORATORIES IN CALIFORNIA BY SPECIALIZATION IN LOW-TO-MODERATE VOLUME TESTS

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PRESERVING LOCAL PUBLIC HEALTH LABORATORIES IN CALIFORNIA BY SPECIALIZATION IN LOW-TO-MODERATE VOLUME TESTS

By

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Committee in charge:

Professor Gertrude C. Buehring, Chair

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Abstract

Preserving Local Public Health Laboratories in California by

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Public health laboratories are the first line of defense in the fight against communicable diseases and bioterrorism. The local public health laboratories in particular serve important functions including the identification and monitoring of pathogens in the community. They have the ability to respond to individual challenges within their jurisdictions with creative and innovative solutions. Unfortunately, instead of investing in and expanding the functions of their public health laboratory, many jurisdictions are forced by budget cuts, workforce shortages, and competition with private/commercial laboratories, to consider downsizing or closure of these essential facilities.[2-4] California has been especially targeted by reorganization approaches, including regionalization, consolidation and privatization, because it has a unique, decentralized system consisting of one state- and 35 local laboratories, many more than other states.[5] Reorganization, however, might be applicable only in a few isolated settings and faces opposition from many lab directors and health officers.[2] It would result in further public health laboratory closures to the detriment of the overall mission of public health.

It would be imperative to strengthen the local public health laboratories, improve their cost-effectiveness and maintain their quality service. This could be achieved through specimen volume increases in certain testing areas. Economies of scale would arise due to costs being distributed over more samples, and quality might be improved. One strategy to achieve volume increases is specialization, or the sharing of testing services amongst several neighboring public health laboratories. If focused on the particularly cost-inefficient low-to-moderate volume tests, specialization might be able to achieve the greatest benefits. It was the goal of this research to identify the current level of support for and the prevalence of specialization in low-to-moderate volume tests in the local jurisdictions of California and to examine how feasible wider implementation would be. Additionally, a Cost-Effectiveness Evaluation Model was developed to evaluate past or future service changes, such as volume increases or service sharing, based on their effect on the cost, revenue and quality of testing. Overall, this alternative strategy to strengthen the public health laboratories was examined so that public health policy makers, administration, and lab directors can make a more informed decision about the future of their public health laboratory.

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1. DEDICATION

This dissertation is dedicated to my first-borne son, Sidney Theodor Calzada, who had to share his mommy with school, the laboratories and the computer on so many occasions.

2. ACKNOWLEGEMENTS

First of all, I would like to thank my dissertation committee, Dr Gertrude Buehring, Dr. Bill Satariano and Dr. Michael Katz, for guiding and supporting me through the processes of finding my project, conducting the research and writing my dissertation. You have made these steps much more manageable and straight forward with your advice and have led me down to the graduation stage. Trudy, you have been with me since the beginning. Without you I would have never had the courage to take this path to one day become a public health laboratory director. Without the LabAspire Training Grant that you enrolled me in, I would not have been able to get my Masters, nor my Doctor in Public Health. You have rekindled my passion for working in a laboratory and helped me combine it with my love for infectious diseases and public health. Bill, I enjoyed your Survey Methods class so very much, that I just absolutely had to rework my research so that I could use this awesome methodology and practice what I've learned from you. Your guidance has helped me write the best survey possible and get such an amazing response rate. Michael, thank you very much for your insight and one-on-one coaching lessons to help me somewhat understand the complicated world of cost-analyses. I know I couldn't have been an easy subject and I really appreciate that you were willing to help me and be on my committee even though I had not previously taken your class.

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3. ABBREVIATIONS

AFB	Acid Fast Bacilli
APHL	Association of Public Health Laboratories
CDC	Center for Disease Control and Prevention
CEEM	Cost-Effectiveness Evaluation Model
CPS	Cost-Per Sample
CT/NG	Chlamydia trachomatis/Neisseria gonorrhoeae
EPA	Environmental Protection Agency
FDA	Food and Drug Administration
FERN	Food and Environment Reporting Network
HIV VL	Human Immunodeficiency Virus Viral Load
JPA	Joint Powers Agreement
LIMS	Laboratory Information Management System
LMVT	Low-to-Moderate Volume Test
LRN	Laboratory Response Network
Max.	Maximum
MHA-TP	Microhemagglutination Assay for Treponema Pallidum
MRSA	Methicillin Resistant Staphylococcus Aureus
PCR	Polymerase Chain Reaction
PH	Public Health
PHL	Public Health Laboratory
PHLD	Public Health Laboratory Director
PHLS	Public Health Laboratory System
PHM	Public Health Microbiologist
QTB	Quantiferon Testing for Tuberculosis
RD	Reagent Discount
RLN	Respiratory Laboratory Network
RPS	Revenue Per Sample
RSV	Respiratory Syncytial Virus
RT-PCR	Reverse Transcription Polymerase Chain Reaction
TAT	Turn-Around-Time
VI	Volume Increase
Vol	Volume

4. BACKGROUND

a. California's public health laboratory system

Public health laboratories (PHLs) were first established in the 1890s in the United States to act as "a first line of defense to protect the public against diseases and other health hazards."[2] The Social Security Act of 1935 and the Public Health Assistance Act of 1944 both provided a variety of incentives to increase laboratory capacity and allow the field of public health (PH) to thrive.[2] However, after the bioterrorism attacks in 2001 it became evident that PHLs in the USA were still underprepared for such events.[6] For this reason, additional resources were made available to improve preparedness of PH branches across the entire country.[6] California's public health laboratory system was already exemplary at the time, being called the 'CDC of the West', and served as a model to other states.[2] However, weakening of the economy over the last decade, in combination with recent administrative opposition, has caused a near reversal of recent improvements in California's PH services. The current PHL system of California consists of 35 local (county or city) and one state PHL. It is a decentralized system with an unusually large amount of local laboratories. Texas, for example, is about 100,000 square miles larger than California, with a comparable population size, but has less than half has many PHLs. The cities or counties that have a population of greater than 50,000 people are actually mandated by the California Health and Safety Code to "have available the services of a public health laboratory." The local laboratories operate fairly independently from the state, as the majority of their funding comes from within their jurisdiction.

Different types of PHLs, including federal, state and local entities, play different roles in protecting society's health. Federal laboratories such as the Centers for Disease Control and Prevention (CDC), the Environmental Protection Agency (EPA), and the Food and Drug Administration (FDA) oversee the national safety of the public.[2] They regulate food products, environmental conditions, and drug safety and make policies for testing and surveillance to ensure the public's health. Every state has at least one laboratory that is responsible for state-wide surveillance of infectious diseases, serves as a reference to confirm diagnoses made by other laboratories, and is responsible for the safety and testing compliance of any smaller laboratories.[2]

Many states also have several local laboratories which have a much tighter link to the communities they are serving. These local entities are responsible for specimen testing, food and environmental safety, and screening programs for communicable and chronic diseases present within their jurisdiction.[7] A laboratory test is defined as "any examination of material derived from the human body for the purpose of providing information for the diagnosis, prevention, or treatment of any disease or impairment, or for the assessment of the health of human beings".[8] Local PHLs perform such examinations in a variety of areas, including mycology, parasitology, serology, bacteriology, and virology.[9] Additionally, city or county PHLs provide confirmatory testing for local clinical and hospital laboratories, and have a critical role in training new staff.[10] They also assist the disease control officer of the local PH department with outbreak investigations, antimicrobial resistance monitoring, and disease surveillance. The counties and cities work closely with the State laboratory, located in Richmond, California, by forwarding samples and reporting disease occurrences. They can also be part of different laboratory networks, such as FERN (Food Emergency Response Network), LRN (Laboratory Response Network) and RLN (Respiratory Laboratory Network), which connect local laboratories across the nation.[2]

b. Private/clinical laboratories

PH- as well as clinical laboratories analyze specimens in a variety of testing areas. They generate reports that inform the individual patient's treatment and management decisions. However, PHLs go much further. Their ultimate goal is the preservation of the community's health.[11] They serve as collecting sites of specimens for state- and nationwide surveillance programs, monitor drug resistance patterns, and influence policy decisions concerning health. Additionally, PHLs provide confirmatory testing for local clinical and hospital laboratories and have a critical role in training new Public Health Microbiologists (PHMs) as well as some clinical laboratory scientists.[10] They also monitor environmental health standards in the community and assist the disease control officer of their jurisdiction with outbreak investigations. Tests, for pathogens such as rabies virus, are required to be performed by a PHL and many more have to be confirmed by one, e.g. tests for Salmonella infections, malaria, tuberculosis. PHLs also often serve a different population. They serve many indigent people that cannot afford to pay for the testing; thus they are often operating at a loss for the good of the public.

Clinical laboratories, which are private, for-profit institutions, have patient-, rather than community care, as their sole mission.[11] They receive patient samples and often run the same tests and have similar equipment as PHLs. Their reports to the physicians also aid in the decisions of treatment and patient management. But their function stops there. They do not actively perform disease surveillance, nor do they influence policy or community health.[12] As soon as the report goes out the door, they are done with the specimen and the patient.

Clinical laboratories are also regulated by a separate statute, the California Business and Professions Code, and their service is not required by law.[2] Even though clinical laboratories possess similar technology and run most of the same assays as public health departments, their focus is different and their testing is driven by profit and competition. Thus, any procedures run by them are, in theory, comparable to those performed in public health laboratories as far as implementation, validation and protocols go. However, when trying to assess the cost-effectiveness, one has to consider many other values that these tests bring to the field of public health. The value of information gained (about disease strains or antimicrobial resistance for example) can often outweigh the hefty price of new technology because it serves the goal of monitoring pathogen changes in the community. Even if a test is tremendously expensive and cost-inefficient, it may still be offered by a PHL if it serves to prevent morbidity and mortality in the community. Therefore, care must be taken when trying to compare the utility and value of new methods between the two entities.

Ideally, clinical and PHLs should be able to work together to maximize the well-being of their patients. Private laboratories should send any confirmatory or reference testing to the local PHL and always forward results on reportable diseases. The PHL, on the other hand, should monitor the quality of testing performed in clinical laboratories and offer consultations in their areas of expertise. However, in reality PHLs are now forced, by the new demands of having to be more cost-effective, to compete for the same market share as the private laboratories. They are losing increasing amounts of their profitable testing to commercial organizations, which can often offer better or cheaper courier services, more competitive prices and sometimes a broader test menu. Additionally, private laboratories are in a good position to secure contracts with large health plans and even the counties, increasing their market share even more. It remains to be seen how the relationship between private and public laboratories will develop as the Affordable Care Act is further implemented.

c. Current challenges to the public health laboratory

It has been predicted that "the scope of responsibilities of local PHLs will only grow in the future in quantity and complexity of testing."[10] However, the existence of many local laboratories is in jeopardy. In California it has been suggested that a few, large, regional laboratories would be sufficient to carry out the PH mission, similar to other states of comparable size or population.[2] The PHLs in California face several challenges, including budget cuts, administrative opposition and workforce shortages.

i. Budget cuts.

California's entire PH system has been forced to compensate for significant budget cuts. One county, for example, had to face a 30% reduction in net county costs over the previous two years, and was subsequently anticipating another 20% cut for 2011.[2] Even more recently (May of 2013), Governor Brown announced a gradual incremental withdrawal of annual funds awarded to counties since 1991 for the realignment of health and human services. These funds are typically used for the care of indigent populations and general public health services.[13] The withdrawal was justified on the assumption that counties will save money once the new healthcare reform is in place, because they will have fewer residents without healthcare.[13] These general cuts in county budgets are often redistributed equally to all departments, so that everyone shares a little bit of the burden.[2] This distribution of budget cuts may have drastic consequences for many of the local PHLs. They have implemented hiring freezes and are searching for further strategies for economic survival. Without adequate funds the PHLs have difficulty performing their duties and safety requirements and cannot invest in new technologies and better testing equipment.[3]

ii. Administrative opposition

The board of supervisors and the PH officer of each county are responsible for allocating funds for the support of various PH programs. They critically evaluate the efficiency of their local laboratory to determine whether or not their community absolutely needs those services. Often, they come to the conclusion that the PHLs operate inefficiently, not only because many tests of PH importance are offered to individuals without healthcare at no cost, but also because tests are being run in areas for which only a few samples are being submitted each month, which can be very costly to maintain (see below).[2]

"Unfortunately, the value of public activity is difficult to measure precisely because some public goods provide value even to people who do not pay for them."[7] Thus, some administrators have come to the conclusion that the PHLs operate inefficiently and are a drain on the county or city. Unfortunately, these officials often also do not understand the function and importance of their laboratory and "appear to regard [it] as a commodity that can be sacrificed."[14] The option of outsourcing their city's or county's samples to private laboratories that offer competitive prices and courier services suddenly becomes appealing.[2] Having several PHLs in close proximity that offer similar testing panels, also raises the question of whether or not each county really needs its own laboratory. Without the support of their administrative superiors, many PHL directors (PHLD) fail to secure a constant flow of specimens from county health clinics and do not have the support to ascertain new sources for testing that might generate additional revenue. In Santa Clara County, for example, the administration decided upon the closure and downsizing of many county clinics and the workload of the lab was drastically reduced.[2]

iii. Workforce shortage

In addition to administrative opposition PHLs are facing a workforce shortage that is due to aging personnel, the lack of new professionals, hiring freezes and loss of staff to private, higher paying, organizations such as Kaiser.[4] There are not enough laboratory directors to manage all of the 35 PHLs because of newly implemented strict licensing requirements, and because most of the qualified directors are close to retirement age.[2] Without a director who meets all the requirements (four years of PHL experience, board certified, a doctoral level degree, a PH microbiologist license) the laboratories cannot remain operational. Additionally, the median age of the laboratory workforce is 48 years and the profession is estimated to lose about 25% of its members over the next 10 years.[15] The hiring of new microbiologists is made difficult due to the "low visibility of the profession, meager salary increases, […] and lack of advancement."[15] The lack of licensed PHMs puts stress on existing employees, who have to pick up the slack and do more than their share of the workload. They have to work overtime, max out their accumulated leave time, and are required to constantly multitask. Constant overtime and stress not only affects the employees' personal lives, but can also negatively affect the quality of their work.[15,16] There is of course no time left to explore new testing areas or ways to increase efficiency. The phenomenon of 'disappearing vacancies', where positions are cut from the budget if they are vacant for too long, only exacerbates the problem.[15] The burden of the above three challenges could lead to vast downsizing and closures.

d. Previous reorganization approaches

Policy makers and PH literature have been considering three different solutions to the problems California's PHLs are facing: privatization, consolidation and regionalization.

i. Privatization

Privatization consists of cities or counties closing their PHLs and outsourcing all of their specimens to private organizations. They would have to pay for tests on a fee-for-service basis, but could save money by cutting the cost of maintaining a fully functional PHL. Even the partial outsourcing of samples may be beneficial to PHLs. They could discontinue tests that are not in high demand and send the few rare specimens that they get to a private laboratory. That would allow them to concentrate on their core functions and eliminate peripheral testing, as has been suggested by Avery.[12] The option of privatization might introduce a healthy amount of competition to the PHLS that would force them to evaluate their efficiency. It has been suggested that privatization could offer "public health agencies the tools and opportunities to identify their strengths and weaknesses, manage their resources in an optimum manner and improve the provision of services."[12]

ii. Consolidation

Consolidation would entail the closure of one or more PHLs in a certain area and the merger with another city's or county's laboratory. They would share equal responsibilities through a joint powers agreement, which is a contract of legal and fiscal responsibility holding both jurisdictions accountable for the provision of funds and the collection and shipment of specimens to the central laboratory.[2] Through this type of contract the cities or counties would be equal partners. For example, Napa and Solano Counties developed such an agreement.[2] Napa was able to reduce their spending by closing their laboratory, and Solano received more funding for testing from Napa.[2] To function together, both counties had to shuffle excess equipment, dismiss Napa PHL personnel and create a courier service to ensure timely delivery of specimens. Due to the increased sample volume the lab was able to run assays more often, expand their testing panels, reduce costs by purchasing equipment and reagents in bulk, and decrease their

turn-around-time (TAT), the time it takes from the receipt of the sample until the result is reported.[2] The Napa-Solano merger was successful because both counties are in close proximity to each other, had a prior working relationship, a sense of joint dependence, and shared similar goals and values. They also serve similar populations and thus address almost identical health problems.[7] Consolidation applied in multiple areas in California may solve the problems of laboratory staff and director shortages and improve the overall efficiency of the PHLS by decreasing each county's funding requirements and creating a greater sample volume for the centralized laboratory.[17]

iii. Regionalization

Another similar approach is regionalization; in which several large, regional laboratories "provide testing services on a contractual fee-for-service basis for multiple counties that have decided to close their PHLs."[2] In this case, participating cities or counties would not have equal financial or legal responsibility for the central lab. They would only pay the price of each tested specimen, set by the regional PHL. Regionalization of laboratory facilities is becoming a very popular trend in other medical settings. Since 1985, over 7,000 independent clinical laboratories have been reduced to 4,500 larger clinical institutions in 1997.[18] It has also been predicted that cost pressures, changing practice patterns and regulatory burdens will result in increasing regionalization of hospital laboratories.[19] Because of this, policy makers are tempted to consider regionalization on a statewide level for the PH setting in California. Regionalization could reduce financial burdens on the jurisdictions involved, solve the workforce shortage and increase sample volume, which would result in better quality due to the personnel getting more experience.

e. The importance of local public health laboratories

Local PHLs work closely together with the disease control officers, PH inspectors and medical professionals of their jurisdiction to identify and solve the specific health problems in their community. In fact, "70% of local PH agencies provide programs and services that require both environmental and human specimen testing."[10] The strong ties between the local laboratory and the other PH departments enable fast and accurate patient care and the rapid identification of outbreaks. Local PHLs support the agenda of their county's health department and generate data to facilitate administrators' evaluations of and decisions about current and future PH programs. However, the local PH department's mission can vary greatly from those of surrounding counties. California is the third largest (158,608 square miles) state and has the most residents (35 million people).[20] It has a vast variety of geographic regions, demographics and climates that cause different disease patterns (e.g. valley fever in the San Joaquin Valley) and testing needs; thus several large regional laboratories, as suggested in the regionalization or consolidation approaches, may not be able to serve all communities equally well.

Local PHLs also serve as collection sites of specimens for state- and nationwide surveillance programs and they provide surge capacity for the state in the case of an emergency, outbreak or bioterrorism attack.[21] Without an adequate number of local laboratories, the state would become vulnerable and the public's safety would be at risk. Texas, for example, could not handle all the novel H1N1 specimens they received in 2010 and had to send some of their samples to Tennessee and Virginia.[22] Texas had to wait much longer for results while the burden on the PHLs of the other states was greatly increased.[22] It is therefore imperative to preserve as many local laboratories in California as possible, so that a situation similar to the one in Texas can be averted and the state can prepare itself to help others during the next epidemic or outbreak. And although many local laboratories currently have vacancies they are unable to fill,

the solution of regionalization or consolidation to address this workforce shortage would extend well beyond eliminating these positions and would cause many more people to lose their jobs.

Most PHLDs and many health officers recognize the important functions of their local institutes and do not support the regionalization, consolidation or privatization options.[2] They are concerned about unresolved issues such as loss of laboratory contact for local clinicians or increased shipping distances, which might result in specimen degradation or longer TAT.[2] These experts are afraid that a large regional lab is too impersonal and does not "adequately represent the needs, concerns and health priorities of all parties."[2] Such a lab might even prioritize samples coming from their own county.[2] Overall, the closure of local PHLs would be an intolerable sacrifice because their important functions could not be replaced by fewer, larger laboratories. California's legislature actually voted unanimously in 2010 that the closure of any PHL would be a threat to national security.[23] Consolidation and regionalization would therefore be very undesirable options.

The third reorganization approach, privatization, is particularly objectionable since it is against the law. The cities or counties in California that have a population of greater than 50,000 people are mandated by the California Health and Safety Code to "have available the services of a public health laboratory."[8] It is debatable whether that requires them to have their own laboratory, or whether it is sufficient to just have access to a PHL in another jurisdiction. However, since the law demands 'public health' laboratory services, the option of outsourcing all samples to a private laboratory would not be possible in California. PHLs also support programs that inspect environmental issues, with food and water testing, or monitoring blood-lead levels. Those programs do not provide direct patient care, but enforce health standards in the community.[10] They are services private laboratories would never offer. Without a county or city PHL the clinical laboratories in the area would also lose their local reference laboratory, upon which they rely for confirmatory testing. Overall, "the state's responsibility for the health of its citizens cannot be delegated."[3] There would be no advocacy for the public's health since the clinical laboratories emphasize only the individual's care and do not concern themselves with disease surveillance, outbreak investigations, antimicrobial resistance monitoring, or environmental testing.

It is also problematic for the cities and counties to give up the expertise to run the tests in their own facility because they would become dependent on the clinical laboratories and would be at the mercy of their price policy.[21] The health department of Sacramento, which evaluated the possibility of laboratory closure and outsourcing samples to the private sector, actually found that it would be less expensive to keep the laboratory open and to run the tests themselves.[2] This is mainly because PHLs also serve the Medicare/Medicaid population and those that could not afford private laboratory testing.[21] Many tests are offered to these populations free of charge or at reduced rates and the local PHL is often able to absorb at least a portion of those costs. The private sector would, in turn charge full price for these services and the city or county would end up losing money.

For the same reason, it is unrealistic of some administrators to expect PHLs to generate revenue. It will always cost the government money to supply the communities with PHL services because their very nature is to offer tests to those who cannot afford to pay for them and to perform assays that are not profitable.[21] To ask a PHL to generate revenue would be like asking the National Guard, who also protects our home front, to make a profit. They do, however, produce valuable information about disease strains or antimicrobial resistance and protect the health of the population.[2] The cost of a PHL should not be the primary issue because

it is a public service. It would, however, be wise to conserve resources as much as possible out of respect for taxpayers' money. Thus, PHLs should streamline their processes, minimize waste, decrease costs, and increase the volume of any testing that does generate revenue, as long as these efforts do not hinder the true mission of the local PHLs.

f. Specialization

Competition with the private sector, as well as administrative opposition, have resulted in extreme decreases in testing volumes.[2] Low-volumes are problematic, not only because the laboratories' function as surveillance center is endangered, but also because cost, revenue, and quality of testing are negatively affected. When offering a low-to-moderate volume test (LMVT) the laboratory has to maintain equipment, trained staff, proficiency testing and reagent inventories whether they receive many samples for this test or not. If volume is low a greater proportion of these costs will be distributed to each sample. For example, one county had to drop their mycology testing because they received only about 20 specimens per year. Given the cost of the reagents, equipment and trained staff necessary to have on hand, the cost per sample was $500 (compared to a few dollars for higher volume tests). [2] Of course the revenue will also decrease if test volumes decline. Additionally, if a laboratory only receives a handful of samples per year, the staff might not have the required practice it takes to run and interpret the test without error. Thus, quality might decline along with sample volumes. Another aspect of quality is the internal TAT of the test, which is measured from receipt of the sample until results are reported. This time may decrease as fewer samples are received and the laboratory is forced to reduce its runs per week.

Until now only the three above described approaches have been considered as solutions for the situation in California. However, they only focus on the restructuring of the PHL system rather than the strengthening of the laboratories through increasing their volumes. The regionalization of LMVTs, here termed specialization, on the other hand, is one strategy to increase sample volumes, increase cost-effectiveness, improve quality of testing, and strengthen the laboratory network. It would entail the close collaboration of several laboratories in a certain area of the state. Each laboratory would specialize in a LMVT and would accept samples from all other laboratories in that region on a fee-for-service basis. The other laboratories could discontinue that test and could save money by not having to have the reagents, equipment or trained staff on hand, while being able to focus on offering core services to their community.

The benefits of higher volumes can be described as economies of scale. They arise "when an increase in outputs reduces average costs."[24] The average cost, or cost per unit of output produced, is calculated by adding the average variable cost to the average fixed cost.[25] When the number of outputs increases, as would be the case with an increasing number of samples tested, the average fixed costs decreases because they are distributed over more products. The average variable cost also declines, "caused by improved efficiency due to specialization and other reasons."[25] Thus, the overall cost decreases with increasing production until a point of saturation is reached at which variable costs plateau as efficiency gains and production capacity are maximized (Figure 1). At this point it may not be advantageous to further increase the output level, unless production capacity is expanded. As this research mainly considers

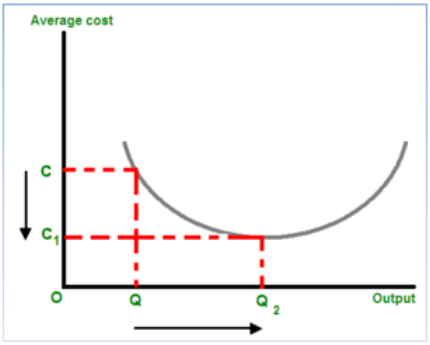

Figure 1: Scale economies: function of average cost over output quantity.[1]

LMVTs, it is unlikely this point will be reached.

The economies of scales, created through specialization, would significantly decrease the costs incurred by the specialized laboratory and would result in a lower fee charged to their partners. More money could be saved if those laboratories extended their relationship to a joint power purchasing agreement, through which they would buy reagents, office supplies, and other equipment together in bulk, for a cheaper price.[2] Additionally, the quality of testing could be improved because each laboratory could expand expertise in their chosen field. The internal TAT can potentially be decreased through the sharing of services, because the specialized laboratory would be able to run the test more frequently due to the higher volume. The local outsourcing laboratories would also remain the contact person for the community and people that order the tests. They would still provide the consulting services to the physicians and health inspectors to interpret the results, which are also important aspects of quality service.

Compared to other reorganization approaches, specialization minimizes the cities and counties' dependence on each other, since they retain their own laboratory. They remain autonomous entities which are only exchanging certain services. However, there will be increased collaboration and alliances between PHLs as the processes of sending, receiving, testing, and reporting have to be streamlined to accommodate the needs of both partners. Additionally, any service contract (i.e. memorandum of understanding) developed could be extended to other areas (i.e. joint power purchasing agreements). Survival prospects of the laboratories would be enhanced by improving their cost-effectiveness and expanding their expertise in their specialized testing area upon which surrounding cities and counties would come to rely. Finally, by maintaining all high capacity tests in their local laboratory, the jurisdictions retain the ability to respond to emergencies so that they can continue to provide surge capacity for the state.

Specialization has been criticized because smaller laboratories, those that are already at risk of being closed down (because they tend to get less funding, receive a fewer amount of samples and have difficulty attracting skilled personnel and directors), have limited personnel and automation and are less likely to be chosen to specialize in a LMVT. However, it is currently unclear who would determine which laboratories would run what tests. More than likely it would be a communal decision among all the laboratories in the network. And if a small laboratory argued strongly for their specialization in one assay, they could actually increase their survival chances because they would become experts in that field. Some people also worry that there may be a loss of expertise if something were to happen to the only laboratory that specialized in a certain test (during a natural disaster or due to laboratory closure).[2] But, if the microbiologist certification process remains the same, all professional laboratory workers would still have to be trained in all testing areas. Additionally, if there are multiple regions of laboratory collaboration, there will be multiple laboratories specializing in the same thing. They would just be spread out over the entire state and be part of different regions. Finally, it would be advisable for all laboratories to maintain all high capacity tests for which they receive many samples and for which they would have to provide surge capacity, so that they retain the ability to respond to emergencies.

The current literature supports the fact that specialization in LMVTs can improve cost-effectiveness and quality. In the 1980s -1990s it was shown by several experts to be effective in the clinical and hospital setting.[14,26,27] The reorganization of tasks of three hospital laboratories in Broome County NY, for example, has resulted in an 8.8% decrease of operational costs and an improvement in quality.[27] A redistribution of laboratory services in the Veterans Administration

Hospital in Columbus, MO resulted in reduction of duplicate efforts, an increase in the availability and quality of services, and an expansion of professional expertise.[26] More recently 'A Practical Guide To Assessing and Planning Implementation of PHL Service Changes' (by the Center for Disease Control [CDC] and the Association of Public Health Laboratories [APHL]) illustrated several examples of how the sharing of testing services can be utilized in PHLs across the nation.[26] It includes the redirection of Chlamydia and gonorrhea testing in the Michigan State laboratory, the multistate service sharing of the Northern Plains Consortium and the Northwest Regional Newborn Screening Program.[26] And although the regionalization of testing services has also been one of the main themes of the 'Laboratory Efficiency Initiative' (of the CDC and APHL),[28] it has not been widely applied to increase the efficiency of PHLs in California nor has it focused solely on LMVTs. The described specialization approach would not only strengthen the PHL network, it would also help preserve local PHLs.

5. RESEARCH QUESTIONS & SPECIFIC AIMS

It is the overall goal of this research to equip the laboratory directors of California with the knowledge and tools to make more informed decisions related to improving the efficiency and survival chances of their local PHLs. In the course of this study the laboratory directors were surveyed to identify cases of volume increases and specialization, to seek their opinion on the two approaches and identify promoting or hindering factors for their implementation. Particularly the external circumstances and the characteristics of tests best suited for volume increases or service sharing were identified. This research also focused on examining the impact of increasing sample volumes in certain testing areas by using a Cost-Effectiveness Evaluation Model (CEEM). The model, developed in the course of this study, incorporates measures of cost, revenue and quality of testing and was used to examine four cases of past volume increases as identified in the survey. The CEEM was also utilized to predict the impact of two future volume increases and to simulate several scenarios. Subsequently, one possible strategy to expand sample volumes was explored. In three case studies, specialization, or the sharing of LMVTs, and the collaboration between the local PHLs involved was assessed with the already developed CEEM. Again the effect of this service change on cost, revenue and quality of testing in both laboratories was examined and factors hindering or enhancing the collaboration were identified.

Until now, it was not known which laboratories could specialize in what fields and which LMVTs would be ideal for outsourcing. This information is imperative to be able to suggest how and where specialization could be implemented. This research attempted to provide this information, which can subsequently be used by the directors to strengthen the position of their laboratories. The specific aims were:

1. Assess the feasibility of implementing volume increases and specialization in low-to-moderate volume tests from the point of view of the public health laboratory directors.

a. Identify laboratories that have implemented, considered or turned down both approaches.
b. Determine which characteristics make a test a desirable candidate for volume increase or specialization.
c. Identify factors promoting or hindering the implementation of either strategy.

2. Evaluate the impact of specimen-volume increases on cost-effectiveness and quality of testing.

a. Develop a cost-effectiveness evaluation model to assess the impact of increasing specimen volumes.
b. Evaluate the impact of four existing volume expansions with the developed model.
c. Utilize the developed model to simulate two potential sample volume increases.
d. Further identify characteristics of tests that are best suited for a volume increase.

3. Assess the effects of specialization on cost-effectiveness and quality of testing.

a. Adjust the developed cost-effectiveness evaluation model for use in a multi-laboratory setting.
b. Evaluate three cases of existing service sharing programs with the adjusted model.
c. Further identify characteristics of tests that are best suited for specialization.

Given the challenges PHLs are facing today and the inefficiencies that exist throughout the entire system, reorganization of the PHL system in California seems inevitable. However, the three currently considered remedies have many flaws. Thus, it is imperative that any other alternatives be explored. Although the sharing of testing services has been receiving more attention nationwide, it has not been focused on the very inefficient LMVTs and has not been studied in California.

Many laboratory directors or policy makers may not be aware of the opportunities regionalization of LMVTs could offer. The data gathered with the proposed survey could suggest which tests would be suitable for specialization. And the factors that facilitate or prevent the execution of the approach will be discovered so that lessons can be learned and implementation be improved. The CEEM will show exactly how much money can be saved and which services improved in a specific situation. It can be used by the directors to simulate a service change or to evaluate an already existing one based on the changes in cost, revenue and quality of testing. This data would be invaluable for the decision making process of implementing or maintaining a service change. Overall, the information provided by this research will create new opportunities to strengthen the local PHLs in California.

6. CHAPTER 1: FEASIBILITY OF IMPLEMENTING THE SHARING OF SERVICES TO INCREASE COST-EFFECTIVENESS AND QUALITY OF TESTING: SURVEY RESPONSES OF PUBLIC HEALTH LABORATORY DIRECTORS OF CALIFORNIA

Abstract

Objectives

To become more cost-effective, many public health laboratories are looking for strategies to maintain costly low-volume tests of public health importance. The objective of this study was to survey the public health laboratory directors of California about the prevalence and implementation of volume increases and the sharing of testing services among local public health laboratories (termed specialization).

Methods

A mixed-methods survey was distributed via Qualtrics to all 35 public health laboratories of California. Respondents included laboratory directors, managers, assistant directors and microbiologists. Follow-up emails and phone calls were used to elicit a higher response rate. Descriptive statistics, lists of characteristics and qualitative quotes were used to analyze and display the data.

Results

The response rate was 88.6%. The main challenge reported was the loss of testing to commercial laboratories. To counteract this trend, most public health laboratories (23/35) made efforts to increase testing volumes, mainly by acquisition of new technology. However, only two laboratories used specialization to increase volumes. Of laboratories currently unable to specialize in a specific area, 95% would like to do so in the future. Tests ideal for the approach, barriers and promoting factors were identified.

Conclusions

The vast majority of respondents agreed that both, volume increases and specialization in low-volume tests, can improve cost-effectiveness and quality of testing. Overall, a concerted effort of local public health laboratories is necessary to eliminate barriers and improve cooperation, so that specialization will become a viable option to enhance the network and retain testing within the public health laboratory network.

Introduction

Public health laboratories (PHLs), the first line of defense in the fight against infectious diseases, face many challenges in today's economy. They encounter budget cuts, workforce shortages, administrative opposition, and competition from private laboratories.[29,30] Particularly in California, with its 35 local PHLs,[5] the prospect of regionalization, consolidation and the closure of some of these essential facilities is impending.[29] Although these strategies may be successful in a few isolated settings[29], most of the health officers and PHL directors in California value their local laboratory and want to protect it at all costs.[2] It is, therefore, imperative to explore new avenues to improve survival chances of the PHLs and to strengthen their network. The improvement of cost-effectiveness is one strategy for laboratories to cope with less funding and signal to policy makers their willingness to cooperate.

Many PHLs in California have lost significant amounts of their testing volumes due to the closure of county clinics, loss of funding and competition with private laboratories.[2,12] Low volumes of certain tests can reduce cost-effectiveness by spreading fixed costs (e.g. equipment maintenance contracts) across fewer patients, resulting in higher costs-per-sample. Quality of testing may also be negatively affected by decreasing volumes. PHLs should never be expected to generate a profit because they provide public services to the entire population that commercial laboratories do not offer, such as disease surveillance, assistance during outbreak investigations, or the provision of surge capacity. However, under the current administrative and budgetary pressures it would help their cause tremendously if they could increase their cost-effectiveness by reclaiming lost volumes, expanding their functions, and retaining current testing within the PHL system. Thus, collaboration among local PHLs becomes essential. One strategy to increase volumes and collaboration is the sharing of testing services among neighboring PHLs, termed specialization. Low-to-moderate volume tests (LMVT) might be ideal for this approach because they can be difficult and costly to maintain.[27] If each PHL in one region could find a niche, specialize in a test, and receive samples from other laboratories around them, economies of scale would arise, costs-per-specimen decrease, and quality improve due to expansion of expertise.

The effects, support, and barriers to regionalization and consolidation have been previously examined in California.[2] While regionalization of testing services has been the focus of some nationwide projects of the Center for Disease Control and Prevention and the Association of Public Health Laboratories;[28,31] this method has not been examined thoroughly in the unique PHL system of California for its prevalence and implementation. In the hopes that the situation in California can be used as an illustration of the described issues and how to counteract them, the 35 PHL directors were surveyed about: existing or planned instances of volume increases (VIs) and service sharing; tests and test characteristics that would make ideal candidates for these two strategies; and factors hindering or promoting their implementation.

Methods

The questionnaire (Appendix 1) was a mixed methods tool designed and administered via Qualtrics, LLC. It was pilot tested with three participants for inclusiveness and clarity of questions. Suggested changes and additions were applied where appropriate. The target population consisted of 35 PHLs in California. Directors leading multiple laboratories were asked to fill out a survey for each. Assistant directors, laboratory managers and supervising PH Microbiologists (PHMs) were allowed as proxies because many directors were already partially retired. The self-administered survey approach enabled participants to respond at a rate and time

convenient for them. The survey was distributed via email. Follow-up reminder-emails were sent biweekly to non-respondents. Four attendees of the semi-annual meeting of the California Association of Public Health Laboratory Directors filled out a hardcopy of the survey. Another director, head of two PHLs, was interviewed in person. Towards the end of the data collection phase, phone calls were made to remaining non-respondents. The total time of data collection spanned three months.

Three indicators for laboratory size (annual testing volume, population size and employee structure) were combined into a scale to stratify the population into small, medium and large laboratories to determine if the groups' answers varied significantly. Similarly, the data were stratified by the type of respondent (laboratory management and others). The majority of the collected quantitative data were analyzed via descriptive statistics to depict the current situation of the PHL system. Qualitative answers and comments were used as quotes to gain deeper understanding of the data. Some qualitative data were placed in categories, displayed in lists, graphs or charts, and analyzed for emerging trends.

Results

The response rate for the survey was 88.6% (31/35). Twenty-four respondents fell within the 'laboratory management' and seven in the 'others' category. PHLs were also divided into 7 small, 16 medium and 8 large facilities. No significant differences were found in answers among the stratified groups. Participants were asked about the severity with which their laboratory had been affected by four challenges (Figure 1). The majority (19) of the PHLs were not affected by administrative opposition. Budget cuts and workforce shortages represented significant challenges to most of the laboratories. Testing lost to non-PHLs was the worst challenge laboratories had to face (10 severely, 10 moderately, 7 mildly affected).

Volume increases:

Twenty-three of the laboratories increased their volume in at least one testing area over the last five years, with the same amount planning to do so in the future. The main method chosen was '*acquisition of a new technology*' (Table 1). Only two laboratories were able to increase volumes by '*sharing testing services with another PHL*' in the past and only one was planning to do so in the future. Tests affected by the VIs are listed in Table 2. Forty-eight percent of past and 51.6% of future VIs originated from both the public and private sector. Only 16% of prior and 9.7% of planned increases were received solely from the private sector.

When asked to rank desirable characteristics of tests considered for VIs (listed in Table 3), the vast majority of respondents indicated *'of public health importance*' as their top priority. Second was '*a high demand for the test*'. Factors ranked in the middle of the field were not well distinguished by their average score (Table 3). Most directors found it least important that '*the laboratory provides surge capacity,*' '*the test is automated*' or '*technically easy to perform*'. '*Having the capacity to expand*' was mentioned four more times in the optional volunteered comments, ranking it higher than the other characteristics in mid-field. The predominant factors said to enhance the ability of a PHL to increase its volume included administrative support (mentioned 7 times), an updated Laboratory Information Management System (LIMS) (6), sufficient workforce (4), good marketing (4), adequate funding (3), good logistics (3), sufficient capacity (2), and cooperation with local clinics and programs (2). The barriers mentioned mainly

reflected the lack of any of these factors; however the most frequently selected difficulty encountered was competition with private laboratories (10).

Specialization

Only 11 laboratories received samples in one or more testing areas on a routine basis from another local PHL. The ones that did specialize chose tuberculosis (8), HIV (4), rabies (2), Chlamydia/gonorrhea (2) and hepatitis testing (2). Some more specific, less commonly mentioned, tests were coccidioides, syphilis, bioterrorism agent rule out, norovirus, West Nile virus, influenza and mycology testing. All except one of the participants previously unable to specialize would like to do so if certain barriers didn't exist. About half of this group knew what area they wanted to focus on; mainly molecular methods (4), virology (4) and tuberculosis testing (3). More specific tests included mycology, dengue, tick-borne diseases, pertussis and environmental molecular methods.

Seventeen of 31 participants used the services of another PHL. Tests for which specimens are typically outsourced include general tests for HIV, hepatitis, tuberculosis and chlamydia/gonorrhea and some more specific areas such as Lyme disease, Coccidioides, and nitrate chemistry. Overall, 10 PHLs do not share testing services, 10 send but don't receive, 4 receive but don't send and 7 do both. The majority of specialized and outsourcing laboratories indicated that neither the cost nor the revenue of the test had changed significantly as a result of collaborating with the other PHL. Approximately 50% of specialized laboratories were unsure how the quality of the test was affected by sharing, whereas 45.8% of outsourcing PHLs believed it increased (Table 4). Twelve participants utilized services of commercial laboratories for areas such as coccidioides testing (3), hepatitis testing (3), general chemistries (3), blood lead levels (1), elemental analysis (1), environmental testing (1), drug susceptibilities (1), T-SPOT for tuberculosis (1), rubella (1), nucleic acid amplification tests for sexually transmitted diseases (1), complete blood count (1), and HIV viral loads (1). Thirty-one percent of this testing could have been sent to a PHL. And for another 36.8% of the testing participants were unsure if this possibility exists. Some reasons given in the optional comments for utilizing private laboratories were better courier services, and lower prices. Four PHLs perform some tests (parasitology, blood lead levels, West Nile virus, bacteriology and mycology) they would rather outsource, but are unable to due to billing issues and because the test represents a valued PH service. The main reason for wanting to outsource was '*low testing volume*'.

When asked to rank characteristics of tests ideal for outsourcing, participants listed '*having a low volume*' as the most important characteristic. '*Cost exceeding the revenue'* ranked second. The middle field was again hard to distinguish. Least important were '*technical difficulty,*' '*degree of manual labor,*' and '*providing surge capacity.*' Factors enhancing specialization included good courier service (6), good cooperation with the other PHL (5), a template for a sharing agreement (3), a standardized fee schedule (3), and the sharing of revenue (2). Logistic issues (10), billing problems (6), cost of testing (3), legal concerns (3), and lower prices of private laboratories (3) were the main barriers indicated. Finally, the survey participants' opinion was queried about the potential of VIs and specialization to improve cost-effectiveness and quality of testing. Thirty of 31 agreed that a VI in a previous LMVT can improve cost-effectiveness, whereas only 21/31 said the same about high volume tests. Twenty-five of 31 participants agreed that increasing LMVT can improve quality, while only 10/31 said the same about high volume tests. The vast majority of directors and managers agreed that

specialization in LMVT can improve cost-effectiveness (22/31), quality of testing (27/31) and strengthen the PHL network (27/31).

Discussion

Many PHLs have been struggling with workforce shortages and budget cuts, which seem unavoidable in today's economy. The widespread prevalence of these issues emphasizes the importance of the cost-effectiveness of PHLs. Testing lost to commercial laboratories, the predominant challenge, is primarily due to administrative policy changes not directly related to financial issues but driven by overall changes in health care. For example, it is one county's current policy, "to restrict clinical PHL services to tests not readily available in the community." The counties' and cities' increasing ties to larger health plans (e.g. Partnership) that require the sending of specimens to private laboratories were mentioned frequently. With the progression of the 'Affordable Care Act' this trend is likely to exacerbate.[32] PHLs will have to stand their ground more firmly in the future, emphasize and proclaim their functions and importance, and find ways to regain their market share to improve their survival chances. The trend to acquire new technologies signifies the laboratories' efforts to be on the cutting edge of their field. Budget cuts and clients' tendencies to hold onto older methods can be barriers to implementing new technology. However, most PHLs are overcoming those circumstances. For example, the increase in Quantiferon testing in 13 PHLs, was mainly due to a nationwide shortage of one reagent of the tuberculin skin test (the often preferred, older method), during which providers were advised to order the Quantiferon test.[33]

Factors enabling laboratories to increase volumes can be grouped into three categories. PHLs must have the means/capacity to expand (space, workforce, technology, funding, administrative support). Secondly, laboratory management has to choose which tests to focus on and evaluate competitors (price, services). Nineteen participants indicated the high value of a tool to assess VIs. Ideally laboratories should find a test addressing the needs of their population, which represents a niche no one else has filled yet. One local PHL, for example, performs "Vibrio parahaemolyticus [testing and has] contracts with private shellfish companies and the state." Finally, having the right tools can lead to improvement of services and higher volumes due to customer satisfaction (marketing, updated LIMS, good courier service). Marketing strategies include electronic and media presence, as well as relationships to clients, other PH programs and administration. Public awareness should emphasize the role and importance of the PHL, while testing quality and TAT should be stressed for clients. The increasing PHL focus on customer service is essential because commercial laboratories excel in this area. The VI barrier most frequently mentioned was the dominance of the private sector in many profitable testing areas. Administrations often dislike their PHL competing with the private sector,[12] but with the current budget restrictions and demands of being cost-effective, PHLs have no other choice. The private laboratories often offer more competitive prices, have a broad test menu, are locked into contracts with large health plans and have an overwhelming presence in the community.[12] It is difficult for PHLs to compete directly with such customer service. However, their value lies in the protection of the public through functions private laboratories do not offer. Thus, the tests' PH importance was valued above all other characteristics by most survey participants. Even a tremendously expensive test should always be offered if it is essential to reduce morbidity and mortality in the public.

Interestingly, there were several VIs in specialized, uncommon tests, possibly signaling a trend toward PHLs creating a niche for themselves. This effort, imperative to regain market shares, is currently aimed at drawing more testing volumes from their community. However, sharing services with other PHLs could accommodate jurisdictions that would like to outsource tests, but don't know where to obtain that service, or are hindered by logistic issues. Additionally, utilization of commercial laboratories, often caused by a lack of information about PHL's testing menus, could be eliminated by creating a comprehensive listing of all services provided by each PHL.

Sharing testing services between local PHLs may be a valid strategy to increase testing volumes, improve cost-effectiveness and quality. Twenty-one participants were already cooperating with other PHLs in some way. However, many stated that the cost of the shared tests did not change. This may be due to very low outsourcing volumes not having a big impact on the specialized PHL's cost, or the lack of ways to measure the effect. Surprisingly, many felt that revenues also remained unchanged, even though PHLs usually reimburse fully for obtained services (other clients often only pay a partial amount). The uncertainty about the effect of specialization on the quality of the testing is likely caused by the difficulty to quantitatively measure this concept and indicates a need for further research. The stated importance of 'low-volume' when considering outsourcing a test indicates that the participants find it more feasible to transfer this type of test and that it might be more costly to maintain.

Factors contributing to a successful partnership between PHLs can again be grouped into three categories. Firstly, a template for a formal memorandum of understanding or other legal agreement (e.g. liability insurance) was highly desired. Secondly, the knowledge of the other laboratories' testing menu and the establishment of a mutually agreeable fee and revenue-sharing plan can contribute significantly to a successful cooperation. One outsourcing laboratory, for example, charged their clients a shipping and handling fee in addition to the testing fee paid to their specialized partner. Finally, the tools for a successful partnership include a good courier service, a compatible LIMS for ease of billing and reporting, and expertise and capacity to expand volumes in the outsourcing laboratory. Overall, a coordinated effort and a good relationship amongst PHLs in one region are imperative to resolve arising problems quickly and avoid duplication of services. Although some also worry about the maintenance of surge capacity and the discontinuation of the test at the other laboratory, these problems can be avoided by the proper agreements.

Conclusion

Based on the high response rate, one can be confident that the situation in California and the opinions of the PHL directors were accurately captured by this survey. There was an almost universal consensus amongst participants that volume increases in some testing areas would be desirable and necessary to regain market shares and improve cost-ineffectiveness of low-to-moderate volume tests (LMVTs). Most PHLs made an effort to increase their volume from both private and public sectors based on the test's PH importance and existing demand. The main barriers encountered were competition with private laboratories, funding and workforce shortages. The vast majority of participants believed volume increases in LMVTs can improve cost-effectiveness and quality of testing, more so than increases in high-volume tests. This is likely due to a sample volume threshold, at which no more quality improvements can be

expected and fixed costs are already spread thinly across specimens. Thus, the focus on the LMVTs with strategies to increase volumes seems warranted.

There was also an overwhelming amount of support for specialization as one strategy to increase testing volume in the participating PHLs. Even among survey participants unable to specialize, 95% would like to do so if certain barriers didn't exist. This makes it imperative for the PHL system as a whole to address these barriers and eliminate them. The survey identified a pool of tests, currently sent to private laboratories or performed in house, that would be good candidates to share with other PHLs. Overall, the main characteristics that triggered a test to be considered for outsourcing were low-volume and high-cost. The vast majority of participants agreed that specialization in LMVTs has a good potential to reduce costs, improve quality and increase competitiveness with private laboratories, while strengthening the PHL network.

Graphs and Tables

Figure 2 Percentages of 31 public health laboratories in California that have been moderately to severely affected by the following challenges.

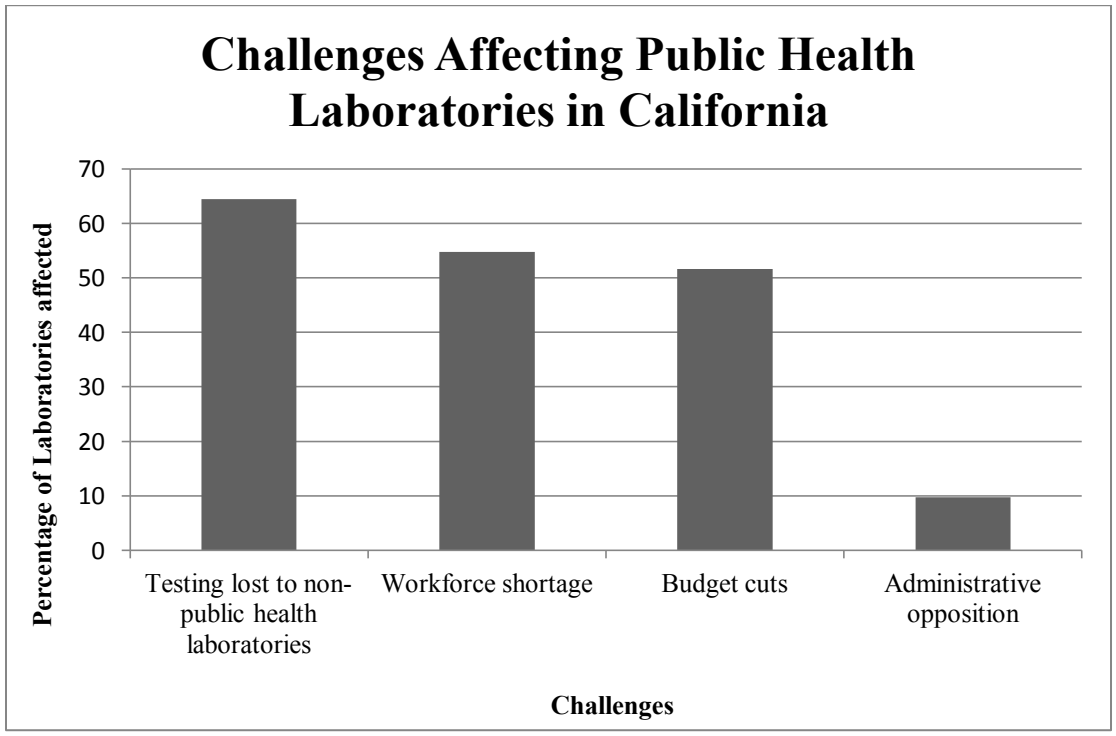

Table 1 The number of times each strategy used for past and future volume increases was mentioned by participants.

Strategy	Number of PHLs that have used the strategy in the past (n=26)	Number of PHLs planning to use the strategy in the future (n=31)
Acquisition of a new technology	12 (46.2%)	15 (48.4%)
Implementation of a new LIMS	2 (7.7%)	8 (25.8%)
Restructuring of health services	2 (7.7%)	1 (3.2%)
Collaboration/sharing of testing services with another PHL	2 (7.7%)	1 (3.2%)
Research project	1 (3.8%)	1 (3.2%)
Collaboration with hospitals or other public health departments	1 (3.8%)	3 (9.7%)
Cooperation with clinical laboratories	1 (3.8%)	0 (0%)
Marketing to current clients	0 (0%)	1 (3.2%)
Expansion of courier service	0 (0%)	1 (3.2%)
Others:	4 (15.4%) in Tuberculosis 1 (3.8%) in RT-PCR	0 (0%)

Abbreviations: LIMS = Laboratory information management system, PH = Public health, PHLs = Public health laboratories, RT-PCR = Reverse transcriptase polymerase chain reaction

Table 2 The number of times a test was mentioned as being part of a past or future volume increase.

Past volume increases		Future volume increases	
Type of test affected	Number (percentage) (n=38)	Type of test affected	Number (percentage) (n=32)
Quantiferon testing	13 (34.2%)	Tuberculosis testing	6 (18.8%)
Influenza PCR	3 (7.9%)	HIV testing	5 (15.6%)
Norovirus PCR	3 (7.9%)	Respiratory panel	4 (12.5%)
HIV viral load	3 (7.9%)	CT/NG	3 (9.4%)
HIV genotype	2 (5.3%)	Syphilis testing	2 (6.3%)
Pertussis testing	2 (5.3%)	Hepatitis testing	2 (6.3%)
Others: RSV, shiga toxin, CT/NG, mycology, MHA-TP, environmental bacteroides, shellfish Vibrio, Coccidioides, water testing, RT-PCR, molecular diagnostics	1 (2.6%) each	Others: Shiga toxin, Trichomonas, blood lead levels, pertussis, water testing, MRSA, group-B-Streptococcal testing, Clostridium difficile, environmental testing, gastro-intestinal screen	1 (3.1%) each

Abbreviations: CT/NG = Chlamydia trachomatis/Neisseria gonorrhoeae, MHA-TP = Microhemagglutination assay for Treponema pallidum, MRSA = Methicillin resistant Staphylococcus aureus, PCR = Polymerase chain reaction, RSV = Respiratory syncytial virus, RT-PCR = Reverse transcriptase - polymerase chain reaction

Table 3 Queried characteristics of a laboratory test that determine its suitability for volume increase and specialization. Average score is based on a ranking from 1-12, with 1 being the most important. (For volunteered comments at the bottom of the table, the number in parentheses signifies the number of times each characteristic was mentioned by survey participants.)

Important characteristics that make it desirable to increase the volume of a test		**Important test characteristics that make outsourcing a test desirable**	
Characteristic	**Average score**	**Characteristic**	**Average score**
The test is of public health importance.	2.839	The testing volume is low.	3.387
There is a high demand for the test.	4.419	The cost of the test exceeds the revenue gained.	4.613
The necessary expertise exists in the laboratory.	5.484	The necessary expertise exists in the other laboratory	5.258
The cost of the test does not exceed the revenue.	5.581	The health officer supports the decision.	5.871
The capacity and capability to increase volume already exist in the laboratory.	5.774	The test is not a public health priority in the region.	5.903
The health officer supports the decision.	6.290	The required turn-around time would be achievable even with the added transport to the other laboratory.	5.935
The required turn-around-time is easily met.	6.387	The decision is supported by your administration.	6.452
Other laboratories (public or private) in the area do not offer the test.	6.581	The capacity and capability exists in the other laboratory to increase its volume.	6.935
The decision is supported by administration.	6.839	Many local laboratories (private or public) offer the test in and around the jurisdiction.	7.677
The laboratory provides surge capacity for this test to the state.	9.194	The test is technically challenging.	8.323
The test is largely automated.	9.226	The test mainly consists of manual labor.	8.806
The test is technically easy to perform.	9.387	Your laboratory does not provide surge capacity to the state for this test.	8.839
Volunteered comments: Capacity (4), the test has to be offered in a way to compete with commercial laboratories (3), demand (2), the tests represents a niche the laboratory can fill (2), grant funding is available for research with the test (2), electronic submission of result is possible with the new client (1)		Volunteered comments: cost of outsourcing (4), logistic issues (4), billing problems (2), retaining expertise (2), surge capacity (1), legal considerations (1), more staff time for other tests (1), revenue loss (1), demand of testing (1)	

Table 4 Number of participants judging the effect of specialization on the cost, revenue and quality of testing.

		Increased/ improved	Did not change	Decreased/ declined	Not sure
Specialized laboratory	How did cost change? (n=26)	2 (7.7%)	16 (61.5%)	5 (19.2%)	3 (11.5%)
	How did revenue change? (n=17)	6 (35.3%)	9 (52.9%)	0 (0%)	2 (11.8%)
	How did quality change? (n=12)	0 (0%)	6 (50.0%)	0 (0%)	6 (50.0%)
Outsourcing laboratory	How did cost change? (n=31)	1 (3.2%)	22 (71%)	5 (16.1%)	3 (9.7%)
	How did revenue change? (n=25)	1 (4.0%)	18 (72.0%)	6 (24.0%)	0 (0%)
	How did quality change? (n=25)	11 (45.8%)	11 (45.8%)	0 (0%)	2 (8.3%)

Table 5 Participants' beliefs about the impact of volume increases in low-to-moderate- and high volume tests and participants' opinion on the effect of specialization on cost-effectiveness, quality of testing and the public health laboratory network (n=31).

		Agree	Neither	Disagree
Volume increase can improve cost-effectiveness of laboratories.	Low-Moderate volume tests	30 (96.8%)	1 (3.2%)	0 (0.0%)
	High volume tests	21 (67.7%)	8 (25.8%)	2 (6.5%)
Volume increase can improve quality of testing.	Low-Moderate volume tests	25 (80.6%)	6 (19.4%)	0 (0.0%)
	High volume tests	10 (32.3%)	15 (48.4%)	6 (19.4%)
Specialization in low-to-moderate-volume tests can improve:	Cost effectiveness	22 (71.0%)	7 (22.6%)	2 (6.5%)
	Quality	27 (87.1%)	3 (9.7%)	1 (3.2%)
	Network strength	27 (87.1%)	3 (9.7%)	1 (3.2%)

7. CHAPTER 2: EVALUATING THE IMPACT OF SAMPLE-VOLUME INCREASES ON COST-EFFECTIVENESS AND TESTING QUALITY IN PUBLIC HEALTH LABORATORIES

Abstract

Objectives:

Low-volume tests have been particularly difficult to maintain in public health laboratories because they incur very high costs per sample and sometimes lack quality due to the low frequency at which they are performed. The objective of this research was to determine what impact an increase in volume would have on the cost, revenue and quality of different public health laboratory tests.

Methods:

A model was developed to quantify cost-effectiveness and quality of testing. It can be used to evaluate past volume increases as well as simulate future ones. The model was applied to four examples of past volume increases, and two hypothetical scenarios of future applications.

Results:

All cases of volume increases produced cost-savings ranging from 0.33 to 31.6%. Reagent discounts, negotiable due to higher volumes, added significantly to the cost-savings. The quality of testing remained the same (proficiency testing results) or improved significantly (decreased turn-around times). The two simulated case studies predicted how the costs and revenues might change with various changes in testing volume.

Conclusions:

In addition to the cost-savings experienced in all case studies, it was particularly profitable if the newly acquired testing volume was received from clients reimbursing fully for the test. Even if a higher profit was not achieved, the public health laboratories' losses were reduced, which significantly improved overall cost-effectiveness.

Introduction

Cost-effectiveness is important for any business in today's economy. Public Health Laboratories (PHLs) will always be cost- rather than revenue-centers, because they were designed to perform immensely important functions to serve their communities (e.g. infectious disease surveillance, emergency preparedness, etc.). Despite their importance, their budgets have become more and more restricted.[2] Particularly California's budget crisis has had a tremendous effect on its 35 PHLs.[2] There have been laboratory closures, workforce shortages, and testing lost to the private sector.[29] The latter factor has been shown to be the most severe problem in the Californian laboratories.[34]

Lower volumes can result in decreased income in testing areas that normally generate revenue.[29] Additionally, private laboratories are gaining more of this market.[18,29] Low volumes also result in increased costs per sample (CPS) because fixed costs are distributed over fewer patients.[35] Trained staff, specific equipment, proficiency testing, and reagents have to be maintained no matter how many samples are received. For extremely low-volume tests, the reagents often expire before a sample is received, increasing the amount of wasted material. Additionally, the quality of the test may decline as volumes drop. For infrequently performed assays, the turn-around time (TAT), from sample receipt to result reporting, is often increased. The staff doesn't get as much practice running the assays, which is particularly problematic for labor intensive, subjectively interpreted tests which require more practice than automated assays. The PHL directors of California ranked 'a low testing volume' as the most important characteristic when considering a test for outsourcing.[34] Increasing the volume in certain testing areas might be a desirable strategy to retain tests within the PHL system and improve their cost-effectiveness and quality of service.

A recent survey of the Californian PHLs showed that 73.1% increased their volume in at least one testing area over the last five years and were planning to achieve further increases in the future.[34] It is clearly a strategy the directors are aware of to improve services and revenues in their laboratory. They were also asked in the same study to rank the characteristics of tests that are ideal for a volume increase. The 'PH importance of the test' was mentioned most frequently.[34] This characteristic reflects the essential function of PHLs to serve and protect their specific community. However, the question remains what effect the increase in sample volume can have on the cost-effectiveness and quality of testing. In an effort to quantify this effect, a Cost-Effectiveness Evaluation Model (CEEM) was developed in the course of this study. The model was used: 1) to evaluate four cases of past volume increases, and 2) to predict the effect of a future increase on cost and revenue of two tests.

Methods

The CEEM was developed with the help of the Tulare County PHL by using elements of activity-based costing, which is a costing-methodology that assigns costs to each activity of a process based on their actual consumption of resources.[36] All factors of the laboratory testing process affected by a sample volume increase were identified by following a sample from its arrival in the Tulare County PHL until results were reported. Each step impacting costs, revenue or quality was included in the model and was recorded in an Excel Spreadsheet (Table 1). The model includes equations, created specifically for this research, that assist in the calculation of the overall costs and benefits (Table 1). The CEEM was not validated because no PHL had a

similar model in place. The comparison of the CEEM with laboratories' typical internal cost calculations produced conflicting results. This is probably not an indicator of the deficiency of either method but rather evidence of the different factors that were considered in each of them. Additionally, the internal cost estimates of the PHLs usually do not consider the revenue, or the quality of the test. However, the model was shown to and discussed with three laboratory directors/managers to verify the accuracy and inclusiveness of factors considered.

Although there are many aspects of quality, only the two most easily measured characteristics were chosen for the model, namely TAT and proficiency testing results (averaged for the year before and after the volume increase). For the latter, samples are sent to the PHL for testing by independent agencies that evaluate the laboratories' performance and score it on a scale of 0-100% accuracy for quality assurance purposes.[37] The model has options to add further test-specific quality measurements (e.g. environmental contamination). The costs included in the calculations cover reagents, proficiency testing, maintenance contracts, equipment, courier, and labor. An overhead measure, for general operational costs of the laboratory (e.g. electricity, rent, housekeeping, etc.), can be added, but was disregarded for this project because many PHLs were not able to easily calculate this number. The labor cost calculation is very complex and takes into consideration what percentage of the test would benefit from batching as in the case of volume increases. The revenue factors considered in the model include specific grants or other funding, liquidated equipment and revenue generated through testing fees. The latter can be entered either as the known annual revenue or the estimated annual income, which would be calculated from the fee charged per sample, the most frequent partial reimbursement rate, and the percentage of fully and partially reimbursed samples.

In the current study the CEEM was used to analyze four cases of past volume increases identified in a previous survey.[34] The cases included in this study were the only PHLs with volume increases able to participate. Unless otherwise noted, a short time study was conducted for each case to determine labor time of the procedure (separating time spent on the entire batch and each individual sample). The TATs of all samples for each year were averaged. The laboratory staff member dedicated to this project provided the remaining information for the year before and the year after the volume increase. Data were entered into the CEEM and results summarized in tabular form. The main outputs were the annual test-specific revenue, revenue per sample (RPS), annual test-specific cost, CPS, annual total net gain, and the net gain per sample. The quality measurements were also compared for both years. For two additional tests at the Tulare County PHL volume increases were simulated. Data were collected in a similar manner for the most recent full year of testing. Extrapolations were made in the CEEM. Most factors other than incremental increases in volume were held constant. Only the sample runs per week, reagent discounts and the reimbursement rates were varied in some of the scenarios chosen.

Case-studies of past volume increases

1. Volume increase in Quantiferon testing for tuberculosis (QTB) - Public Health Laboratory A

Background:

Laboratory A utilizes the Bio-Rad (Hercules, CA) Evolis system for their QTB screen. This fairly high volume, automated test can accommodate 52 samples per run (for more test

characteristics view Table 1). The laboratory had a volume increase from 4417 to 6065 (37.3%) from 2012 to 2013 and performed the test three times per week. For the labor cost, the assistant laboratory director estimated times PH microbiologists and laboratory assistants spent on the test. The revenue was $40 per sample and all tests were fully reimbursed. Over the period of one month, 669 samples were received by the PHL for a research project. They were included in sample counts, costs and revenue (also fully reimbursed) calculations, but were excluded from the TAT consideration, since such a large increase in one month would not be the norm.

Results

As detailed in Table 2, the RPS remained $40. the TAT increased slightly from 64.98 to 66.48 hours (Table 2), and the proficiency testing grade remained constant at 100%. The CPS decreased significantly from $25.86 to $22.20, resulting in a net gain-per-sample of $3.65 (25.8%). The overall annual profit gain was $45,450.95, an increase of 73% over the previous year's revenue of $62,445.62.

Discussion

This test is fairly automated, so that great labor and reagent cost decreases can be achieved by running larger batches. Any fixed costs such as proficiency testing fees, and maintenance contracts were also spread over more specimens. The extensive increase in annual profit is due to the cost savings per sample as well as the increased revenue from the extra specimens. The slight increase in TAT may not be significant, since the lab still performed three runs-per-week, and the maximum batch size was never reached. If sample volumes would increase to a level where the lab could justify adding another run per week, TAT would likely decrease.

2. Volume increase in Quantiferon testing for tuberculosis (QTB) - Public Health Laboratory B

Background:

During 2010-2011 PHL B had a significant volume increase in their QTB testing from 6110 to 7000 samples (14.5%). In 2013 the testing volume increased by another 1524 specimens (39.5% over 2010). The laboratory utilized the QuantiFERON-TB Gold essay (Cellestis Limited, Carnegie, Victoria, Australia) on the Dynex DS2 equipment (Dynex Technologies, Chantilly, VA), a highly automated, medium volume test (Table 1). It was performed three times per week in the first two years and five times in 2013. In the last year they also had a salary decrease of 2.8% and their fee increased from $86.58 to $150 per test. These two changes were taken out of the consideration because they are factors that do not vary based on volume and would distort the data. In the same year the PHL was able to negotiate a significant reagent discount, which was considered because it was likely due to their higher volume. PHL B is part of a Federally Qualified Health Center and does not receive reimbursements per patient. They receive an overall budget, a proportion of which was designated for this test (for this project calculated as testing volume over the total volume for all tests). The budget amount has not changed in many years and does not vary by volume. There are a few private patients for which the laboratory receives reimbursement, who were considered in this study.

Results:

The RPS decreased slightly over the three years from $32.61 to $28.49 (Table 3). However, the laboratory still registered an increase in annual income for this test (0.1% in 2011, 18.5% in 2013). The CPS decreased moderately in 2011 from $29.10 to $28.94 (0.6%) and quite drastically in 2013 to $20.38 (30.0% from 2010). If the discount in reagents is disregarded for 2013, the cost would still decrease significantly by $6.96 (23.9%). The annual total test-specific cost increased from 2010 to 2011, but decreased quite drastically in 2013. The net gain per sample, decreased significantly in 2011 from $3.51 to -$0.45 (by 112.8%), while in 2013 the numbers increased again to $7.31 (108.3% over 2010) (Table 3). The proficiency testing results remained the same throughout all three years and the TAT decreased from 2.91 days in 2010 to 2.64 days in 2011 (9.2%) and to 2.46 days in 2013(15.5%).

Discussion:

The RPS decreases over the three years were due to the fixed budget being distributed over a greater amount of samples. However, the very slight increase in annual revenue in 2011 was traced to the volume increase being mainly in non-reimbursed tests, while the number of private patients that paid the PHL directly for their services declined drastically (56.7%). This number increased again in 2013, well past the level of 2010 (29.0%). When comparing the last two scenarios of Table 2, it can be deduced that only a small amount of the cost decrease in 2013 can be attributed to the reagent discount ($1.76, or 20.2%), because when reagent discounts were excluded from the calculation, the cost still decreased by $6.96. Thus, 79.8% of the total cost decrease in 2013 was contributed by savings in labor costs and a better distribution of fixed costs. The reagent discount, however, is a very real benefit of higher volumes (because they are often based on testing volume) and should always be pursued. The CPS decrease in 2013 is even more impressive because the number of runs per week was increased, which usually causes a slight increase in labor costs. The annual profit (as well as profit per sample) decreased drastically in 2011 because the revenue did not increase enough to cover the costs associated with the testing of higher volumes. In 2013, however, the annual profit almost tripled the amount earned in 2010, showcasing the benefits of increased volumes in reimbursable tests, decreased reagent costs and economies of scale for fixed and labor costs. The decrease in TAT is encouraging to see and follows the logic that if the runs per week increase (as in 2013), the TAT should shorten.

3. Increase in Human Immunodeficiency Virus Viral Load testing volume - Public Health Laboratory B

Background:

PHL B registered a volume increase of 905 samples (58.6%) from 1544 to 2449, in their HIV viral load test from 2009-2011. Compared to the total annual testing volume of the laboratory this would be considered a lower volume test. The AmpliPrep system was utilized for this procedure along with the Cobas TaqMan (both by (by Roche Molecular Diagnostics, Pleasanton, CA) for amplification. It is a fairly automated procedure (Table 1), which was typically performed in the PHL two times per week (maximum sample size 42). The revenue was measured similarly to the previous case study.

Results:

Even though the proficiency testing grades remained constant at 100%, the quality of testing still improved significantly because the TAT was shortened by .74 days or 23.1% (Table 4). Annual as well as per-sample revenue increased significantly by $97,899.63 and $30.69 (252.4%, 122.2%) respectively. Thus, the net gain per sample and per year also increased over the two years. The CPS decreases by $0.35 (0.5%). This relatively modest amount is due to the labor costs (and associated savings due to batching) being only a small proportion of the overall cost.

Discussion:

This case study is a good example of a volume increase where most (78.0%) of the new tests are fully reimbursed. The increases in RPS and annual net gain are remarkable and are mainly due to the newly acquired testing source stemming from another local PHL that reimbursed fully for the test. The decreased CPS adds to this effect. However, because most costs originated from the reagents rather than the labor (where the benefit of higher volumes mainly take place due to batching), the decrease in costs is not as impressive. It could be expanded if the volume increased enough to negotiate reagent discounts. Even with only a 5% discount, the CPS would decrease by another $3.22 (4.5%). With a 10% decrease in reagent costs the CPS would decline by $6.45 (9.0%).

4. HIV Viral Load volume increase - Public Health Laboratory C

Background

PHL C performed the HIV viral load assay using the same equipment as PHL B. The fairly automated procedure (Table 1) was performed twice a week. The laboratory recorded a sample increase from 903 to 1503 samples (66.4%) during 2008-2009. In 2008 PHL C still performed the assay with an older method, using the COBAS Amplicor machine (Roche Molecular Diagnostics, Pleasanton, CA), which was more labor intensive with a lower reagent price. In order to separate the effect of the technology change from that of the volume increase three different scenarios were simulated. First, the actual situation of technology change and volume increase was considered. Secondly, the old methodology used both years, was compared to the new methodology used both years, in order to eliminate the effect of the technology change. For this case all other variables (such as proficiency testing, total annual sample volume, and runs per week) were held constant. Lastly, the same sample volume was used for both years (first the 2008 and then the 2009 volume) to eliminate the effect of the volume change.

All testing was directly reimbursed by the California HIV Voucher program at $100 per test. The reagent and labor CPS were derived from worksheets to determine test costs that were put together by laboratory staff in 2005 (for the old procedure) and 2013 (for the new method). For the TAT one of the microbiologists in the laboratory randomly pulled 40 patient records from each year, for which the internal as well as external (from blood draw until result reporting) TAT were averaged.

Results:

For all scenarios, the income changed proportionally to the volume, thus there was no revenue gain per sample. The proficiency testing grade remained constant at 100%, while the internal TAT increased from 4 to 5.72 days (by 31.75%) and the external TAT increased from 6.95 to 8.92 days (28.35%). For the first scenario (actual situation) the CPS increased by $1.37 (1.55%). However, the total annual revenue still increased by $5002.19 (47.1%) due to increased sample number. In the second scenario the CPS decreased by $0.30 due to volume increase alone (0.33% decrease). There was a significant increase in annual profit ($6510.2) if the new technology were used for both years and an even higher increase if the old technology were used ($7,512.20) because this technology had a lower cost. Lastly, for the third scenario the CPS would increase drastically with the new technology (by $13.13 or 16%). Due to this higher cost the annual profit would decrease by $11,856.39 (with 2008 volumes) and $19,734.39 (with 2009 volumes), although there would still be some positive annual gain since the revenue is higher than the cost.

Discussion:

Overall, the effect of the volume increase alone is a decrease in CPS. Only with a change to the more expensive technology is the cost decrease canceled by the cost increase of technology. The new technology is more expensive, but as long as an increase in sample volumes is guaranteed, PHL C can still increase its annual revenue (if new clients will pay for the test in full) and free up valuable microbiologist time for other tasks with the more automated, newer procedure. Because the benefit of batching was not determined through a time study that would separate time spent on individual samples versus the whole batch (due to lack of time of PHL's staff), increasing the volume cannot be shown to have a beneficial effect on the labor cost. Additionally the reagent cost was not available as the annual total cost but rather as the CPS. Therefore, savings due to the elimination of waste and higher sample numbers per batch could not be shown. The only benefit of volume increases that could be examined through this study was through distribution of other fixed costs over a higher number of samples. It is very likely that the true cost-savings are actually much higher than $0.30 per sample. The number of samples used to determine the overall TAT was fairly small, the result of the increasing TAT may, therefore, not be representative. Because the laboratory did not change the number of runs per week, it is likely that the TAT changed minimally, and that quality was probably maintained.

Case-studies of future volume increases

1. Simulated volume increase in Chlamydia trachomatis/Neisseria gonorrhoeae (CT/NG) testing - Public Health Laboratory D

Background:

PHL D was interested in analyzing the effects of a potential volume increase in their CT/NG test. Normally it is a high volume test, (5562 annual samples, 2781 for each disease, for the fiscal year 2012/13). The PHL utilized the Becton Dickinson (Franklin Lakes, NJ) Probe Tec system, which is an amplified DNA assay for the direct, qualitative detection of CT/NG via fluorescent labels. It can process 90 samples and 6 controls in one batch. Data required for this analysis were collected for fiscal year 2012/13. The averaged internal and external TAT,

proficiency testing results and environmental contamination results were collected for that year for future use, but were not included in the simulation because changes in these factors would be difficult to predict. The laboratory's Encounters and Charges Report was used to find the overall revenue for the fiscal year. For most of the scenarios the income was changed proportionally to the increase in volume (except for the scenarios where all new tests are reimbursed). The reagent costs were also increased proportionally to volume. However, it is likely that any newly added specimens would incur only a minimum of extra reagents until the maximum batch size is reached. Thus, costs determined in this simulation are an over-estimation of what would be incurred.

For simulating the different scenarios, the volume was changed (doubled, increased by 50%, or to maximize batches of the 2.98 runs per week). For the scenarios where the number of samples per run would have exceeded the maximum batch size, the number of runs per week was adjusted to the minimum number of runs to accommodate all samples.

Results:

The current RPS is $13.89, the CPS $8.95, yielding a net gain per sample of $4.93. As runs per week were decreased to 2.4, the lowest possible number that can accommodate the current sample volume (maximizing the batch size) the CPS was decreased by $0.15 (1.68%) and the net gain per sample and year increased ($0.15 and $837.05 respectively). On the other hand, if the runs per sample were increased to four, the CPS would increase by $0.26 and the lab would lose money annually.

If the sample volume were increased by 50% the CPS would decline by $0.17 with a marked increase in RPS and year ($0.17 and $15,182.94). These savings could be further increased by negotiating reagent discounts. If all new samples were to come from a client that would fully reimburse the PHL for its services the RPS would nearly double and the annual revenue would increase by approximately $100,000. Doubling the sample volume, under the same circumstances would create an even more drastic effect (refer to Table 6). Maximizing the batch size at 2.98 runs per week would require 6973 samples and would result in cost savings similar to the 50% increase scenario.

Discussion:

Overall, any kind of volume increase would be beneficial for this test, since there is always a positive net gain per sample associated with it. A decrease in the number of runs per week would result in cost savings to a certain degree even without increasing the sample volume. However, the TAT for results may be affected negatively (increasing patient anxiety and likelihood to spread the disease further). The revenue gains associated with the volume increases are striking, especially if all or most new clients reimburse the lab fully for testing. The achieved cost savings would likely be even higher than estimated here, since there would be savings in reagent costs (not simulated here) due to elimination of waste and better use of controls by maximizing the batch sizes.

2. Simulated Volume Increase in Acid-Fast Bacilli (AFB) Culture - Public Health Laboratory D

Background:

The procedure used to culture AFB is very labor intensive and involves multiple steps. First, the samples are processed and decontaminated, before they are stained by an acid fast stain and inoculated on liquid and solid media. For the liquid culture the Mycobacteria Growth Indicator Tubes are used in the Becton Dickinson (Franklin Lakes, NJ) BACTEC 960 equipment, which is an automated system to detect bacterial growth. The cultures have to be incubated for at least six weeks to be reported as negative. All solid culture plates have to be examined for growth at least once a week by a microbiologist, which is extremely time-consuming. If there is growth on the solid culture a second stain is performed and further measures are taken to identify the organism (reread stain, molecular methods such as TB-Probe, susceptibility testing). Thus, positive and negative samples have significantly different labor times, which were measured separately in the time study. Each time was then used together with the typical percentage of positive and negative samples to determine the annual and per sample labor cost. The test was performed five times per week at PHL D. For the internal TAT, 253 accession numbers were randomly sampled (20 positive and 233 negative) and averaged. The annual reimbursement was derived the same way as in the previous case study.

Many scenarios were simulated (Table 7). When volume was changed the reagent costs were adjusted proportionally. However, it is likely that any newly added specimens would incur only minimal extra reagents until the maximum batch size was reached. Thus, the costs presented here are an over-estimation of what would actually be incurred. For most of the scenarios the income was changed proportionally to the increase in volume. Therefore, no revenue was gained per sample. However it is desirable that any newly acquired testing volume will be from clients that will pay for the test in full.

Results:

About 75% of this test's labor time can benefit from batching. However, there are on average only two samples per run, when the maximum is 14. The average TAT for positive samples was 36.3 days and for negative ones 43.66. The proficiency testing grade from the last 3 years combined was 90.5%. The current RPS is $17.34, while it costs $135.77 to run each specimen (the majority of this cost originates from expensive reagents). Needless to say, the PHL loses a large sum of money per sample ($118.43) and annually ($58,622.23). This CPS can be significantly decreased, by decreasing the runs per week (to three would decrease the CPS by $15), or by increasing the sample size (Table 7). The highest amount of cost savings of the simulated scenarios can be achieved through maximizing the batches at 5 runs-per-week with a 10% reagent discount and all new samples being fully reimbursed (decrease of CPS by $41.39 with a lowest possible net loss of -$62.65). However, even in this ideal scenario the costs still exceed the revenue of the test and the annual net loss is very high.

Discussion:

PHL D will always lose money on this test whether they increase the volume, decrease the number of runs or receive reimbursement for most tests. Even the ideal scenario projects

significant losses. However, because tuberculosis causes extensive morbidity and mortality in the population and the causative bacteria is spread only by people with active disease, it is a large public health problem and imperative for the laboratory to continue to offer this test to as many patients as necessary to identify all cases, regardless of their reimbursement capabilities. The laboratory could achieve cost savings by decreasing the number of runs-per-week, which would significantly decrease CPS and save about $7,410.36 annually. However, this scenario might negatively affect the TAT. Reagent discounts should be pursued since this is a test with very expensive reagents. It would not be advisable to actively seek out more specimen sources for this test, unless the laboratory would drastically increase its fee and were to be reimbursed completely for the new volume of tests.

Conclusion

As can be seen in Table 1, two high-volume, one moderate-volume and three low-volume tests were examined with the six case studies. Based on past volume increases, it seems that high and moderate volume tests produced the highest cost savings per sample. The extent of the volume increases did not seem to correlate with the cost decrease. Those tests that benefited the most from batching (as far as labor costs go) showed the most extreme cost per sample decreases. However, not enough cases were examined in order to determine whether these associations were significant. Because most of the assays had very high reagent costs, the laboratories were or would be able to profit greatly from negotiating discounts. Laboratories that were usually fully reimbursed for their testing were able to register significant increases in their annual revenue, even if the revenue per sample didn't change. If the percentage of reimbursed tests increased with the new testing volume, the revenue per sample can also increase. The TAT either remained similar, e.g. PHL A, or decreased significantly. The sharp increase in TAT PHL C may be due to the low number of records examined or to the switch in testing methods that took place.

The two case studies in PHL D showed the versatility of the developed cost-effectiveness evaluation model. It was able to show whether laboratories were losing or making money with the examined tests. Furthermore, it predicted how the cost and revenue for the test might change if the volume or the runs per tests were altered. The analysis showed that it would definitely be financially beneficial for the laboratory to pursue a higher testing volume for their CT/NG testing, ideally with clients that fully reimburse for the service. The AFB test on the other hand is very costly and results in significant financial loss to the laboratory, but due to its public health importance, it must continue to be offered. The model was able to show the ideal scenarios that would enable the laboratory to reduce the financial loss on this test. Overall, the developed model is a useful tool for the laboratories to become more cost-efficient or to evaluate their services. It is important to consider that most of the information produced is of financial nature. The effect on quality of testing was measured minimally and future studies are necessary to devise a way of quantifying all aspects of quality so they could be entered into the basic cost-effectiveness model. Unlike private testing laboratories, the first priority of a PHL is to serve the public community and essential tests should never be discontinued or decreased because of expense. However, the continuing loss of the laboratory testing market to the private sector and the closure of some PHLs is forcing the realization that cost-effectiveness must be achieved in order to survive.

Table 6 Data collected and equations used in the cost-effectiveness evaluation model.

	Reference #	Data from evaluation	Equations used	Outcome measures
General	1)	Annual test-specific sample volume	Enter value	Annual Net Gain: =annual revenue - annual sample =revenue per sample- cost per sample
	2)	Total annual sample volume (for all tests)	Enter value	
	3)	Maximum samples per run (batch size)	Enter value	
	4)	Average number of runs per week	Enter value	
	5)	Average number of samples per week	= 1) / 52	
	6)	Average number samples per run	= 5) / 4)	
Revenue	7)	Annual test-specific income received through fees	Enter value	Annual Revenue: = 7)+13)+14) Or = 12)+13)+14) Revenue Per Sample = annual revenue / 1)
	8)	Fee charged per sample	Enter value	
	9)	Percent tests fully reimbursed	Enter value	
	10)	Percent tests partially reimbursed	Enter value	
	11)	Most frequent partial reimbursement rate	Enter value	
	12)	Estimated annual test-specific income received through fees	= [8)*9)*1)] + [11)*10)*1)]	
	13)	Specific grants/other funding / year	Enter value	
	14)	Assistance from the state	Enter value	
Cost	15)	Annual cost of reagent	Enter value	Annual Labor cost: ={[24)*4) + 25)*5)] *52*23)}+ { [26)*4) + 27)*5)] *52*22) } Annual Cost: = 15)+16)+17)+18) +19)+21)+ annual labor cost Cost Per Sample: = annual cost / 1)
	16)	Annual cost of proficiency testing	Enter value	
	17)	Equipment price (purchased)	Enter value	
	18)	Cost of maintenance contract per year	Enter value	
	19)	Courier price per year	Enter value	
	20)	Total annual overhead	Enter value	
	21)	Test-specific annual overhead (based on sample #)	= [20) / 2)] * 1)	
	22)	Hourly rate of microbiologist salary & Benefits	Enter value	
	23)	Hourly rate of laboratory assistant salary & Benefits	Enter value	
	24)	Laboratory assistant time spent on whole batch (hours)	Enter value	
	25)	Laboratory assistant time spent on individual sample (hours)	Enter value	
	26)	Microbiologist time spent on whole batch (hours)	Enter value	
	27)	Microbiologist time spent on individual sample (hours)	Enter value	
	28)	Percent of test that benefits from batching	=[24)+26)]/[24)+25)+26)+27)]	
Quality	29)	Internal turn-around time	Enter value	
	30)	Proficiency testing result	Enter value	
	31)	Test specific quality measure	Enter value	

Abbreviations: * = multiply

Table 7 Overall comparison of six examined case studies.

	PHL A QTB	PHL B QTB	PHL B HIV VL	PHL C HIV VL	PHL D CT/GC	PHL D AFB
Percentage test volume of total annual volume before volume increase (after volume increase)	10% (13%)	4% (6%)	1% (2%)	2% (3%)	14.5%	1.2%
Percentage of how much the volume increased	37.3%	14.5% (39.5% in the second year)	58.6%	66.4%	N/A	N/A
Percentage of test that benefits from batching (as determined by the time study)	95.7%	94.9%	68.3%	Not determined	91.4%	74.7%
Labor cost (percentage of total cost) before (after) volume increase	3% (4%)	11% (17%)	5% (5%)	14.6% (8.0%)	26.9%	37.6%
Reagent cost (percentage of total cost) before (after) volume increase	81% (84%)	76% (80%)	90% (90.5%)	84.5% (91.5%)	51.4%	60.1%
Reimbursement structure (percentage received)	100%	<100%	<100%	100%	<100%	<100%
Percentage of turn-around-time change	2.3%	-9.2% (15.5% in the second year)	-23.1%	31.8%	N/A	N/A
Cost per sample decrease (in dollar/percent) due to volume increase	-$3.65 (14.1%)	-$0.16 (0.6%) [-$8.72 (30.0%) in the second year]	$0.35 (0.5%)	$0.30 (0.3%)	$0.15(1.3%) - to $0.77 (6.8%) (depending on scenario)	$14.97 (11.0%) to $41.39 (30.5%) (depending on scenario)

Abbreviations: AFB= Acid fast bacilli culture, CT/GC = Chlamydia trachomatis/neisseria gonorrhoeae, HIV VL = Human immunodeficiency virus viral load, QTB = Quantiferon test for tuberculosis

Table 8 Summary statistics for the Quantiferon testing volume increase in public health laboratory A.

	Output measures	2012	2013	Difference
Cost/revenue	Annual test-specific revenue	$176,680.00	$242,600.00	$65,920.00 (37.3%)
	Revenue per sample	$40	$40	$0 (0%)
	Annual test specific-cost	$114,234.38	$134,703.43	$20,469.05 (17.9%)
	Cost per sample	$25.86	$22.21	-$3.65 (-14.1%)
	Annual total net gain	$62,445.62	$107,896.57	$45,450.95 (72.8%)
	Net gain per sample	$14.13	$17.79	$3.65 (25.8%)
Quality	Internal turn-around-time	64.98 hrs	66.48 hrs	1.5 hrs (2.3%)
	Proficiency testing grade	100%	100%	0%

Table 9 Summary statistics for the Quantiferon testing volume increase in public health laboratory B.

	Output Measures	2010	2011	Difference	2013	Difference from 2010	2013 (no reagent discount)	Difference from 2010
Cost/revenue	Annual test-specific revenue	$199,272.96	$199,422.26	$149.30 (0.1%)	$236,043.23	$36,770.27 (18.5%)	$236,043.23	$36,770.27 (18.5%)
	Revenue per sample	$32.61	$28.49	-$4.13 (-12.7%)	$27.69	-$4.92 (-15.1%)	$27.69	-$4.92 (-15.1%)
	Annual test-specific cost	$177,807.20	$202,571.12	$24,763.92 (13.9%)	$173,730.28	-$4,076.91 (-2.29%)	$188,706.76	$10,899.57 (6.1%)
	Cost per sample	$29.10	$28.94	-$0.16 (-0.5%)	$20.38	-$8.72 (-30.0%)	$22.14	-$6.96 (-23.9%)
	Annual total net gain	$21,465.77	-$3,148.86	-$24,614.63 (-114.7%)	$62,312.94	$40,847.18 (190.3%)	$47,336.46	$25,870.70 (120.5%)
	Annual net gain per sample	$3.51	-$0.45	-$3.96 (-112.8%)	$7.31	$3.80 (108.3%)	$5.55	$2.04 (58.1%)
Quality	Internal turn-around-time (in days)	2.91	2.642	-0.268	2.46	-0.45 (-15.5%)	2.46	-0.45 (-15.5%)
	Proficiency testing grade	100%	100%	0%	100%	0%	100%	0%

Table 10 Summary statistics for the HIV viral load testing volume increase in public health laboratory B.

	Output measures	2009	2011	Difference
Cost/revenue	Annual test-specific revenue	$38,782.49	$117,850.59	$79,068.10 (203.9%)
	Revenue per sample	$25.12	$48.12	$23.00 (91.6%)
	Annual test-specific cost	$106,421.17	$167,941.12	$61,519.95 (57.8%)
	Cost per sample	$68.93	$68.58	-$0.35 (-50.8%)
	Annual total net gain	-$67,638.69	-$50,090.53	$17,548.16 (25.9%)
	Annual net gain per sample	-$43.81	-$20.45	$23.35 (53.3%)
Quality	Internal turn-around-time (in days)	3.20	2.46	-0.74 (-23.1%)
	Proficiency testing grade	100%	100%	0%

Table 11 Summary statistics for the HIV viral load testing volume increase in public health laboratory C.

	Scenarios	Revenue per sample	Cost per sample	Net gain per sample	Change of cost per sample from baseline	Total annual net gain over baseline
Scenario 1	Actual Scenario 2008	$100	$88.24	$11.76	N/A	N/A
	Actual scenario 2009	$100	$89.61	$10.39	$1.37	$5,002.19
Scenario 2	(New method both years) 2008	$100	$89.91	$10.09	N/A	N/A
	(New method both years) 2009	$100	$89.61	$10.39	-$0.30	$6,510.20
	(Old method both years) 2008	$100	$88.24	$11.76	N/A	N/A
	(Old method both years) 2009	$100	$87.94	$12.06	-$0.30	$7,512.20
Scenario 3	(2008 sample vol.) 2008	$100	$82.51	$17.49	N/A	N/A
	(2008 sample vol.) 2009	$100	$95.64	$4.36	$13.13	-$11,856.39
	(2009 sample vol.) 2008	$100	$82.19	$17.81	N/A	N/A
	(2009 sample vol.) 2009	$100	$95.32	$4.68	$13.13	-$19,734.39

Table 12 Summary statistics for the simulated Chlamydia trachomatis/Neisseria gonorrhea testing volume increase in public health laboratory D.

	Revenue per sample	Cost per sample	Net gain per sample	Decreased cost per sample from baseline	Total annual net gain over baseline
Baseline	$13.89	$8.95	$4.93	$0	$0
Baseline 2.4 runs per week	$13.89	$8.80	$5.09	$0.15	$837.05
Baseline 4 runs per week	$13.89	$9.22	$4.67	-$0.26	-$1,472.05
1.5x vol.	$13.89	$8.78	$5.11	$0.17	$15,182.94
1.5x vol. + 5% RD	$13.89	$8.48	$5.40	$0.47	$17,615.23
1.5x vol. + 10% RD	$13.89	$8.19	$5.69	$0.76	$20,047.51
1.5x vol. (all new fully reimbursed)	$27.26	$8.78	$18.48	$0.17	$126,741.33
2x vol.	$13.89	$8.76	$5.12	$0.19	$29,528.83
2x vol. + 5% RD	$13.89	$8.47	$5.41	$0.48	$32,771.88
2x vol. + 10% RD	$13.89	$8.18	$5.70	$0.77	$36,014.93
2x vol. (all new fully reimbursed)	$33.94	$8.76	$25.18	$0.19	$252,645.61
Max. batch	$13.89	$8.78	$5.11	$0.17	$8,158.01
Max. batch + 5% RD	$13.89	$8.49	$5.40	$0.46	$10,190.92
Max. batch + 10% RD	$13.89	$8.20	$5.69	$0.75	$12,223.83
Max. batch (all new fully reimbursed)	$22.00	$8.78	$13.22	$0.17	$64,758.45

Abbreviations: Max. = maximum, RD = reagent discount, vol. = volume

Table 8 Summary statistics for the simulated acid fast bacilli testing volume increase in public health laboratory D.

	Revenue per sample	Cost per sample	Net gain per sample	Cost per sample change from baseline	Total annual net gain from baseline
Baseline (5 runs per week)	$17.34	$135.77	-$118.43	N/A	N/A
Decrease to 3 runs per week	$17.34	$120.80	-$103.46	$14.97	$7,410.36
2x Sample vol.	$17.34	$116.61	-$99.26	$19.16	-$39,649.65
2x Sample vol. + 5% RD	$17.34	$112.53	-$95.18	$23.24	-$35,608.11
2x sample vol. + 10% RD	$17.34	$108.45	-$91.10	$27.32	-$31,566.58
2x Sample vol. (all new fully reimb.)	$25.67	$116.61	-$90.94	$19.16	-$31,405.64
2x Sample vol. (all new fully reimb.) + 5% RD	$25.67	$112.53	-$86.85	$23.25	-$27,364.10
2x Sample vol. (all new fully reimb.) + 10% RD	$25.67	$108.45	-$82.77	$27.33	-$23,322.57
Max. batch 5 runs per week (current reimb. %)	$17.34	$102.55	-$85.21	$33.23	-$251,543.56
Max. batch 5 runs per week (current reimb. %) + 5% RD	$17.34	$98.47	-$81.13	$37.31	-$236,682.85
Max. batch 5 runs per week (current reimb. %) + 10% RD	$17.34	$94.38	-$77.05	$41.39	-$221,822.14
Max. batch 5 runs per week (all new fully reimb.)	$31.74	$102.55	-$70.81	$33.23	-$199,138.83
Max. batch 5 runs per week (all new fully reimb.) + 5% RD	$31.74	$98.47	-$66.73	$37.30	-$184,278.12
Max. batch 5 runs per week (all new fully reimb.) + 10% RD	$31.74	$94.38	-$62.65	$41.39	-$169,417.41
Max. batch 3 runs per week (current reimb. %)	$17.34	$102.69	-$85.35	$33.08	-$127,789.01
Max. batch 3 runs per week (current reimb. %) + 5% RD	$17.34	$98.61	-$81.27	$37.17	-$118,873.39
Max. batch 3 runs per week (current reimb. %) + 10% RD	$17.34	$94.53	-$77.19	$41.25	-$109,957.78
Max. batch 3 runs per week (all new fully reimb.)	$30.22	$102.69	-$72.46	$33.08	-$99,640.31
Max. batch 3 runs per week (all new fully reimb.) + 5% RD	$30.22	$98.61	-$68.38	$37.17	-$90,724.69
Max. batch 3 runs per week (all new fully reimb.) + 10% RD	$30.22	$94.52	-$64.30	$41.25	-$81,809.08

Abbreviations: Max. = maximum, RD = reagent discount, reimb. = reimbursed, vol. = volume

8. CHAPTER 3: ASSESSING THE EFFECTS OF SPECIALIZATION ON COST-EFFECTIVENESS AND QUALITY OF TESTING IN PUBLIC HEALTH LABORATORIES

Abstract

Objectives:

The sharing of testing services among neighboring public health laboratories in California, also termed specialization, may be a viable solution to improve cost-inefficiency and lack of quality associated with low-to-moderate-volume tests. To quantify the effect of such collaborations, this study examined three cases of existing service sharing.

Methods:

A cost-effectiveness evaluation model was used to measure the cost, revenue and quality changes that occurred due to specialization. The current situation of shared testing services was compared with the scenario of the outsourcing laboratories performing the tests themselves.

Results:

The turn- around-time decreased in two of the three specialized public health laboratories (by 23.1%- 37.8%). Whereas turn-around-time was likely to increase for the outsourcing laboratories, due to the transport of the specimens, cost-savings ranged from $0.10 to $0.31 per sample in the specialized laboratories. Despite offering the test at an overall loss, all outsourcing PHLs were able to decrease their costs significantly (by 72.9-98%) by adding a service charge to their clients. One outsourcing laboratory was able to increase its revenue per sample (by 111.5%) by raising their fee and charging for shipping and handling.

Conclusions:

The effect of specialization in low-to-moderate-volume tests was overwhelmingly positive for all public health laboratories involved in the examined case studies. All participants were able to reduce their costs and improve their annual and per sample net gain (either by reducing loss or increasing profit), while quality was maintained. In addition to creating economies of scale, the collaboration likely improved the relationship among the partner laboratories and strengthened the overall public health laboratory network.

Introduction

Volume increases in certain testing areas have been a preferred strategy of public health laboratory (PHL) directors in California to improve cost-efficiency, quality, and scope of services.[34] Cost-savings (0.3-31.6%) and quality improvements were shown for six cases of testing volume increases in PHLs.[34] Past methods to increase volumes focused on the acquisition of new technologies.[34] A different strategy, 'sharing of testing services,' is a key target of the Laboratory Efficiency Initiative[28] and was used successfully in hospital and private settings.[14,26,27] "A Practical Guide To Assessing and Planning Implementation of PHL Service Changes" illustrated examples of shared testing services in PHLs across the country.[26]

However, the sharing of services has not been widely used in the California PHL system, which is unique with its 35 local PHLs, and has been under considerable budgetary pressures.[29] Only two of 31 PHLs previously surveyed used this method.[34] The strategy has also not been focused on low-to-moderate volume tests (LMVTs). In addition to creating lower revenues, LMVT costs for trained staff, specific equipment, service contracts and reagents are distributed over very few patients. Testing quality may also be affected. The fewer the samples, the less practice laboratory staff are able to get, which means a potential decline in accuracy. The internal turn-around-time (TAT), from sample receipt to result reporting, might also be negatively affected by fewer batch runs per week.

The purpose of this study was to examine the regionalization of such LMVTs, also termed specialization, as a strategy to increase volumes, and improve quality and cost-effectiveness in local PHLs of California. Through an agreed upon collaboration, neighboring PHLs would each specialize in a LMVT, for which they would accept samples from surrounding PHLs, who could discontinue the test. Resulting economies of scale would theoretically decrease costs per sample (CPS) and improve performance expertise in the provider laboratory.[35] The outsourcing PHLs could continue to offer the service to their community and remain the contact point. In this manner, PHLs could collectively enhance their individual prospects for survival while still maintaining a laboratory prepared to perform testing to investigate epidemics or outbreaks and provide surge capacity for the state during emergencies.

Specialization could strengthen the PHL network while preserving the autonomy of all 35 PHLs in California. To ascertain the potential of shared testing services to improve cost-effectiveness and quality of testing among local Californian PHLs, this study examined three cases of existing collaboration.

Methods

Three sets of PHLs sharing testing services and willing to partake in this study were identified by examining participants' answers to a previously conducted survey.[34] The cost-effectiveness evaluation model (CEEM), developed in a previous study was applied to each situation and results were compared.[34] The model utilizes elements of activity based costing; a sample was followed from receipt in the laboratory until results were reported, and all steps affecting testing costs, revenue, and quality were recorded.[36] The main equations used in the model can be viewed in Table 1. Quality indicators were TAT (typically an average of all samples) and proficiency testing results. The latter are scores ranging from 0-100% given by independent testing agencies that evaluate the laboratories' performance for quality assurance purposes.[37] Income generated through fees, grants (either private or public, for which the

laboratories have to apply) and assistance from the State PHL (in the form of vouchers or specialized programs to assist those patients that are not covered under any other health care plan) were the input values for the revenue. Reagents, proficiency testing fees, maintenance contracts, courier fees, and labor costs were entered for the laboratories' expenditures.

Unless otherwise noted, a time study of the testing procedure was conducted in the specialized PHL to estimate labor costs. Steps involving the entire batch or the individual sample were timed separately so that the benefit of batching could be determined. The PHL staff, dedicated to this project, was interviewed for most of the information. Data were gathered for the year before and after the collaboration began. Two of the outsourcing PHLs had never performed the test themselves. Scenarios were simulated that estimated costs and revenues if the outsourcing PHLs were to perform the test in-house. Results were calculated for both, outsourcing and specialized partner, laboratories and compared.

Case Studies

1. Collaboration of Public Health Laboratory A and B for hepatitis Screening

Background:

In 2009 PHL A processed 14,019 specimens utilizing the Abbott Architect (Abbott Park, IL) to screen for hepatitis antibodies and antigens five times per week. In 2010 it began receiving samples on a regular basis from PHL B and in 2011 17 samples were received from PHL B and 20 from another jurisdiction. This contributed to the 2-year increase of 1,044 samples (7.4%) experienced by PHL A. The laboratory is part of a Federally Qualified Health Center and does not get reimbursed per test, except for some private patients and out-of-county testing. Therefore, a set portion of PHL A's annual budget was arbitrarily designated (based on testing volume over the total volume of tests) for hepatitis testing for input into the CEEM. Most costs were derived as described above by the laboratory manager. However, reagent and labor costs were only provided on a per-sample basis. Finally, a scenario was simulated in which the 37 out-of-county samples represented the only volume increase. Reagent and labor costs were adjusted accordingly. For revenue, the 2009 in-county reimbursements were added to the out-of-county revenue. There was no income from grants.

In 2009 PHL B performed hepatitis screens using the Enzyme Linked Immuno Sorbent Assay (ELISA) from Bio-Rad (Hercules, CA) on 650 samples in batches of three runs a week. Costs, proficiency grades, and TATs were calculated as described above. Labor times were estimated by laboratory staff. In 2010 the PHL lost most of their hepatitis testing volume, due to closure of county clinics, making the assay too expensive to run. They began sending their specimens to PHL A because of its proximity and high testing volume. In addition to the fee paid for the testing to PHL A, PHL B had some remaining labor costs for sample shipment, handling and result reporting, for which it was able to charge its clients an additional $25. All tests were fully reimbursed. To eliminate the impact of the sharp volume decrease, a scenario was simulated where PHL B would have only received 17 samples in 2009, while still performing the test themselves. Reimbursement, labor and reagent costs were recalculated to reflect the new volume.

Results:

For the detailed numbers please refer to Table 2 for PHL A and Table 3 for PHL B. Despite a significant internal TAT decrease of 37.8% (0.7 days) in PHL A, the TAT for PHL B, the outsourcing laboratory, more than tripled. Proficiency testing grades remained constant in PHL A and across both laboratories. Both PHLs decreased their CPS, PHL A from $25.12 to $24.83 (~1%) and PHL B from $56.27 to $55.43 (1.5%). However, at a testing volume of 17 samples, PHL B's CPS would be $204.63 in-house and would decrease by 72.9% due to outsourcing.

PHL A increased their annual profit by $4,982.66, despite a small decrease in revenue per sample (RPS). Instead of losing $22,927.75 annually, as in 2009, PHL B spent only $187.23 out of pocket per year (a saving of 99.2% or 94% respectively) by outsourcing the test, raising their fee to match PHL A's, and including the shipping and handling charge, so that their RPS increased from $21.00 to $44.41 (111.5%) in 2011.

Considering the scenario in PHL A where the volume increase consisted only of the 37 samples from the other PHLs, the cost, revenue and net gain would only be slightly, but still positively, impacted.

Discussion:

For PHL A the addition of the 37 hepatitis specimens did not have a large impact on their cost-effectiveness because of the large prior volume. However, even the addition of only 37 samples produced a small decrease in costs and increase in RPS. If PHL A could receive samples from other local PHLs as well, these effects could be multiplied.

For PHL B the collaboration with PHL A produced even more benefits. Their RPS more than doubled and the CPS decreased by $0.85. Instead of losing over $20,000 a year they now spend only about $200. Considering performing the test in-house for only 17 samples, the benefits of outsourcing become even more apparent. Cost-savings were likely underestimated, because reagent costs were considered per sample and waste due to expiration of reagents could not be estimated. The main disadvantage for PHL B was the increase in TAT, which occurred despite the decrease in internal TAT at PHL A. PHL B will have to decide whether the current TAT is sufficient to serve their clients. One solution might be to evaluate and alter the courier service currently used.

2. Collaboration of Public Health Laboratory A and C: HIV Viral Load Testing

Background:

PHL A performed HIV viral load testing on 1544 samples in 2009 and 2449 in 2011, an increase of 58.6%. Most of this volume increase (84.0%) was from PHL C. PHL A utilized the COBAS AmpliPrep and TaqMan equipment (by Roche Molecular Diagnostics, Pleasanton, CA) and performed the test twice a week. The fairly automated method has low labor (<$4) and high reagent ($64.51) CPS. Annual revenue was estimated similarly to the previous case study. PHL A was fully reimbursed by PHL C's HIV/AIDS program ($100 per sample) for all tests they provided. Other measures were derived as outlined above.

PHL C did not receive any reimbursements for the test, but still incurred costs for sample processing, packaging, shipment and result reporting. Samples were sent twice a week starting in 2010. Prior to that, PHL C had not performed the HIV viral load assay themselves since 2004. Because a different method was used and data from that time period would be difficult to obtain, the scenario of performing the assay in-house was simulated. Sample volumes and reimbursements from PHL C were combined with per sample labor and reagent costs and proficiency testing fees from PHL A. However, the COBAS AmpliPrep is a system designed for very high volumes. Due to PHL A's high volume, fixed costs (equipment and service contracts) typically factored into the price of reagents, were spread over more specimens, keeping their reagent CPS relatively low ($64.51). A sales representative from Roche Molecular Diagnostics (Pleasanton, CA), who normally negotiates the prices with the PHLs based on their sample volume, estimated reagent CPS for an annual testing volume close to PHL C's to be $300. This factor was considered in a third scenario, with every other variable held constant.

Results:

Please refer to Table 4 for PHL A's and Table 5 for PHL C's detailed results. The internal TAT in PHL A was shortened from 3.20 to 2.46 days (23.1%), while proficiency grades remained constant. The current total TAT in PHL C is 8.75 days. Both PHLs decreased their CPS, PHL A slightly from $68.93 to $68.58 (~1%) and PHL C dramatically from $69.44 (if the test were to be performed in-house with PHL A's reagent prices) to $23.57 (66.1%) (hypothatical scenario). Even with the higher costs, PHL C, the outsourcing laboratory, would still achieve a higher profit of $23,225.32 by performing the test themselves (compared with the current situation of losing $17,915.58 annually), because they would get reimbursed at $100 a sample. However, if PHL C had to perform the test with the reagent price estimated by the Roche sales representative, their CPS would amount to $304.93 and the laboratory would lose $155,747.08 annually. Outsourcing the test to PHL A, in this case, achieved a decrease in CPS of 92.2% and a reduction in annual losses of 88.5%. PHL A was also able to reduce their annual loss from $67,638.69 to $50,090.53 (25.9%) due to the VI in 2011, and achieved associated revenue gains of 203.9% annually and 91.6% per sample.

Discussion:

At their current sample volume, PHL C is benefitting financially by not performing the COBAS Ampliprep HIV viral load procedure in-house. To mitigate out-of-pocket expenses, they could negotiate with their HIV/AIDS program to receive a small reimbursement for shipping and handling. Alternatively, they could seek a revenue-sharing agreement with PHL A for a small portion of the $100 reimbursement. However, this endeavor may not be successful, because PHL A lab already performs the test at a loss. The TAT would probably shorten by having the test in-house, provided PHL C performed the procedure at least once a week. However, this gain would be far outweighed by the increased cost burden.

PHL A significantly shortened their TAT, while slightly decreasing their costs for the HIV viral load assay. This decrease is likely an underestimation because reagent costs were calculated per sample, so that savings due to batching and elimination of waste could not be considered. Furthermore, the laboratory significantly increased their revenue. Unfortunately, the laboratory still performs this test at a loss because they are not reimbursed directly for most patients. However, the portion of the annual budget assigned to the HIV viral load assay for this

project may not represent the actual amount available for the test. While it may not be financially feasible for PHL A to increase in-county samples (unless relevant for their PH mission), the collaboration with another jurisdiction that reimburses fully for the test seems profitable and strengthens the ties between the counties.

3. Collaboration of Public Health Laboratory D and E: HIV Viral Load Testing

Background:

PHL D registered a 600 sample volume increase (66.4%) for their HIV viral load testing between 2008 and 2009. They received 137 samples of the volume increase (22.8%) from PHL E. In 2009 PHL D also utilized the Cobas AmpliPrep and TaqMan equipment (Roche Molecular Diagnostics, Pleasanton, CA). However, in 2008 they performed a different, less reagent- but more labor-intensive test. To eliminate the effect of the technology change and focus on the impact of the volume increase, a scenario was considered for this research which assumed the new technology was used for both years. A State Voucher Program reimbursed PHL D ($100 per sample) for their HIV viral load testing. Although discontinued in August 2009, the revenue was extrapolated for this project as if all samples were reimbursed. Labor and reagent costs were calculated per sample during a prior cost estimation. The internal TATs were averaged from a random sample of 40 patient records.

PHL E began sending their HIV viral load samples to PHL D in March 2009 (twice a week). They never performed the test themselves. The amount for annual testing volume entered into the model was the summation of 55 samples sent to another jurisdiction in January and February and the 137 specimens processed in PHL D. Calculations for PHL D did not account for this higher volume because they did not receive more samples from PHL E). PHL E received no reimbursement, despite incurring costs for courier services and labor time to receive, package, and ship samples and report results. To simulate a scenario where PHL E would test for HIV viral loads in-house, their data from 2009 were combined with proficiency testing fees, reagent and labor CPS from PHL D. However, because the Ampliprep system is specifically designed for high volumes, PHL E's true reagent costs were estimated by a Roche sales representative at $719.56. This number was used in a second scenario of PHL E performing the test in-house.

Results:

For detailed results please refer to Table 6 for PHL D and Table 7 for PHL E. While the proficiency testing grades remained the same in PHL D, their internal TAT increased from 4 to 5.72 days (43.0%). The total TAT for PHL E was 20.88 days. Both counties would be able to decrease their CPS due to their collaboration (PHL D from $89.91 to $89.61 or by 0.3%, and PHL E from $94.71 to $14.42 or by 84.8%). Considering the higher reagent prices for PHL E's low volume, their CPS would be $732.32 in-house and would decrease by 98.0% due to outsourcing. PHL D improved their annual net gain from $9,113.44 to $15,623.64 (by 71.4%). PHL E would be able to achieve an annual profit of $1,016.28 by performing the test in-house with reagent prices close to PHL D's. They would, thus, register a loss of 372.5% to -$2,768.92 annual profit if the test is outsourced. However, with the more realistic reagent costs, the laboratory would decrease their annual loss from $121,404.84 (in-house) to $2,768.92 (outsourced) (97.7%).

Discussion:

The increase in TAT was unexpected because PHL D did not change its number of runs per week and never reached maximum sample size. The sample of 40 patients was possibly too small and not representative of the true TAT. The achieved cost decrease was probably a substantial underestimation because both labor and reagent costs were measured per sample. Therefore, effects of larger batches on labor time, reagent usage, and elimination of waste were not captured. The volume increase also produced an extensive increase in annual profit. It would definitely be desirable for PHL D to increase their HIV viral load testing further, as long as their staff can handle the workload and all new samples would be reimbursed. Although termination of the State's voucher program has made it more difficult to ensure proper reimbursement, PHLs from other jurisdictions that do not offer the test or would like to outsource it could be a reliable revenue source.

PHL E was losing money in 2009 by outsourcing its HIV viral load testing to PHL D because they were not being reimbursed for labor and courier service costs. Even though their TAT could be improved by performing the test in-house, that option would not be financially feasible using the same technology as PHL D. Despite the termination of the State's voucher program PHL E has been able to improve their situation. In 2013 they received an average RPS of $98.21 from their clients, partially due to the addition of a shipping and handling fee. Also, PHL D lowered its fee to $90.91, so that PHL E was able to cut its annual ($1,435.08) as well as per sample net loss ($7.97) almost in half.

Conclusions

The effect of specialization on the PHLs described here was largely positive. Although not directly measured, the collaboration between the laboratories likely strengthened their network and their relationship. Proficiency testing grades stayed the same in all specialized laboratories. This quality indicator may, however, not be sufficiently discriminatory, particularly for highly automated tests, which depend mainly on functioning equipment rather than microbiologists' skills. The internal TAT in two specialized PHLs decreased significantly. However, this effect was partly due to in-county volume increases. Overall the quality of testing in specialized PHLs remained the same or improved. TAT for an outsourcing laboratory could increase due to added shipping time, as it did for PHL B. However, the specialized laboratory may perform the test more often, which could counteract added time for shipment.

The cost decreased in all laboratories. In specialized PHLs it decreased slightly, typically less than 1%, because the volume increase was small compared to large existing volumes. In all cases the cost decrease was probably an underestimate because benefits of larger batches could not always be fully captured. All outsourcing laboratories experienced (or would have) a drastic cost decrease (at least 72%), clearly showing the cost-inefficiency of low-to-moderate volume tests and the benefits of economies of scale.

Outsourcing laboratories will of course suffer revenue losses. However, PHL B and E managed to offset this loss by charging clients a shipping and handling fee. PHL E was also able to negotiate a lower testing fee with its partener laboratory. If all outsourcing laboratories could achieve this they should be able to cover most of their out-of-pocket expenses. Two specialized laboratories experienced a positive annual net gain due to collaboration. PHL A had been losing

money annually and per sample for their HIV viral load test, mainly due to the lack of reimbursement for their in-county samples. However, they significantly reduced their loss by collaborating with PHL C. All outsourcing PHLs had been offering the testing services at a loss. However, compared to performing the tests themselves, outsourcing was less expensive. PHLs are non-profit entities that normally offer services, for which they are often not reimbursed in order to benefit their community. All that can be expected of PHLs is to be as cost-effective as possible. The data presented here indicates that specialization in low-to-moderate volume tests might be an effective strategy to minimize testing losses and improve cost-effectiveness.

Table 1 Data collected and equations used in the cost-effectiveness evaluation model.

	Reference #	Data from evaluation	Equations used	Outcome measures
General	1)	Annual test-specific sample volume	Enter value	Annual Net Gain: =annual revenue - annual sample Net Gain Per sample: =revenue per sample - cost per sample
	2)	Total annual sample volume (for all tests)	Enter value	
	3)	Maximum samples per run (batch size)	Enter value	
	4)	Average number of runs per week	Enter value	
	5)	Average number of samples per week	= 1) / 52	
	6)	Average number samples per run	= 5) / 4)	
Revenue	7)	Annual test-specific income received through fees	Enter value	Annual Revenue: = 7)+13)+14) Or = 12)+13)+14) Revenue Per Sample: = annual revenue / 1)
	8)	Fee charged per sample	Enter value	
	9)	Percent tests fully reimbursed	Enter value	
	10)	Percent tests partially reimbursed	Enter value	
	11)	Most frequent partial reimbursement rate	Enter value	
	12)	Estimated annual test-specific income received through fees	= [8)*9)*1)] + [11)*10)*1)]	
	13)	Specific grants/other funding / year	Enter value	
	14)	Assistance from the state	Enter value	
Cost	15)	Annual cost of reagent	Enter value	Annual Labor cost: ={[24)*4) + 25)*5)] *52*23)}+ { [26)*4) + 27)*5)] *52*22) } Annual Cost: = 15)+16)+17)+18) +19)+21)+ annual labor cost Cost Per Sample: = annual cost / 1)
	16)	Annual cost of proficiency testing	Enter value	
	17)	Equipment price (purchased)	Enter value	
	18)	Cost of maintenance contract per year	Enter value	
	19)	Courier price per year	Enter value	
	20)	Total annual overhead	Enter value	
	21)	Test-specific annual overhead (based on sample #)	= [20) / 2)] * 1)	
	22)	Hourly rate of microbiologist salary & Benefits	Enter value	
	23)	Hourly rate of laboratory assistant salary & Benefits	Enter value	
	24)	Laboratory assistant time spent on whole batch (hours)	Enter value	
	25)	Laboratory assistant time spent on individual sample (hours)	Enter value	
	26)	Microbiologist time spent on whole batch (hours)	Enter value	
	27)	Microbiologist time spent on individual sample (hours)	Enter value	
	28)	Percent of test that benefits from batching	=[24)+26)]/[24)+25)+26)+27)]	
Qua-lity	29)	Internal turn-around time	Enter value	
	30)	Proficiency testing result	Enter value	
	31)	Test specific quality measure	Enter value	

Abbreviations: * = multiplication

Table 2 Summary statistics for the hepatitis testing volume increase in public health laboratory A.

	Output measures	2009	2011	Difference	2011 (37 Samples)*	Difference (From 2009)
Cost / revenue	Annual test-specific revenue	$352,131.91	$374,045.87	$21,913.97 (6.2%)	$352,941.91	$810.00 (0.2%)
	Revenue per sample	$25.12	$24.83	-$0.29 (-1.2%)	$25.10	-$0.03 (-0.1%)
	Annual test-specific cost	$263,160.69	$280,092.00	$16,931.31 (6.4%)	$263,825.17	$664.48 (0.3%)
	Cost per sample	$18.77	$18.59	-$0.18 (-1.0%)	$18.76	-$0.01 (-0.1%)
	Annual total net gain	$88,971.22	$93,953.87	$4,982.66 (5.6%)	$89,116.74	$145.52 (0.2%)
	Net gain per sample	$6.35	$6.24	-$0.11 (-1.7%)	$6.34	-$0.01 (0.2%)
Quality	Internal turn-around-time	1.85	1.15	-0.70 (-37.8%)	?	?
	Proficiency testing grade	100%	100%	0 (0%)	?	?

*This is a simulated scenario of the volume increase in 2011 consisting only of 37 samples.

Table 3 Summary statistics for the outsourcing of the hepatitis testing from public health laboratory B.

	Output measures	2009	2011	Difference	2009 (17 samples)*	Difference (from 2011)
Cost/ revenue	Annual test-specific revenue	$13,650.00	$755.00	-$12,895.00 (-94.5%)	$357.00	$398.00 (111.5%)
	Revenue per sample	$21	$44.41	$23.41 (111.5%)	$21	$23.41 (111.5%)
	Annual test-specific cost	$36,577.75	$942.23	-$35,635.52 (-97.4%)	$3,478.79	-$2,536.56 (-72.9%)
	Cost per sample	$56.27	$55.43	-$0.85 (-1.5%)	$204.63	-$149.21 (-72.9%)
	Annual total net gain	-$22,927.75	-$187.23	$22,740.52 (-99.2%)	-$3,121.79	$2,934.56 (-94.0%)
	Net gain per sample	-$35.27	-$11.01	$24.26 (-68.8%)	-$183.63	$172.62 (-94.0%)
Quality	Internal turn-around-time	2.12	9.29	7.17 (338.2%)	?	?
	Proficiency testing grade	100	N/A	N/A	?	?

*This is a simulated scenario of the testing volume being only 17 samples in 2009.

Table 4 Summary statistics for the HIV viral load testing volume increase in public health laboratory A.

	Output measures	2009	2011	Difference
Cost/ revenue	Annual test-specific revenue	$38,782.49	$117,850.59	$79,068.10 (203.9%)
	Revenue per sample	$25.12	$48.12	$23.00 (91.6%)
	Annual test-specific cost	$106,421.17	$167,941.12	$61,519.95 (57.8%)
	Cost per sample	$68.93	$68.58	-$0.35 (-0.5%)
	Annual total net gain	-$67,638.69	-$50,090.53	$17,548.16 (-25.9%)
	Net gain per sample	-$43.81	-$20.45	$23.35 (-53.3%)
Quality	Internal turn-around-time	3.197	2.457	-0.74 (-23.2%)
	Proficiency testing grade	100	100	0

Table 5 Summary statistics for the outsourcing of the HIV viral load testing from public health laboratory C.

	Output measures	2011 in-house*	2011 outsourced	Difference	2011 in-house (high reagent price)*	Difference (from outsourced)
Cost/ revenue	Annual test-specific revenue	$76,000.00	$0.00	$76,000.00 (100%)	$76,000.00	$76,000.00 (100.0%)
	Revenue per sample	$100	$0	$100 (100%)	$100	100 (100.0%)
	Annual test-specific cost	$52,774.68	$17,915.58	$34,859.10 (66.1%)	$231,747.08	$213,831.50 (92.3%)
	Cost per sample	$69.44	$23.57	$45.87 (66.1%)	$304.93	$281.36 (92.3%)
	Annual total net gain	$23,225.32	-$17,915.58	$41,140.90 (177.1%)	-$155,747.08	-$137,831.50 (88.5%)
	Net gain per sample	$30.56	-$23.57	$54.13 (177.1%)	-$204.93	-$181.36 (88.5%)
Qua- lity	Internal turn-around-time	?	8.75	?	?	?
	Proficiency testing grade	?	N/A	?	?	?

*These are simulated scenarios of the public health laboratory performing the test in-house at two different reagent prices.

Table 6 Summary statistics for the HIV viral load testing volume increase in public health laboratory D.

	Output measures	2008	2009	Difference
Cost/ revenue	Annual test-specific revenue	$90,300.00	$150,300.00	$60,000.00 (66.5%)
	Revenue per sample	$100	$100	$0 (0%)
	Annual test-specific cost	$81,186.56	$134,676.36	$53,489.80 (65.9%)
	Cost per sample	$89.91	$89.61	-$0.30 (-0.3%)
	Annual total net gain	$9,113.44	$15,623.64	$6,510.20 (71.4%)
	Net gain per sample	$10.09	$10.39	$0.30 (3.0%)
Quality	Internal turn-around-time	4.00	5.72	1.72 (43.0%)
	Proficiency testing grade	100	100	0 (0%)

Table 7 Summary statistics for the outsourcing of the HIV viral load testing from public health laboratory E.

	Output measures	2009 in-house*	2009 outsourced	Difference	2009 in-house (high reagent)*	Difference (from outsourced)
Cost/ revenue	Annual test-specific revenue	$19,200.00	$0.00	$19,200.00 (100.0%)	$19,200.00	$19,200.00 (100.0%)
	Revenue per sample	$100.00	$0	$100.00 (100.0%)	$100.00	$100.00 (100.0%)
	Annual test-specific cost	$18,183.72	$2,768.92	$15,414.80 (84.8%)	$140,604.84	$138,401.99 (98.4%)
	Cost per sample	$94.71	$14.42	$80.29 (84.8%)	$732.32	$720.84 (98.4%)
	Annual total net gain	$1,016.28	-$2,768.92	$3,785.20 (372.5%)	-$121,704.84	-$119,501.99 (98.2%)
	Net gain per sample	$5.29	-$14.42	$19.71 (372.5%)	-$632.32	-$620.84 (98.2%)
Quality	Internal turn-around-time	?	20.88	?	?	?
	Proficiency testing grade	?	N/A	?	?	?

*These are simulated scenarios of the public health laboratory performing the test in-house at two different reagent prices.

Table 8 Overall comparison of the three case studies examining the sharing of testing services.

	Volume increase due to specialization	Change in revenue per sample	Change in cost per sample	Change in annual profit	Change in turn-around-time
Hepatitis - PHL A	0.3% (High volume test)	-$0.03 (0.1%)	-$0.01 (0.1%)	$145.52 (0.2%)	37.8%
Hepatitis - PHL B*	(sent 17 samples)	$23.41 (111.5%)	-$149.21 (72.9%)	$2,934.56 (94.0%)	38.2%
HIV Viral Load - PHL A*	49.2% (High volume test)	$24.49 (97.5%)	-$0.31 (0.4%)	$23,855.47 (35.3%)	-23.1%
HIV Viral Load - PHL C*	(sent 760 samples)	-$100 (100%)	-$281.36 (92.3%)	137,831.50 (88.5%)	?
HIV Viral Load - PHL D	15.2% (low-to-moderate volume test)	$0	-$0.30 (0.3%)	$6,510.20 (71.4%)	43.0%
HIV Viral Load - PHL E*	(sent 137 samples)	-$100 (100%)	-$720.84 (98.0%)	$119,501.99 (97.7%)	?

Abbreviations: PHL = Public health laboratory *The laboratory operates this test at a loss

9. LIMITATIONS & ASSUMPTIONS

The research conducted for this dissertation focused solely on the PHLs of California. It is a unique system with many more local PHLs than other states have. This presents unique possibilities as well as problems. Many policy makers question the necessity of having as many as 35 laboratories in close proximity. However, California has always been at the forefront of PH and has long been a model for other states. As described above, the local PHLs of California are essential to protect the health of the public in their jurisdiction and contribute to the PH excellence of the state. This warrants the research reported here, which examines another survival strategy for the local laboratories to improve their cost-effectiveness, quality of testing and expertise. Although focused mainly on California, many aspects of the research can be translated to situations in other states. The survey could be slightly modified to elicit information about volume increases and specialization in states that have multiple PHLs. It could also be used to examine any service sharing between different state PHLs. And although the results from the two case-study projects are mainly applicable in California, where local laboratories are abundant and within close proximity, the CEEM can be used in any laboratory setting.

The survey was delivered to the participants in different formats. Most PHLDs filled it out online through the Qualtrics software. However, four respondents filled out hard-copies of the survey presented to the directors during the CAPHLD annual meeting in October of 2013, and one director, head of two laboratories, was interviewed in person. The different modes of presentation of the questions may have prompted participants to answer differently, although the impact remains elusive. The laboratories that didn't participate in the survey were two small and two medium sized PHLs. Although a very high response rate was achieved, it is possible that a common reason caused these four laboratories not to respond (e.g. extreme understaffing), which would have been valuable information to have.

For both case-study projects, participants were selected based on availability of the laboratories. No other PHLs were, at the time, willing or able to participate. Therefore, a bias towards PHLs that have the man-power and time available to participate in research projects is conceivable. However, many other laboratories did have the staff available to achieve volume increases and to collaborate with other PHLs. Only 4 of 13 identified past volume increases, and 3 of 11instances of shared testing services were examined. These case numbers may not be sufficient to generalize the findings to the other scenarios. The study of further examples of volume increases and specialization may shed more light on the effects of those strategies on cost-effectiveness and quality of testing in different situations.

Finally, this dissertation was heavily focused on the financial and economical aspects of increasing volumes and sharing services. This was due mainly to the increasing demands of policy makers for their laboratories to be more cost-effective and operate with much less funding. By addressing and complying with these demands, the PHLs were deemed to have a higher survival chance from the administrative viewpoint, by retaining their current clients and reclaiming some of their testing lost to private laboratories. In addition, PHLs have to maintain or improve their quality of service. There are many aspects of quality. For each case-study project the most easily measured quality indicators (TAT and proficiency testing grades) were considered. More important, but harder to measure, are other facets of quality, e.g. customer service and PH impact, were not included in this research, but should be explored in subsequent studies.

10. CONCLUSIONS

The economic challenges, such as workforce shortages and budget cuts, faced by the Californian PHLs have been well known and previously described.[2] However, through the survey conducted for the first paper of this dissertation, the main challenge of testing volumes lost to commercial laboratories emerged. This challenge is only partially due to economic forces which would prevent PHLs from investing in new technologies and from providing customer service at the same level as private laboratories. The PHLs are also faced with administrative and health policies that hinder their competition with their commercial counterparts. The resulting loss of testing volumes is problematic because costs per sample increase and cost-effectiveness decreases. Particularly the inefficiencies of extremely low volume tests have been highlighted in the case studies of specialization described here, where it would be absolutely unfeasible for the outsourcing PHLs to perform the assay in-house at their current volume. The benefits of increasing the number of specimens have been confirmed through the four case studies of past volume increases. Regardless of prior test-specific volume, all PHLs were able to decrease their cost and maintain or improve their quality of testing. The annual revenue was typically increased as well, which was enhanced if the most of the new volume came from a source, such as another PHL, that reimbursed fully for the test. The participants of the survey indicated that they were most likely to focus their efforts to increase volumes on tests of particular PH importance that were in high demand in their community. The main barriers faced were competition with commercial laboratories, insufficient funding, workforce and administrative support. Overall, volume increases seem to be a preferred strategy of the directors to improve services in their PHLs.

The main strategy to increase testing volumes examined with this research, was the sharing of low-to-moderate volume testing services among neighboring PHLs, also termed specialization. The three case studies examined in the third paper of this dissertation demonstrated that all laboratories involved in this approach were able to benefit from it. They all decreased their costs and improved their annual and per-sample net gain (either through gaining profit or decreasing loss). The TAT in specialized laboratories was for the most part decreased, while it increased for the outsourcing PHLs. In the survey the majority of PHL directors agreed that specialization in low-to-moderate volume tests can produce cost-effectiveness, improve quality and strengthen the PHL network. They also indicated that low volume tests, with high costs, were the ideal candidates to outsource. Specialization in low-to-moderate volume tests seems to be at least a partial solution to improving PHLs' cost-effectiveness and quality and could potentially better their chances of survival.

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12. Appendix

1. The following 14 pages include the survey handout that was given to attendees of the semi-annual meeting of the California Association of Laboratory Directors. The majority of participants filled out the survey online via the Qualtrics software, which had the same questions but in a slightly different format.

Assessing the Feasibility of Implementing Specialization in Low-to-Medium Volume Tests

Dear laboratory directors,

Please answer the following questions to the best of your ability. The more descriptive information you provide the more helpful it will be for my analysis of the results and the more inclusive my final report will be. The whole survey should not take you much more than 15 minutes to complete.

If you are heading multiple laboratories, I would like to ask you to fill out one survey for each lab. You are welcome to have your assistant director or laboratory manager complete the answers in your place. If you run into any technical problems or have any questions, feel free to contact me any time at annabaker84@yahoo.com or 803-445-7133.

Your participation in this study is absolutely voluntary and refusal to participate or the decision to discontinue the survey at any point will involve no penalty or loss of benefits to you. There will be no costs, risks or discomforts inflicted upon you.

The data acquired will be handled as confidentially as possible. If results of this study are published or presented, individual names and other personally identifiable information will not be used. De-identified data may also be shared with the other laboratory directors. Please indicate how you wish to proceed:

- ❍ I've read and understood all the information presented to me above and agree to all of the conditions mentioned. I choose to participate in this survey.
- ❍ I do not agree and choose not to participate in this survey.
  (Would you be so kind to specify the reasons why you chose to discontinue the survey?)

  _____

  _____

  → *If you select this choice, please skip to the end of this survey.*

Q 1.1 **Please enter your name:** _____

Q 1.2 **Please enter the name of your local public health laboratory:**

_____

Q 1.3 **What is your position at the laboratory?** *(Please select ONE of the following choices.)*

- ❍ Laboratory director
- ❍ Assistant laboratory director
- ❍ Laboratory manager
- ❍ Other (*please specify*): _____

Q 2.1 **Please estimate the total annual volume of tests performed in your laboratory:**
(Include all testing; dairy, environmental, public health, clinical, ... Please select ONE of the following choices.)

- ❍ less than 10,000 tests per year
- ❍ 10,001 to 25,000 tests per year
- ❍ 25,001 to 50,000 test per year
- ❍ 75,001 to 100,000 tests per year
- ❍ Greater than 100,000 tests per year

Q 2.2 **Approximately how large is the population your laboratory serves?** *(Please select ONE of the following choices.)*

- ❍ Less than 50,000 people
- ❍ 50,001 to 100,000 people
- ❍ 100,001 to 250,000 people
- ❍ 250,001 to 500,000 people
- ❍ 500,001 to 1,000,000 people
- ❍ 1,000,001 to 3,000,000 people
- ❍ over 3,000,000 people

Q 2.3 **Please indicate the number of Full Time Equivalents (FTEs) that are currently employed and that are vacant in your lab:**
(Do NOT place an employee in more than one category, although you are welcome to use partial FTEs (0.5, 0.3); place a 0 for the categories your lab does not have.)

	FTEs currently employed	FTEs currently vacant
Laboratory director		
Assistant director/manager		
Senior Microbiologist		
Public Health Microbiologist		
Laboratory assistant/technician		
Clerical staff		
Clinical Laboratory Scientists		
Others (*please specify*): _____		

Q 2.4 **Please indicate how severely your laboratory has been affected by the following challenges:**
(For each challenge select ONE of the following choices. Please feel free to leave comments about any of the challenges in the space provided.)

	Not at all affected	Mildly affected	Moderately affected	Severely affected	Please leave any comments about the challenges
Budget cuts	❍	❍	❍	❍	
Lost testing to non-PH labs	❍	❍	❍	❍	
Workforce shortage	❍	❍	❍	❍	
Administrative opposition	❍	❍	❍	❍	
Others (please specify): _____	❍	❍	❍	❍	

Q 3.1 **Have you, IN THE PAST 5 YEARS, achieved a significant increase in sample volume in a specific testing area through any of the following methods? Significant, in this case, means an increase to a sustained level above normal fluctuation.**
(Please select all that apply and indicate which tests were affected. Please also indicate whether the increased volume came from the public sector, private sector or both.)

	Select all methods that helped you achieve a volume increase.	Please enter all tests that were affected by the method.	The source of the increased testing volume was:			
			Public sector	Private sector	Both sectors	Not sure
Collaboration/sharing of testing services with another PHL	❑		❍	❍	❍	❍
Implementation of a new Laboratory Information Management System	❑		❍	❍	❍	❍
Acquisition of a new technology	❑		❍	❍	❍	❍
Restructuring of health services	❑		❍	❍	❍	❍
Research project	❑		❍	❍	❍	❍
Others (please specify): _____	❑		❍	❍	❍	❍
We have not been able to increase our sample volume in any area	❑		❍	❍	❍	❍

Q 3.2 **Are you CURRENTLY trying to achieve an increase in sample volume in a specific testing area through any of the following methods?**

(Please select all that apply and indicate which tests might be affected. Please also indicate where you expect the new sample volume might originate, in the public sector, private sector or both.)

	Please select all methods that you are planning on using.	Indicate all tests that might be affected by the methods.	Expected source of new sample volume:			
			Public sector	Private sector	Both sectors	Not sure
Collaboration/sharing of testing services with another PHL	❑		❍	❍	❍	❍
Implementation of a new Laboratory Information Management System	❑		❍	❍	❍	❍
Acquisition of a new technology	❑		❍	❍	❍	❍
Restructuring of health services	❑		❍	❍	❍	❍
Research project	❑		❍	❍	❍	❍
Other (please specify): _____	❑		❍	❍	❍	❍
We are currently not able to pursue a sample volume increase in any testing area	❑		❍	❍	❍	❍

Q 3.3 **Please rank the importance of the following characteristics when considering a test for a potential sample volume increase:**
(Please enter the number you would like the characteristics to have in the space provided, from 1 being most important to 12 being least important.)

_____ The test is largely automated.
_____ The cost of the test does not exceed the revenue (achieved through reimbursement, specific funding, ...).
_____ The health officer supports the decision.
_____ The necessary expertise exists in the laboratory.
_____ The lab provides surge capacity for this test to the State.
_____ The test is of public health importance.
_____ The test is technically easy to perform.
_____ The required turn-around time is easily met.
_____ There is a high demand for the test.
_____ The capacity and capability to increase volume already exist in the lab.
_____ The decision is supported by administration.
_____ Other labs (public or private) in the area do not offer this test.

Q 3.4 **Please suggest any other characteristics that should be considered in the decision of increasing testing volume and indicate how important the characteristics might be:**
(Enter 'none' if you have no further suggestions.)

_____
_____
_____
_____

Q 3.5 **What barriers have you encountered or are expecting when trying to achieve an increase in sample volume?**
(Please enter 'none' if you have not encountered or do not expect any.)

_____
_____
_____
_____

Q 3.6 **What factors and circumstances have been or would be helpful to achieve an increase in sample volume?**
(Please enter 'none' if you have not encountered any or do not have any further suggestions.)

____

____

____

____

Q 4.1 **Do you currently RECEIVE samples in a particular testing area from another public health lab on a regular basis (this would mean that you have specialized in this test)?** *(Please select ONE of the following choices.)*

- ❍ Yes → *Please answer Q4.2, then skip to Q4.5.*
- ❍ No → *Please skip to Q 4.3 and continue the survey from there.*

Q 4.2 **For which test do you currently receive samples from what public health laboratory?**
(Please also indicate how the cost, revenue and quality of the tests were affected by this additional sample volume. Only choose ONE answer choice for each category.)

Please indicate the test for which you receive samples.	Enter all public health labs from which you receive samples for this test.	Indicate how the cost per sample of this test was affected in your laboratory.				Indicate how the revenue of the test was affected in your laboratory.				Indicate how the quality of the test was affected in your laboratory.			
(Only enter one test per row.)	(Feel free to enter multiple labs per row.)	Incre ased	Didn't change	Decre ased	Not sure	Incre ased	Didn't change	Decre ased	Not sure	Impr oved	Didn't change	Decli ned	Not sure
		❍	❍	❍	❍	❍	❍	❍	❍	❍	❍	❍	❍
		❍	❍	❍	❍	❍	❍	❍	❍	❍	❍	❍	❍
		❍	❍	❍	❍	❍	❍	❍	❍	❍	❍	❍	❍
		❍	❍	❍	❍	❍	❍	❍	❍	❍	❍	❍	❍
		❍	❍	❍	❍	❍	❍	❍	❍	❍	❍	❍	❍
		❍	❍	❍	❍	❍	❍	❍	❍	❍	❍	❍	❍

→ *Please skip to Q4.5.*

Q 4.3 **Please describe factors that may have hindered you from specializing in a certain test**:

_____
_____
_____
_____

Q 4.4 **If circumstances were more favorable for specialization and the barriers you described in question 4.3 would not exist, is there a particular testing area that you would like to focus on?**
(Please select ONE of the following choices.)

- ❍ Yes, in that case we would like to specialize in the following testing areas: *(Please list the tests you would be most interested in.)*
  _____
- ❍ We would like to specialize in a testing area but are not sure which one.
- ❍ No, we would not be interested in specializing.

Q 4.5 **Do you CURRENTLY utilize the services of another LOCAL public health lab (not the State lab) on a regular basis for a test your lab does not perform?**
(Please select ONE of the following choices.)

- ❍ Yes → *Please continue the survey with Q4.6.*
- ❍ No → *Please skip Q4.6 and continue the survey with Q4.7.*

Q 4.6 **For which tests do you currently utilize the services of another LOCAL public health laboratory?**
(If your laboratory has performed these test in the past please also indicate how the cost, revenue and quality of the tests were affected by the service change of sending them to another lab. If your lab has always send samples for the tests to the other laboratory, please leave the columns about the cost, revenue and quality change blank. Select only ONE answer choice for each category.)

Please indicate the TEST you send to another public health lab.	Enter the PUBLIC HEALTH LAB to which you send the samples for this test.	Has your laboratory performed this test in the past		Indicate how the cost per sample was affected by the service change to the other lab.				Indicate how the revenue of the test in your lab was affected by the service change to the other lab.				Indicate how the quality of the test was affected by the service change to the other lab.			
(Only enter one test per row.)	(Please enter the main lab you send specimen to.)	Yes	No	Increased	Didn't change	Decreased	Not sure	Increased	Didn't change	Decreased	Not sure	Improved	Didn't change	Declined	Not sure
		❍	❍	❍	❍	❍	❍	❍	❍	❍	❍	❍	❍	❍	❍
		❍	❍	❍	❍	❍	❍	❍	❍	❍	❍	❍	❍	❍	❍
		❍	❍	❍	❍	❍	❍	❍	❍	❍	❍	❍	❍	❍	❍
		❍	❍	❍	❍	❍	❍	❍	❍	❍	❍	❍	❍	❍	❍
		❍	❍	❍	❍	❍	❍	❍	❍	❍	❍	❍	❍	❍	❍
		❍	❍	❍	❍	❍	❍	❍	❍	❍	❍	❍	❍	❍	❍

Q 4.7 **Are you utilizing the services of a commercial/private lab for tests your laboratory does not perform?**
(Please select ONE of the following choices.)

❍ Yes → *Please continue the survey with Q4.8.*
❍ No → *Please skip Q4.8 and continue the survey with Q4.9.*

Q 4.8 **Please indicate which tests you send to a commercial/private laboratory and whether the possibility exists of sending the samples to a local public health lab instead.**
(Feel free to leave any comments about these tests in the space provided.)

	Which tests do you send to commercial/private labs?	Does the possibility exist to send the samples to a local PH lab.			Leave any comments about these tests in the space below:
	(Please only enter one test per row.)	Yes	No	Not sure	
Test No. 1		❍	❍	❍	
Test No. 2		❍	❍	❍	
Test No. 3		❍	❍	❍	
Test No. 4		❍	❍	❍	

Q 4.9 **Are there any other tests your lab is currently performing that you would prefer to send to another LOCAL public health lab?**
(Please select ONE of the following choices.)

❍ Yes → *Please continue the survey with Q4.10.*
❍ No → *Please skip Q4.10 and continue with Q4.11.*

Q 4.10 **Please indicate which tests you'd like to send to which LOCAL PHL and the reasons why you'd like to send them (e.g. volume is too low to be sustainable, the other lab employs a specialist in this area,...).** *(You are also welcome to comment on any barriers.)*

	Indicate which test you'd like to send to another PHL:	If known, indicate to which LOCAL PHL you would like to send this test.	Indicate the reasons why you would like to send this test out:	Please comment on any barriers that may have kept you from sending this test to another lab:
Test No. 1				
Test No. 2				
Test No. 3				
Test No. 4				

Q 4.11 **Please rank the importance of the following characteristics when considering to transfer an in-house test to another LOCAL PHL.**
(Please enter the number you would like the characteristics to have in the space provided, from 1 being most important to 12 being least important.)

_____ The test mainly consists of manual labor.
_____ The cost of the test exceeds the revenue gained (including reimbursement, specific funding,...).
_____ Your health officer supports the decision.
_____ The necessary expertise exists in the other laboratory.
_____ Your lab does not provide surge capacity to the state for this test.
_____ Your testing volume is low.
_____ The test is not a public health priority in your region.
_____ The test is technically challenging.
_____ The required turn-around time would be achievable even with the added transport to the other lab.
_____ The capacity and capability exists in the other laboratory to increase its volume.
_____ The decision is supported by your administration.
_____ Many local laboratories (private or public) offer the test in and around your jurisdiction.

Q 4.12 **Please suggest any other characteristics that should be considered in the decision of utilizing the services of another LOCAL public health laboratory for a test:**
(Enter 'none' if you have no further suggestions.)

Q 4.13 **Overall, what barriers have you encountered or are anticipating when trying to share testing services between neighboring public health laboratories?**
(Please enter 'none' if you have not encountered or do not expect any.)

Q 4.14 **Overall, what factors and circumstances have been or would be helpful when trying to share testing services among neighboring public health laboratories?**
(Please enter 'none' if you have not encountered any or do not have any further suggestions.)

Q 5.1 **Please select how strongly you agree or disagree with the following statements:**
(Please select ONE of the following choices. You are also welcome to comment on any of the statements in the space provided.)

	Please choose how strongly you agree with all of these statements					Please feel free to leave any comments about the statements.
	Strongly agree	Agree	Neither agree nor disagree	Disagree	Strongly disagree	
Sample volume increase in a previously LOW-TO-MODERATE VOLUME test can improve the COST-EFFICIENCY of local PHLs.	❍	❍	❍	❍	❍	
Sample volume increase in a previously HIGH VOLUME test can improve the COST-EFFICIENCY of local PHLs.	❍	❍	❍	❍	❍	
Sample volume increase in a previously LOW-TO-MODERATE VOLUME test can improve the testing QUALITY of local PHLs.	❍	❍	❍	❍	❍	
Sample volume increase in a previously HIGH VOLUME test can improve the testing QUALITY of local PHLs.	❍	❍	❍	❍	❍	
SPECIALIZATION, or the sharing of LOW-TO-MODERATE VOLUME testing among several neighboring PHLs, can improve the COST-EFFICIENCY of local PHLs.	❍	❍	❍	❍	❍	
SPECIALIZATION can improve the testing QUALITY of local PHLs.	❍	❍	❍	❍	❍	
Specialization can strengthen the NETWORK of local PHLs in California.	❍	❍	❍	❍	❍	

Q 5.2 **Do you have a tool to evaluate the impact of a previous or prospective service change (such as specialization or volume increase) on quality and cost-efficiency?** *(Please select ONE of the following choices.)*

- ❍ Yes, we do have a tool; it is *(please specify)*: _____
- ❍ No, we do not have a tool, but it may be useful to have
- ❍ No, we do not have a tool and do not anticipate ever needing one

Q 5.3 **Please describe the most helpful elements such an evaluation tool should have:**

_____
_____
_____
_____

Q 5.4 **If I have any follow-up questions, would you allow me to contact you?**

- ❍ Yes → *Please answer Q5.5.*
- ❍ No → *Please skip to the end of the survey.*

Q 5.5 **What is the best way to contact you?**
(Please check all that apply and enter your contact information in the space provided.)

- ❑ Email _____
- ❑ Phone _____
- ❑ In person

Thank you so very much for taking the time to complete this survey.
Your collaboration is greatly appreciated.
The results of this study will be presented to the laboratory directors at the next CAPHLD (California Association of Public Health Laboratory Directors) meeting after the completion of this research.