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California's Public Health Laboratories: Inter-organizational cooperation models to bolster
laboratory capacity

By

Kristina Hsieh

A dissertation submitted in partial satisfaction of the

requirements for the degree of

Doctor of Public Health

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of the

University of California, Berkeley

Committee in charge:

Professor Gertrude C. Buehring, Chair

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Professor James R. Lincoln

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Abstract

California's Public Health Laboratories: Inter-organizational cooperation models to bolster laboratory capacity

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Professor Gertrude C. Buehring, Chair

Background: California has 61 local health departments that are currently served by 37 local public health laboratories. These laboratories act as the first line of defense against health threats by providing community disease surveillance, food and environmental safety testing, newborn disease screening, identification of causal agents during an outbreak, and national disease screening for biological agents of warfare, resulting in a decreased burden on the health care system. In January 2009, the Little Hoover Commission released a report "First Year Checkup: Strategies for a Stronger Public Health Department" to address ways in which the California Department of Public Health can improve public health and safety. One of the five major recommendations made was for the California Department of Public Health to continue to provide leadership to strengthen the state's laboratory capacity by helping to facilitate consolidation of county public health laboratories into regional laboratories. Due to the California budget crisis and the shortage of public health laboratory directors qualified to run laboratories, regionalization has been proposed as a strategy to address resource constraints as well as to obtain economies of scale in the provision of laboratory services. However, there is resistance from a subset of county public health laboratory directors as well as county health officers to regionalize local public health laboratories. In addition, neither the California Department of Public Health nor the state has the legal authority or financial resources to enforce county public health laboratory regionalization. The rationale and the feasibility of implementing the Little Hoover Commission's recommendation need to be more thoroughly explored.

Purpose: This dissertation research was conducted to incorporate the perspectives of county public health laboratory directors, county health officers, and state public health officials in order to assess whether reorganization of county public health laboratories is a feasible solution to bolster California's public health laboratory capacity. **Methodology:** Case studies of inter-organizational forms of cooperation among public health laboratories in California were conducted to assess necessary "factors of success" when engaging in an inter-organizational partnership between public health laboratories. Qualitative interviews were also conducted with public health laboratory directors, health officers, and state public health officials to assess 1) the

feasibility of public health laboratories engaging in inter-organizational partnerships and 2) the impact that an inter-organizational partnership will have on addressing the state's insufficient PHL capacity. Lastly, policy options aimed at bolstering the state's laboratory capacity were proposed based on findings from the case studies and the interviews. **Findings:** Analysis of the data collected through the case studies and qualitative interviews with public health laboratory directors, county health officers and state public health officials suggests that an inter-organizational form of cooperation such as a regionalization effort of local county public health laboratories led by the state is not a feasible solution to help bolster laboratory capacity. However, a consolidation effort of public health laboratories led by county administrators and public health laboratory directors through a joint powers agreement is a potential solution for 1) ensuring affordable and continuous provision of public health laboratory testing services for all public health departments and 2) a short-term measure to address the shortage of board certified, doctoral level public health laboratory directors available to supervise laboratories located in rural counties. The three policy options that would be effective at addressing the state's insufficient laboratory capacity include 1) amend the state PHLD requirements, 2) promote locally driven PHL consolidation efforts through utilization of joint powers agreements and 3) provide state funding for PHL services in rural counties.

DEDICATION

To Mrs. Joan Murray, this could not have been possible without you.

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Experience: that most brutal of teachers. But you learn, my God do you learn.
-C.S. Lewis

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Abbreviations

Abbreviation	
AAFP	American Academy of Family Physicians
APHL	Association of Public Health Laboratories
ARUP	Associated Regional and University Pathologists
BDP	Berkeley Daily Planet
BSL	Biosafety Level
BT	Bioterrorism Threat
CA-DoT	California Department of Transportation
CAPHLD	California Association of Public Health Laboratory Directors
CDC	Centers for Disease Control and Prevention
CDPH	California Department of Public Health
CLIA	Clinical Laboratory Improvement Act
CLIA'88	Clinical Laboratory Improvement Amendment of 1988
CMS	Centers for Medicaid and Medicare Services
DGS	Department of General Services
FDA	Food and Drug Administration
IOM	Institute of Medicine
HHS	Health and Human Services
HRSA	Health Resources and Services Administration
HO	Health Officer
IOM	Institute of Medicine
JPA	Joint Powers Agreement
KP	Kaiser Permanente
LAO	Legislative Analyst's Office
LFS	Laboratory Field Services
LHC	Little Hoover Commission
LRN	Laboratory Response Network
MOU	Memorandum of Understanding
PH	Public Health
PHD	Public Health Department
PHL	Public Health Laboratory
PHLD	Public Health Laboratory Director
PHM	Public Health Microbiologist
RDT	Resource Dependence Theory
TAT	Turn-Around Time

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Chapter One: Introduction

The Little Hoover Commission (LHC), formerly known as the Milton Marks “Little Hoover” Commission was created in 1962 as an independent state oversight agency. Its mission is to investigate state government operations, and through reports, recommendations and legislative proposals, help promote efficiency, economy, and improved services for California. The LHC is comprised of a bipartisan board of 13 individuals: five citizens appointed by the governor, four citizens appointed by the legislature, and two senate and two assembly members. The six main areas of government operation that the LHC investigates include 1) education, 2) energy, environment and resources, 3) general government, 4) health and human services, 5) infrastructure and 6) public safety. The topics they consider come to their attention through citizens, legislators and other sources. It also has a statutory obligation to review and make recommendations on government reorganization plans (LHC 2009a). Unlike other state and private sector entities that analyze and evaluate state programs, the LHC reviews how programs could and should function, crafts documented reports for legislation and follows through with legislation and or administrative changes to implement its recommendations.

In 2003, the LHC assessed California’s preparedness level following the September 11, 2001 attacks and found that the public health (PH) system was the “weakest link in California’s homeland defense.” One of the major recommendations from this assessment was for a new Department of Public Health to be created within the Department of Health Services that would allow the department to operate public health programs separate from the health care programs for low income and uninsured Californians i.e. MediCal (LHC 2003). In 2006 the California Public Health Act was passed which reorganized the Department of Health Services into two departments: 1) the California Department of Health Care Services (DHCS) which focuses on patient care delivered by Medi-Cal, and 2) the California Department of Public Health (CDPH), in charge of public health programs that protect Californians from environmental contamination, disease and infection (LHC 2009b). With the creation of a separate department of public health California hopes to prioritize public health concerns such as tracking and monitoring emerging and reemerging diseases, foodborne outbreaks, bioterrorist attacks, and prevention of epidemics. It is also hoped that the reorganization will elevate the visibility and responsibility of the Public Health Department (PHD) to the same level as other first responders like the police or fire department in the eyes of the state and the community (LHC 2003).

In January 2009, the LHC conducted a comprehensive assessment of the reorganization of the CDPH that was mandated in 2006 and implemented in 2008. A major finding from their report, “First Year Check-up: Strategies for a Stronger Health Department” was that there is a major deficiency in public health laboratory (PHL) capacity due to limitations in testing capacity and shortages in the workforce, especially public health laboratory directors (PHLDs). The adequate supply of the PHLD workforce has been affected since the introduction of the federal Clinical Laboratory Improvement Amendment in 1988 (CLIA’88). This amendment mandates that PHLDs have a doctoral degree and a board certification to supervise an accredited PHL. Federal law supersedes the state requirement that a PHLD need only have a bachelor’s degree to supervise and manage a PHL. However, if there were more stringent regulations in the state pertaining to the qualifications for the PHLD, the state could enforce those requirements. To become a PHLD in California one must meet the federal requirement of having a doctoral degree

and a board certification from an approved national accreditation program. The state requirements include a baccalaureate level public health microbiologist (PHM) certification and four years training in a PHL, two of which are in a supervisory PHM capacity. Due to the combination of the federal and state requirements for the PHLD a workforce shortage has developed in California. There is a limited pipeline of qualified applicants able to replace many of the PHLDs that will be retiring from the local county PHLs in the next few years. This is significant because without a CLIA'88 qualified PHLD supervising the PHL, a PHL is required to shut down. In order to address this concern one of the recommendations made by the LHC in their 2009 report stated that:

The California Department of Public Health should continue to provide leadership to develop the state's laboratory capacity.

- *The department should facilitate consolidation of county laboratories into regional laboratory programs.*
- *The department should determine its laboratory capacity priorities and ask the governor and Legislature to help lift barriers to workforce development, such as microbiologist salary structures that cannot compete with private and county laboratories.*

While a regionalization effort would decrease the number of PHLs and as a result decrease the number of PHLDs needed to supervise the laboratories, regionalization of PHLs is not well received by a subset of PHLDs and HOs and has continued to be a topic of debate among state PH officials and county PHLDs for the past two decades. A subset of local PHLDs have expressed that 37 county PHLs are necessary to provide rapid and quality testing services for their communities. However, state PH officials argue that regionalizing PHLs will not affect the quality of services provided to the community and will help alleviate workforce shortages and bolster laboratory capacity by obtaining economies of scale with regards to laboratory testing which will strengthen the public health laboratory network (LHC 2009b). The hypothesis of this dissertation research is that the LHCs report was based on insufficient data. The Commission did not 1) determine whether the local laboratories and their county health officers (HOs) would be willing to participate in a regionalization effort and 2) determine how the CDPH can help facilitate a regionalization effort when the counties function and operate independently from the state. The specific aims of this research are to address the following primary and secondary questions:

Primary Research Question:

Would inter-organizational partnerships among California's county public health laboratories be a feasible solution to address insufficient state laboratory capacity?

Secondary Research Questions:

- 1) What effect would inter-organizational partnerships have on laboratory capacity and on the demand for laboratory directors?
- 2) How can the California Department of Public Health provider leadership to help strengthen the state's PHL capacity?

This specific aims will be accomplished by 1) establishing determinants that are integral for the success of partnerships among PHLs through case studies of inter-organizational forms of

cooperation that have occurred between local PHLs, 2) obtaining the perspective of all local county PHLDs and a subset of HOs and state public health officials to determine whether regionalizing county PHLs is a feasible option to pursue among local counties and 3) policy options were developed based on the findings of the case studies and qualitative interviews to provide solutions to bolster the state's laboratory capacity. This dissertation will be the first attempt at incorporating the perspective of state public health officials as well as county PHLDs and HOs on the feasibility of regionalizing county PHLs.

The next section will describe a theoretical framework to identify determinants that predispose organizations to enter into inter-organizational relationships and define the three different types of strategic partnerships that will be assessed in this dissertation.

Theoretical Framework

With environmental constraints such as a shortage of the PHLD workforce, competition from clinical laboratories and decreased availability of funding to support county PHDs, regionalization of PHLs has been proposed as a solution to pool limited resources. Regionalization will result in fewer physical PHLs and is a mechanism to obtain economies of scale with respect to provision of PHL services as well as a means to reduce the number of CLIA'88 qualified PHLDs to manage PHLs. Inter-organizational forms of cooperation that will be examined in this dissertation as a means to manage environmental constraints¹ include regionalization of PHLs and two types of strategic alliances. The strategic alliances include a consolidation of PHLs through a joint powers agreement or contracting for the purposes of joint purchasing power and centralizing testing needs.

The complexities of engaging in inter-organizational relationships in health and human services domains may be better understood by drawing on theories and research in organizational sociology. There is an extensive body of organizational theory literature aimed at exploring and explaining why organizations enter into exchanges/ inter-organizational relationships² (Levine and White 1961, Aiken and Hage 1968, Schermerhorn, 1975, Oliver, 1990). The exchange approach³ introduced by Levine and White 1961 has been an important theoretical framework for addressing why health and social welfare agencies engage in inter-organizational exchange relationships. The decision to engage in a voluntary inter-organizational model of cooperation may be based on factors such as goal attainment (Levine and White 1961), internal efficiency benefits (Oliver, 1990), transaction cost efficiencies (Williamson, 1981), equalizing power advantages, (Pfeffer and Salancik 1978), and competition for resources (Pfeffer and Nowak 1976). Engagement in the relationship may help to provide stability in an unpredictable environment by securing access to resources available from the parties involved (Gulati and Sytch, 2007; Benson, 1975). Resources may encompass but not be limited to funding, facilities, services, clients, and the workforce (Reid, 1964).

¹ Definitions of these three types of inter-organizational relationship will be described in another section in this chapter

² Inter-organizational relationship-the relatively enduring transactions, flows and linkages that occur among or between an organization and one or more organizations in its environment through a conscious and intentional decision.

³ Exchange approach- any voluntary activity between two organizations which has consequences, actual or anticipated for the realization of organizations respective goals or objectives.

Examples of organizational factors that are important to consider prior to engagement in inter-organizational cooperation include: 1) geographical proximity of potential partners (Lincoln et. al., 1992; Reid, 1964); 2) an organization's internal capacity to support cooperative activities and mobilize resources (Warren, 1972); 3) the availability of resources to build and explore ventures (Aiken and Hage, 1968; Reid, 1964; Thompson and McEwen, 1958); 4) size (Adamek and Lavin, 1975; Laumann et. al., 1978); 5) financial standing (Allen, 1974; Laumann et. al. 1978); 6) organizational prestige (Hirsch, 1975; Young and Larson, 1965; Elling and Halebsky, 1961, Provan et. al., 1980); 7) obtainment of legitimacy (DiMaggio and Powell, 1983); 8) ensuring stability (Oliver, 1990); 9) response to crisis (Gueztkow, 1966; Schermerhorn, 1975) and 10) adaptation to environmental pressures (Clark, 1965).

In addition to the organizational factors listed above, there are also social determinants of inter-organizational relationship formation. Organizations are inclined to engage in exchanges with organizations with which they had prior relationships (Larson, 1992, Keister, 2001, Ring and Van de Ven, 1992), thus, social factors such as trust and social networks have increasingly been shown to predict the formation of inter-organizational relationships (Gulati, 1995, 1998). Social exchange processes that result in an establishment of embedded⁴ (Granovetter, 1985; Uzzi, 1996) relationships where there is mutual trust and a thick bond of ties among organizations helps to preserve and build long-term relationships. These relationships become increasingly stable over time by reducing uncertainty⁵ when exchanging with the partnering organization (Lincoln et. al., 1992, Keister, 2001; Beckman and Haunschild, 2004). Recently organizational scholars have found that social factors may spur engagement in inter-organizational form of cooperation more readily than obtainment of cost efficiencies or gain in power advantages (Gulati 1995, Zaheer et.al., 1998; Lincoln et. al, 1992; Keister, 2001). The PHL network through CAPHLD has established a long history of mutual trust and reliance garnered through camaraderie and active information and resource exchange which will be beneficial if PHLs decide to engage in an inter-organizational form of cooperation to address environmental constraints (Gulati and Gargiulo, 1999; Walker et. al., 1997; Zaheer, 1998).

Resource dependence theory (RDT) and the classical institutional theory framework of organizational sociology may be appropriate for understanding and predicting the type of inter-organizational relationship that county administrators as well as PHLs may choose to engage in to manage environmental constraints and secure access to limited resources

Resource Dependence Theory

Resource Dependence Theory (RDT) has implications of efficiency, however; it more often relies on power in explaining organizational outcomes (Pfeffer and Salancik, 1978; Benson, 1975). RDT was formalized by Pfeffer and Salancik in 1978, but the ideas of power relations between organizations were derived from the work of other organizational sociology theorists such as Levine and White (1961), Blau (1964), Thompson (1967), and Emerson (1962). RDT assumes that organizations strive to gain access to resources in order to minimize their dependence on other organizations and obtain control of resources that would require other organizations to depend on them (Pfeffer and Salancik, 1978). Thus, RDT focuses on 1) resources 2) the exchange of resources between organizations 3) dependencies and power

⁴ Embeddedness- refers to the process by which social relations shape economic action

⁵ Uncertainty- the difficulty firms have in predicting the future, which comes from incomplete knowledge.

differentials created as a result of unequal resources exchange 4) the constraining effects such dependence has on organizational action and 5) the efforts by organizational leaders to manage dependence (Thompson, 1967).

“Organizations are rational and adaptive. They need resources from the environment and face constraints from the environment, thus dependence leads to power imbalance and control attempts especially if resources are critical and high in uncertainty. Organizations must do something to reduce resource dependencies and reduce uncertainty.”-- Pfeffer and Salancik 1978

According to the resource dependence literature, there are three overarching principles that often guide an organization’s attempt to adapt and negotiate with the environment; 1) organizational decision-makers seek to ensure the continued survival of the organization via exchanges of resource and power within the environment (Pfeffer and Salancik, 1978; Thompson, 1967). Due to limited resources in the environment, this is achieved by safeguarding the flow of resources by adjusting the behavior and structure of the organization; 2) managers of organizations try and reduce external constraints that cause internal organizational disruption (Benson, 1993) and 3) in order to maintain organizational autonomy and adaptability, leadership within the organization will attempt to maximize their organizations independence (Pfeffer and Salancik, 1978; Silver, 1993). Therefore organizational actors e.g. PHLDs, HOs etc. will look for strategies to manage their dependence on the environment in order to minimize loss of power and autonomy while adapting to future environmental changes and contingencies (Pfeffer and Salancik, 1978). While the local PHLs do engage in inter-county exchanges of testing reagents and expertise, there has been resistance toward regionalization as a means to address environmental constraints because it would entail closure of a PHL. According to RDT, while an inter-organizational cooperation among counties for provision of PHL services may be cost efficient, it will not be a desirable option if county administrators are unable to maintain some form of authority/power with relation to the PHL and provision of laboratory services. Thus, RDT predicts that county administrators would choose the least constraining mechanism to manage interactions with exchange partners by choosing an inter-organizational relationship that would minimize dependence on another county while maximizing autonomy (Pfeffer and Salancik, 1978). Thus, strategic partnerships such as a strategic alliance through a consolidation of PHLs or a contract for joint purchasing power and centralized testing may be preferred.

Hypothesis: Under conditions of resource constraint county administrators will choose an inter-organizational form of cooperation such as a strategic alliance to maintain autonomy in decision making power for the PHL.

Institutional Theory

Another theory that may offer insight into organizational behavior and action surrounding inter-organizational exchange relationships is institutional theory introduced by Selznick in 1949. Institutional theory addresses the issue of social structure and how “schemas, rules, norms and routines” establish procedures for social behavior (Scott, 2004). “Institutionalization” is a social process where an organization’s culture, processes, strategies and structure acquires a “rule like status” which serves to legitimize the organization in the environment (Selznick, 1996; Meyer and Rowan 1977). The organization takes on a special character, competence and capacity

“infusion with value beyond the technical requirements of the task at hand” (Selznick 1949; Scott 2004). This process may not be concerned with efficiency, but rather social pressures from the environment and the idea of how things “should be done” (Selznick, 1996; Scott, 1995, 2004; Westphal et. al 1997; Meyer and Rowan, 1977, Scott 1995). According to many HOs interviewed for this dissertation, having a PHL operational within a county is the cornerstone for communicable disease control, which is a major function of the PHD. Having a PHL grants “legitimacy” to the PHD because it is viewed as common organizational practice to have available the services of a PHL as “close to the scene of action” as possible. While management of resource dependencies is important in deciding whether to engage in inter-organizational relations, the established culture and pressures from the institutional environment or perceived legitimacy of an organization following engagement in an inter-organizational relationship may equally influence the decision (DiMaggio and Powell, 1983; Meyer and Rowan, 1977, Tolbert and Zucker, 1983; Westphal et. al, 1997). Institutional theory’s focus on organizational culture and obtainment of legitimacy in the organizational environment predicts that PHDs will not likely participate in an inter-organizational relationship for provision of PHL services if their ability to conduct communicable disease control and surveillance is compromised. Thus, institutional theory like RDT predicts that county administrators would prefer to engage in an inter-organizational form of cooperation that would allow them direct access to a PHL such as strategic alliances.

Hypothesis: Under conditions of resource constraint county administrators will choose an inter-organizational relationship such as a strategic alliance to maintain the legitimacy of the PHD.

In addition to utilizing institutional theory as a framework for understanding inter-organizational relationships, institutional theory provides a lens to understanding why a subset of CAPHLD members have continued to pursue obtaining an amendment from the CLIA’88 requirements for California PHLDs. In a study of the rate of adoption of civil services reform, Tolbert and Zucker (1983) found that when coercive pressures such as state/federal regulations are imposed, organizations tend to quickly adopt new structures to meet the new requirements. However, if there is a lack of consensus on the value of a legal requirement, there are situations where organizations will choose not to adopt the requirement. Due to the addition of the “grandfather” clause in the CLIA’88 requirements for PHLDs, a subset of California PHLDs have continued to serve as PHLDs without having to obtain a board certification or doctoral degree. This has reduced the pressure for California PHLDs to meet the federal requirements. Currently, the majority of PHLDs supervising PHLs do not have a doctoral degree or board certification in spite of the fact that the CLIA’88 amendments were introduced more than 20 years ago. This culture has been “institutionalized” and accepted as legitimate by a subset of PHLDs as well as county administrators and has minimized a movement towards change. This is an example where “schemas, rules, norms and routines” become established as a guideline for social behavior (Scott, 2004). Oliver (1991) recognized the value of connecting resource dependence arguments with institutional models and suggested that organizational actors e.g. PHLDs, county administrators may not simply comply with institutional demands but rather impose “strategic” responses such as acquiescence, compromise, avoidance, defiance etc. In the case of the CAPHLD members, a subset of PHLDs has continued to avoid acceptance of the federal requirements by trying to introduce legislative proposals to amend the regulations. Thus,

adoption of the federal CLIA '88 requirements may only occur through a gradual and diffuse process when more counties start having board certified doctoral level PHLDs directing the laboratories (Tolbert and Zucker, 1983). The institutional environment has strongly influenced county administrators and PHLDs perspectives on the legitimacy of the state requirements for a PHLD (Meyer and Rowan, 1977, Dimaggio and Powell, 1983).

“Organizational success depends on factors other than efficient coordination and control of productive activities. Independent of their productive efficiency, organizations which exist in highly elaborated institutional environments and succeed in becoming isomorphic with these environments gain the legitimacy and resource needed to survive.” (Meyer and Rowan, 1977)

The next section describes and defines the three different forms of inter-organizational relationships among PHLs that county administrators and PHLDs could choose to engage in as a means to cope with environmental constraints. These three forms of strategic relationships were chosen based on recommendations made by the LHC as well as interviews with PHLDs, HOs, and state PH officials.

Inter-organizational Forms of Cooperation

According to county HO's and PHLDs that were interviewed, entering into an inter-organizational relationship with other PHLs may not be an ideal option since a cooperative agreement with another county implies that some autonomy over decision-making processes will be relinquished (Zeitz, 1980). Maintenance of power and legitimacy as described by RDT and institutional theory, respectively, may outweigh the need for county administrators to voluntarily engage in an inter-organizational relationship as a means to manage environmental constraints. However, if constraints such as a lack of funding, increased competition from commercial laboratories or a shortage of PHLDs become an insurmountable problem, engagement in strategic partnerships can ensure access to resources and continued provision of PHL services. According to the organizational theory literature, organizations are likely to choose a partner with common and complementary goals in order to reduce the possibility of conflict. Thus county administrators and PHLDs may prefer to engage in a strategic relationship with a PHL rather than a clinical laboratory since PHLs share a higher degree of domain consensus⁶ (Aiken and Hage, 1968, Thompson and McEwen, 1958; Evan, 1965; Levine and White, 1961). A description and definition of three strategic forms of inter-organizational cooperation is discussed in the next section.

Regionalization

According to the Merriam-Webster dictionary, regionalization involves dividing into regions or administrative districts. The Laboratory Response Network is an example of a regionalized PHL system. There are 15 reference laboratories that provide laboratory services for 58 county and 3 city health departments. These reference laboratories detect bioterrorism agents for surrounding counties designated in their catchment area. For the purposes of this dissertation, regionalization is defined as one PHL providing testing services on a contractual fee-for service basis for multiple counties that have decided to shut down their PHL or do not have their own PHL and is

⁶ Domain Consensus- agreement among participants in organizations regarding the appropriate role and scope of the agency

responsible for financing their own PHL testing services e.g. provision of PHL services by the Sonoma County PHL for Mendocino and Lake Counties.

If counties choose to engage in a regionalization effort and their PHL is not the regional laboratory, this form of relationship would present the least authority over the PHL. A regionalization effort would entail closing PHLs and contracting for PHL testing services from another county. By contracting on a fee-for-service basis the county pursuing the contract would not have equal financial or legal responsibility for the regional PHL. The relationship would entail full dependence on the regional laboratory for provision of PHL testing services. However, this also implies that if a county is not the regional laboratory, the county administrator will have the ability to exchange with multiple partners and will not be bound to one organization for laboratory testing (Thompson, 1967).

Strategic Alliance

Strategic alliance is a formal arrangement between two or more organizations for the purpose of ongoing cooperation and mutual risk/gain sharing through a long-term or short-term contract. Alliances may help organizations gain access to their partner's technologies through a joint venture, or joint investment to share in the costs of managing the PHL (Child and Faulkner, 1998; Gulati, 1995). This form of cooperation can also be a functional agreement where projects or certain types of tests or analyses, technical assistance, or technology are exchanged between two partners while each organization remains relatively independent of one another (Cauley de la Sierra, M., 1995). According to Child and Faulkner,

“Cooperation can be described as one of attempting to absorb the uncertainties of an effectively complex environment. Help absorb uncertainty by means of working closely with one or more partners to enhance its capacity to adapt by providing competences and resources that are complementary to and extend its own” (Child and Faulkner, 1998 pg. 348).

Some advantages of a strategic alliance of county PHLs in comparison to a regionalization approach include enhanced diversity with regards to personnel and technology and maintaining independence and autonomy while managing a complex environment. Some disadvantages include hastiness in initiating an alliance and finding that one organization is incompatible with the other or that it is not a financially sound option. The relationship may also be unpredictable since the partners can act jointly or independently which may cause a greater degree of uncertainty and ambiguity in the long-term sustainability of the partnership (Doz and Hamel, 1998). Two different types of strategic alliance include “pooling” which brings together organizations that seek to contribute similar resources. The other type is “trading” which brings together organizations that seek to contribute different resources (Zajac, D'Aunno and Burns, 2005). The two forms of strategic alliances that are assessed in this dissertation; consolidation and contracting for joint purchasing power and centralized testing are both “pooling” relationships since PHLs are generally similar in their function and thus share similar resources. Both of these forms of strategic alliances may help reduce uncertainty and risk in an unstable economic and political environment.

When selecting an alliance partner each organization must select one that can achieve compatibility between their goals as well as be able to integrate the partner’s cultures and systems (Child and Faulkner, 1998). There are seven reasons why organizations should engage in cooperative agreements (Table 1.1) and three motivators for engagement which include; 1) an alliance represents the lowest transaction cost alternative, 2) improves their strategic position in the economy and 3) allows an opportunity for organizational learning (Child and Faulkner, 1998).

Table 1.1: Reasons to Engage in a Strategic Alliance

1) Risk reduction
2) Achievement of economies of scale and or rationalization
3) Technology exchange
4) Co-opting or blocking competition
5) Overcoming government mandate trade or investment barriers
6) Facilitating expansion of smaller companies
7) Linking complementary resources of the partners into a value chain

Reference: (Child and Faulkner, 1998)

Some preconditions for success of a strategic alliance include; 1) entering an alliance with appropriate attitudes and organizational habits that seek to leverage the strategic alliance as a means to stretch the resources of all parties involved to maximize goal attainment, 2) compatible cultures of the organization and 3) open communication, effective teamwork and alignment of goals and purpose will be integral to the success of a strategic alliance (Doz and Hamel, 1998). These conditions are already inherent with the county laboratory directors due to their history within the CAPHLD association. Currently the county PHLDs have an informal agreement “Hands across the County” where they commit to sharing resources when needed.⁷

Consolidation

Consolidation or a joint venture is a form of strategic alliance and defined as the unification of two or more corporations by pooling resources within a common legal organization (Kogut, 1988). For the purposes of this dissertation, consolidation is defined as one or two county PHLs closing down and consolidating with another county’s PHL. The consolidation process would involve sharing equal responsibility of the joint PHL through a JPA or a contract that requires all parties involved to have equal legal and fiscal responsibility for the PHL. The Napa and Solano County PHL partnership is an example where two counties consolidated their laboratories into one physical space in Solano County and are jointly managing the PHL.

Through utilization of a JPA all parties involved would maintain authority over the joint PHL and work together to manage the PHL. This type of partnership involves a small sacrifice of autonomy and power for all parties involved however; it helps to maintain symmetry in power dependence (Pfeffer and Salancik 1978; Cook 1977). Furthermore, one or both organizations will

⁷ Richard Alexander (Orange and Contra Costa County PHLD), Personal Communication, May 15, 2009.

secure access to resources such as man-power, expertise, technology, funding, expansion of testing menu etc. which may benefit both organizations and the community in the long run (Nelson and Winter, 1982; Aiken and Hage, 1968; Thompson, 1967; Cyert and March, 1963; Pfeffer, 1972). Consolidation through the use of a JPA versus a fee-for-service contract for the exchange of goods implies the increased likelihood of interdependence and inter-organizational exchange among the parties involved (Aiken and Hage 1968; Guetzkow, 1966). According to the organization theory literature, formation of inter-organizational partnerships is high when organizations share the greatest interdependence (Levine and White, 1961; Aiken and Hage, 1968; Gulati, 1998). Furthermore, a beneficial feature of a consolidation through a JPA versus a regionalization effort is that a consolidation entails joint ownership rights and mutual responsibility of resources which minimizes opportunistic behaviors from either party. This helps to reduce the uncertainty of the other organizations' cooperation level since both organizations are equally responsible for the maintenance of the joint entity (Kogut, 1988). According to RDT and institutional theory this type of inter-organizational partnership would help to maintain an organization's "power" over the laboratory as well as its perceived legitimacy since all parties involved have equal access and decision making authority relating to the PHL.

Contracting for joint power purchasing and centralized testing

A strategic alliance where PHLs contract for joint purchasing power and centralized testing needs will not require the closure of PHLs. Rather, this form of strategic alliance would allow county administrators to maintain a PHL within their own county while observing cost efficiencies through joint power purchasing and centralization of testing needs. Joint power purchasing would accrue cost savings through bulk purchasing of laboratory necessities e.g. reagents, office supplies etc. Centralized testing is a form of "regionalization of testing services" where a "region" of counties would work together and each specializes in certain low volume tests e.g. mycology or parasitology, rather than all the PHLs in a particular region doing the tests. This would result in economy of scale not only for reagents and supplies, but also equipment, personnel training, and proficiency testing. In addition to economies of scale, utilization of a contract for joint purchasing and centralized testing would minimize a county's dependence on another county for laboratory services in comparison to a consolidation or regionalization effort because this would not entail closure of a PHL (Cook, 1977; Aiken and Hage, 1968). This type of partnership would be conducive to maintaining a county administrator and PHLD's "power advantage" because it allows counties to engage in alternative exchange relationships if the strategic partnership fails. This type of contractual strategic alliance may be preferred over the other two forms of inter-organizational relationships, a regionalization or consolidation through a JPA of PHLs because it would help preserve the current system of 37 county PHLs and ensure that county administrators obtain full autonomy over their laboratory. However supporting the PHL infrastructure in each county would require substantial financial investment in comparison to a regionalization or consolidation effort. Thus environmental constraints would continue to pose a problem for the sustainability of the PHLs in the long run if this form of strategic alliance for PHLs was adopted among counties.

Dissertation Format

This dissertation is organized around six chapters. The following are brief descriptions of the different chapters in this dissertation including the purpose, relevant research questions, and methodologies utilized, as appropriate.

The first (and current) chapter is the introduction which provides a brief discussion of why the topic of California PHL regionalization was chosen as a dissertation topic. A theoretical framework is provided to explain why organizations engage in inter-organizational forms of cooperation. Resource Dependence Theory and Institutional Theory will be used to predict the type of partnership that county HOs and PHLDs might choose to help alleviate environmental constraints that are affecting the sustainability of PHLs. The definitions of three inter-organizational forms of cooperation (regionalization, consolidation and contracting for joint power purchasing and centralized testing) that are being proposed as a means to manage resource constraints are described.

The second chapter provides background information on PHLs in a national as well as state specific context to help the reader gain a better understanding of the PHL network that exists in California. In addition to the historical background of PHLs, this chapter highlights current environmental constraints that are limiting resources and impacting the sustainability of PHLs. The primary research question this dissertation aims to address is presented: “*Would inter-organizational partnership among California’s county public health laboratories be a feasible solution to address insufficient state laboratory capacity?*” The secondary research questions are 1) What is the effect of laboratory regionalization on laboratory capacity and on the demand for laboratory directors? and 2) How can the California Department of Public Health provide leadership to help bolster the state’s laboratory capacity?

The third chapter presents three case studies of inter-organizational relationships among PHLs that currently exist or were discussed within the past ten years. The cases highlighted are between Napa and Solano Counties, Mendocino and Sonoma Counties, and a discussion of a partnership among Alameda, Contra Costa and San Francisco Counties. The main focus of the case studies is to address the question: *What factors contributed to the success or failure of an inter-organizational cooperation among PHLs?* A cross case comparison of the three cases highlight “factors of success” and “points of improvement” gained from an inter-organizational cooperation between county PHLs to establish determinants for an inter-organizational relationship.

The fourth chapter illustrates the perspective of current and past PHLDs, HOs and state PH officials regarding the feasibility of regionalizing county PHLs as a means to address the state’s deficient laboratory capacity. This chapter also focuses on 1) discussing other methods that PHLs have tried to implement to manage environmental constraints, 2) problems impacting laboratory capacity in addition to the PHLD workforce shortage 3) concerns that PHLDs and HOs have regarding engaging in an inter-organizational relationship, 4) the type of relationship that may be most suitable for county PHLs to pursue and 5) the type of PHLs that may be suitable for engagement in an inter-organizational relationship based on criteria identified from the case studies.

The fifth chapter is a synthesis of the information obtained from the case studies and the data obtained from the previous chapter to inform policy options that aim to provide solutions to help bolster the state’s states laboratory capacity. This chapter aims to address the remaining secondary research question: *How can the California Department of Public Health provide*

leadership to help bolster the state's laboratory capacity? Seven policy options are assessed utilizing a SWOT (strength, weakness, opportunities and threat) analysis.

The last and sixth chapter completes the dissertation with a description of the limitations of the research, concluding thoughts and next steps beyond the dissertation.

Chapter Two: Public Health Laboratory Background

What is a Public Health Laboratory?

According to a report released by the Institute of Medicine (IOM) in 2003 “The Future of the Public’s Health in the 21st century”, critical components in the infrastructure that support the public health system in carrying out essential functions include the workforce, information and data systems, and the PHL (IOM, 2003). In its discussion on the governmental public health infrastructure the IOM stated that:

“Public health labs are a critical component of the disease surveillance resources of the PH infrastructure, providing essential capacity to detect, identify and monitor the presence of infectious or toxic agents in the populations and the environments in which those populations live” (Institute of Medicine, 2003 pg. 136).

Public health laboratories support PH infrastructure in each of three core PH functions:

Table 2.1: Functions of the Public Health Laboratory

Function	Description
Assessment	1) Laboratory testing for infectious diseases, reference testing, specialized test and test significant to public health 2) Data collection, documentation of infectious agents in the environment providing surveillance data for epidemiologists 3) Research
Policy Development	1) Provide data and technical expertise to programs for policy development in areas such as HIV/AIDS, STD and TB as well as environmental health and food safety
Assurance	1) Provide testing for populations that cannot afford tests 2) Newborn screening, laboratory and personnel licensing, personnel training and environmental monitoring.

Reference: (Institute of Medicine 2003, Health and Human Services, 2009)

Functions of the Federal, State and Local Public Health Laboratory

Public health laboratories were first established in the 1890’s by local and state health departments. The first one was located in Massachusetts and was a cooperative venture between the state board of health and the Massachusetts Institute of Technology (MIT) (IOM, 1988). The focus of the laboratory was to monitor and improve sanitation through detection and control of bacteria in water. Today, PHLs are taking on many more roles to ensure the safety and health of the public. They are often the silent first line of defense against health threats. They oversee specimen testing when an outbreak occurs, community disease surveillance, food and environmental safety, newborn disease screening and national disease surveillance, resulting in a decrease of the burden on the health care system (APHL, 2000; Passiment, 2006). For example, PHL are responsible for rabies surveillance by testing animals suspected of rabies. In a single year, laboratory scientists prevented the trauma and expense of rabies injections for more than 71 million people, saving over \$100 million (CDC, 2008). Newborn screening is provided for all

newborns in California, testing for many illnesses like sickle cell anemia and cystic fibrosis. This has helped reduced deaths due to disease by 84%, saving a national average of \$36 million (CDC, 2008). The data generated by the PHLs monitor emerging and reemerging infectious agents and assess the effectiveness of public health programs and interventions, such as immunization campaigns (Health and Human Services, 2009).

Federal Public Health Laboratories

The PHL infrastructure is made up of an extensive network of federal, state and local PHLs. The federal laboratory, i.e. Center for Disease Control and Prevention (CDC), focuses its efforts on providing national disease surveillance. They provide information on national policies for testing, develop new tests for detecting micro-organisms and offer services for rarely performed testing which is often not available at the local or state PHL level (Skeels, 1995). The CDC has many national research centers many of which aid in advancing PHL knowledge. These research centers include but are not limited to 1) the National Center for Environmental Health, 2) the National Center on Birth Defects and Developmental Disabilities, 3) the Office of Genomics and Disease Prevention, 4) the National Center for Infectious Diseases, 5) The National Immunization Program and 6) the national Center for HIV, STD and TB Prevention (CDC, 2009).

The Federal Drug Administration (FDA), the United States Department of Agriculture (USDA), and the Environmental Protection Agency (EPA) also operate public health related laboratories. The FDA focuses on finished food products, the USDA focuses on the safety of raw agriculture products and the EPA focuses on environmental contaminants such as pesticides (The Lewin Group, 1997)

State Public Health Laboratories

Currently every state in the United States and affiliated territories has a state PHL. The state laboratory function will vary within each state. Generally, state PHLs are the backbone for providing communicable disease surveillance, analysis of food, drug and other chemical and microbiological and environmental contaminants as well as surveillance and testing for agents used for biological warfare (Inhorn et. al., 2010). State laboratories have the capability to identify new infectious or etiologic agents and are the main resource for providing reference capability to clinical and other local PHLs. They provide continuous assurance for the competency of all laboratories and acts as a reliable resource for many of the esoteric, non-standard tests that other laboratories do not have the expertise or technology to conduct (McDade and Hausler, 1998). In addition to their role as reference laboratories, the state PHLs provide leadership and services in multiple different areas. They are responsible for setting the standards for laboratory compliance throughout the state and are entrusted to monitor reportable infectious agents in a comprehensive statewide reporting system for transmitting laboratory data to the federal agencies responsible for disease surveillance and control. A more detailed description of the state laboratory functions is listed in Appendix 1. According to the Association of Public Health Laboratories (APHL), a national PHL organization:

“State public health labs are part of a national network of public and private labs linked in the shared goal of control or elimination of disease and interacting with laboratory

services providers throughout the community” (Association of Public Health Laboratories, 2000 pg.3).

The varying functions and structures of the state PHL will affect its role in the PH infrastructure (Ahn et al., 1997). Many states operate with regional laboratories acting as an extension of the central state laboratory where the state laboratory is responsible for coordinating testing and reporting of tests to the local PH departments (PHDs) i.e. Maryland and Tennessee. There are also instances where there is only one central state PHL which is seen in Oregon and Wyoming (The Lewin Group, 1997). California is unique in the sense that the state and local PHLs operate fairly independently in a decentralized fashion. County PHLs report directly to their local PH agencies and only interact with the state laboratory in response to sporadic outbreaks or for esoteric testing.

Local Public Health Laboratories

The local PHLs have functions similar to the state PHL; however their focus is to provide data relevant to support the mission of their local PHD. The local PHLs collect and provide testing data to inform local PH decisions. They utilize testing results to monitor local disease outbreaks, including food-borne, vector-borne, and environmental-borne infectious diseases. Since local PHLs are in tune with the problems in their community, they are able to prioritize samples and address issues that need immediate attention in order to respond to emergencies in a timely manner. They may also act as reference laboratories to their local hospital or private clinical laboratories (Wilson, Gradus, and Zimmerman, 2010). If the local PHL is unable to diagnosis a sample, or further diagnosis of a specimen is required e.g. sub speciation, it will send the samples to the state laboratory for further analysis.

Furthermore, local PHLs often act to provide surge capacity in case the state laboratory is bombarded with samples during an emergency situation. In the case of the 2009 H1N1 outbreak, many of the local PHLs in California diverted resources to testing potential H1N1 samples to help ensure the safety of their community as well as the state.

Clinical and Commercial Laboratories

The clinical laboratories, unlike the local and state PHLs prioritize individual patient health rather than population/community health. The laboratory data requested from clinical laboratories is used to help doctors diagnose, monitor and treat patients while PHLs provide data that helps to assess a community’s health status as well as support local PH programs (Wilson et.al, 2010; Pentella, 2009). If a clinical laboratory is unable to diagnosis a specimen, they may send the sample to the local PHL for reference testing because PHLs have slightly more sophisticated mechanisms for specimen diagnosis, especially for esoteric diseases. A comparison of the difference between the clinical laboratories versus the PHL is listed in Table 2.2.

The federal government recognizes PHLs as a subset of clinical laboratories and regulates both the PHL and clinical laboratory in the same fashion. However, in California, the clinical laboratories are regulated by the California Business and Professions Code of 1978 while the PHLs are regulated under the Health and Safety Codes of 1979 (Capener et al., 1992). Due to these separate codes of regulation PHLs and clinical laboratories are regulated as separate entities. PHLs are not subject to state licensing and inspection. They are only subject to the

federal CLIA inspections biennially as well CLIA licensing fees. This also includes the state PHLs. All other private or public clinical laboratories i.e. county hospital laboratories, commercial laboratories, private doctor’s laboratories are subject to state licensing and inspection.

Table 2.2: Clinical versus Public Health Laboratory Functions

	Clinical Laboratory	Public Health Laboratory
Health Focus	Health care of individuals	Health of the public
Provision of Information	Provide information about a patient to a physician	Provide information about the population to public health professionals
Testing Diagnostics	Diagnostic, therapeutic, and disease management testing	Some diagnostic testing, screening, epidemiologic typing, human and environmental testing to monitor the population’s health
Desired Outcome	Patient recovery from illness	Health of population, detection and intervention, prevention

Reference: Beebe, 2006

California’s Public Health Laboratory System

California is the most populous state in the United States with a population of 37 million people, and the third largest in land mass at 163,696 square miles in the USA after Alaska and Texas (Encyclopedia Britannica, 2009). In 1911, the California state board of health adopted a resolution that required cities with populations greater than 50,000 to establish their own PHLs to encourage the availability of laboratory resources as “close to the scene of action” as possible (Capener, 1992). In 1935, the Social Security Act provided incentives for generating laboratories to help with the control of venereal disease. Following World War II there was a surge of federal funding for local health administrations with the passage of the Public Health Assistance Act of 1948, which provided financial incentives for the establishment of many laboratories across California. By the 1970’s there were 39 autonomous county and city PHL facilities located across the state and one state PHL located in the City of Berkeley (Capener et al., 1992). The state laboratory facility has since moved to its current location in Richmond, California.

Since the establishment of county PHLs in the 1950’s, only two PHLs have shut down, decreasing the number of physical laboratories from 39 to 37 local PHLs in California serving 61 local health jurisdictions (58 counties and the cities of Berkeley, Long Beach and Pasadena). The Napa and Solano County PHLs consolidated into a single PHL in 1999 and the PHL in Mendocino County shut down in 2009. The state facility houses six major laboratories with different testing capabilities. The six laboratories include the Microbial Disease Laboratory (MDL), Viral and Rickettsial Disease Laboratory (VRDL), Genetic Disease Laboratory (GDL), Food and Drug Laboratory (FDL), Environmental Health Laboratory (EHL) and Drinking Water and Low Level Radiation Laboratory (DWLLRL) (CDPH, 2009).

The cost of establishment and maintenance of a city or county PHL is borne by the city or county. The two main responsibilities of city and county health departments are public health and indigent medical care (LAO, 2001). Unlike California's court system which is fully funded by the state, the PHL is funded primarily through local city or county funds. These funds include but are not limited to: 1) realignment funds, which are revenue received by a county from a percentage of vehicle licensing fees and sales tax to fund the areas of mental health, social services and health, 2) county general funds from revenues generated through property taxes 3) revenue generated by third party payers for testing services rendered from the PHL and 4) funding from the federal government that is funneled through the state for public health emergency preparedness and public health emergency response. Unlike PHLs in other states, the 37 PHLs operate very independently of the state. The county PHLs are funded in large part by their own county along with a patchwork of federal and state funds.

Counties with a population, $\leq 50,000$ people obtain their PHL testing services through the state laboratory or from a neighboring county PHL financed by the state laboratory. The San Joaquin County Public Health Services and the Shasta County Department of Health and Human Services have a contract with the CDPH for the San Joaquin and Shasta County PHL to provide laboratory testing services for neighboring counties with $\leq 50,000$ people. San Joaquin and Shasta County PHLs receives \$32,000/year from CDPH to provide laboratory testing services in lieu of provision of services from the state laboratory.

The only laboratory test that is conducted solely by PHLs is rabies testing. Under Title 17 Sections 2505 & 2641.5-2643.2 of the California Health and Safety Codes samples of suspected tuberculosis, malaria and salmonella cases need to be sent to a local PHL or the state PHL for definitive identification. In addition to these infectious agents, there is a list of over 40 infectious agents that can be tested by a hospital based clinical laboratory or commercial laboratory, however testing results suggestive of the disease must be reported to the local health department.

Laboratory Response Network

In addition to being able to detect common infectious agents, a subset of the county laboratories has the capability of detecting bioterrorism (BT) agents like anthrax, tularemia, botulism and many more. The National Laboratory Response Network (LRN) was established program in 1999 under a Presidential Decision Directive. LRN founding partners are the Centers for Disease Control and Prevention (CDC), Federal Bureau of Investigation (FBI) and Association of Public Health Laboratories (APHL). The mission of the LRN is to maintain an integrated network of federal, military, state and local public health and international laboratories fully equipped to respond quickly to acts of chemical or biological terrorism, emerging infectious diseases and other public health threats and emergencies (Marshall et. al., 2010). The California branch of the LRN began in 1999 and is funded through the CDC. Financing for the LRN comes from the CDC Emergency Preparedness funds that are allocated to the CDPH and the funds are then allocated among Centers, Divisions and Branches within CDPH.

The Emergency Preparedness funds provided for PHLs were initially granted to only the 50 states, and three large city PHLs in New York City, Chicago and Los Angeles. However, due to the geography and population of California, the state laboratory officials requested to designate

three additional county laboratories as LRN laboratories⁸. The local county PHLs that were chosen included the Sacramento, San Joaquin and the San Diego County PHLs, making a total of five LRN laboratories. It was not until the September 11, 2001 event in New York and the 2002 anthrax attacks, that California began bolstering its LRN capacity and capabilities. A surge of emergency preparedness funding was provided to California which then allowed the state to add 10 additional county PHLs to the LRN. Currently, there are a total of 15 LRN reference/confirmatory laboratories; the largest in the nation⁹. Their locations and the catchment areas they serve are listed in Appendix 2.

LRN reference laboratories have Biosafety level-3 (BSL-3) capabilities and are able to handle samples of potential BT agents. The funding provided by the CDC emergency preparedness fund helps to develop the infrastructure, instrumentation and training to perform confirmatory testing of BT agents and provides direct service to law enforcement. There are also LRN sentinel laboratories. These laboratories operate a BSL-2 facility. The sentinel laboratories are able to handle clinical samples and some environmental swabs. Their function is to perform “rule-out or refer” tests, i.e. rule out that the agent is a bioweapon or else refer it to LRN reference laboratories. The remaining 22 county PHLs not designated as an LRN reference laboratory are designated as sentinel LRN laboratories. These sentinel PHLs are tasked to work with their local clinical laboratories to train personnel in sentinel laboratory detection methods. No data is available on the number of local clinical laboratories that may have sentinel laboratory detection capability¹⁰.

Other networks besides the LRN with state and county participant laboratories are the Food Emergency Response Network (FERN) established by the Food and Drug Administration (FDA) and the United States Department of Agriculture (USDA). In addition to federal funded programs, the state Viral and Rickettsial Disease Laboratory (VRDL) established a state sponsored Respiratory Laboratory Network (RLN) during the 2009 H1N1 epidemic to ensure that the county PHLs had the proper equipment, reagents and protocols to accurately diagnosis H1N1 to keep up with the influx in workload during the epidemic.

Public Health Laboratories are vital to the health of the people of this state and have been since 1905. Whether it is new novel viruses like West Nile virus in mosquitoes, food-borne outbreaks like salmonella in spinach or tracking the seasonal influenza virus for a pandemic, PHLs in California have been an outstanding and vital partner in disease control and prevention. With the latest influenza pandemic the state could not have responded as well without the pivotal role of the PHL network. This pandemic showed the dual use that the LRN serves. It is not just about terrorism preparedness it is also about protecting the public from natural disease outbreaks too. --Dr. Mark Horton, Director of the California Department of Public Health (July 2007-March 2011), 2010 LRN National Meeting

⁸ California was the first state to request additional laboratories to be designated as LRN laboratories

⁹ Dr. Paul Duffey (Division chief of the Biologics and Immunoserology section of the state Microbial Disease Laboratory), Personal Communication, April 5, 2011)

¹⁰ Dr. Paul Duffey (Division chief of the Biologics and Immunoserology section of the state Microbial Disease Laboratory), Personal Communication, April 5, 2011)

California Laboratory Regulations

In 1923 a system of inspection and certification of laboratories both public and private was authorized by the California State Board of Health (Schaeffer, 1981; Kellogg, 1931). It began as a voluntary system of certification for PHLs and their personnel led by Dr. Wilfred H. Kellogg, who at the time was chief of the state hygienic laboratory. In 1928, the first public health microbiologist (PHM) was certified by the state. Eventually clinical laboratories expressed interests and requested to be included in the certification process (Kellogg, 1931).

In 1937 the state passed its first Clinical Laboratory Act which required that all clinical laboratory employees be licensed and certified to perform tests (Schaeffer, 1981). The law was passed with the interest of the citizens of California, “*to provide the best possible laboratory services to the patient*”. Dr. Kellogg created the Division of Laboratories office within the Department of Health Services that employed laboratory examiners to inspect and certify public health and clinical laboratories to ensure that the laboratories were operating according to state regulations. California initiated the earliest efforts for setting standards for PH and clinical laboratories and has evolved the most comprehensive laboratory regulatory system in the United States (Schaeffer, 1981).

The Division of Laboratories included the state laboratories. However in 1991 this relationship was dissolved and the state laboratories became decentralized and separated from the component of the Division of Laboratories that conducted laboratory regulations and examinations. The six laboratories were affiliated with the public health programs that they supported rather than with the division of laboratory services. The Microbial Disease Laboratory (MDL) and Viral and Rickettsial Disease Laboratory (VRDL) work with the Infectious Disease Branch, the Genetic Disease Laboratory (GDL) work with the Genetics Branch, the Food and Drug Laboratory (FDL) work with the Food and Drug Branch, and the Environmental Health Laboratory (EHL) and Drinking Water and Low Level Radiation Laboratory (DWLLRL) work with the Environmental Health Branch.

Laboratory Field Services

In 1953, the unit within Division of Laboratories that was responsible for laboratory regulations was named Laboratory Field Services (LFS) and is currently operating under the Department of Public Health. Laboratory Field Services was created in order to accommodate the legal responsibilities to inspect and license the increasing numbers of laboratories as well as laboratory personnel. When this unit was first established, there were only a handful of employees, by 1967 over 30 people and in 2011 a staff of over 80 employees.¹¹

In 2008 with the creation of a separate CDPH, the state public health officer and director of the CDPH at the time, Dr. Mark Horton, combined the Licensing and Certification program with the LFS Branch to create a Center for Healthcare Quality (LHC, 2009b). The function of LFS has not changed since its’ inception and continues to:

“Provide for the assurance of reliable laboratory services in California from clinical and public health labs and from blood and tissue banks by effectively administering a comprehensive licensing and certification program mandated by laws and regulations to

¹¹ Kathy Williams (LFS program manager), Personal Communication, April 7, 2011

assure compliance with standards applicable to these labs and their personnel” (CDPH website).

According to Kathy Williams, a program manager for LFS, there is over 19,000 state licensed laboratories and over 25,000 State licensed and certified laboratory personnel working in California, of which there are about 250 active certified PHM. The licensing of clinical laboratories and personnel generates approximately \$3-5 million of revenue for the CDPH. This amount is anticipated to increase following Senate Bill 744 that was passed in the Fall of 2010 that replaced the flat fee for clinical laboratory licensing for a sliding fee schedule based upon the volume of testing conducted in the clinical laboratory.

Clinical Laboratory Improvement Act

In 1967 Congress passed The Clinical Laboratory Improvement Act (CLIA) and required federal licensing and inspections of laboratories that tested specimens across state lines. These federal regulations brought changes for both public and private laboratories: different standards, different authorities, and different interpretation of technical and administrative principles, different priorities and different enforcement procedures. *“When legislation is enacted to establish minimum requirements for lab operations and personnel, and the program is adequately conducted with periodic inspections and proficiency testing significant improvement in the quality of performance invariably ensues”* (Schaeffer, 1981).

Clinical Laboratory Improvement Amendment of 1988 (CLIA ’88)

In the 1980’s newspaper and magazine articles started reporting that there were erroneous results associated with reporting Papanicolaou (Pap) smear testing which resulted in negative health consequences and a few deaths. While these articles were mainly associated with cytology laboratories, Congress passed the Clinical Laboratory Improvement Amendment in 1988 (CLIA ’88) which stated that all laboratories including physician offices were required to meet uniform quality laboratory standards. The minimum good laboratory practices are listed in Table 2.3 (Schaeffer, 1981).

Table 2.3: Good Laboratory Practices

1. Having trained and competent testing personnel
2. Following manufacturers procedural direction (calibrations, maintenance, routinely performing and evaluating daily quality control, responding to out of control result and correcting problems)
3. Applying total quality management and continuous quality improvement principles and practice
4. Participating in external quality assessment i.e. proficiency tests
5. Documenting all activities

Congress passed CLIA’88 to establish quality standards for all laboratories testing as well as laboratory personnel to ensure the accuracy, reliability and timeliness of patient test results in any moderate to high complexity testing laboratories¹². This required PHLDs to have a doctoral

¹² A moderate or high complexity laboratory is licensed and inspected every two years and needs to comply with CLIA’s six areas of regulation: proficiency testing, personnel, inspection, patient test management, quality control, and quality assurance (CLIA 2003). Tests designated high complexity are usually the tests not classified by the Food

degree and a board certification to supervise an accredited PHL. Prior to the introduction of the federal CLIA'88 amendment, the state requirements to become a PHLD included a bachelor's degree or higher, a baccalaureate level public health microbiologist (PHM) certification and four years training in a PHL, two of which are in a supervisory PHM capacity. A grand-father clause was added to the CLIA'88 which allowed time for the state to build a pipeline of directors who would meet the federal educational requirements for the PHLD. California has not adequately met this expectation.

The Center for Medicaid and Medicare services (CMS) is responsible for enforcement of CLIA regulations including approval of proficiency testing programs, accreditation programs and state exemptions for laboratories while the Centers for Disease Control and Prevention (CDC) is responsible for technical and scientific areas related to the regulations, i.e. test categorization, waivers etc. (HHS, 2009; Ahn et al., 1997). All the PHLs in California are designated high complexity laboratories and are subject to the CLIA regulations as stated above.

Proficiency Testing Standards

CLIA requirements were passed to ensure laboratory testing quality by providing "minimum quality practices that incorporate total quality management". One of these practices is proficiency testing. A 2004 study analyzed data from proficiency tests conducted from 1994-2002 by clinical laboratories. The study utilized subjective indicators to assess the impact of proficiency testing and found that CLIA '88 requirements did in fact help to improve the quality of laboratory testing. Thus the choice to incorporate proficiency testing as a main component of CLIA '88 has been useful to gauge the quality of laboratory practice (Ehrmeyer and Laessig 2004).

Federal requirements for proficiency testing are regulated at a federal level. In order to be a CLIA certified laboratory, a PHL needs to complete and pass three national proficiency tests a year for any test that is offered by the laboratory. If the PHLs pass their annual proficiency tests, there are no further requirements for a minimum volume of specimens the laboratory needs to receive to be proficient in testing.¹³

California Public Health Laboratory Personnel Licensure and Certification

Public health microbiologists (PHMs) that work in PHLs are certified by the state. To qualify as a PHM trainee, a bachelors or higher degree with appropriate courses in the sciences from an accredited college or university is required. Trainees must complete a six-month training program and pass the California public health microbiology examination before they are certified to work as a PHM in a California PHL. Certification is active for the lifetime of the PHMs and not subject for renewal like the licenses of clinical laboratory scientists in California. Senate Bill No. 594 (SB594) was introduced in 2011 to change this law and require that PHMs obtain continuing education units to renew their PHM certification; as of the end of June 2011, the SB594 has been moved into a two year bill cycle and will not be resolved until the 2012

and Drug Administration (FDA). For non-FDA classified tests or modified FDA approved tests laboratories must validate the test performance specifications. Laboratories performing low complexity tests or waived PPMP (Provider Performed Microscopy Procedures) are not subject to the same regulations and are not routinely inspected.

¹³ Kathy Williams (LFS project manager), Personal Communication, April 7, 2011

legislative season. In addition to license renewals, unlike clinical laboratories or clinical laboratory scientists, the PHLs and the PHMs are not required to pay laboratory licensing or certification fees to the state.

California is the only state that requires a state specific certification to become a PHM. Other states like Texas and Florida accept certificates obtained through national programs like the American Society of Microbiology (ASM) or American Society for Clinical Pathology (ASCP) for their public health laboratorians. Currently 14 states and one territory license laboratories and their personnel. These states include; Alaska, California, Florida, Georgia, Hawaii, Louisiana, Montana, Nevada, New York, North Dakota, Rhode Island, Tennessee, West Virginia, and Puerto Rico (HRSA, 2006). States like North Carolina and Texas that do not license laboratories or personnel do not require that an individual possess a national certification to work in a PHL. As long as an individual meets the qualifications specified under the CLIA regulations that person is able to seek employment in a PHL. For example, under CLIA regulations in order to become a technical consultant in a PHL an individual must have 1) earned a bachelor's degree in a chemical, physical or biological science or medical technology from an accredited institution and 2) have at least two years of laboratory training or experience or both in non-waived testing, in the designated specialty or subspecialty areas of service for which the technical consultant is responsible. Individuals that meet the educational requirements and have the necessary years of work experience qualify to work in a PHL without additional licensure or certification from the state. The CLIA requirements for different categories of laboratory personnel are listed in Appendix 3 (AAFP, 2010).

There is currently no set minimum number of microbiologists needed to maintain a PHL in California. The individual county or city health departments decide the number of PHMs and service their PHL will provide. This will determine the testing capabilities that the PHL will have as well as the number of personnel needed to operate the laboratory. In general, moderate to large sized PHLs (more than five employees) have greater testing capabilities than smaller PHLs. The size range for county PHLs can range from a single person running the laboratory to 121 employees. (Appendix 4 lists the number of personnel working in each of the county PHLs).

California Association of Public Health Laboratory Directors

The California Association of Public Health Laboratory Directors (CAPHLD) played a major part in the early history of the state and county laboratory relationship. It was established in 1949 to enhance the relationship among PHLs and included personnel of the local county and the state PHLDs. This organization was established to enhance the relationship between the state and local public health laboratory personnel. A major task when CAPHLD was first formed was to delineate the testing performed by the state versus the county laboratories. As their relationship developed, a majority of the testing was passed to the county PHLs so the state could become the major reference laboratory for more complex testing as described by Schmidt and Madoff:

“In a regionalized state lab system a central state lab would provide only reference and special services with most testing done at the regional or local level, this would allow strengthening of the research, technology transfer and laboratory licensure functions of the central state public health laboratory” (Schmidt and Madoff, 1977; pg. 435)

Another mission of CAPHLD has been to improve laboratory services in California by improving and expanding continuing education for its laboratory directors and public health microbiologists. The success of CAPHLD is confirmed by the collegiality among state and local PHLs that still exists today.

When the federal CLIA'88 requirements for the PHLD were introduced in 1988, a subset of CAPHLD members went to Washington D.C. to lobby for change of the federal requirements. The organization was unsuccessful at convincing the federal government that California's requirements of a baccalaureate degree, a public health microbiology certification and four years of PHL experience was sufficient for becoming a PHLD. To this day, a subset of CAPHLD members is adamant that the state requirements are adequate and sufficient for becoming a PHLD. These individuals have continued to introduce and support legislative proposals at both the state and federal level to amend the CLIA'88 requirements for California PHLDs. Thus far, they have not been successful at obtaining an amendment from the CLIA'88 requirements.

In May 2011, the executive director of CAPHLD, Mr. Dennis Ferrero who has spearheaded many of the legislative proposals for amending the federal CLIA'88 requirements decided to resign from his position. It remains to be seen whether Mr. Ferrero's absence will change the platform that CAPHLD takes on amending the CLIA'88 requirements.

In addition to opposing acceptance of federal requirements for the PHLD, regionalization of local PHLs faces resistance by a subset of members of the CAPHLD association as well. Research suggests that four common reasons people tend to resist change are: 1) the desire not to lose what they have, 2) misunderstanding of the change and its implications, 3) belief that change does not make sense for the organization and 4) low tolerance for change (Kotter and Schlesinger, 1979). Some reasons reported by national laboratory and microbial disease organizations for the strong resistance to regionalization of PHLs are 1) fears that the state laboratory will have a stronger oversight of regionalized laboratories, 2) testing services will be compromised due to delays in specimen processing and transport, 3) quality assurance will decrease due to an increased workload, 4) patient care may be affected if the turn-around time for test results are delayed, 5) longer distance samples and information needs to travel and 6) a decreased doctor and laboratory scientist interaction (Public Health Laboratory Issues in Brief, 2004; Infectious Diseases Society of America, 2001). In addition, political aspects of state and county regulations, budgetary constraints, capital costs of merging laboratories, and personnel issues all need to be dealt with when considering strategies of inter-organizational forms of cooperation (Dowdle, 1993; Gray, 2001). Furthermore, if PHLs are relatively unknown to the public, regionalizing PHLs into fewer laboratories may further decrease PHL presence in the community (Dowdle, 1993). During interviews with the PHLDs as well as HOs, many of these issues were described when discussing their concerns about regionalizing county PHLs.

While these are legitimate concerns, there are other states that have successfully regionalized laboratories including, Georgia, which has a central laboratory facility and two regional laboratories (Georgia PHL, 2009), Virginia which has a division of consolidated laboratory services (DGS, 2009) and Michigan, which currently has five regional laboratories serving 41 health districts (LabLink,1995). The costs of the laboratories are split among the different regions and all three states have reported that they have been able to improve quality of testing

by standardizing procedures to provide efficient and cost effective testing. It remains to be seen whether a regionalization effort of PHLs or another form of inter-organizational cooperation between county PHLs can help to alleviate the deficiencies in the state's laboratory capacity.

Comparison of California to the New York, Texas and Florida PHL systems

Georgia, Virginia, and Michigan have consolidated and regionalized PHLs, however the area and population of these states are not comparable to California and thus an inter-organizational model of PHLs may not be applicable. New York, Texas and Florida however, are comparable in area and population (Table 4). A description of the New York, Texas and Florida PHL and how it compares to the California PHL system is provided in the following section.

New York

New York (NY) has 62 counties that are served by 42 health departments. There are three county/city PHLs that are moderate/high complexity in addition to the Wadsworth Center, which is the state laboratory that employs over 1100 people. New York laboratories are exempt from the CLIA requirements because the state has its own comprehensive laboratory oversight program that licenses laboratories as well as personnel. Laboratorians must meet the NY state licensure requirements or obtain a certificate of qualification before they are allowed to work in a NY clinical or PHL facility. In an interview with Dr. Jill Taylor and Dr. Victoria Derbyshire the Deputy Director and Assistant Director respectively, for the NY State Department of Health, Wadsworth Center, all PHLDs working in a moderate/high complexity county or state laboratory have a medical or doctoral degree and state issued certification. The NY state requirements are thus as stringent as or more stringent than federal CLIA requirements. Unlike California, the local PHLs in New York interact closely with the state department of health and receive significant resources from the state.

Texas

Texas has 254 counties but not all of them have local health departments. The state is divided into 11 health service regions, grouped into seven functional areas where the regional health department acts as the local health department for counties without a local health department. In an interview, Dr. Grace Kubin, laboratory director of the Laboratory Services Section, of the Texas Department of State Health Services, indicated that Texas has 16 state/county/city PHLs that are moderate/high complexity. The main state laboratory is located in Austin and two satellite state PHLs in San Antonio and Harlingen. Texas does not have a state licensing requirement for clinical laboratory personnel. The PHL staff adheres to the educational standards and work experience requirements set by CLIA. Many of the city/county PHLDs have either a doctoral degree or medical degree. Similar to California, the county or city provides the majority of the financial support for the city/county PHL with some from the state for particular types of testing e.g. HIV and STD testing.

Florida

The Florida Department of Health Bureau of Laboratories consists of five regional state PHLs and six city/county operated PHLs located throughout Florida. These 11 moderate/high complexity PHLs serve 67 county health departments and are largely funded by the state. The county laboratories may perform syphilis testing and Gram stains to make presumptive diagnosis for urgent treatment, but the majority of the samples are sent to the state PHLs for testing. The

five main regional state PHLs are located in Jacksonville, Miami, Pensacola, Tampa and Lantana. The PHL in Lantana is anticipated to be shut down during the 2011/2012 fiscal year. According to Dr. Philip Amuso, the Associate Bureau Chief of the Florida Department of Health Bureau of Laboratories, the four remaining state PHLs along with the county PHLs will be adequate to serve the citizens of Florida.

Like California, the Florida Department of Health has its own licensure program and regulations but personnel licenses for both clinical and public health laboratorians are accepted from national certification agencies. All PHLDs of high complexity PHLs in Texas have a medical degree or doctoral degree and are board certified with the exception of one PHLD who was “grandfathered-in” under the CLIA’88 grandfather clause.

Table 2.4 below compares the total area (square miles), the population (millions) and the number of moderate and high complexity PHLs between California, New York, Texas and Florida.

Table 2.4: Comparison of the Public Health Laboratory System

	California	New York	Texas	Florida
Total Area (sq. mi)	163,696	54,556	268,581	65,755
Population (mill)	37.25	19.37	25.15	18.8
Number of Moderate/High Complexity PHLs	38	4	16	11

Environmental Constraints Currently Impacting California’s Public Health Laboratories

Currently, three environmental constraints stand out as impacting the availability of resources available to PHLs. These constraints include: reduction in funding, market competition from clinical laboratories and regulatory changes. As illustrated above, California has two to three times as many PHLs to support in comparison to states of comparable population and size. According to organizational theorist Levine and White (1961) *“if all essential elements are in infinite supply there is no need for organizational interaction and for subscription of cooperation. Under conditions of scarcity inter-organizational exchanges are essential to goal attainment”*. The magnitude of these constraints may impact whether or not counties decide to engage in a model of inter-organizational relationship in the near future. The following section describes the current environmental constraints that are impacting the sustainability of PHLs.

Economic Forces

The dot.com boom of the late 1990’s generated ample taxable income in California, resulting in a 10% surplus in funding reserves during the fiscal year of 1999-2000 (BDP, 2000). It was anticipated that in the 2000-2001 fiscal year there would still be a 4% surplus. However, when the dot.com bust hit in 2000, the state had to honor prior obligations and the surplus was depleted. Governor Gray Davis speculated California would have a budget deficit as high as \$23.6 billion for 2002-2003 and \$34.6 billion by 2003-2004 fiscal year (Hill, 2003).

When Arnold Schwarzenegger became governor in 2003 he had great expectations of drastically reducing California’s huge budget deficit. Although the budget deficit decreased during his administration, upon leaving office in January 2011, California still had a \$28 billion budget

deficit in spite of temporary tax increases (California Department of Finance, 2010; Jaffe, 2011). Counties continued to suffer the burden of providing public services with a continuously shrinking annual county budget due to reductions in funding from the state as well as realignment funds.

“Our public health department has taken 30% reduction in net county costs in the last two years and we are going to be taking another 20% in the following year starting July 2011. They (county health services agency) allow you to pick and choose which programs you decimate and how you structure your department so that you can do things more efficiently.” – Dr. David Herfindhal, Deputy HO Riverside County

Unfortunately the increasing cuts in funding to the counties will continue to persist under the new governor Jerry Brown. He has proposed major cuts for many public services e.g. health and human services programs and higher education to curtail the \$19.1 billion projected shortfall for 2011-2012 fiscal year (Soman, 2010). His strategy is to “realign” state funded programs by transferring back to local county governments responsibilities such as court security costs, fire and emergency response in wild land areas, and substance abuse treatment programs. Governor Brown proposed that the extension of existing tax increases would help generate funds for the counties when they realign state funded programs, however it was recently announced in May 2010 that the Republican state lawmakers are not supporting an extension of tax increases. Governor Brown says that realignment will not be implemented until there are sufficient funds available to help the counties adjust, however this means that there will be more severe cuts for state funded programs (Los Angeles Times, 2011). Brown’s budget proposal has not been approved by the legislature and the persisting financial dilemma is a long way from being resolved.

The current economic climate in California has forced some county HO’s to examine whether programs funded by the health department need to be eliminated or reduced to cut operational costs. According to HOs, a county may alleviate the burden of funding cuts by distributing cuts across different departments so that all programs take up the burden of funding reductions. The PHD may take a funding cut which subsequently affects programs such as public health nursing, lead prevention, the PHL etc. For the past several years these programs have decreased their annual operating budget by instating furlough programs, terminating personnel, or eliminating/reducing testing services. While some counties may protect the PHL in spite of increased county budget constraints, other counties may not have this ability.

“Something that we would have never ever done is to even look at the labs and asked do we really need to have one... For right now we definitely want to fight to keep it, we are going to do what we need to do. If the economy just keeps spiraling down we don’t know what will happen.” --Dr. Eric Marshall, HO Pasadena City

Commercial Laboratory Competition

In addition to economic forces market competition from commercial laboratories has also resulted in a decrease in the workload in PHLs over the past 10-20 years. PHLs differ in function as compared to clinical laboratories that generally fall into the three categories: hospital-based laboratories, independent commercial or reference laboratories and physician office laboratories

(The Lewin Group, 1997). There are overlaps in the populations that PHLs and clinical laboratories serve which result in competition for clients. The functional differences between PHLs and clinical laboratories are that PHLs traditionally serve the Medicare/Medicaid population, however as managed care organizations are taking on testing for this population and contracting commercial laboratories to conduct the tests, PHLs will lose this market (Ahn et al., 1997). It is becoming increasingly difficult for the PHLs to compete with national commercial laboratories like Quest Diagnostics, LabCorp and Associated Regional and University Pathologists (ARUP). Commercial laboratories are able to offer extensive courier services, competitive costs due to high volume and quick turn-around time for results. Many county hospitals and county PH clinics are even sending specimens to commercial laboratories. According to Dr. Patty McVay, the San Diego County PHLD, in 1997, Humboldt County was the only PHL that had the ability to do chlamydia and gonorrhea (GC) nucleic acid amplification technique (NAAT) testing. The income from Chlamydia/GC NAAT and also Drug of Abuse Testing allowed the Humboldt County PHL to hire more staff expanding personnel. However, within a few years commercial laboratories entered the Chlamydia/GC NAAT market offering to provide the test at a lower rate than the PHL could offer and most of this testing was lost. Furthermore, several good rapid urine drug of abuse tests became available through commercial laboratories and the ability to bill MediCal for drug of abuse tests became more complicated and for a period of time disallowed entirely. This led Humboldt County to eliminate their Drugs of Abuse program. A combination of these events decreased the testing volume for the Humboldt County PHL from 30,000 tests per year in 2001 to approximately 3000 tests annually by 2006. The greatest disadvantage of losing the PHL market for disease testing is that the ability to report disease surveillance data is lost as commercial laboratories often fail or are slow to report notifiable diseases.

Commercial laboratory competition is not a problem for all counties in California. There is a subset of PHLDs who report that they have a collegial relationship with the commercial and clinical laboratories since they are not competing for the same types of tests. According to Richard Alexander, PHLD for both Orange and Contra Costa County, it is a policy in Orange County that the PHL do as much of the PH testing as possible and only tests that the PHL chooses not to do go out to bid by commercial laboratories. *“We do send some samples to private commercial labs from the clinics but if it is anything that the Orange County PHL does we get first shot at it.”* – Richard Alexander, Orange and Contra Costa County LD.

Commercial laboratory competition is a problem that PHLs face. Some counties have ordinances that steer off competition from commercial laboratories, however not all of the counties have these rules and policies. According to Kathy Williams the program manager for Laboratory Field Services, there are no laws or regulations stipulating that county public health clinics or programs are required to send laboratory samples to their county PHL. Besides rabies testing which are only done in PHLs, under Title 17 Sections 2505 & 2641.5-2643.2 of the California Health and Safety Codes, samples of infectious agents of PH concern such as suspected tuberculosis, malaria and salmonella cases can be tested in clinical laboratories but still need to be sent to a local PHL or the state PHL for definitive identification.

Public Health Laboratory Director Requirements

Regulatory constraints are also a major problem affecting the sustainability of PHLs. As stipulated by federal and state law a county cannot operate a moderate or high complexity PHL without a PHLD that meets the federal CLIA'88 requirements for a laboratory director (CLIA 2003). Prior to the addition of the federal requirements, California state law required that PHLDs have: 1) bachelor's degree, 2) public health microbiology certification, and 3) four years of laboratory training, two of which are in a supervisory position. However, when the CLIA'88 was introduced the federal mandates required that any laboratory director for a moderate or high complexity laboratory had to have 1) doctoral degree (M.D., Ph.D., D.Sc., D.D.S., D.V.M, DrPH) and 2) be eligible to take and pass a state board exam from an accredited organization. All PHLs in California are high complexity laboratories and are subject to this requirement. Federal law superseded the state requirement that a laboratory director needed to have a bachelor's degree, however if there were more stringent regulations in the state pertaining to the qualifications for the PHLD the state could enforce those requirements listed above. These requirements have resulted in a shortage of the PHLD workforce due to the constraints both the federal and state requirements place on the requirement to become a PHLD. The federal CLIA'88 requirements are preventing current laboratory managers and supervising microbiologists who do not have doctoral degrees from becoming the PHLD if the PHLD decided to retire. This was not the case prior to the introduction of the CLIA'88 requirements. Many of the PHLDs currently directing a PHL started as a microbiologist and were promoted to become the laboratory director. The state requirements have also contributed to the shortage of the PHLD workforce by enforcing the PHM certification and four years of PHL experience requirement. Board certified doctoral level PHLDs from other states would need to take a baccalaureate level PHM certification exam in order to be eligible to enter the workforce in California. Furthermore, clinical microbiology laboratory directors would not be eligible to become a PHLD because they would need four years of experience in a PHL to qualify to become a PHLD.

Many of the PHLDs in California did not have a doctoral degree when CLIA introduced the amendment in 1988. To circumvent a massive closure of PHLs, the federal government added a grandfather clause to the CLIA'88, which stated that, any laboratory director who served as a PHLD or qualified to serve as a PHLD prior to February 28, 1992 could be "grandfathered" in and remain as a PHLD under the CLIA'88 regulations. Public health laboratory directors who began working after February 28, 1992 would be required to have a doctoral degree, and after February 4, 2003 would be required to have both a doctoral degree and have passed a board exam (CLIA, 2003). The intent of this grandfather clause was to allow time for states to develop a pipeline of laboratory directors that met the more stringent CLIA'88 requirements. However, California, unlike many of the other states has not adequately built a pipeline of CLIA'88 qualified PHLDs. Following more than twenty years since the passage of the federal CLIA'88 requirements, there are currently only seven laboratory directors that have a medical or doctorate degree. A break-down of the number of directors with doctoral degrees who are currently directing a county PHL in California is displayed in Table 2.5 (LHC, 2009). Furthermore, one-third of the county PHLs lack a full-time PHLD and many PHLDs are overseeing multiple laboratories, including Butte, Contra Costa, Napa/Solano, Fresno, Humboldt, Marin, Merced, Orange, Stanislaus, and Sutter Counties. Of the 33 PHLDs, the majority of the PHLDs are eligible for retirement, and eight of the PHLDs have retired, but have continued to work for the

county PHL until the county is able to find a suitable replacement. A supply of eligible candidates is not readily available to replace the retirees. It is imperative that an adequate pipeline of PHLDs be available in the next 5-10 years to ensure a robust PHL network.

Table 2.5: Public Health Laboratory Director’s with Medical or Doctorate Degrees

	M.D./Doctorate Degree	No M.D./Doctorate Degree
33 PHLDs	7	26
1 state laboratory (6 director positions)	6	0

Reference: (LHC, 2009)

The PHLD workforce shortage is not unique to California. A national study reported that local PHDs are experiencing shortage of individuals to fill PH positions such as health educators, environmental scientists, microbiologists, and qualified individuals for laboratory director positions (LHC, 2009; Capener et al. 1992). In 2003, a survey conducted by the APHL focused on laboratory services, staffing and support systems (525/1800 responded, a 29% response rate). In addition to collecting this data, focus groups were conducted with laboratory directors from 14 local PHLs representing 12 different states. The results from the focus group interviews and surveys found that many local PHLs were having difficulty maintaining their current testing programs due to budget constraints, laboratory personnel shortages and difficulty finding a qualified laboratory director to manage the laboratory (Public Health Laboratory Issues in Brief, 2004). An example of this occurred in California when Mendocino County shut down its PHL in 2009. Mendocino County was unable to recruit a full time laboratory manager or PHLD. The county administration felt it would be in the best interest of the county to outsource their PHL testing to another PHL.

“I wanted Dr. Gordon, who is the head of the laboratory in the Ukiah Medical Center (to direct the PHL). He’s an M.D, but he was not “qualified” to run the PHL. The state regulations shot us in the head. We went through hiring and recruitment two or three times. We would hire someone and they would come but they did not stay.” – Dr. Marvin Trotter, Mendocino County HO 1999-2010

Recruiting individuals that meet both the state and federal requirements has posed a challenge for many counties of California. Competition from academic institutions as well as private industry further exacerbates the problem of the PHLD shortage by limiting the pool of available applicants. If PHLs shut down due to these constraining forces and an adequate strategic plan to continue coverage and provision of PHL testing services is not devised, this will further diminish the state’s laboratory capacity. Thus, these environmental constraints may drive counties to consider engaging in a form of inter-organizational cooperation to obtain the necessary resources to sustain the state’s PHL system capacity.

Research Questions

A regionalized laboratory system may have resulted in quality improvements in testing, or cost savings for PHLs in other states, however, California is unique in its geography and the population that it serves. It remains unclear whether regionalization of county PHLs will help to

bolster the state's laboratory capacity as recommended by the LHC. The main purpose of this dissertation aims to address the following questions:

Specific Research Question: Would inter-organizational partnerships among California's county public health laboratories be a feasible solution to address insufficient state laboratory capacity?

Secondary Research Questions:

1. What is the effect of inter-organizational partnerships on laboratory capacity and on the demand for laboratory directors?
2. How can the California Department of Public Health provide leadership to help bolster the state's laboratory capacity?

Conclusion/Significance of Research

California has a rich PHL history. Its PHL system has been in place for over 100 years and has been successful in averting public health threats like the black plague, small-pox, and in recent years with West Nile outbreaks and the 2009 H1N1 pandemic. California continues to be at the forefront of PH related research e.g. newborn disease screening, molecular testing methods for infectious diseases, personnel licensure, and creation of a strong PHL network. However, over the past 20 years environmental pressures such as the introduction of revised federal regulations for PHLDs, the increasing growth of large commercial reference laboratories and the reduction of state funding, counties with PHLs need to consider the feasibility of sustaining individual PHLs (The Lewin Group, 1997). As California looks toward another 100 years of providing PHL services, these forces will become increasingly difficult to manage and will force county administrators to assess its PHL needs. Strategic plans need to be put in place to ensure the viability of PHLs and the seamless provision of quality laboratory testing services. It would be detrimental to the health and safety of Californians to have this rich network of PHLs deteriorate due to economic as well as political pressures. Strategies of inter-organizational cooperation through regionalization, consolidation or a strategic alliance may be possible option to address these concerns. The following chapter highlights case studies of counties in California that have participated or discussed participation in some form of inter-organizational cooperation. The case studies are examined in order to help identify causal factors that are integral to inter-organizational relationship success. It will also help to establish whether inter-organizational models of cooperation are a feasible cost-reduction adaptation for PHLs and how best to design the type of inter-organizational relationship.

Chapter Three: Case Studies of Inter-organizational Models of Cooperation

“Consolidation must be justified by the capacity to provide better services. With consolidation there must be an effective association between those in the lab and those responsible for the service activities” -- Hardy A.V.: The Public Health Laboratory-Looking to the Future pg. 930

Introduction

The case studies described below illustrate different forms of inter-organizational relationships currently implemented or discussed among local county PHLs in California. The main purpose of the case studies is to identify the causal factors that are integral to the success or failure of a strategic partnership. This can help to establish whether local PHL partnerships are a feasible adaptation to manage environmental constraints as well as the best design for such partnerships. The main research question addressed in this chapter is: *What factors contributed to the success or failure of an inter-organizational cooperation among PHLs?*

Research Methodology

An exploratory multiple-case study was conducted in order to highlight different forms of strategic cooperation/partnerships implemented or discussed between local county PHLs in California as a means to cope with financial constraints as well as the shortage of CLIA’88-qualified PHLDs. Factors of “success” and “failure” were defined across each case study to elucidate criteria for a successful long-term PHL relationship. As described by Stake and Yin it is important to understand how the different cases perform in different environments and thus the evidence from multiple case studies may be more convincing than a single case study (Stake, 2006; Yin, 2009). A descriptive presentation of the three case studies is provided in the current chapter. Each of the case studies are presented individually to provide 1) background information on the counties and individuals involved with the initiation or discussion of the strategic partnership, 2) the specific type of strategic partnership that was utilized or discussed 3) the factors that the counties utilized to determine whether to engage in a strategic partnership, 4) the factors that were most influential in a “successful” inter-organizational PHL relationship and 5) recommendations on how to improve the inter-organizational cooperation.

Case Selection Criteria

The three cases were selected based on public information and interviews with local county PHLDs. One successful and two unsuccessful forms of inter-organizational cooperation between county PHLs were chosen. The case studies aim to assess whether 1) inter-organizational models of cooperation is a feasible option to address the state’s insufficient laboratory capacity and 2) to establish factors integral to successful inter-organizational partnership performance. As described by Stake (2006) it is necessary to highlight “successful” and “unsuccessful” forms of inter-organizational laboratory cooperation in order to *“build in variety and create opportunities for intensive study”*.

Purposive sampling, a non-probability sampling method was utilized because a limited number of examples are available (Patton, 2002). While this method of sampling decreases the

opportunity to statistically generalize the findings as compared to random sampling this method of sampling was applicable for this project due to the limited cases available within California (Patton, 2002).

Interview Participant Selection

The interview participants were also purposefully sampled. It was necessary to interview individuals who were the richest sources of information. People that were directly involved in the discussion or initiation of a partnership were selected. In order to obtain additional key interviewees, snowball sampling as described by Patton (2002) was utilized. Following each interview, participants were asked if there were other individuals that were involved in the discussion or initiation of a PHL partnership. Through this method, several key interviewees were identified. Verbal consent to participate in the interview and use of their names was confirmed by all interviewees. Purposeful sampling may decrease the opportunity to statistically generalize the findings as compared to random sampling but was applicable for this project due to the limited key informants available (Patton, 2002).

Data Collection

Interviews

Ten in-depth interviews were conducted for the three case studies. The semi-structured interview guide is listed in Appendix 5. Interviews were conducted either in person or over the telephone. The number of interviewees varied in number across the three case studies since there were limited numbers of individuals with specific knowledge of the PHL partnership.

Interviews were conducted between March and August 2010 and lasted about an hour, with some ranging from 30 minutes to an hour and a half. Follow-up questions were explored through a combination of in person interviews, electronic mail exchange or telephone conversations.

These interviews revealed what stimulated interest in considering and discussing a laboratory partnership and illustrated the context within which these partnerships were developed. Areas of success, points of improvement and lesson learned were extrapolated from the cases. The interview guide aided the exploration of issues surrounding the initiation of a partnership, criteria that were utilized when finding a partnering laboratory, maintenance of the partnership, success factors and areas of improvement of the partnership. Follow-up questions were explored through a combination of in person interviews, electronic mail exchange or telephone conversations.

After reviewing the study protocol and interview instrument, the UC-Berkeley Committee for the Protection of Human Subjects (CPHS) approved an exempt Institutional Review Board IRB (IRB) for data collection on the basis that the participants were providing an account of how their counties decided to engage in or discuss inter-organizational forms of cooperation relating to the PHL. This research poses minimal risks to the individuals involved and exempt status approval was granted on January 15, 2010 under protocol number 2009-10-303.

Document Review

A review of documents obtained online and through information interviews with county and state PHLDs provided additional background information about the strategic laboratory partnerships that were selected for review which better informed the interviews.

Analysis

Interview Protocol

Notes were taken during all interviews and audio recordings were made with the verbal consent of the participants. The participant's name was used only with expressed permission. Interviews were transcribed to help fill in notes and to ensure accuracy of the quotes from the participants. Recording of interviews helped to provide further rigor than relying solely on hand written notes. Participation was voluntary and a written description of the project was provided upon request. Participants were told that they could choose to decline to answer or stop the interview at any time if they were uncomfortable with any of the questions.

Coding

Coding was done by hand for each interview transcript. A set of preconceived codes was developed working through the research questions as well as the development of the interview guide. As coding began on the interview transcripts new codes were developed and original codes were modified and discarded as needed. Cross comparison of the codes and the interviews helped identify major themes that were integral in assessing the areas of success and points of improvement across the three cases.

Case Study Analysis

Data was collected through interviews as well as internet document reviews. The interview transcripts were coded and analyzed across the three cases. Factors that maintained and improved the sustainability of the inter-organizational relationship were described after each case. In addition, a comparative cross case analysis was conducted to determine factors that were integral for success of the strategic relationship across all three case studies. A list of these factors is available at the end of this chapter.

Case Study Write-Up

Information gathered from interviews was written up descriptively. The case studies highlight different forms of strategic cooperation. Each case study is presented in a format that best illustrate the factors that were integral to the success of the inter-organizational form of cooperation. A list of interview participants as well as the county laboratory history is included for all three cases. Interview participants are listed for each case and a description of their involvement are described.

Member Checks

Participants were contacted to confirm the accuracy of the information and quotes attributed to each individual. The interviewees were asked to provide feedback and address any inaccuracies in the information presented to ensure that statements and conclusions that were developed were reasonable and plausible (Maxwell, 2005; Yin, 2009). The inclusion of feedback helps to ensure the accuracy and reliability of the information presented in each of the case studies. Eight of the 11 participants responded. Minor feedback was provided by a few interviewees. The respondents indicated that the information presented in the case study was accurate and the quotes that were utilized are representative of what they had said during the interview.

Case One: Napa and Solano County Public Health Laboratory Consolidation

Interviewees:

Sandra Kaddas, Napa County PHLD 1989-1999

Napa/Solano PHL Assistant Laboratory Director 1999-2006

Al Shabandi, Napa/Solano PHLD 2005- March 2011

Thomas Charron M.D, Solano County Health Officer 1989-2003

Karen Smith M.D, Napa County Health Officer 2005- present

Laboratory History

Napa and Solano Counties are located in the greater San Francisco Bay Area between San Francisco and Sacramento. Napa and Solano Counties were formed in 1850 and the PHLs were formed in 1951 (Capener, 1992). Table 3.1 includes the county demographics and PHL profile of Napa and Solano Counties (Wikipedia, 2010a, b).

In 1997, the Health and Human Services Agency in Napa County received funding from the county to update their campus. The PHL was located in a trailer and was invited to participate in the campus update. However, after careful review of the costs of building a new laboratory facility, and maintaining a PHL, the administration realized that they could not afford to undertake this endeavor. Napa County Health Officer, Dr. Robert Hill and PHLD, Sandra Kaddas and agency administrators decided to explore the option of consolidating with another PHL to continue provision of PHL services. During that time Solano County Health Services Department Director Mr. Don Row and Public Health Division Director/Health Officer Dr. Thomas Charron were advocating for obtaining economies of scale with public health programs and thus engaged in discussions with Napa County to consolidate the PHLs. Both Napa and Solano Counties were facing major budget deficits and problems with hiring laboratory personnel and decided to consolidate the laboratories as a cost saving measure.

Table 3.1: Napa and Solano PHL Profile and County Demographics

	Napa County	Solano County
No. of personnel*	3	9
No. of specimens tested	1500	30-35,000
Population served (2007)	133,433	424,823
Total Land Mass (sq. miles) (2007)	788.5	909.4

*Personnel includes technical and clerical categories

Initiation of Public Health Laboratory Consolidation

The Napa County administration and PHLD agreed upon two criteria when considering a partnering county: 1) compatibility of testing capabilities and 2) the distance of specimen transport. Bids for a PHL partner were sent to neighboring Sonoma, Contra Costa and Solano Counties. After careful consideration, the Solano County PHL was chosen to be the consolidation partner. In addition to having compatible testing capabilities and closeness in proximity (~20 miles) the following two factors were critical in the decision-making process:

- 1) **Napa and Solano County PHLs had a prior working relationship.** The Solano PHL often acted as the “back-up” laboratory and assisted in testing specimens for the Napa County PHL. Thus, the Solano County PHL personnel were familiar with the procedures and protocols for handling the Napa County laboratory specimens. This streamlined the transition process during the initial phases of the merger.
- 2) **Utilization of Napa County personnel in new joint laboratory.** Solano County was willing to create an assistant PHLD position for Sandra Kaddas (Napa County PHLD) in the new joint Napa/Solano County PHL. Sandra represented the voice of Napa County as Napa and Solano County adjusted to managing a joint laboratory.

In 1999, a joint powers agreement (JPA) was created and approved by both the Napa and Solano County officials and the boards of supervisors. A JPA is a contract between a city, a county and or a special district in which the city or county agrees to perform services, cooperate with, or lend its powers to the other city, county or special district (Dictionary by Farlex, 2009). The JPA allows a single laboratory to serve multiple adjacent counties and leverage scarce resources to create economies of scale for specimen testing, proficiency testing, supplies and reducing personnel needs. This agreement resulted in the closure of the Napa County PHL and creation of a joint Napa/Solano County PHL. The employees are hired and paid by Solano County, but Napa County provides financial support to maintain the PHL and continued provision of laboratory services for Napa County. Health Officers of both counties have deemed this a successful venture as evidenced by the renewal of the JPA in 2005 and in 2008; a copy of the current JPA is listed in Appendix 6. Today, the Napa/Solano County PHL is located in Fairfield, California.

Areas of Success

Sandra Kaddas the Napa County PHLD and laboratory personnel of the Solano County PHL did not recall experiencing major difficulties with daily laboratory operation and function following consolidation of the laboratories. The consolidation process progressed smoothly with minimal expenses. The noticeable problem noted by Miss Kaddas was finding storage space for excess equipment.

The joint Napa/Solano County PHL established a courier service to pick up specimens in Napa County to ensure that samples were transported to the joint PHL in a timely manner. The courier service was integral in minimizing degradation of specimen samples during transport between counties. If specimens had to be packaged and shipped to the new facility there might have been delays or mishandling of samples. Public health laboratory directors, HOs, and staff from Napa and Solano Counties did not recall major problems with an increase in testing errors, delays with reporting results, or a dramatically increased workload due to the consolidation of the PHLs. By engaging in a consolidation effort, Napa County was able to offer a broader testing menu to its clients as well as a quicker turn- around time on reporting results. For example, HIV testing was conducted once a week at the Napa County PHL due to a shortage in staff and low specimen volume. At the Solano County PHL the same test was conducted several times a week which resulted in a shorter turn- around time for specimen results. According to the county HOs from Napa and Solano Counties, the Napa/Solano County PHLD, and the laboratory personnel, the merger had minimal negative impact for either PHDs or the communities they served. While it would be ideal to have a PHL in both Napa and Solano Counties for a faster laboratory response

during an outbreak and/or testing for rabies exposure, the joint Napa/Solano County PHL has been able to efficiently and effectively provide laboratory services to both communities.

“Over time the Napa tests and the type of testing done in the Napa County PHL had decreased dramatically and so it became inefficient and very expensive to maintain a separate lab that was doing very few tests.” -- Dr. Karen Smith, Napa County Health Officer

The consolidation was also financially beneficial for both counties. Napa County reduced its annual fiscal expenditures by sharing a laboratory facility and Solano County benefited financially with increased funding for testing and creation of an assistant laboratory director position. According to Dr. Karen Smith, the Napa County HO, there are no major issues with loss of programming specific to local health programs in Napa County. Napa and Solano County administrations are both equally invested and responsible for the PHL and, both HOs work to ensure that the health needs of each of their counties are properly served.

Another area of success was the implementation of a JPA (Joint Powers Agreement) rather than a contract or memorandum of understanding (MOU). The use of the JPA solidified the investment of both counties in the partnership. The benefits of the JPA included:

- 1) **Utilization of a joint name for the laboratory.** Rather than using only the Solano County PHL name, the joint PHL was renamed to the Napa/Solano County PHL, a name recognized by local county and state PHLs in California. The JPA allows utilization of a joint name for the laboratory. This cannot be granted under a contract or a MOU.
- 2) **Access to government funding.** Any government funding designated for the Napa County PHL is accessible to the joint PHL. If the agreement was contractual the “parent” lab i.e. Solano County would not have access to funding designated for Napa County.
- 3) **Equal footing and responsibility of the PHL.** The counties jointly operate the laboratory and both counties’ HOs function in an advisory capacity with decisions involving the PHL. This provides assurance to Napa County that Solano County cannot make changes to the PHL without their involvement. Dr. Karen Smith has stated that *“it works in the best interest of both counties that we jointly operate the lab rather than Napa County simply contracting services on a fee for service basis”*.

Points of Improvement

Major points of improvement that the PHLDs and HOs have identified include: 1) allow flexibility with funding provisions from Napa County and 2) utilization of Solano County payroll office. Funding provided by Napa County should not be limited to funding for the assistant PHLD position; it should be made available for purchasing of laboratory reagents, supplies and equipment. In addition Sandra Kaddas was required to utilize the Napa County payroll office to turn in timesheets and file paperwork because her position in the joint PHL was provided by Napa County. It would be more efficient and less confusing for the payroll staff in Napa County if the assistant PHLD could utilize the payroll services of the Solano County PHD.

With the renewal of the 2010 JPA, Dr. Karen Smith, and the acting Solano County Health Officer, Dr. Mike Stacey, agreed that the provisions for funding in the JPA needed to be changed. According to Dr. Smith, the renegotiated JPA stipulates that the funding provided to Solano County for the PHL services does not need to be attached to a specific position i.e. the assistant PHLD position. This allows the PHLD greater flexibility in deciding how the funds should be utilized. In addition, a new provision to the JPA allows the financial contribution made by Napa County to be linked to the consumer price index so that funding reflects inflation. Prior to this agreement, Solano County did not ask for an increase in monetary support from Napa County even though operating costs had gone up considerably in the past three years.

The PHLDs from Napa and Solano County were initially not supportive of the idea of closing down a PHL. According to Sandra Kaddas if she had a choice the Napa County PHL should remain independent, however she understands that with the current economic and political conditions merging laboratories may be necessary to preserve PHLs. Napa County could have lost the PHL entirely if the administration had not had the foresight to participate in a consolidation effort with the Solano County PHL.

“The whole process really worked because of the people involved. Everyone had the same goal in mind which was to strengthen the lab services in both counties and become more efficient and cost effective and that was accomplished and still being accomplished with this agreement.” – Dr. Karen Smith, Napa County HO

Discussion

The factors that were integral to the success of the joint venture are consistent with the organizational theory literature which indicates that social factors such as high mutual dependence (Lawler and Yoon, 1996), prior working relationships (Larson, 1992), trust¹⁴ (Zaheer et. al., 1998) and relational embeddedness¹⁵ (Gulati, 1995; Poldony, 1994) predisposes organizations to enter into inter-organizational partnerships. The sense of joint dependence and commitment generally results in shared similarities in goals, values, and success which nurture a sense of commitment resulting in long-term cooperation and exchange arrangements as demonstrated in the joint venture of the Napa/Solano County PHL (Kogut, 1988; Gulati and Sytch, 2007; Lawler and Yoon, 1996; Provan, 1993; Gulati and Gargiulo, 1999, Turner et.al., 1979; Mizruchi, 1989; Lincoln, 1992). Utilization of the JPA as a binding agreement held both parties accountable for the joint entity. According to organizational scholars, *“the shared ownership structure effectively deters opportunistic behavior”* (Gulati, 1995). The Napa/Solano County PHL consolidation exemplifies the trust associated with high mutual dependence and commitment from both organizations, a major factor in the success of the consolidation effort. In addition to social factors, organizational determinants of inter-organizational cooperation such as geographical proximity (Lincoln, 1992), and a shared mission and value of having a PHL (Meyer and Rowan, 1977) are integral to the success of this strategic partnership. The short distance between Napa and Solano Counties and the compatibility between the county administrations were key to the success of the partnership.

¹⁴ Trust- the expectation that another organization may be relied upon to fulfill its obligations to behave predictably and to act and negotiate fairly even when the possibility of opportunism is present.

¹⁵ Relational Embeddedness- highlights the effects of cohesive ties between social actors on subsequent cooperation between those actors.

Currently the merger is being maintained and the JPA has been renewed several times with minimal hindrance since 1999. Both the PHLs and HOs have expressed that the merger between the two PHLs has been beneficial for both counties. Dr. Smith, the HO for Napa County emphasized that she values having her own PHL because she has a voice in managing the laboratory. She does not believe that a “mega” PHL where three or four PHLs combine services would have been a better alternative solution. The “mega” laboratory becomes too impersonal and would not adequately represent the needs, concerns and health priorities of all the parties involved. In addition, physicians will not be able to develop relationships with the PHMs because clinicians would lose the direct access to laboratorians as is the case when one contracts with big commercial laboratories like Quest Diagnostics or ARUP. The organizational theory literature suggests that minimizing the number of organizations involved in the exchange process will result in better management of information due to a small set of exchanges (Eccles, 1981; Larson, 1992). Developing a partnership between two counties rather than three or four counties contributed to the continued success of the joint Napa/Solano County PHL. The factors that have made the consolidation process between Napa and Solano Counties “successful” are summarized in Table 3.1a below.

Table 3.1a: Decisive Factors for the Successful Consolidation of the Napa and Solano County PHL

<i>Distance</i>	<ul style="list-style-type: none"> • Short distance between the counties ~20 miles
<i>Size</i>	<ul style="list-style-type: none"> • Small size of Napa County PHL (<5 personnel) resulted in a minimal increase in personnel and workload for the joint laboratory • Minimal challenge with moving the laboratory • Minimal personnel negatively affected • Minimal increase in laboratory testing volume (Napa County: 1500 specimens/year) • Minimal exchange partners (only two counties involved in the partnership)
<i>Leadership</i>	<ul style="list-style-type: none"> • Support of county administration from both counties • Strong working relationship between PHLDs • Strong leadership provided by the PHLDs
<i>JPA</i>	<ul style="list-style-type: none"> • Creates equal footing and responsibility for both counties with regards to the PHL • Utilization of both counties names for the PHL
<i>Transportation</i>	<ul style="list-style-type: none"> • Lengthy discussions of logistics to minimize a rocky transition; ultimately a courier service was decided upon
<i>Bridging Communication</i>	<ul style="list-style-type: none"> • Utilization of Napa county personnel in a management position in the new joint laboratory • Two years of strategic planning between the counties before the consolidation process moved forward
<i>Alignment of Goals</i>	<ul style="list-style-type: none"> • Compatibility of goals between the partnering counties with relation to the PHL, and between PHLDs and the county administration.

Conclusion

Napa County wanted to have access to a PHL without having to maintain a physical laboratory. By consolidating the Napa and Solano County PHLs, Napa County continues to have access to a laboratory without having to maintain and finance one. Solano County benefitted from this partnership by obtaining access to an additional funding source and economies of scale for testing due to an increase in the workload from consolidation of the two laboratories.

PHLs provide a natural place to look at efficiencies that can be gained from a strategic partnership, however engaging in an inter-organizational relationship may not be suitable for all counties. Each of the county PHLs in California operates independently of one another and may have differing capabilities and capacities depending on the needs of the PHD and the community. There are also barriers such as distance or economic or political barriers which may impede a partnership between PHLs. The following section describes the “discussion” of a partnership where structural incompatibilities e.g. workload volume and laboratory space and lack of political support prevented the formation of an East Bay Consortium of PHLs.

Case Two: Proposed Alameda County, Contra Costa County and San Francisco County East Bay Consortium of Public Health Laboratories

Interviewees:

Ann Chandler, Alameda County Laboratory Director 1984-2004

Richard Alexander, Contra Costa Laboratory Director 1998-present

Sally Liska DrPH, San Francisco Laboratory Director 1994-2010

Laboratory History

Alameda, Contra Costa, and San Francisco Counties are among three of the nine counties located in the greater San Francisco Bay Area. Contra Costa and San Francisco Counties were established in 1850 and Alameda County in 1853. The three PHLs located in these counties were established in 1951 and are located within 40 miles of each other (Capener, 1992) Table 3.2 is a summary of the three counties' demographics and PHL profiles (Wikipedia, 2010c, d, e).

Table 3.2: Alameda, Contra Costa, and San Francisco County Laboratory Profiles and County Demographics

	Alameda	Contra Costa	San Francisco
No. of personnel* (2010)	12	15	26
No. of tests conducted/yr (2010)	20,000	149,110	108,672
Population Served	1,556,657 (2009)	1,051,677 (2008)	809,000 (2008)
Total Land Mass (sq. mi)	821	719.95	46.7

*Personnel includes technical and clerical categories

Discussion of Potential Partnerships

In 2000 the PHLDs and HOs from Alameda, Contra Costa, and San Francisco County met to discuss the possibility of consolidating the three PHL facilities. The meeting was called by the HO of Alameda County, at the time, Dr. Arthur Chen because he was asked to consider relocating the existing Alameda County PHL. The San Francisco PHL was also considering the possibility of relocating to a new facility and they were invited to the table to discuss a potential partnership. Contra Costa County constructed a new PHL in 2001 that was attached to the Contra Costa Regional Medical Center and was being considered as an option to house all three laboratories.

It was realized early in the discussion by the PHLDs and HOs that the Contra Costa County PHL was not large enough nor did it have the testing capacity to handle the workload for two additional laboratories that served over one million people. The PHLDs and HOs discussed the possibility of acquiring existing government laboratory facilities, or constructing a new "super lab" in government surplus buildings that would be large enough to handle the workload for all three counties. The PHLs would share one physical facility to save on costs of operating three

separate PHLs, but they would maintain three separate PHLDs and separate laboratory reporting systems. Partnering three large laboratories would require a consultant to evaluate the laboratories and design a plan that would best accommodate everyone. Funding was unavailable to support this endeavor at that time. Furthermore, merging the three PHLs was not a priority for the PHLDs or the HOs at the time and thus there was no political champion to move this idea forward. Ultimately, it was decided by the PHLDs as well as the county HOs that consolidating the PHLs of Alameda, Contra Costa and San Francisco Counties into an East Bay Consortium of PHLs was not financially feasible or a desirable option.

Ann Chandler, the laboratory director for the Alameda County PHL at the time, was not supportive of having a “mega lab” for all three counties. According to Ms. Chandler when anthrax was used in a bioterrorist attack in the United States in 2002, all the PHLs in California worked overtime to test potential anthrax specimens to ensure the safety of the public. The network of 37 PHLs serve over 37 million people and all of the PHLs were necessary to prevent a back log in testing potential anthrax specimens. Another reason Ms. Chandler was not supportive of combining the three PHLs was that in the event of an earthquake it would be crucial to have PHLs operating on either side of the Bay Bridge and Golden Gate Bridge to minimize specimen transportation. Each of these three counties serves populations larger than a majority of other counties in California as well as in comparison to entire states. According to Ms. Chandler it does not make sense to consolidate or regionalize PHLs in populous counties.

According to Richard Alexander, the PHLD for the Contra Costa County PHL, consolidating the three laboratories was not a feasible option for his county because 1) they had just moved into their new laboratory space at the Contra Costa Regional Medical Center and 2) a majority of their workload came from the county’s Health Plan and the Regional Medical Center. They were also doing a large volume of fee-for-service testing for a private nonprofit organization i.e. Planned Parenthood, which generated a majority of their revenue. By having their own PHL in Contra Costa County they could prioritize specimen testing depending on the needs of the county community.

Dr. Sally Liska, the PHLD of the San Francisco County PHL, did not comment on the discussion that took place during this meeting, but she offered comments about consolidation in general. Ms. Liska remarked that larger PHLs are often more cost effective than smaller PHLs because they have larger specimen workload volumes and instrument automation, which reduces the amount of time spent on preparing and running samples. Smaller PHLs are also less likely to have redundancy of positions so when short staffed, smaller PHLs may have to turn to another PHL for “back-up”. Thus, engagement in inter-organizational relationships between PHLs may be more advantageous and beneficial for smaller PHLs in less populated areas. A local laboratory established through a consolidation process e.g. the Napa/Solano County joint PHL venture, would be preferred over a regional laboratory because the local PHL can offer customized testing for unique populations in their jurisdiction.

Currently, all three PHLs are operating out of their original facility, the Alameda PHL on Broadway in Oakland, the Contra Costa PHL on the Contra Costa County Regional Medical Center campus, and the San Francisco County PHL on Grove Street in San Francisco. There are

plans by Alameda and San Francisco Counties to move their PHLs into newer facilities; however it may be several years before this may happen.

Discussion/Conclusion

The PHLs in Alameda, Contra Costa and San Francisco County are within 40 miles of each other; however, plans for a partnership did not come to fruition because all three laboratories are serving populous counties. Due to automation of equipment and large testing volumes, combining the workload of three populous counties might have negatively impacted specimen quality, testing performance, and cost efficiencies and hindered the PHLs ability to provide quality testing services to their communities.

The choice of an inter-organizational cooperation requires long term planning and should be informed by objective research. According to Ann Chandler, any major reform to the California PHLs such as a regionalization or consolidation will need 1) financial and political leadership from the state, 2) recruitment of an individual well recognized among the PHL community that would be willing to spearhead a campaign for reorganizing the PHLs and 3) authorization of this individual to implement action if needed. Once a county decides to engage in a partnership and give up their laboratory it would be hard to reestablish the PHL. While it may not be practical to for all PHLs in California to pursue inter-organizational relationships, it may be worthwhile to discuss the pros and cons of establishing a partnership in order to assess how California PHLs can maximize efficiencies in providing laboratory testing services to the community. According to experts on inter-organizational relationships, the drive to pursue an inter-organizational exchange may be greater if the parties involved anticipate a greater return on increasing efficiencies (Aiken and Hage, 1968; Gulati, 1998). In this case, the benefit of pooling resources would not have been mutually beneficial and could have negatively impacted the efficiencies of the laboratories. Table 3.2a below list the factors that impeded the establishment of a PHL partnership among Alameda, Contra Costa and San Francisco Counties.

Table 3.2a: Factors Impeding a Strategic Partnership

Size	<ul style="list-style-type: none"> • Large laboratories serving populous counties (over one million) and each with large testing volumes (over 80,000 specimens/year).
Leadership	<ul style="list-style-type: none"> • Lack of support from the county administrators to proceed with a strategic partnership due to financial and political limitations
Alignment of Goals	<ul style="list-style-type: none"> • Incompatibility of county administration goals with those of the PHLs.

Case Three: Sonoma and Mendocino County Public Health Laboratory Regionalization

Interviewees:

David Yong Ph.D., Sonoma County Lab Director 1986-2009

Mark Netherda M.D., Sonoma County Deputy Director 2008- present

Marvin Trotter M.D., Mendocino County Health Officer 1999-2010

Erika Nosera, Interim Coordinator for the Communicable Disease and Immunization Program, Mendocino County 2005-present

Laboratory History

Sonoma and Mendocino Counties are located on the northern coast of California in the greater San Francisco Bay Area. Sonoma and Mendocino Counties were established in 1850 and the PHLs were established in 1951 and 1978 respectively (Capener, 1992). The PHLs are approximately 63 miles apart and as of December 2009, Mendocino County officially shut down its PHL. Table 3.3 below is a summary of the county demographics and PHL profiles (Wikipedia, 2010f, g).

Table 3.3: Sonoma and Mendocino County PHL Profiles and County Demographics

	Sonoma County	Mendocino County
No. of personnel* (2007)	14	2
No. of tests conducted/yr. (2007)	31,000	3,808
Population (2009)	472,102	86,040
Total Land Mass (sq. mi.)	1768	3878

*Personnel includes technical and clerical categories

Initiation of Partnership

When the Mendocino County health administration could not find a permanent replacement for their PHLD, Jack Voss after he retired in 2003, Dr. Mavin Trotter the Mendocino County HO at the time recommended to his administration that Mendocino County contract with Sonoma County for PHLD services to maintain a PHL in Mendocino County. In 2004, Dr. David Yong agreed to serve as the part-time PHLD for the Mendocino County PHL while simultaneously serving the Sonoma County PHL.

While Dr. Yong was essential in the negotiation process, it was mainly the HOs and county administrators who acted as the driving force for the partnership. The administrations from both counties agreed that Dr. Yong would be stationed at the Sonoma County PHL and visit the Mendocino PHL once a month. Mendocino County paid Sonoma County a flat fee to have Dr. Yong supervise the Mendocino County PHL. According to Dr. Yong the negotiation process proceeded fairly smoothly and an amicable contract was agreed upon by both parties. Both counties gained financially from this partnership because Sonoma County received revenue for sharing the PHLD, and Mendocino County did not have to employ a full-time PHLD.

Initially, this was a promising arrangement. Dr. Yong was supported by a laboratory manager and two PHMs. During the first year, one PHM retired which left one PHM and the laboratory manager to handle the workload for the entire laboratory. When the laboratory manager decided to retire and the PHL could not find a qualified applicant to fill the position, sustaining the PHL became a problem. Under federal and state requirements, PHLs may employ a part-time PHLD if there is a full-time supervising PHM working in the laboratory. Unfortunately due to the low salary scale, the Mendocino County PHL could not attract applicants to fill the laboratory manager position. After having difficulty recruiting a PHL manager as well as a full-time PHLD to work in the Mendocino County PHL, Dr. Marvin Trotter decided that the quarter of a million dollars needed to maintain the PHL would be better spent on other PH programs. In 2009, the administrators of Mendocino County decided to close the Mendocino County PHL. The majority of their laboratory samples were sent to clinical laboratories in hospitals around Mendocino County and specimens of PH concern were sent to the Sonoma County PHL. According to the Sonoma County Deputy Director, Dr. Mark Netherda the agreement between Sonoma and Mendocino Counties following the closure of the Mendocino County PHL was not discussed at length. Rather than a methodically planned strategic transition it was a “we have to do something right now” situation.

Currently, Mendocino and Sonoma Counties are engaged in a contractual agreement for PHL testing services. Samples of PH concern such as Mycobacterium tuberculosis are transported to the Sonoma County PHL and charged on a fee-for-service basis. The counties have a courier service to transport samples between Mendocino and Sonoma County, but if a sample from Mendocino County misses the courier pick-up, the specimen(s) have to be held a day longer for transport to the laboratory. According to Erika Nosera, the interim coordinator for the Communicable Disease and Immunization program in Mendocino County, the major problem she is experiencing is a delay in turn-around-time for receiving test results for specimens that are sent to the Sonoma County PHL. However, she realizes that this may be due to the cut backs that Sonoma County has been experiencing with funding and personnel, and the increased workload from Mendocino and Lake Counties. While she would prefer to have a PHL in Mendocino County, she realizes that it is not financially feasible for her county at this juncture.

A major concern that both PHLDs and HOs have with regards to a PHL partnership is priority of specimen testing during an outbreak situation. However, according to Ms. Nosera, while there may be delays in turn-around time for test results, she does not feel that Sonoma County prioritizes their laboratory samples over Mendocino County’s laboratory samples. She feels that Mendocino County’s PH testing needs is being well served.

“I do not know outside of the fact that Sonoma does what it can, it is not like Mendocino is put on hold over Sonoma County’s [specimens]. The biggest thing they [Mendocino County] sends down directly from the public health department to Sonoma County’s PHL is when she is doing induced sputum for possible active TB cases. As soon as they [the Sonoma County PHL] get the specimens they are running it. The labs have a priority of communicable disease and I do not think it matters who sends it” –Erika Nosera, Interim Coordinator for the Communicable Disease and Immunization Program, Mendocino County

Discussion/Conclusions

The major limitation for sustaining the partnership between Sonoma and Mendocino Counties was the inability to recruit a PHL manager to work for the Mendocino County PHL. Due to financial constraints, the Mendocino County administration could not increase the pay scale for the position and had difficulty finding a suitable candidate. It is required that a laboratory supervisor/manager be available to provide daily management and oversight of laboratory personnel and reporting of test results if a laboratory employs a part-time PHLD. Without a laboratory manager supervising the daily operations of the PHL, Dr. Yong would be required to manage the Mendocino County PHL on a full-time basis, which was not a feasible option for Sonoma County. Financial and personnel constraints ultimately led to the decision by Mendocino County administrators to terminate the contract with Dr. Yong and close the Mendocino County PHL and engage in a contractual fee- for- service relationship with the Sonoma County PHL. This form of inter-organizational partnership does not entail the same level of mutual reliance and commitment for the PHL that an engagement in a consolidation effort through a JPA requires. According to an employee of the Sonoma County PHL, Mendocino County is being charged a marginal fee for their testing services which does not contribute to the overhead cost of supporting a PHL or the costs of maintaining a CLIA’88 qualified PHLD. According to Dr. Yong, if this partnership could be “redone”, a joint powers agreement (JPA) would have been preferred to their current agreement of fee-for-service testing. Similar to the Napa/Solano County PHL agreement, Mendocino County would share joint responsibility of the PHL and be required to provide funding specifically to support the operation and maintenance of the PHL. These terms may help both parties become more invested in the partnership and minimize the “free-rider” effect. Conventional wisdom as well as economic theorists has found that if mandates are not set, groups tend to contribute no more than the minimum to the cost of a public good or service even though a greater contribution could help all parties involved (Kim and Walker, 1984). Table 3.3a is a list of factors that may help improve a partnership between Sonoma and Mendocino County PHLs.

Table 3.3a: Factors for Improving the Partnership Process between Sonoma and Mendocino County PHLs

JPA	<ul style="list-style-type: none"> Utilization of a JPA to ensure legal and financial investment of parties involved in the PHL
Alignment of Goals	<ul style="list-style-type: none"> County administration and PHLD did not share compatible goals relating to the PHL i.e. increasing laboratory manager salary to attract qualified applicants
Leadership	<ul style="list-style-type: none"> Continued support of the partnership by both counties’ health administration
Transportation	<ul style="list-style-type: none"> Improvement of courier service to expedite delivery and transportation of specimens to improve turn-around-time for testing results
Bridging Communication	<ul style="list-style-type: none"> Strategic and methodically planned transition from contracting for PHLD services to closure of the Mendocino County PHL

Discussion

Environmental factors are influencing the county PHLs access to resources due to shifts in federal regulations, competition from other organizations such as commercial laboratories, and the current economic status of the state and the nation. The local county PHL system in California is the largest network of local PHLs in the United States with 37 local PHLs serving 61 health jurisdictions. Due to the decentralized manner in which the counties function, county administrators and PHLDs need to decide whether engaging in a form of inter-organizational relationship between PHLs as a means to cope with resource limitations is a desirable and/or feasible choice for the county. As was illustrated from the three case studies there are several factors to assess when considering engagement in inter-organizational forms of cooperation among PHLs. A “one size fits all” scenario does not apply due to the political, financial, and structural differences among the county PHLDs. Goals of the county administration and the PHLDs need to be aligned and continued support by county administrators is required to ensure a successful long term relationship as exemplified in the consolidation of the Napa and Solano County PHLs. Counties considering engaging in inter-organizational forms of cooperation need to have extensive strategic planning prior to initiating a partnership and the compatibility, capability and commitment of the partnering laboratory need to be considered (Cauley de la Sierra, M. 1995).

“If we want regionalization to take place, individuals need long term planning and foresight. They need awareness of fiscal realities of the future. The lab directors, health officers and administration need to look to the future to solve problems. We cannot maintain the infrastructure as conceived in the 1920’s. You need a way to implement programs through strategic planning. You need to figure out how to deal with the problem and get to the final goal.” --Dr. Thomas Charron, Solano County Health Officer 1989-2003)

The main factors for a successful partnership that played a role for all three case studies are summarized in Table 3.4. In addition to these factors, Appendix 7 lists additional considerations which may be helpful when choosing and designing a partnership.

Table 3.4: Summary of Factors for a Successful Laboratory Partnership

Alignment of Goals	<ul style="list-style-type: none"> • Alignment among the potential partners of goals regarding the significance of the PHL and the role it serves in providing services to the community.
JPA	<ul style="list-style-type: none"> • Utilization of a JPA to ensure legal and financial investment from all parties in the joint venture such as a PHL.
Leadership	<ul style="list-style-type: none"> • Continued support and evaluation of the strategic partnership by all the parties involved.
Transportation	<ul style="list-style-type: none"> • Adequate and timely mechanism of specimen transportation among the counties involved in the strategic partnership to ensure specimen integrity.
Size	<ul style="list-style-type: none"> • Partnering of small PHLs (less than 5 employees) with large PHLs (more than 10 employees).
Bridging Communication	<ul style="list-style-type: none"> • Strategic and well- planned discussion prior to engaging in the strategic partnership to assess the political and fiscal

	compatibilities prior to engaging in a partnership.
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Conclusion

The economic climate in California for the past several years has had a detrimental impact on public health services. The county and state PHDs have downsized their staff and public health services to cope with yearly budget reductions. This trend is anticipated to continue for several more years as California’s economy is stricken with a \$19.1 billion deficit. In addition, federal and state requirements for the PHLD will make it increasingly difficult to recruit a PHLD to manage the PHL as current PHLDs begin to retire from the field. As financial and regulatory conditions worsen, county administrators may need to assess different options to maximize utilization of resources when operating a PHD.

This chapter illustrates three cases where counties in California have engaged in or contemplated engagement in a form of inter-organizational relationship as a means to address resource constraints. Due to the decentralized county system each county needs to decide whether an inter-organizational form of cooperation is a feasible option to consider, given the economic and political pressures facing PHLs in the near future. The following chapter discusses the feasibility of county PHLs participating in a strategic relationship as a means to manage environmental and resource constraints that are impacting the state’s PHL capacity.

Chapter Four: Feasibility of Regionalizing Public Health Laboratories

Background

Inter-organizational forms of cooperation e.g. strategic alliance or regionalization are forms of addressing environmental constraints and are well- documented in organizational theory literature (Pfeffer, 1972; Gulati and Gargiulo, 1999). These forms of cooperation have been seen throughout history in many industries. In today's economy inter-organizational partnerships among the food, banking, manufacturing, transport, hospital, and biotechnology industries continue to steadily increase. Organizations may choose to participate in an inter-organizational form of cooperation for a variety of reasons: enhancement of market power and market share, access to new technologies, increased efficiencies, decreased competition, economies of scale, risk sharing etc. (Gulati, 1998; Baldwin, 2001; Powell et. al., 1996).

The trend toward inter-organizational forms of cooperation has been documented in many fields of laboratory sciences including clinical, dental, and commercial laboratories. Schmidt and Madoff (1977) hypothesized that automation and large independent laboratory facilities will become increasingly popular, providing a majority (47%) of the laboratory services across the United States. Many hospital laboratories have or are merging to reduce costs and enhance testing capabilities. In 1985 there were over 7,000 independent clinical laboratories compared to only 4,500 reported in 1997 (Ahn et al., 1997). Several trends in health care that have been affecting clinical laboratories include 1) development of integrated delivery systems, 2) increasing regulatory burdens, 3) changing practice patterns, 4) increased public awareness, and 5) reduced revenue per laboratory test (Ash, 1996; Gausewitz, 1999; Cooney and Stith, 1974). It has been found that a regional laboratory organization structure is best for providing services when trying to contain costs and help improve quality of laboratory services in the clinical hospital laboratory setting. This is because regional laboratories can cover a large selection of laboratory testing needs and provide geographic coverage to the patients that need the services. *“Cost pressures will result in increasing consolidation of hospital laboratory testing facilities, integrated regional labs are a way to accomplish consolidation while gaining improvements in the quality of the lab service and minimizing costs” (Gausewitz, 1999)*

A 1988 survey by the American Society for Microbiology (ASM) found that 33% of 351 respondents acquired another institution, 26% merged with another institution and 50% reported increased partnerships or affiliation with other laboratories (Eldere, 2005). As financial pressures begin to diminish the profit margin per test, different strategies of laboratory reorganization have been utilized to curb the cost of running a laboratory. These changes are more prominent in the private for profit and nonprofit hospitals rather than in the government owned hospitals (Cuellar and Gertler, 2003).

Regionalization of clinical laboratories can help 1) cost effectiveness by offering economy of scale, 2) reduce the number of staff needed, 3) reorganize laboratories to use advanced testing methods e.g. molecular tests and instruments which can double the number of tests performed with fewer manpower and 4) relocate expensive and rare laboratory tests to a central laboratory (Eldere, 2005). More important however, the community can benefit if regionalized laboratory services result in cost savings for tests and higher quality of testing. *“More comprehensive high*

quality and cost effective lab services can benefit patient care, reduce overall capital investment from the community, result in adequate income for employees and provide better service for physicians” (Cooney and Stith, 1974 1-30).

In 1999, ClinMicroNet (a worldwide electronic information network of leading clinical microbiology laboratory directors, not available to the public) survey was distributed to clinical laboratory experts to assess experiences with laboratory consolidation (Peterson et. al., 2001). Some of the members who participated in the survey had direct involvement in the laboratory consolidation process. Table 4.1 summarizes the top five benefits and drawbacks of consolidating clinical microbiology laboratories. The drawbacks outnumbered the benefits 2:1. Communication was a major issue that detracted from cost saving benefits (Peterson et. al., 2001).

Table 4.1: Benefits and Drawbacks of Clinical Microbiology Laboratory Consolidation

Benefits	Drawbacks
1. Cost reduction due to economies of scale	1. Poor communication between physicians and laboratory personnel
2. Perceived improvements in test accuracy on rarely performed tests occurring as a result of increased volume in the centralized laboratory	2. Recurrence of serious delays with specimen transport
3. Expanded testing menus resulting from a larger number of patients being covered by the laboratory	3. Time consuming customized reporting due to a lack of report standardization at various patient care sites
4. Standardization of test methods among several laboratories	4. Impaired Gram stain analysis resulting from initial smears being read by generalists at on-site rapid response laboratories
5. Increased funding for education due to profitability of a centralized laboratory	5. Compromised infection control surveillance resulting from a lack of personal interaction with staff at the hospital

Regionalization of the clinical testing industry is rapidly occurring among hospital laboratories, private commercial laboratories, and physician office laboratories in California as well as nationally (The Lewin Group, 1997). As economic market pressures build organizations are forced to assess cost efficiencies of operating a laboratory. The following section provides two examples of clinical laboratory “restructuring” that have been documented in Canada as a response to economic constraints. While some reports show that restructuring is a beneficial and cost effective strategy others have found that it could lead to a decrease or no change in the quality of services provided.

*Clinical Laboratory Restructuring
Alberta, Canada*

In 1994 the Alberta government in Canada faced a major budget deficit. To address this issue the government expected a 40% reduction in the number of clinical laboratories operating in Alberta. The laboratory services were characterized by duplicated services and excess capacity. The

restructuring process involved private and public laboratories forming alliances to operate in a more coordinated and efficient manner (Fagg et al., 1999).

Vancouver, a nearby city had 60 licensed collection sites for a population of 2.7 million. In the state capital of Alberta with a population of 900 thousand there were 129 licensed laboratory collection sites. In June 1994 the Alberta government enacted a regional health authority act, which established 17 health authorities to help develop a strategic plan for delivering health services, including laboratories. During the planning process they discussed four possible delivery methods; 1) collaborative/joint venture model, 2) competitive model, 3) a model in which multiple providers provided an array of services and 4) a model in where there would be a division of services between the private and the public provider to allow each sector to capitalize on its respective strengths and provide a breadth of services to the community. While this last model was not the most cost efficient method it was the one that demonstrated the best option for delivering quality laboratory services while maintaining cost savings (Fagg et al., 1999).

The initial restructuring of the laboratories was the reduction of 129 collection sites down to 27 and 50 microbiology laboratories down to 34 based on geography, demographics and accessibility to transportation (Fagg et al., 1999; Church, 2000). Throughout this process the individuals charged with implementing the restructuring felt that providing “*seamless delivery of laboratory services with elimination of duplicated processes and efforts*” was of top importance (Fagg et al., 1999). To evaluate the final product a survey was conducted of the hospital staff post-restructuring. The majority of the people surveyed stated that the overall quality of services provided by the laboratory was similar or had improved. The restructuring helped to improve many factors that contributed to better laboratory performance, these included; 1) implementation of a single laboratory information system that linked data to each laboratory location, 2) renovation of specimen processing areas to improve workflow and 3) a reduction in duplicative services and a standardization of instrumentation and testing. The major drawback was the lay-offs of over 600 workers which left staff morale low. However, the restructuring process helped the government of Alberta incur cost savings benefits while maintaining quality, timely and cost efficient laboratory services for the community (Fagg et al., 1999).

Ontario, Canada

In 1992 the Ontario Ministry of Health reviewed the province’s laboratory services system with the goal of curtailing the costs of providing laboratory services (Richardson, 1999). A Laboratory Services Restructuring Secretariat was created in 1995 by the Ontario Ministry of Health to regionalize public and private laboratories to help ameliorate financial constraints that the government of Ontario was facing. This resulted in reductions and downsizing of clinical laboratories by the formation of centralized laboratories. In 1991, there were 21 fewer hospital-based laboratories in Ontario due to the restructuring, and since 1991, the number of private laboratories decreased from 173 to 77 due to decreases in fee for service billing. While there are fewer laboratories, there are reports of negative impacts of downsizing on laboratory practice and service. There was a lack of knowledgeable technologists, scientists, and managers due to layoffs or early retirement of the experienced laboratorians. There were also major deficiencies found on proficiency testing surveys sent out by the Laboratory Proficiency Testing Program (LPTP). As laboratories shifted from discipline based to technique based, many challenges were encountered: 1) increased workload, 2) supervision of less skilled employees, 3) new and

unfamiliar analytical systems and 4) revised quality control requirements (Richardson, 1999). Technicians are cross trained on different disciplines of laboratory testing rather than on a single discipline practice which has reduced the knowledge needed for trouble shooting and quality control measures. All of these problems combined have adversely affected the quality of performance by the laboratories.

The restructuring of laboratories in Ontario, Canada was fiscally driven without thoughtful consideration of the impact on health outcomes or quality of laboratory testing services. *“Laboratory services are not a production line with its product a number of lab test results. Rather it is an information service that must follow and serve the patient seamlessly from the hospital to the home or other community health provider”* (Richardson, 1999). While this may not have been viewed as an endeavor that enhanced laboratory service quality, the Ontario government is focused on healthcare reform and an integrated healthcare delivery system. Thus a restructured integrated laboratory system regardless of the outcome is anticipated for the future.

The PHL market is not as extensive as the clinical laboratory market and both PHLDs and HOs have concerns about engagement in an inter-organizational form of cooperation among PHLs. Unlike Canadian clinical laboratories, California county PHDs and their PHLs operate in a decentralized manner and independently from the state. This allows the counties autonomy in deciding how to structure their PHD and administer services. While the decline of the state’s laboratory capacity needs to be addressed, the LHCs recommendation for the state to help facilitate regionalization of county PHLs as a means to address this problem was not adequately investigated. To ensure that there are feasible mechanisms to bolster the state’s laboratory capacity and strengthen the PHL system it is necessary to obtain the perspectives of the county PHLDs and HOs to assess whether inter-organizational forms of cooperation among PHLs is a feasible option to pursue. This chapter documents the opinions of county PHLDs and HOs about inter-organizational PHL relationships through their answers to specific research questions.

Specific Research Question: Would engaging in an inter-organizational partnership among California’s county public health laboratories be a feasible solution to address:

- 1. insufficient state laboratory capacity*
- 2. the demand for qualified public health laboratory directors?*

Methodology

Interview Participant Selection

County PHLDs and HOs are key to determining the significance of the PHL within the health department. PHLDs and HOs often work closely together to determine the types of services the PHL will provide to facilitate communicable disease surveillance and ensure the health and safety of the community. This dissertation includes the perspective of all the county PHLDs as well as a subset of HOs to gain a comprehensive perspective of the feasibility of PHLs engagement in inter-organizational partnerships as a means to address the state’s deficient laboratory capacity.

Data Collection

Interviews

There are currently 37 California PHLs and 33 PHLDs. Four of the directors serve as PHLDs in two counties. These individuals are: 1) Greg Costo (Butte and Sutter Counties), 2) James Spolsdoff (Fresno and Merced Counties), 3) Mark Miller (Humboldt and Stanislaus County) and 4) Richard Alexander (Orange and Contra Costa Counties). Interviews were conducted either in person or by phone with 29 of the 33 PHLDs (an 88% response rate). Four of the 33 PHLDs (from El Dorado, Madera, Pasadena City and Shasta Counties) declined to participate in the interview. The semi-structured interview guide used during the interviews with the PHLDs is listed in Appendix 8 and participants and non-participants are listed in Appendix 9.

The 58 Counties and 3 cities with Health Departments are listed in Appendix 10. The 12 regions of California are demarcated by the Department of Transportation (CA-DoT, 2010). Of the 38 county and city HOs, 31 were contacted. The seven HOs that were not contacted included HOs from Contra Costa, Fresno, Imperial, Long Beach City, San Francisco, San Joaquin and Solano Counties. These individuals were not contacted because permission was not granted by the PHLD or a minimum of one HO responded in that particular region of California. Of the 31 HOs that were contacted, 23 HOs participated in the interview (approximately a 74% response rate). The eight county HOs from Butte, Kern, Madera, Placer, San Bernardino, Shasta, Sutter and Tulare Counties were not because they did not respond to email requests for an interview. The semi-structured interview guide used during the interview is listed in Appendix 11 and a list of participants and non-participants are listed in Appendix 9. Verbal consent to participate in the interview was obtained and the majority of the participants approved release of their names for use in the dissertation. Purposeful sampling was applicable for this project due to the finite number of PHLDs and HOs located within California (Patton, 2002).

These interviews captured the perspectives of the majority of PHLDs as well as HOs regarding the feasibility of PHL regionalization to improve laboratory capacity in California. The interview guide helped format data regarding the function and significance of the PHL within a county, issues with PHL funding, PHLD recruitment challenges, laboratory competition, defining laboratory capacity, the effects of the economic budget constraints on PHLs, issues surrounding the federal versus state requirements to become a PHLD and the feasibility of engaging in inter-organizational relationships such a regionalization effort or a strategic alliance among PHLs.

Interviews were conducted between July and December 2010 and lasted about an hour, with some ranging from 30 minutes to two hours. Follow-up questions were explored through a combination of in person interviews, electronic mail exchange or telephone conversations.

After reviewing the study protocol and interview instrument, the UC-Berkeley Institutional Review Board (IRB), Committee for the Protection of Human Subjects (CPHS), approved an exempt status on January 15, 2010 under protocol number 2009-10-303. The basis for the exemption was that that providing their perspective on public issue, feasibility of county PHLs engaging in inter-organizational cooperation, would pose minimal risks to the individuals participating.

Document Review

Information about county demographics and the county's public health department were retrieved through internet searches to better inform the interviews.

Analysis

Interview Protocol

Notes were taken during all interviews and audio recordings made with the verbal consent of the participant. The use of a participant's names was only utilized with expressed permission. Interviews were transcribed to help fill in notes and ensure greater accuracy of the quotes from the participants than relying solely on hand written notes. Participation was voluntary and a written description of the project was provided upon request. Participants were told that they could choose to decline to answer or stop the interview at any time if they were uncomfortable with any of the questions.

Coding

Coding was done by hand for each interview transcript. A set of preconceived codes were developed working through the research questions as well as the development of the interview guide. As coding began on the interview transcripts new codes were developed and original codes were modified or discarded as needed. Cross comparisons of the codes and the interviews helped identify major themes that were pertinent to addressing the research questions.

Data Analysis

In analyzing the in-depth interviews, the responses of the PHLD and HO responses were broken down based on the 12 regions of California as demarcated by the California Department of Transportation. Comparison of interviews were made among counties within a specific region, across regions and between counties located in Northern versus Southern California. The major issues that were extrapolated during these comparisons included; 1) concerns regarding recruitment of PHLDs that met the federal CLIA requirements to manage PHLs located in less populated rural counties, 2) the federal and state requirements for becoming a PHLD, 3) decline of the functions of the State Public Health Laboratory and 4) the potential of PHLs engaging in a strategic partnership. Data extrapolated from these interviews are written up descriptively through the remainder of this chapter.

Research Findings

Significance of County Administration and the Public Health Laboratory

The administrative structure of the 58 county and 3 city health departments vary slightly in the services they provide and, in the structure, funding, and administration of the health department (Kelch, 2011). These differences stem from the fact that the counties operate very independently from one another as well as from the state. The similarity that the health departments share is the requirement by the Health and Safety Codes to "preserve and protect" the public's health by providing public health services, including public health nursing, communicable disease control activities and environmental health programs (Kelch, 2011). Each county is also required to have a HO that is a medical doctor or an equivalent that is appointed by the Boards of Supervisors (Kelch, 2011). The HO is charged with "*the responsibility for enforcement of PH laws and regulations*" (Abbot and McGurk, 1998). The HO has the statutory authority for enforcing the health and safety codes e.g. quarantine or isolation of individuals during an outbreak for the

purpose of protecting the health of the community and its citizens. A local county health department shall have available the “services” of a public health laboratory to assist in communicable disease control/surveillance. In most counties the position of the HO and the PHD director are served by different people; however, in San Luis Obispo County the HO and the PHD director are the same individual. The HO understands the significance and purpose of the PHL within the health department and often works closely with the PHLD, PHD director and/or Health Care Agency director to justify to the county Board of Supervisors, the need for provision of PHL services for the purpose of communicable disease control and surveillance. The organizational and administrative structure of health departments varies among counties and there is no general description of how a county’s Health Care Agency is administratively organized with respect to the PHD and PHL. In general, if a county has a PHL, the laboratory is under the jurisdiction of the PHD.

The majority of the PHLDs and HOs that were interviewed have a supportive PHD administration that understands the importance and significance of having a PHL located within the county. However, there are situations where the views of the HO differ from the Health Care Agency or PHD administration and the importance of having a PHL within the county is doubted. This has occurred in Santa Clara, Alameda, and Sacramento Counties within the past ten years. These counties have experienced a period where the health department administrators assessed the option of shutting down the PHL and outsourcing specimens to clinical or commercial laboratories for testing. A description in the next section of how the PHLD and HO dealt with the situation exemplifies the importance of obtaining the perspective of both the PHLDs as well as HOs for assessing the feasibility of regionalizing PHLs in California.

Santa Clara County

In the early 1990’s a merger occurred between the Santa Clara County Public Health Department and the existing hospital services. The existing PH clinics became ambulatory care clinics and were under the management and supervision of the Santa Clara County Health and Hospital System (SCCHHS) and the Valley Medical Center (VMC), the county hospital for Santa Clara County. The transfer from PH Clinics to Ambulatory Care Clinics reduced the workload of the PHL drastically. When Ms. Patricia Dadone, joined the laboratory as the PHLD in 1999, the PHL was running approximately 2500 tests per year and had only one PHM working in the laboratory. At the time there were talks in the county about shutting down the PHL and utilizing the clinical laboratories for PHL services. However, due to state regulations the county was unable to combine the services of the PHL with the clinical laboratory because 1) the PHL is regulated under the Health and Safety Codes, while the hospital laboratory is regulated under the Business and Professions Codes, and 2) no one in the clinical laboratory met the requirements to be a PHLD. Ms. Dadone along with the county HO and the deputy HO fought to rebuild the PHL even though they received resistance from both the Health and Hospital administrations. The county hospital would not provide work for the PHL so Ms. Dadone worked to build a wider user base for PHL testing services. She created a PHL manual documenting the state regulations for the PHL, compiled cost analysis data for different tests, and started a newsletter so the community and PHD better understood the role of the PHL. Currently, Ms. Dadone is working as a full-time PHLD and has a staff of 11 employees. She has also increased the PHL work volume up to 30,000 tests per year.

Alameda County

The Alameda County PHL faced a similar situation in 2004 when the PHD administration was not supportive of the PHL. A prior director of the health administration was determined to reduce the function of the PHL by dismantling the structure that made the PHL viable. The clinics were separated from the PHD and individual non-profit organizations managed the clinics, drastically reducing the workload for the laboratory. This director has since left the health department and over the past several years there is a recommitment by the PHD administration to the PHL. Dr. Muntu Davis the current HO of Alameda County, has a strong vested interest in making the PHL successful and has spared the PHL from budget cuts.

The PHL is currently supervised on a full-time basis by Dr. James Carlson, has 12 employees and a workload of about 20,000 tests per year. Dr. Carlson is working closely with Dr. Davis to visit hospitals and clinics in the county to broaden their clientele base and increase their testing volume.

Sacramento County

Most recently in 2009, the Sacramento County health administration considered outsourcing laboratory samples and shutting down the Sacramento County PHL as a cost savings measure. When the HO, Dr. Glennah Trochet and the PHLD, Dr. Anthony Gonzalez looked into this option, they found that it would cost the county more money to outsource samples than to maintain their laboratory. The Sacramento County PHL is a LRN reference laboratory that supports other local PHLs as well as clinical laboratories in the area. It would be detrimental to their county as well as surrounding counties if the laboratory shut down.

The Sacramento PHL is still operating today. Dr. Gonzalez established a courier system to ensure the laboratory maintains a robust workload. A microbiologist from the laboratory goes to neighboring clinics, community based organizations and the county jail system to pick up specimens. The PHL has made a concerted effort to work out issues with the clinics regarding specimen management, quality assurance, test ordering and any other issues that arise to help ensure customer satisfaction. The laboratory continuously strives to increase the community's awareness of services they provide. *"I think what has been helpful is starting the courier service. We have established a pretty good relationship with the clinics. They [clinics] do not have to send us their samples; we really need to work hard at it every day."* – Dr. Anthony Gonzalez, Sacramento County PHLD.

As demonstrated in the examples above, it is integral to include the HO and PHLD in deciding whether inter-organizational partnerships among PHLs is a feasible option to pursue. Due to the decentralized fashion in which county PHDs operate, the participation of the county administration is essential in deciding whether inter-organizational forms of cooperation between PHLs is a feasible option.

Laboratory Capacity

Laboratory capacity should not be confused with laboratory capability. Capability is often used to define what a laboratory is able to do with the resources they possess e.g. instrumentation, personnel, expertise etc. The definition of laboratory capacity has not been officially defined because the definition may vary depending upon the function of the PHD and the context of the

discussion. For example, the definition of laboratory capacity for a PHL functioning on a routine basis may include providing accurate diagnosis and monitoring of community health, effectiveness of PH interventions, disease surveillance, proper testing for the right disease, workforce development, proper communication within and between laboratories, diagnostic support for the PHD, clinics, local hospitals and medical communities, accurate and safe testing, and continued education technical training (LHC, 2003; Bangladesh Environmental Technology Verification, 2009; El Dorado Public Health Laboratory, 2009). During an emergency outbreak situation definitions may include surge capacity, efficient exchange of information, and accurate diagnosis of specimen, a sufficient workforce to meet the demands of testing, and proper cross-training of staff to keep up with increased workloads during an outbreak. The LHCs recommendation that the CDPH continue to provide leadership to facilitate the regionalization of county PHLs aimed at addressing the workforce component of laboratory capacity¹⁶, specifically the shortage of federally qualified PHLDs.

According to PHLDs that were interviewed, laboratory capacity extends beyond the availability of PHLDs. Definitions that were provided are listed in Table 4.2. The number one answer was the ability to handle surge capacity during an emergency situation; other responses are not listed in any particular order.

Table 4.2: Definitions of Laboratory Capacity

1.	Ability to handle surge capacity during an emergency e.g. outbreaks, bioterrorist attacks, pandemics etc.
2.	Automation and appropriate technology to keep up with emerging new diseases
3.	Accuracy of testing and availability of a broad testing menu
4.	Adequate staff and space to accommodate workload
5.	Ability to process and receive routine test volumes within an appropriate turn-around time (TAT)
6.	Having the right tools to diagnose the next emerging disease
7.	Having an adequate laboratory network where you can share and exchange information and reagents
8.	Rotation of employees (cross-training) through different sections of the laboratory to maintain proficiency in different testing sections in case of an emergency outbreak situation
9.	Maintaining support functions for other programs within the Health Department that utilize the PHL
10.	Efficient electronic reporting systems to transfer testing information

The shortage of laboratory directors was not mentioned as a concern for laboratory capacity because: 1) PHLDs anticipate that CLIA requirements can be changed and will not affect the supply of PHLDs, 2) PHLs located in populous counties or metropolitan cities do not anticipate a problem recruiting CLIA-qualified PHLDs and 3) PHLDs plan to serve on a part time or contractual basis after retirement until a qualified replacement is found or until California is able to amend the CLIA'88 requirements. A few examples are: 1) Duncan Gillies, Santa Cruz County PHL, retired for over three years and continues to direct the laboratory on a part-time basis, 2)

¹⁶ Whitney Barazotto (Project Manager), Personal Communication, January 11, 2010

Stanley Kwan, Yolo County PHLD, agreed to take an early retirement and work as the part-time laboratory director as a means of cost savings for the county, and 3) Mark Miller and Greg Costo returned from retirement to serve as the part-time contractual PHLD for Humboldt and Stanislaus Counties and Butte and Sutter Counties respectively. The PHLDs are dedicated to the field of PH and believe strongly in continuing to have PHLs. The laboratory director shortage is not as important for building laboratory capacity as ensuring that the laboratory is able to function optimally on a routine basis and during emergencies to best serve the PHD and the community.

“I don’t know why they [LHC] put the number of PHLDs [as the most important issue]. I would think the number of labs that could do something if there was a big outbreak so that none of the testing would fall through the cracks, or that you wouldn’t have to say that the PHL couldn’t handle it, or to say that there is no other PHL out there that wouldn’t help us, to me is what laboratory capacity means.” – Stanley Kwan, Yolo County PHLD.

Decline of the State Public Health Laboratory

The LHC Report stated that limitations in testing capacity and PHLD workforce shortage are impacting PHL capacity. According to the PHLDs, the provision of services provided by the state laboratory has deteriorated drastically since the county PHL system was set up in the early 1950’s. Fifteen years ago, the state PHL was considered the “CDC of the West”. Over the years, there has been a degradation of services available through the state PHLs due to shortage of staff and decline in funding. The state often loses PHMs to Kaiser Permanente (KP) laboratories because the state salary for a microbiologist is not competitive with the KP hospital salary structure. According to Dr. Paul Duffey, a microbiologist at KP hospital can make \$20,000-\$30,000 more than a person working in a similar level at the state PHL. This stark discrepancy has led many state PHL scientists and PHMs to be recruited to work for KP or federal laboratories. Table 4.3 displays the vacancy rates for the six laboratories housed at the state in 2008 (LHC, 2009). Over the next several years, the vacancy rates will only continue to increase due to retirements and PHL personnel leaving to work for other public or private laboratories. These individuals may not be replaced due to hiring freezes that may be instated by the governor to reduce state expenditures. In addition, budgetary constraints have forced state PHLs to test specimens legally mandated by law, rather than provide a broad spectrum of testing capabilities for county PHLs. The Microbial Disease Laboratory alone has cut testing for mycology, serology and parasitology¹⁷. In the past, county PHLs were able to send specimens to the state if they did not have the capability of perform the test. Currently, rather than sending samples to the state PHL, PHLs are sending specimens to other county PHLs for testing. Many of the larger county PHLs participate in the federal Laboratory Response Network (LRN) as well as the state funded Respiratory Laboratory Network (RLN) which has expanded testing capability and limited reliance on the state laboratory for services.

“...there is a transformation of the relationship between the state and the county labs and now the state labs focus is on supporting state programs, so their relationships with

¹⁷ Dr. Paul Duffey (Division Chief of the Biologics and Immunoserology section of the state Microbial Disease Laboratory), Personal Communication, April 5, 2011.

county health departments are not really core partners or clients. Now it is like everybody takes care of themselves.” – Gerry Guibert, Monterey County LD.

Table 4.3: California Department of Public Health Laboratory Personnel Vacancy Rate by Division (2008)

Division	Vacancy Rate
Microbial Disease Laboratory	23%
Viral and Rickettsial Disease Laboratory	15%
Environmental Health Laboratory	33%
Food and Drug Laboratory	21%
Sanitation and Radiation Laboratory	3%
Genetic Disease Division	12%

Source: California Department of Public Health. April 2, 2008. “Vacancy Report – Budget Item 4265-001-0001.” Rates are rounded to the nearest whole number.

Decreasing the services available through the state PHL will only place more responsibility on the county PHL to provide laboratory services to people in their community. According to the PHLDs, an aspect of developing laboratory capacity will be to ensure that the state PHL has the adequate funding and support to continue as the backbone for providing PHL services in California and in support of local county PHLs.

“If the state PHL could get an infusion of money to rebuild their expertise and be able to hire some people, it would help the overall laboratory system in California. There are experts at the state and the expertise has not diminished but they have not been able to provide it to the local labs like they have been able to [in the past]. Most of this is due to the budget constraints.” – Steve Willis, San Joaquin County LD

Rural Versus Urban Public Health Laboratories

In addition to the decline of the state PHLs, PHLDs have expressed that PHLs located in rural areas are facing challenges of personnel shortages, funding and recruitment of PHLDs. In larger counties and cities located near metropolitan areas recruiting and attracting candidates for the PHLD position is not as difficult compared to less populated counties. The pay range for PHLDs in rural, less populated counties is less than urban or metropolitan counties.¹⁸ A list of the salary ranges are listed in Appendix 12. The smaller sized PHLs are mostly located in the Northern and Central part of California with the exception of the Pasadena City PHL located in Southern California.

To address the shortage of CLIA qualified PHLDs, PHDs in small counties are contracting for federally qualified PHLDs part-time while a laboratory manager supervises the daily operations of the laboratory. Laboratory managers are not subject to the higher education requirements under federal regulations. This arrangement is currently being utilized in Humboldt, Stanislaus, Santa Cruz, Contra Costa, Fresno and Tulare Counties. In interviews with PHLDs, HOs and PHMs working at county PHLs, having a PHLD full-time would be preferred if given the option.

¹⁸ Appendix 4 lists a table of the PHLs and the number of personnel and population for each county

However, there are barriers to utilizing this strategy as a long term solution for smaller counties. Mendocino County had difficulty recruiting a laboratory manager due to the low pay structure. Mendocino County was able to hire a part-time PHLD, but it was not a feasible option without a full-time laboratory manager supervising the laboratory, which resulted in the decision to shut down the Mendocino County PHL.

“Closing the Mendocino PHL and sending samples to the Sonoma County PHL was a success in that the technicians and people that worked in the PHL were hired by the local Ukiah Valley Medical Center, and we got an excellent standard of care from the Sonoma County PHL. Now the quarter of a million dollars it cost to operate the PHL is available for nursing care rather than a functional lab.” –Dr. Marvin Trotter, Mendocino County HO 1998 - February 2010.

Public Health Laboratory Director Regulations

In 1996, under Governor Pete Wilson, the Maddy Bill (SB113) was enacted which adopted the federal CLIA’88 requirements for laboratory personnel into state law. The two gubernatorial administrations since Governor Wilson have continued to support the federal requirements for laboratory personnel and have not supported CAPHLDs efforts to amend the federal requirements. The CAPHLD association has continued to lobby in support of amending the federal CLIA’88 requirements in spite of the lack of support from the state. Early in the spring of 2010, CAPHLD submitted a Senate Joint Resolution No. 15 (SJR-15) to the California Senate and Assembly asking Centers for Medicare and Medicaid Services (CMS), the Congress and the President to amend the CLIA requirements for California to waive California from the federal CLIA requirements for the PHLD. The SJR is listed in Appendix 13. The California Senate and the Assembly passed the SJR unanimously in June 2010; however amending the CLIA requirements for PHLDs is dependent on the approval by the federal government. The CAPHLD association is trying to recruit a California legislator to carry the legislation to the federal government. A candidate has not yet been found. While states like New York and Washington are exempt from CLIA, their state laws for their PHLDs are as stringent as or more stringent than the CLIA’88 requirements for PHLDs. The likelihood of California gaining an exemption from the federal CLIA’88 requirements for the PHLD is slim if CAPHLD continues to propose that the federal government allow individuals who do not meet the minimum CLIA’88 requirements to serve as PHLDs.

A subset of PHLDs seems certain that California can set its own state mandates and obtain an amendment from the federal requirements but others are not as optimistic. Attempts to change CLIA’88 requirements have been unsuccessful the past 20 years and solutions to address the PHLD shortage need to be assessed. Without federally qualified PHLDs supervising the laboratory PHLs will be forced to shut down. Thus, solutions to build the PHLD pipeline will be imperative to the future of PHLs in California. Bill Lawrence, the Riverside County PHLD and Dr. Sally Liska the San Francisco County PHLD had the foresight to “train their replacements”. The following section describes the succession plan utilized by these counties.

San Francisco Public Health Laboratory

Dr. Sally Liska the San Francisco County PHLD implemented a succession plan in anticipation of her retirement. She did not foresee a problem recruiting doctoral level applicants since San

Francisco is a large metropolitan city and offers a competitive salary for their PHL personnel. Dr. Liska wrote up the job description and did not include PHM certification as a minimum job requirement because she did not want to limit her search to people that worked in California. The position required having a doctoral degree in a biological field and training in conducting polymerase chain reaction assays. Dr. Mark Pandori was recruited to work in the San Francisco PHL in 2005. His employment however, was contingent upon successfully passing the state public health microbiology (PHM) certification within a year of when he was hired. Dr. Pandori completed the PHM training and passed the state administered PHM certification exam.

The first two years that Dr. Pandori was working in the San Francisco PHL (SFPHL) he was funded through a federal bioterrorism grant. For the following two years, Dr. Pandori was funded as an assistant laboratory director at SFPHL by the LabAspire program. Dr. Pandori satisfied the state requirement to become a PHLD; four years of experience in the laboratory, two in a supervisory microbiologist position. In 2009 he met the federal requirements and passed the American Board of Bioanalyst (ABB) exam. Dr. Sally Liska retired in June 2010 and Dr. Pandori became the PHLD for the SFPHL.

Riverside County Public Health Laboratory

Mr. Bill Lawrence the PHLD for Riverside County intended for his laboratory manager to assume the position of PHLD when he retired. However, California was not granted an amendment from the federal requirements and the laboratory manager did not meet the federal requirements to become a PHLD. Mr. Lawrence worked with his county administration to create an assistant laboratory director position and establish a competitive salary structure. Mr. Lawrence recruited and hired Dr. Megan Crumpler in 2008 to be the supervising PHM for the Riverside County PHL. Similar to Dr. Pandori, her employment was contingent upon passing the state PHM certification within the first year of her employment. Dr. Crumpler successfully passed the state PHM exam in April 2010, and is working to take a board certification exam in the Fall of 2013. Mr. Lawrence has retired but is acting as the part-time PHLD until Dr. Crumpler meets both the state and federal requirements to become a PHLD.

Ventura and Santa Cruz Counties

Not all counties with PHLs have the budget that Riverside and San Francisco Counties have. Financial constraints may not allow a county to establish an assistant PHLD position or increase the salary scale for their laboratory employees. Brett Austin the PHLD for Ventura County discussed establishing a PHLD succession plan with his county's Health Care Agency; however reductions in the PH budget have delayed these plans.

In Santa Cruz County, HO Dr. Poki NamKung has interviewed several applicants for the PHLD position; however she has been unsuccessful at recruiting applicants. The cost of living in Santa Cruz County is high, and due to budgetary constraints she cannot increase the salary scale for the PHLD position. This has posed a challenge to recruiting and hiring qualified applicants for the position.

The majority of PHLDs interviewed do not have a succession plan in place. They either 1) do not have the intention of retiring soon or 2) there is no money in the PH budget to create an assistant laboratory director position. The general consensus among PHLDs and HOs is recruitment will

not be a problem in metropolitan cities or larger counties. The salary scale in these areas is generally competitive and the draw of a large city is an added incentive in the recruitment process. Smaller counties located in rural areas will likely experience difficulty recruiting individuals that meet both the state and federal requirements for becoming a PHLD.

“They [Butte and Sutter County] will never get one [PHLD applicant] that will meet the CLIA requirements. CAPHLD is working with the federal people to try and get the requirements for the PHLD changed. They are not doing anything locally because Butte and Sutter County do not have the money. They will not be able to increase the pay scale for the PHLD position.” – Greg Costo, Butte and Sutter County LD

State versus Federal Requirements

An issue of debate among HOs, PHLDs and state PH officials is whether the federal CLIA’88 requirements or the state requirements are limiting the pipeline of PHLDs in California. The federal CLIA’88 requirements to become a laboratory director include: 1) a doctorate degree e.g. Ph.D., DrPH, M.D., D.Sc., D.D.S, or D.V.M and 2) board certification from an approved accreditation program. The state requirements include 1) a baccalaureate level degree, 2) obtaining a public health microbiologist certification and 3) four years training in a PHL, two of which are in a supervisory microbiologist capacity. In order to become a California PHLD an individual is required to fulfill both the state and federal requirements. Other states require that an individual meet either the state requirements or the federal requirements, not both. The following section highlights arguments supporting whether it is the state or federal requirements limiting the pipeline of PHLDs in California.

State Requirement Limitations

Dr. James Beebe, the PHLD for San Luis Obispo (SLO) County has been working in California since 2007. Prior to coming to California, he was the Colorado State PHLD. He has a Ph.D. in Microbiology and is American Board of Medical Microbiology (ABMM) certified. He took the PHM exam and obtained his PHM certification and currently meets both state and federal requirements to be a PHLD. Dr. Beebe feels the PHM certification is a barrier to attracting qualified PHLDs from other states to work in California. He has written a statement (Appendix 14) in support of using a certified the board certification e.g. AMBB, ABB, HCLD in lieu of the PHM certification.

Dr. Patty McVay, the current San Diego County PHLD has a medical degree and prior to becoming a PHLD, had five years of experience as a Laboratory and Medical Director managing the Northern California Community Blood Bank. She also had four years of experience working at the San Francisco General Hospital; however she was required to obtain the PHM certification as well as complete four years of work experience in a PHL to qualifying as a PHLD in California.

“State law is too restrictive in California for the PHLD position. An American Board of Pathology certified Clinical Pathologist should not be required to also have four years of PHL experience before they can run a PHL. The differences between a PHL and a clinical laboratory in California only take a few months to learn. There should be a

separate licensing exam for PH Laboratory Directors OR alternate criteria for experience such as microbiology experience in a hospital setting.

After earning an M.D. and then doing four years of additional training and passing an examination I am permitted to run any size or type of clinical laboratory in California. To run a blood bank/transfusion service, there is only one more year of training and one more examination. To then ask for FOUR more years of experience for the few minor changes related to PH makes no sense at all." – Patty McVay, San Diego County PHLD

Recent and past PHM trainees have stated that the course material for the PHM certification exam is not up to date with the information they are taught. There is outdated information in areas of syphilis and bacterial serology, complement fixation, and biosafety level classifications. The PHM certification is necessary for individuals that do not have an extensive microbiology background however; individuals who have obtained a national microbiology board exam or equivalent have the knowledge to sufficiently direct a PHL without PHM certification. Utilizing a certified board exam in lieu of the California PHM certification and lessening the required four years of experience to one or two year will increase the PHLD applicant pool and ultimately the laboratory director pipeline.

Federal Requirement Limitations

There are currently many well qualified and experienced non- Ph.D. laboratory managers that have the experience and skills to become a PHLD but are ineligible under the federal CLIA '88 requirements. Many of the PHLDs feel strongly that the current PHL system has worked effectively at providing quality laboratory services for the past 60 years and there is no need to conform to federal standards. These laboratory directors are adamant that it is the federal requirements that are limiting the pipeline for the PHLD rather than the state requirements. The CAPHLD association released a white paper citing a dissertation by Michael Kenney written in 1984 stating that "*Education above the bachelor's level for director did not equate to quality. Education, training, and experience at the bench level are related to high quality testing.*" The white paper is listed in Appendix 15. The federal requirements allow high school graduates to work as microbiologists in a PHL. In California a PHM working in a PHL needs to have a bachelors' degree in a biological field and participate in a six month training program. A portion of the CAPHLD association members feel strongly that microbiologists working in California are well trained and have the capability of directing a PHL as well as or even better than an individual with a doctorate degree and board certification.

"The problem is the requirement of the Ph.D. and board certification especially in the smaller counties. If we are forced to shut down PHLs because we cannot find PHLDs to fill the position it is going to change the system in California. Other PHLs can pick up the slack but it certainly will not be efficient for the counties taking on the extra workload." - Richard Alexander, Orange and Contra Costa County PHLD

Health Officers are split on the issue of obtaining a waiver for the federal CLIA requirements. Some do not believe that California PHLDs should be held at a lower standard than PHLDs in other parts of the nation. However, there are also those that believe the standards are too stringent and are not applicable to directors running PHLs.

“We had a PHL D that wasn’t a Ph.D. that was grandfathered in who has done a great job. By my assumptions, having a background in microbiology and experience on the job could count for a lot and we could get good PHL Ds that way. A Ph.D. I’m not against it but it just doesn’t seem to be feasible”-- Dr. Ann Lindsay, Humboldt County HO

“I think we should stop trying to change the CLIA’88 requirements and work on starting to get enough PHL Ds to fill the needed slots. I’m not sure how it [lowering the educational requirements for the PHL D] will benefit California in the long run” – Dr. Glennah Trochet, Sacramento County HO

According to Kathy Williams the PHL program manager who works in Laboratory Field Services (LFS), the current statute requiring the PHM certification and the number of years of work experience to become a PHL D can be amended. The CAPHLD association or state public health officials would need to submit a resolution to LFS to amend the state regulations. Due to the divide among CAPHLD and state PH officials as to the state or federal regulations that are limiting the PHL D pipeline an amendment has not been proposed or brought forth to LFS.

LabAspire Program

The current and previous Governor’s administration and the CDPH have not been supportive of CAPHLD’s proposal to amend the federal requirements for California’s PHL Ds. However, the state recognizes the PHL D workforce shortage and established the LabAspire program as a means to bolster the pipeline. Ms. Patricia Dadone (Santa Clara County PHL D), Dr. Paul Kimsey (State PHL D), Dr. Sydney Harvey (previous PHL D for Los Angeles County PHL), Dr. Mike Janda, (State Microbial Disease Laboratory PHL D), and Dr. Ann Lindsay (Humboldt County Health Officer) worked together to bring the LabAspire program to reality. Together they lobbied the California State Senate and Assembly and were granted \$2.5 million by the state in 2007 to start the LabAspire program. In 2008 there was a 10% reduction in the budget for all programs funded through California’s general funds and the LabAspire funding was cut to \$2.25 million.

The University of California, Berkeley (UCB) and University of California, Los Angeles (UCLA) received LabAspire funding to begin a graduate level laboratory director training track. The state PHL in Richmond, California and UCLA received funding to start a post-doctoral fellowship training program. In addition, an administrative group at the University of California, Davis is charged with marketing the LabAspire program and the PHL field to students ranging from middle school through college students and post-graduates.

As of May 2011, four doctoral students are funded through the LabAspire program at UCB and six at UCLA. It will take another five to ten years before many of these students are eligible to become PHL Ds.

Two post-doctoral fellows Dr. Nicole Green and Dr. Robert Tran have completed the state laboratory post-doctoral program as of May 2010 and are currently working in PHLs in Los Angeles and San Mateo Counties respectively as assistant laboratory directors. In addition, three post-doctoral fellows are currently completing their training at the state PHL in Richmond,

California. Two are anticipated to complete the program in May 2011 and if funding permits will be placed in local county PHLs as assistant PHLDs. However, if there is shortage in funding for placement, these post-doctoral fellows may be lost to the private sector or other federal laboratory programs.

The UCLA CPEP (Committee on Post-graduate Education Program) accredited post-doctoral fellowship program started in 1976 and LabAspire contributed funding for the program in 2007. Four post-doctoral fellows completed this program as of December 2010 however; these individuals did not pursue positions in California PHLs.

The majority of the current PHLDs are eligible to retire within the next three to five years and there are an insufficient number of eligible candidates to take over directorship of PHLs especially in small rural county jurisdictions. If amendments to the CLIA'88 requirements for PHLDs are not granted by the federal government solutions in addition to the LabAspire program need to be implemented to alleviate the PHLD workforce shortage. The following section documents situations where inter-organizational relationships are feasible to pursue to alleviate the PHLD workforce shortage.

Regionalization of Public Health Laboratories

Regionalizing PHLs will result in fewer laboratories and decrease the number of PHLDs that the state needs, however provision of laboratory services may become a problem with fewer PHLs. Every HO interviewed whether they worked in a small or large county valued having a PHL operating under their health department's jurisdiction, having a PHL is an essential component in being an autonomous health department.

“On a scale of 1-10 the lab is a 10... The PHL is THE way of doing communicable disease control, which is a base function of a health department. You need to get lab support and the question is where can you get it and how well can you do it with distant lab support. I don't think you can do it well with distant lab support.”—Dr. Scott Morrow, San Mateo County HO

“I figure if we even did try to send samples to another lab they will charge us as much as we are paying anyway. I do not know how much they will charge to contract out the lab services so before I would do that in order to keep our autonomy and keep our status as an independent health department I would really look to increasing revenue and doing some other things to save money for the lab.”—Dr. Eric Walsh, Pasadena City HO/Health Director

Some county health departments have made it their goal to protect the PHL during budget cuts.

“The PHL is one of the things that we have been protecting in the budget cuts because we consider it essential. If we can't have access to rapid lab data and control exactly what we want to have done we cannot do our job at all”—Dr. Dave Herfindahl, Riverside County Deputy HO.

In spite of the funding constraints at the local, state and federal level in support of PH, HOs that were interviewed have continued to support keeping the PHL operational. Many of HOs stated that they would be open to a discussion about regionalization only if their laboratory was the regional laboratory. HOs as well as PHLs are fearful they will not have ultimate decision making power if the PHL is not located within their jurisdiction because counties operate independently and there are legal authorities within county lines. If a county decided to close the PHL and send samples to another county they would become totally dependent on another county for the types of testing available, the turn-around time (TAT), the cost etc.

“I can see situations where in our county we might want to offer a special fee arrangement with the local hospital or our community clinic... and another county does not want to do that because that is a greater or lesser percentage of their revenue...so they have that discrepancy within the same region which can cause all kinds of billing issues.” – Dr. Takashi Wada, Santa Barbara County HO

“I would share with someone else if it [the PHL] was in my county and I had access to it. I would never send my stuff to another county in a million years. I just do not trust that I have access to it. I do not have the ability to tell them what to do, and I don’t have the ability to change their direction, or tell the microbiologists to do a certain thing today etc. I would be happy to take other people’s work but no way am I sending things to other counties.” – Dr. Scott Morrow, San Mateo County HO

A list of the concerns PHLs and HOs have surrounding a regionalization effort is summarized in Table 4.4.

Table 4.4: Regionalization Concerns

1.	Are the partnering PHLs also in a financial crisis?
2.	Will there be enough personnel to handle the workload of an extra county laboratory?
3.	Will turn around time be delayed because a PHL prioritizes their county’s samples?
4.	Will it be difficult to agree on terms for sharing resources? How do you ensure equity?
5.	What will be the political logistics of operating the laboratory?
6.	What will happen to the personnel working in the laboratory that is being closed?
7.	How will decision making abilities for the laboratory be affected if samples are sent to another county PHL?
8.	Will there be enough laboratories and personnel to handle the workload in case the laboratory needs surge capacity for an emergency outbreak i.e. H1N1?
9.	If the strategic partnership does not work out in three to five years, what will happen next? One PHL has already been shut down and will not likely be reopened; will that county be scrambling for services?
10.	If PHLs engage in a regionalization effort, who looks over the regionalized laboratories? Does the state or the regions affected? If it is the state, how will the state manage to provide oversight of county PHLs when the state PHL has had to decrease provision of many of its’ services due to budgetary constraints.

Currently, Marin and Lake Counties are facing some of the concerns that are discussed. The following section describes the struggles that the counties are experiencing and the impact on laboratory system capacity.

Marin County PHL

In the summer of 2010, Ms. Lynn Murrin the Marin County PHLD was asked by the county administrators to discuss the possibility of closing the PHL and partnering with either the Napa/Solano or the Sonoma County PHL to provide laboratory testing services. The Napa/Solano and Sonoma County PHLs are approximately 40 miles from the Marin County PHL. Issues with method of transport, degradation of specimen during transport, turn-around time for tests results, cost of transportation and electronic reporting are some of the concerns Ms. Lynn Murrin considered. In addition, the Marin County PHL has a state of the art laboratory information system which interfaces with the Marin County clinics and hospitals. Sonoma and Napa/Solano County PHLs do not have the same electronic reporting system. She also maintains an emergency contact list with the hospitals and clinics which is updated every six months so that the appropriate individual can be contacted during emergencies. If the Marin County PHL were closed and the PHL testing outsourced the relationship with the hospitals and clinics would not be as intimate. According to Ms. Murrin both the Napa/Solano and Sonoma County PHLs are experiencing a shortage of laboratory personnel and are trying to cope with financial reductions in their laboratory budget. Sonoma and Napa/Solano County PHLs serve over 500,000 people in their counties respectively. She questions whether either PHL will be able to adequately handle the additional workload from Marin County. If they are unable to, it would negatively impact the citizens of Marin County and diminish the state's PHL system capacity. Ms. Murrin has compiled data to demonstrate to the county administrators that it is cost efficient and cost effective to maintain a PHL within the county rather than shutting down the Marin County PHL and utilizing the services of a neighboring PHL.

The Marin County administration has decided against closing the Marin County PHL for the 2010/2011 fiscal year. According to Ms. Murrin, Sonoma County did not have the capability to conduct many of the tests available at the Marin County PHL. It was also logistically problematic for Marin County to ship samples to multiple places to obtain testing services. While the Marin County PHL is currently operational, the PHL is still under scrutiny by the county administration for closure for the 2011/2012 fiscal year.

Lake County Laboratory Services Provision

There are currently 37 PHLs serving 61 health jurisdictions in California. Counties that do not have their own PHL either contract for PHL services with a neighboring PHL or receive services from the state PHL. According to the Health and Safety Code of Regulations, (Title 17, Chapter 3) any county with less than 50,000 people can obtain PHL services through the state laboratory. However, there are still a few counties which have more than 50,000 people that are struggling to obtain PHL services due to limited financial resources. Dr. Karen Tait is the HO for Lake County with a population of 65,000. She has reached out to the CDPH for suggestions on how rural counties can economically obtain PHL services. Lake County was previously served by the Mendocino PHL which was approximately 35 miles away, approximately 45 minutes by car. Due to the closure of the Mendocino County PHL in 2009, Lake County subsequently developed a partnership with the Sonoma County for the provision of PHL services. Sonoma County is

approximately 65 miles away and approximately an hour and a half drive. Dr. Tait has stated that the relationship with the Sonoma County PHL has been excellent; however their ability to utilize the PHL has been limited since Sonoma County's finance department is not willing to bill third party payers such as Medi-Cal or other insurance companies on behalf of Lake County. In addition to the limitation of third party billing, there are also issues with transportation and shipping costs; 1) there is no timely or cost efficient means of picking up a specimen if it originates at the south end of Lake County, 2) shipping containers cost the county \$20 per box and 3) there are problems with the turn-around time for testing since specimens that are shipped "overnight" via Fed-Ex take two days to arrive in Sonoma County. The cost of transporting and packaging specimens alone is an exorbitant amount for a small county with a limited budget. In the end, Lake County resorted to utilizing commercial laboratories for their testing needs. The down side of commercial laboratory testing is the higher likelihood of false positive reports when testing Mycobacterium tuberculosis, resulting in unnecessary isolation of suspect cases. In addition there are consistent delays in reporting positive results to clinicians and PHDs of sexually transmitted diseases. According to Dr. Tait:

"In a perfect world, Lake County would have an arrangement with a PHL that would allow for its routine use for testing of PH significance within inordinate barriers of 1) How can we get the sample to the laboratory in a timely way, even if it originates from the south end of the county? 2) How can we overcome cost issues for packaging and courier services? 3) How can third party payers be billed, when available? A source of funding to assist us with PHL services would be beneficial as the direct competition of shrinking realignment dollars will make it increasingly difficult to use those funds for laboratory services."

The closure of the Mendocino PHL was regionalization in action and has diminished the state's laboratory capacity by negatively impacting the ability of PHLs to provide timely and affordable PHL services to the community. The state laboratory director, Dr. Paul Kimsey, the branch chief for the Microbial Disease Laboratory (MDL), Dr. Mike Janda and the acting branch chief of the Viral and Rickettsial Disease Laboratory (VRDL), Dr. Sharon Messenger have been trying to come up with solutions to address this issue and have not been successful. This begs the question; will regionalization of PHLs help build the state's laboratory capacity? There might be a need for fewer PHLDs; however there may be limitations in testing capacity and PHL services available to Californians.

"If you regionalize the laboratories and you start sending [specimens] out to another county, the priorities are going to be important. If you are in the midst of some epidemic or outbreak and things get backed- up, your community will not be given the priority it needs to be protected from a communicable disease issue."--Mark Miller, Humboldt and Stanislaus County PHLD

Consolidation of Public Health Laboratories

The HOs and PHLDs interviewed expressed that regionalization of PHLs is not a feasible or desirable option to address laboratory capacity if the effort was led by the state. However, a majority of them have expressed that a strategic alliance such as a consolidation effort between PHLs is feasible if decided upon voluntarily among local counties. If a suitable partner can be

located i.e. the Napa/Solano County PHL consolidation, a partnership will be mutually beneficial and can build the state’s PHL system capacity.

“Because the issues are different, to have the state come in and say that this is what we are going to do doesn’t make sense. But regionally as HOs and health administrators get together in their region to have these discussions you will get a better fit and better idea. It’s a lot more beneficial to give birth to the regional models at a local level” – Anonymous PHL.

“Consolidation or joint efforts are the reality of where they are going but it has to be based off of solid medical criteria and not just numbers on a grid for business purposes. You need to take a look at the geographic area, is one an only urban or rural setting because each of these types of living situations carry their own needs. Can you get specimens back and forth efficiently and within the designated timeframe? Do you have to look into an interface between laboratory computer systems? The devil is in the details, the details are going to drive whether it is going to be a partnership or if it is going to be a closure of a lab. There are so many variations that to say consolidation is bad is very narrow in thought” – Patty Dadone, Santa Clara LD

Factors mentioned by PHLDs and HOs for a successful strategic alliance are listed in Table 4.5.

Table 4.5: Factors for a Successful Public Health Laboratory Consolidation

1.	Voluntary cooperation between counties, it needs to be a local decision and not mandated by the state
2.	Adequate transportation system i.e. courier and highway systems
3.	Short distance between counties , preferably contiguous
4.	Alignment of goals between both counties’ administrations
5.	Small sized PHL merging with a larger sized PHL
6.	Compatible communication system/computer interface
7.	Compatible and complementary testing menu
8.	Mutual financial advantage for both PHLs
9.	Serving similar types of populations

If counties are unable to recruit a CLIA’88 qualified PHLD to direct their PHL or it becomes financially challenging to support a PHL an inter-organizational relationship such as a consolidation effort through a JPA is a feasible option if the factors mentioned above are met. The Napa and Solano County PHL consolidation has been in place for the past ten years and the success was due to meeting a majority of the factors mentioned. Many of the PHLDs and HOs that were interviewed have expressed that engaging in a consolidation effort like the Napa/Solano County PHL would be preferential to completely shutting down PHLs.

“I honestly think that consolidation/regionalization is better than losing the services of a lab. If that is a choice that they have to make, consolidating/ regionalizing would be better than not having service at all and under state law they have to have the services of someone that meets the requirements of a PHLD so why not join with one of their neighbors.” – Bill Lawrence, Riverside County PHLD

“Given the proper setting, given the proper agreement and having counties that transportation is workable, I do think that consolidation is a feasible option. I would hate to see PHLs disappear because I think that would be a mistake. There are things that PHLs do that you would never be able to get from a commercial lab. But I’m not sure that every county necessarily needs one if you have a good viable regional option.”—Dr. Mark Netherda, Sonoma County Deputy Health Officer.

It is agreed among PHLDs and HOs that shutting down PHLs and shipping samples to commercial laboratories is detrimental to the state’s PHL system capacity. In addition to being at the whim of the commercial laboratory for pricing and availability of testing PHLDs and HOs have reported experiencing delays in turn-around time, poor quality assurance and false results for specimens sent to commercial laboratories. Outsourcing samples to commercial laboratories results in a loss of intimate relationships that are developed with the microbiologists working in PHLs. Physicians working in a county hospital or clinic can call the PHL and speak directly with the microbiologists handling their sample. They can inquire about a preliminary report on a specimen, or request that a certain sample receive priority testing. A commercial laboratory typically receives thousands of specimens a day and technicians load the machines and run the samples. It would be difficult to establish a relationship with the individual handling your sample. Furthermore, unlike a county PHL, a commercial laboratory does not have the flexibility to stop and prioritize samples. The PHL has the flexibility to refocus their attention on specific specimens and testing during an emergency situation. Many of the PHLs shifted personnel and testing schedules during the 2009 H1N1 outbreak to meet the demands of the health department.

“...do we need the PHL, can we contract out the services to Quest? The answer is yes we can contract the services out but we cannot get someone to get the foodborne illness testing in the evening or on the weekend. We cannot get immediate testing for rabies, or PCR testing if we send tests outside of the region. The case that I have been making in the six years that I have been here is that we need to keep our lab. It is expensive and it consumes space but it is of extreme value to us and once you lose a lab it is very difficult to get it back.” – Dr. Hugh Stallworth, Monterey County HO

There is also the aspect of surveillance reporting for epidemiological tracking of diseases. Commercial laboratories use tests that are designed for patient management. An example of this is the tests for enteric pathogens. Tests done in commercial laboratories are sufficient for patient treatment and management, but PHLs will characterize specific isolates and specific subtypes of pathogens e.g. *Escherichia coli* 0157:H7 to determine whether a patient’s illness is a one-time occurrence or if it is part of a larger contamination that is affecting the community (McDade and Hausler, 1998). Public health laboratory tests and methods are unique and utilized for PH surveillance purposes and programs. The information collected by the PHL is transmitted to a database which tracks whether a particular strain of pathogen is involved in an outbreak either locally or in another state (McDade and Hausler, 1998). This type of data tracking and surveillance is not available from the testing results commercial laboratories provide.

The 2009 LHC report focused on the significance of laboratory capacity in the context of an adequate supply of PHLDs, however, PHLDs have expressed that laboratory capacity needs to

encompass the ability to provide accurate and timely testing services to their clients. According to PHLDs, having “surge” capacity when an outbreak or bioterrorist threat occurs was one of the key definitions of laboratory capacity. With the recent 2009 H1N1 outbreak all the PHLDs reported that the 29 PHLs that are part of the Respiratory Laboratory Network (RLN) worked around the clock to keep up with the demand for H1N1 testing. The smaller PHLs without the testing capabilities helped to prepare and ship samples to local PHLs with the capabilities to streamline the testing process. The state depended on the local county PHL network to keep up with the surge of testing. If PHLs regionalize there will be fewer PHLs to handle the extra workload in a national or local emergency outbreak situation. If California is concerned about building laboratory capacity, will shutting down laboratories help increase capacity especially during an emergency outbreak situation? These are issues and concerns that will need to be addressed if and when counties are considering options to manage resource limitations. In the case with the Napa/Solano County PHL, laboratory services were not interrupted and the consolidation of the laboratories resulted in increased testing menu, cost savings for both counties and continued support of health programs for both counties health departments. On the other hand, the closure of the Mendocino County PHL had negative ramifications on Lake County’s provision of affordable PHL services. Thorough and methodical planning between health administrators and PHLDs need to take place to ensure a successful long-term partnership between local PHLs.

“It is not a cookie cutter type of thing where we can just divide California into different regions. There are many different alignments that you can come up as far as what labs serve what areas, they have to check all these to see if potential regionalization will work” – Dr. James Beebe, San Luis Obispo County PHLD

Discussion

The federal regulations for PHLDs are not likely to change. Counties will have to consider alternative options for increasing the PHLD pipeline as the pool of PHLDs that were “grandfathered-in” continues to shrink. The LabAspire program funded by the state to build the PHLD pipeline is one solution, however the funds for this program are not guaranteed due to the changing economic landscape in California. There will be a staggering need for board certified doctoral-level CLIA’88 qualified PHLDs to supervise California PHLs in the next 10-20 years.

In addition to the PHLD workforce shortage, there are multiple environmental and political factors impacting the sustainability of county PHLs. These factors are listed in Table 4.6. To ensure that California has a strong PHL system that can provide testing services to the community inter-organizational forms of cooperation need to be assessed to manage environmental and political constraints.

Table 4.6: Factors Affecting Sustainability of County PHLs

1.	The California budget crisis has decreased the level of funding available to the counties which results in less funding for the public health department and ultimately less funding for the PHL.
2.	Non-competitive salary scales for PHLDs in small rural counties results in difficulty recruiting CLIA’88- qualified PHLDs to PHLs in rural areas.
3.	Commercial laboratories compete for laboratory personnel and workload.

4.	The pool of PHLDs that were “grandfathered-in” during CLIA’88 is diminishing.
5.	Attempts to obtain an exemption from the federal CLIA’88 requirements have been unsuccessful.
6.	There is a limited pipeline of individuals that meet both the CLIA’88 and state regulations to become a PHL in California.
7.	It is difficult to recruit public health microbiologists to work as laboratory managers in PHLs located in rural counties.
8.	Some county administrators are considering closing their county’s PHL as a form of cost savings.

As predicted by both RDT and institutional theory, regionalization where PHLs are shut down and county administrators become dependent on another county for provision of PHL services is not desirable among HOs, or PHLDs. A strategic alliance initiated at the county level however, may be a feasible option for addressing environmental constraints. Many of the interview participants stated that having a PHL under the control of a county jurisdiction is important in conducting communicable disease control, a primary function of the PHD. Having to depend on another county for provision of PHL services will have a negative impact on the PHDs ability to gather epidemiologic data on communicable diseases, prioritize health needs, and investigate outbreaks in a timely manner. The need to preserve decision making autonomy and ability of the PHD to perform communicable disease surveillance makes regionalization of PHLs an undesirable option. However, a locally driven consolidation of PHLs through the use of a JPA or long term contract between two or three counties is a feasible option to ensure that PHLs continue to provide timely, accurate and cost effective laboratory services at the county level enhancing the state’s laboratory capacity and ensuring a strong PHL network.

According to data extrapolated from the case studies in chapter three, a factor that is important for the “success” of a partnership are small PHLs (≤ 5 employees) partnering with a larger PHLs (≥ 10 employees). The small sized PHLs are located in Butte, El Dorado, Kings, Madera, Merced, Santa Cruz, Sutter, Yolo Counties and Pasadena City. Currently, six of the nine PHLs listed have a part-time PHLD supervising the laboratory because the county administration cannot recruit a full-time PHLD, do not require the services of a full time PHLD, or do not have funding to support a full-time director. The small sized PHLs listed above are located near large sized PHLs. Butte, El Dorado, Sutter and Yolo County PHLs are within two hours of the Sacramento and Placer County PHLs. Kings and Madera County PHLs are located within two hours of the Fresno, Kern and Tulare County PHLs. The Merced County PHL is located within an hour and a half of the San Joaquin and Stanislaus County PHLs, the Santa Cruz PHL is located within thirty five minutes of the Santa Clara PHL, and the Pasadena city PHL is located within an hour and a half of the PHLs located in cities of Long Beach and Los Angeles and Ventura County.

The county PHLDs and administrators are most familiar with the laws and politics within their county and their neighboring counties. A locally driven consolidation effort would increase the chances of engaging in a partnership with a compatible partner, as opposed to a state lead effort. A consolidation effort could enhance economies of scale for reagents, equipment, and laboratory personnel and decrease the number of PHLs that require hiring a PHLD. More importantly, it would ensure that counties obtained timely and affordable PHL testing services.

Conclusion

The county PHLDs and HOs are aware of the realities of the future. The California PHL network infrastructure is slowly changing under the impact of economic and political forces. Deficient funding solutions for the PHL and the PHLD workforce shortage are immediately impacting the sustainability of PHLs. Many of the HOs are already anticipating another year of reductions to their county budgets for the following fiscal year. If this trend continues, counties will be forced to assess the future of their PHD and determine the services they are able to offer to its citizens. Besides the closure of the Mendocino County PHL in 2009, county PHLs have not had to close, however environmental pressures may force counties to assess whether engagement in an inter-organizational partnership may be necessary to manage environmental constraints and prevent the closure of additional county PHLs. A decision fostered by the counties will likely result in a long term partnership which will ensure that the state's PHL network remains strong and active to monitor and protect the health and safety of Californians.

The following chapter examines seven policy options in addition to inter-organizational partnership formation as a solution to manage the environmental constraints that are diminishing the state's PHL system capacity. A SWOT (strength, weakness, opportunities, threat) analysis of the seven different policy options is utilized.

Chapter Five: An Analysis of Policy Options

California PHLs are experiencing a major decline in PHL capacity due to limitations in testing capacity and shortage of the PHLD workforce. One recommendation to address this problem is for the CDPH to facilitate regionalization of county PHLs. However, after interviewing PHLDs and HOs that have a PHL located within their county, a state led regionalization effort is not a feasible option to help alleviate the problem. The 58 counties operate independently from each other and the state. Each county has its own rules, regulations and mechanisms for providing PHL services. To ensure that California maintains a strong PHL network, contingency plans must be established to ensure the continued presence of PHLs to provide quality-testing services to the citizens of California. This chapter assembles evidence and utilizes SWOT (strength, weakness, opportunities and threats) analysis to explore the outcome of seven policy options designed to address the concern of the state's deficient laboratory capacity. These seven options are proposed following synthesis of the data that was collected for this dissertation. In addition this chapter will attempt to answer the secondary research questions: *How can the California Department of Public Health provide leadership to help bolster the state's laboratory capacity?*

Defining the problem

The LHC considers the PHLD workforce as a major component of laboratory capacity. While PHLDs do not consider this as a major component of laboratory capacity, without a CLIA'88 qualified PHLD a high complexity laboratory e.g. the PHLs in California are not legally permitted to provide testing services. Of the 33 PHLDs only six meet the federal educational requirements, more than half are eligible to retire in the next five years and seven have already retired and are continuing to work part-time until a suitable replacement can be found.

If PHLs shuts down due to economic or regulatory constraints and a proper strategic plan to share the laboratory workload is not in place, this will increase strain on the remaining county PHLs as well as the state PHL. This was described in the case (Chapt. 4 pg. 66) when Lake County experienced problems with obtaining affordable PHL testing services following the closure of the Mendocino PHL in 2009. To ensure that California retains a robust PHL system, solutions in addition to the LabAspire program need to be assessed to manage economic and regulatory constraints. The following section identifies seven strategic options that can strengthen the state's diminishing laboratory capacity. They are not mutually exclusive. A SWOT (strengths, weaknesses, opportunities, and threats) analysis is utilized to examine the impact each option has on bolstering PHL capacity.

Options Identified

1) *Maintain status quo*

All 37 county PHLs remain open and operational while CAPHLD continues its pursuit to amend the federal requirements. Until an amendment is granted, the state will rely on the LabAspire program to build the pipeline of federally qualified laboratory directors.

Strength	This option would minimize anxiety and frustration among a subset of CAPHLD members who feel strongly that the state requirements are sufficient for becoming a PHLD in California. It would preserve the 37
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	local PHLs until more CLIA'88 qualified LabAspire graduates fill the pipeline.
Weakness	This option is dependent on the LabAspire program to address the shortage of CLIA'88 qualified PHLDs. If the program is cut due to budgetary constraints and the state is unable to obtain an exemption from the federal regulations, there are no alternative solutions to address the PHLD workforce shortage
Opportunity	This option requires minimal involvement from the state besides continued provision of funding for the LabAspire program. The state PHLs will continue to be supported by a network of 37 local PHLs.
Threat	<p>This option will result in a loss of PHLs if counties are unable to recruit a CLIA'88 qualified PHLD. This will weaken the capacity of the state's PHL network because laboratory workload will likely be redirected to the remaining local and state laboratories.</p> <p>There are currently 10 doctoral students in the LabAspire program but the students will not be eligible to become PHLDs for another five to ten years. The current post-doctoral fellows at the Richmond and UCLA programs will be eligible to become PHLDs in the next two years; however, there is no guarantee that these individuals will pursue a position in a PHL. In addition to the LabAspire program, there need to be other options to address the diminishing pool of PHLDs that were grandfathered-in.</p>

2) Obtain state support for an amendment to the CLIA'88 requirements

For the past 20 years and through three administrations, the state's Health and Human Services administration has supported the federal CLIA'88 requirements in its entirety. The Secretary of the Health and Human Services Agency Dr. Kim Belshe, the Director of the Public Health Department Dr. Mark Horton, and the state laboratory director Dr. Paul Kimsey, who worked under the Schwarzenegger administration, oversaw laboratory policy in California and are in support of the federal CLIA'88 requirements for PHLDs. If the state administration is willing to change their position and support CAPHLDs fight to obtain an amendment that would exempt California from the CLIA'88 requirements, this may increase the possibility of obtaining the amendment. This would allow California to utilize the state requirements (bachelor's degree, PHM certificate and four years of experience working in a PHL) in lieu of the federal CLIA'88 standards (doctoral degree and board certification).

Strength	This option may increase the possibility of obtaining an amendment to the CLIA'88 requirements. If the federal requirements are amended, the PHLD workforce shortage will be eliminated. PHMs working in PHLs can "move up the ranks" and become PHLDs as they have prior to the introduction of the federal requirements. There are currently 250 active PHMs working in California who may be eligible to become PHLDs. According to the PHLDs interviewed, there are PHMs currently working in the PHLs that would make excellent directors.
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	This option would ensure that the PHL system capacity is not interrupted because PHLs would remain operational and continue to provide laboratory services to the community.
Weakness	This option is dependent on the CDPH supporting CAPHLDs pursuit of obtaining an amendment to the federal CLIA’88 personnel requirements. The CDPH and the past three Governors and their administrations have felt strongly that the educational requirements for the PHLD are necessary to keep up with the multitude of emerging PH threats. Even if the CDPH supported CAPHLD, California would still be dependent on the federal government to grant exemption from the federal requirements for PHLDs.
Opportunity	This option would eliminate the need for the LabAspire program if California gained exemption from the federal requirements. Those funds could be redirected to the state PHLs to rebuild their laboratory capacity.
Threat	This option would not address the PHLD workforce shortage if the state were denied exemption from the federal requirements and the state would need to depend on the LabAspire program to build the pipeline of PHLDs to address the workforce shortage.

3) Contract for a CLIA’88 qualified part-time PHLD combined with a full-time PHL manager
Five of the PHLs currently contract for a CLIA’88 qualified PHLD on a part time basis while a full-time PHL manager supervises the daily operations of the laboratory. These PHLs include Contra Costa, Humboldt, Stanislaus, Fresno, and Tulare Counties.

Strength	This option is currently being utilized in many PHLs, and is a stop-gap measure to alleviate the problem of the PHLD workforce shortage. A PHLD can work part-time if there is a full-time laboratory manager monitoring the daily operations of the PHL. The laboratory manager is not subject to the same educational standards as the PHLD under the federal standards. In addition, the county can maintain a PHL without the financial burden of supporting a full-time laboratory director.
Weakness	This option poses a problem for less populous counties. In the case of the Mendocino County PHL, the county was able to recruit a part-time PHLD; however due to financial constraints the county was unable to increase the salary scale for the PHL manager to attract qualified applicants. This resulted in the closure of the Mendocino County PHL in 2009. In addition, the HO and county administrators may not agree to have their counties PHLD work part-time in another county. The Sonoma County PHLD Dr. David Yong was willing to provide part-time oversight for the Humboldt County PHL, but due to the distance between the counties, the Sonoma County administration decided against this arrangement. Finally, this option is not sustainable in the long run if the pool of “grandfathered-in” PHLDs decreases and there is an inadequate pipeline of CLIA’88 qualified PHLDs to fill positions.

Opportunity	This option could allow for a PHL system where PHL managers supervised the daily operation of the laboratory while a CLIA'88 qualified PHLD worked part-time. According to state and federal law if a laboratory manager is onsite on a full-time basis, the PHLD can work part-time. In California, a PHLD can supervise up to five different PHLs. This set-up could allow for 8 CLIA'88 qualified PHLDs to supervise the 37 local PHLs, which would resolve the workforce shortage and allow all 37 PHLs to remain operational. Economic efficiencies would be obtained from splitting the cost of a PHLD among five different counties.
Threat	This option presents several potential negative consequences due to the failure to maintain a PHLD full-time; 1) Quality assessment of tests may be overlooked, and/or major problems with the laboratory may not be handled expeditiously if a PHLD works part-time, 2) As illustrated in the case with Santa Clara, Sacramento, and Alameda County PHLs, a PHLD is needed full time to work alongside the HO to justify the existence of the PHL, 3) This option only provides a short-term solution to the PHLD shortage. The pool of PHLDs that were “grandfathered-in” will continue to shrink, and the LabAspire program may not generate an adequate supply of PHLDs. Without alternative options for increasing the PHLD pipeline, the PHLD workforce shortage will continue to be a problem and negatively impact the state’s laboratory capacity in the long run.

4) Regionalize PHL services

Regionalizing PH testing services can address laboratory capacity specifically for provision of laboratory services. Economic efficiencies need to be considered as California and the nation faces an economic recession. If a PHL sends low volume tests e.g. mycology to a PHL that specializes in mycology testing this will ensure cost savings. The cost of maintaining proficiency testing for low volume laboratory tests is high given the cost of reagents, maintenance of instrumentation, and time required for training laboratory staff. According to Dr. Patty McVay, the PHLD for the San Diego County PHL, she is supportive of regionalizing testing services because certain tests are not cost efficient to perform.

“Our laboratory dropped mycology testing because we were doing 20 tests per year; plus proficiency testing it was costing us \$500 a specimen if you figure in the staff training time. [For] certain tests that are low volume it would make sense if two or three labs regionalized that one test.”—Dr. Patty McVay, San Diego PHLD

As PHDs annual budget continues to shrink one has to consider the economic feasibility of performing a test “in-house” versus outsourcing specimens to another PHL, hospital laboratory or commercial laboratory.

Strength	This option would provide cost savings for laboratories and decrease the cost of individual tests due to workload efficiencies. A county will save money on overhead costs by shipping specimens that are not routinely tested in their PHL to another PHL. It will also ensure accuracy of testing results and save time and money required for proficiency testing and
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	<p>instrument maintenance.</p> <p>This option will continue to support and strengthen the PHL network because the local PHLs will be relying upon each other to build testing capability and capacity.</p>
Weakness	<p>This option does not address the PHLD workforce shortage. Regionalization of services allows for all 37 PHLs to remain operational. This option will result in cost savings and enhance provision of testing services but the shortage of CLIA'88 qualified PHLDs remains a problem to be addressed.</p>
Opportunity	<p>This option would ensure accurate and timely diagnosis of infectious agents. If a few PHLs specialized in particular tests, those laboratories would become the experts. The quality of the work would likely be enhanced due to constant exposure and turn-around time would be faster due to efficiency in testing procedures.</p>
Threat	<p>This option presents a potential loss of expertise in conducting specific types of testing if samples are sent to a few regional PHLs. In the case of a natural disaster or if the county decides to shut down the PHL, expertise will be lost, and the capabilities and capacity of the PHL network may be negatively impacted over time. In addition, this option may exacerbate the sustainability of small sized PHLs because smaller laboratories may see a reduction in their workload if it is cost efficient to outsource specimens to other PHLs.</p>

5) Amend the state PHL requirements

Dr. James Beebe, the PHLD for San Luis Obispo County PHL, is in support of amending the state requirements and suggests that a board certification e.g. American Board of Bioanalysis, American Board of Medical Microbiology etc. be accepted in lieu of the PHM certification. The PHM training and certification is a great program for individuals who do not have a strong microbiology background, and have no PHL work experience. Dr. Beebe had to obtain the baccalaureate level PHM certification prior to becoming a laboratory director in California in spite of the fact that he is board certified in medical microbiology and was the state laboratory director in Colorado. Amending the state requirements will decrease the barrier for PHLDs from other states to apply for positions in California. In addition, reducing the years of required PHL work experience from four years to one to two years will attract qualified clinical microbiology laboratory directors to build the pipeline in California

Strength	<p>This option will attract experienced and qualified PHLDs from other states to work in California, as well as clinical microbiology laboratory directors within and outside of the state. This will increase the pool of PHLD candidates. There are currently laboratory director positions in several counties (e.g. Santa Cruz, Humboldt, and Contra Costa Counties) that have not been filled for several years. According to the HO's that were interviewed in these counties, there were only a few CLIA'88 qualified applicants during the recruitment process.</p>
Weakness	<p>This option may not address the problem of recruiting PHLDs to smaller</p>

	rural counties. While this option may increase the opportunity for PHLDs from other states and clinical microbiology directors to apply for positions in California, applicants may look to relocate to metropolitan or coastal cities. The shortage of PHLDs for rural counties may continue to be a problem and exacerbate laboratory capacity in rural counties.
Opportunity	This option may attract PHLDs from other states that have experience dealing with situations that do not normally occur in California. This will enhance and diversify California’s emergency preparedness strategies with relation to the PHLs. This would also allow for clinical laboratory directors working in counties to take on dual positions as a PHLD and a clinical laboratory director to circumvent having to shut down smaller rural PHLs due to difficulty in recruiting laboratory directors to rural counties.
Threat	This option may not be acceptable for a subset of CAPHLD members who are adamant that the PHM certification and the four years PHL work experience is necessary for developing an in-depth understanding of directing a PHL. It also requires amending state legislation which will be difficult if there is no champion spearheading the drive for change.

6) Consolidation of PHLs through locally driven negotiations

According to PHLDs and HOs interviewed, the option to engage in regionalization of PHLs led by the state is not a feasible option to address resource constraints. There are many large counties in Southern as well as Northern California that have the financial capacity to support a PHL. As illustrated in the case studies in chapter three (pg. 40) consolidating PHLs in Alameda, San Francisco and Contra Costa was not a feasible option for county administrators due to heavy work volumes and the large population each county served. On the other hand, there may be an opportunity for small, rural counties to consolidate PHLs as a form of costs savings as demonstrated in the case study with the Napa and Solano County PHLs,

Strength	This option would reduce the number of physical PHLs if counties choose to consolidate laboratories. This would reduce the number of PHLDs needed to direct PHLs and increase the number of full-time PHLDs working in PHLs. In addition, rather than having PHLs close due to the inability to recruit a CLIA’88 qualified PHLD, and/or close due to financial constraints, HOs as well as PHLDs have the opportunity to explore and strategically plan an engagement in a strategic partnership to ensure continuous provision of quality PHL services for their county.
Weakness	This option would require addressing political barriers that arise when negotiating a strategic partnership between counties. The HOs that were interviewed stated if it were financially feasible, having a PHL functioning within the county would be preferred. If county administrators continue to financially support their laboratory, this option would not resolve the PHLD workforce shortage.
Opportunity	This option would build efficiencies when administering county services. If counties consolidate PHL testing services, consolidation of other programs/services within the PHD may follow. This would promote

	economies of scale with respect to provision of health services. Due to budgetary constraints PHDs are often working on a shoe string budget. This would be an opportunity to assess different opportunities for cost savings.
Threat	This option would result in fewer local PHLs in California as counties decide to engage in a consolidation effort. While the Napa/Solano County PHL consolidation has proven to be a successful endeavor, there are always uncertainties when dealing with multiple jurisdictions and administrators. With fewer PHLs there is the possibility that counties will not have access to affordable PHL services, as described in the case of Lake County (pg. 66). This will negatively impact the state's laboratory network capacity over time.

7) Introduce legislation for state funding of PHL services in rural counties

According to Title 17 of the California Health and Safety Code, city or county health departments serving a population of $\geq 50,000$ people for the purposes of protecting the community and the public's health, shall have available PHL "services" provided by an approved PHL. This can occur either through the provision of services from a county's PHL facility, or through an equivalent set of services obtained from another county's PHL. The state PHL is not legally obligated to assist in provision of PHL services for those counties with a population of more than 50,000 inhabitants, however for counties with a population of less than 50,000 people the state laboratory is the designated PHL and is required to provide PHL testing services. There are many counties in Northern California that have less than 50,000 people and depend on the state laboratory for testing services. However, rather than transporting specimens to the state PHL, a few counties have permission from the State to contract with a neighboring PHL for testing services.

The San Joaquin County Public Health Services and the Shasta County Department of Health and Human Services have a contract with the CDPH for \$32,000/year to provide laboratory testing services for neighboring counties with a population of less than 50,000. The Shasta County PHL provides laboratory services for the counties of Glenn, Lassen and Modoc. San Joaquin County provides laboratory services for five neighboring counties which include; Alpine, Amador, Mariposa, Mono, and Sierra Counties. Due to the budgetary cut-backs that the state laboratory has endured over the past several years, the expenditures allotted for these contracts have decreased, and the volume of testing that is provided has subsequently decreased. However, these contracts have been in place for several decades and in spite of the reductions in funding this system have worked well as a solution for providing PHL services "close to the scene of action".

This system has been successful for counties with less than 50,000 people and do not have a PHL. However, there are many small rural counties that do not qualify under state law to seek laboratory services through the state PHL. Lake County does not have a PHL and, with a population of 65,000 people, do not qualify to obtain PHL services through the state PHL. As described in Chapter Four (pg. 66), the county has limited financial means to obtain PHL testing from the Sonoma County PHL. Policy options need to be considered to ensure that all counties have access to affordable PHL services. This option was suggested by state laboratory officials,

and is an opportunity for the state to provide funding to counties that do not have access to affordable PHL testing services as a means of bolstering the state’s laboratory capacity.

Strength	This option would provide affordable PHL services for small counties that do not have their own PHL, or for counties that choose to close their PHL and consolidate with a larger PHL. The savings could be used to subsidize a PHLD salary, hire laboratory personnel, purchase new equipment etc. It would also increase the volume of work for the PHL that is contracting to provide services and this would maximize cost efficiencies for testing. This is likely to enhance laboratory testing services and bolster the laboratory capacity of the state’s PHL network.
Weakness	This option does not directly address the issue of the PHLD workforce shortage. If California PHLDs are not granted an amendment to the CLIA’88 requirements the need to recruit and hire federally qualified PHLDs to supervise PHLs still exists. A second major limitation of this option is funding from the state is limited and sporadic. Given the current economic climate California is facing, this option may not be financially feasible.
Opportunity	This option would provide additional sources of state funding to the counties for provision of PHL testing services.
Threat	This option may further exacerbate the problem of sustaining smaller PHLs that do not have the personnel or breadth of testing to handle the extra workload from neighboring counties. The state funds would likely be disbursed to PHLs that are larger in size (greater than 5 employees) and have the personnel, instrumentation and automation to provide a wide array of laboratory testing services.

Discussion

The seven policy options identified and assessed through SWOT analysis in the previous section present options for increasing the state’s laboratory capacity with an emphasis on addressing the PHLD shortage. While there are limitations for all seven options, the first four options; 1) maintain status quo, 2) obtain state support to amend the CLIA’88 requirements, 3) contract for a CLIA’88 qualified part-time PHLD while having a full-time PHL manager and 4) regionalize PHL services, all fail to address key issues of building the PHLD pipeline and this may compromise the state’s PHL system capacity in the long-run. By contrast, options five through seven, 5) amend the state PHLD requirements, 6) consolidate PHLs through locally driven consolidations, and 7) introduce legislation for state provision of funding for PHL services in rural counties, while likely to face resistance from a subset of CAPHLD members and county administrators, will address several of the fundamental long term issues that are at the root of the diminished PHL capacity in the state.

Option one: Maintain status quo would continue to depend solely on the LabAspire program to build the PHLD workforce. However, if budgetary constraints at the state level cut funding for this program, there will be no additional resources dedicated to building the PHLD workforce.

This will negatively affect the capacity of the PHL network if PHLs are closed because the county is unable to recruit a CLIA'88 qualified PHLD.

Option two: Obtain state support to amend CLIA'88 requirements will continue the efforts of CAPHLD to amend the federal CLIA'88 requirements for PHLDs in California. This option would alleviate the problem with the PHLD workforce shortage and ultimately secure laboratory capacity in the long-run. However, the likelihood of obtaining an amendment from the federal CLIA'88 requirements even with the support of the state is slim given that the educational requirements for California PHLDs will not be as stringent as the federal educational requirements. Interviews were conducted with state laboratory directors from PHLs located in New York, Florida and Texas which are comparable in size and population to California. According to the individuals interviewed, 99% of the PHLDs working in New York, Florida and Texas who supervise moderate/high complexity PHLs meet the federal CLIA'88 requirements. Furthermore, in 2007, the Matsui Bill was proposed by Congresswoman Doris Matsui on behalf of the CAPHLD association that would allow the use of the state educational requirements for California PHLDs. This Bill was met with opposition from several national organizations e.g. the Association of Public Health Laboratories (APHL), the College of American Pathologist (CAP) and the American Society for Clinical Pathology (ASCP). The response from the president of APHL at the time, William J. Becker on behalf of these organizations is listed in Appendix 16.

“...we strongly oppose your draft legislation that would lessen the academic requirements for directors of local PHLs performing high complexity testing. If enacted, these provisions would dramatically threaten patient safety by putting laboratory quality in jeopardy—an outcome we cannot support or endorse.”—William J. Becker

Option three: Contract for a CLIA'88 qualified part-time PHLD and employ a full-time PHL manager is a stop-gap measure to address the PHLD shortage. If California is not granted an exemption from the CLIA'88 requirements and the pool of “grandfathered-in” PHLDs continues to shrink, this will pose a severe problem for PHL capacity in the next 10-20 years. Without a CLIA'88 qualified PHLD supervising the laboratory it will be forced to shut down. Even if a laboratory manager without a doctoral degree could supervise the PHL on a daily basis while a PHLD worked part-time there is no guarantee that a county will be able to hire a laboratory manager. In the case of Mendocino County the HO decided to shut down the PHL because they were unable to recruit a full-time laboratory manager. Furthermore, according to the HO of Humboldt County Dr. Ann Lindsay the Humboldt County PHL, there was a period of time when the laboratory manager was a nurse and not a trained PHM. This was not an ideal situation, but one that had to be implemented in order for the laboratory to stay operational.

This option would allow PHLs to remain operational until LabAspire graduate students and post-doctoral fellows matriculate through the program, however, the problem of recruiting individuals with a doctorate degree and a board certification to work in less populated rural counties remains a problem. If a PHLD cannot be recruited and the financial constraints of maintaining a PHL continue to increase, smaller counties may be forced to shut down their PHL. Following the closure of the Mendocino County PHL, Lake County has not been able to obtain affordable and timely provision of PHL testing services (pg. 66) which compromises the state's laboratory system capacity.

Option four: Regionalize PHL services may help PHLs with cost savings by obtaining economies of scale; however, this option does not address the issue of the PHLD workforce shortage especially in rural counties. Smaller sized PHLs have limited personnel and automation and are unlikely to be chosen as a regional testing facility, which will further exacerbate the viability of smaller PHLs.

The first four options described above are considered by a subset of PHLDs to be an optimal solution for addressing the PHLD workforce shortage, but they, do not directly address the problem with the PHLD pipeline. The latter three options below, while likely to face resistance from a subset of CAPHLD members and HOs, have the potential to alleviate the multiple concerns brought up by the LHC regarding the diminished laboratory capacity of California's PHLs.

Option five: Amend the state PHLD requirements proposes that a qualified national board certification to be utilized in lieu of the state requirement for the PHM certification, and reduction of the four years of experience working in a PHL to one to two years if an individual has experience working in a clinical microbiology laboratory.

Utilization of a board exam in lieu of the PHM certification and decreasing the number of experiential years working in a PHL from four to one or two years is cost neutral and an easily implementable option to help increase the PHLD pipeline. The PHM certification is an important component of learning the fundamental components about public health microbiology and California regulations on how to report diseases. However, an individual who has taken a national board exam in medical microbiology or the equivalent, and who has experience working as a PHLD for another state, can learn the nuances of working in a California PHL on the job. This also applies to clinical laboratory directors that are board certified but do not have the PHL work experience. Reducing the state requirement of four years of PHL experience to one or two years of PHL experience is not likely to jeopardize an individual's ability to supervise a PHL.

Option six: Locally driven consolidation of PHLs presents the strongest potential to ameliorate the PHLD workforce shortage and to increase laboratory capacity. It ensures the need for fewer PHLDs as well as continued and affordable PHL services for the community. Counties that operate a PHL with less than five employees, and/or where the majority of the workload is in processing clinical laboratory samples should assess whether the option of consolidating with a moderate or large sized PHL (greater than 5 employees) may benefit the county financially in the long-run. There are nine counties that fall into this category. These PHLs are located in Butte, El Dorado, Sutter, Yolo, Kings, Madera, Merced, Pasadena City, and Santa Cruz Counties. Shasta County was not included in this list because it is the only PHL serving the Northern Region (as demarcated by the California Department of Transportation) of California whereas the other PHLs listed are surrounded by multiple PHLs in their region.

The potential efficacy of this policy option is illustrated in the case study of the Napa and Solano County PHL consolidation, discussed in chapter three (pg. 34). When the Napa County administration realized it would become financially challenging to sustain the PHL, they had the foresight to strategically plan a consolidation effort with Solano County's PHL. The PHLDs,

HOs, and county administrators from both counties carefully reviewed the process to ensure seamless transition and quality provision of PHL services for both Napa and Solano Counties. The joint powers agreement that was utilized in their negotiations held both counties accountable for the maintenance and support of the PHL. Both counties are equally invested in ensuring the success of the joint PHL. The closure of the physical structure of the Napa County PHL did not cripple the PHL system in California because Napa County made an effort to guarantee that the Napa/Solano County joint PHL would continue to provide the same quality and timely laboratory services for the citizens of both counties. This case demonstrates that with careful strategic planning, seamless provision of laboratory services is possible and will bolster the state's PHL network capacity.

Many of the smaller PHLs do not qualify to participate in the federal and local testing networks such as the LRN, FERN, and RLN that provide emergency testing services in the case of bioterrorist threat, environmental or food outbreaks, and influenza epidemics respectively. The smaller PHLs do not have the capability to provide the surge capacity that is needed because the PHLs do not have the capabilities to conduct the testing. Consolidation of a small PHL with a moderate to large sized PHL will have minimal negative impact on the PHL system if executed with proper strategic planning.

A current example of the potential application of this policy option is highlighted in the case of Sutter County. Greg Costo, the PHLD for Sutter County announced at the 61st annual CAPHLD meeting in Monterey in the Fall of 2010 that the Sutter County PHL may be closing within the next year. The workload for the Sutter County PHL has decreased considerably since December 2010 when the county clinic was taken over by a federally funded clinic. The federally funded clinic is utilizing private clinical laboratories for their testing needs rather than the Sutter County PHL. If Sutter County would like to maintain a PHL a consolidation effort similar to the case with Napa and Solano Counties may be beneficial. The Sacramento County PHL is about an hour away. It provides a broad testing menu, large staff, and a PHL that operates daily. If Sutter County considers consolidating with the Sacramento County PHL, this may improve provision of PHL services for Sutter County. Furthermore, with a well-planned, methodically driven strategic plan for provision of laboratory services, consolidating the Sutter and Sacramento PHLs will have minimal impact on the laboratory capacity of the state's PHL network. Shutting down PHLs without an adequate strategic plan documenting the provision of PHL services on the other hand will negatively impact laboratory capacity and ultimately the health and safety of Californians. Other examples of potential consolidation efforts are listed below.

Consolidation Potential (based on geographical location, not political and financial considerations)

Butte, El Dorado, and Yolo County PHLs could consolidate with Placer or Sacramento County PHLs. Butte and El Dorado Counties are approximately equidistant to Placer and Sacramento Counties, 90 miles and 35 miles, respectively. Yolo County is closer to Sacramento than Placer County 27 miles versus 55 miles, respectively.

Kings and Madera County PHL could consolidate with Tulare or Fresno County PHL. Kings and Madera County PHLs are 26 miles and 70 miles respectively from Tulare County PHL and 41 miles and 24 miles, respectively from the Fresno County PHL.

Merced County PHL could consolidate with either Stanislaus or San Joaquin County PHLs. Stanislaus would be a little closer at 41 miles rather than 69 miles to San Joaquin.

Pasadena City PHL could consolidate with either the Los Angeles PHL or the Long Beach City PHL. The Los Angeles and Long Beach City PHLs are 24 miles and 35 miles from the Pasadena City PHL respectively.

Lastly, Santa Cruz has more than five employees however, Dr. Poki NamKung the HO of Santa Cruz County stated that the majority of the laboratory samples are clinical samples from the county clinics. The county has not been able to successfully recruit a PHLD for the past three years. If this trend continues and the PHLD, Duncan Gillies decides to “officially” retire, Santa Cruz County may need to consider working with Santa Clara County for provision of PHL services. Santa Cruz could change their PHL to a clinical laboratory and hire a clinical laboratory director to supervise the laboratory. The Santa Cruz County PHL and Santa Clara County PHL are located approximately 28 miles apart.

Option seven: Introduction of legislation for state provision of funding for PHL testing services in rural counties is aimed at providing funding for counties that do not have their own PHL either through the introduction of new legislation or by expanding current granting mechanisms. Similar to the situation where San Joaquin and Shasta Counties are receiving grant money from CDPH to provide PHL services, a similar model can be utilized for small counties without a PHL. If a rural county decides it is not financially feasible to operate a PHL and chooses to shut down the PHL, this option may help to ensure that affordable PHL services can be attained through a neighboring county PHL. Furthermore, this option indirectly addresses the PHLD workforce shortage if HOs in small, less populated counties decide to close the PHL and utilize state funding to support their PHL testing. This option would gain the most impact if utilized in conjunction with options four and five, which involve amending the state PHLD requirements and locally driven engagement in a consolidation effort, respectively.

If California is not granted an amendment from the CLIA’88 requirements for the PHLDs, the shortage of CLIA’88-qualified PHLDs will continue to be exacerbated. While the LabAspire program aims to address this workforce shortage, it will take another 5-10 years to build a substantial PHLD pipeline. In addition to the LabAspire program alternative options to address the workforce shortage need to be considered especially in less populous counties where it is difficult to attract a board certified, doctorate level PHLDs. The salary range for laboratory director positions in rural counties on average are less competitive in comparison to larger metropolitan areas (see Appendix 12) and increasing the PHLD salary to attract applicants is not likely to occur due to local budget constraints. According to Dr. Marvin Trotter, the previous HO for Mendocino County, operating a small PHL with two laboratory personnel and a part time PHLD cost the county a quarter of a million dollars. Smaller counties with small sized PHLs will need to evaluate whether engaging in a strategic partnership similar to the Napa and Solano County partnership will be financially beneficial for the county in the long-run.

“Cost hadn’t been a big problem over the history of PHL but it is now. One of the things about keeping your individual labs open is that there is a certain amount of basic

overhead that needs to be in place for compliance, equipment, licensing, proficiency testing etc. Depending on the lab, half the cost may be the lab overhead” – Dr. Michael Lancaster, Kern County PHL

Many of the larger counties in Southern as well as Northern California have large county budgets and are not likely to engage in a partnership to manage resource constraints. PHLDs as well as HO in populous counties have expressed that consolidating PHLs in larger counties is not politically or financially feasible due to barriers with limited space in testing facilities and workload volume limitations. To build or move into a larger space that can accommodate personnel and instrumentation from multiple large laboratories is financially irresponsible in today’s economy. As described in the case study of the Alameda, Contra Costa and San Francisco Counties (pg. 40) partnering the three laboratories to form an East Bay Consortium was not politically or financially feasible to pursue. In contrast, smaller PHLs (<5 employees) typically have less testing capabilities and often do not work at maximum capacity in comparison to moderate/large PHLs (>5 personnel). If a small county voluntarily pursues a consolidation with a larger county to provide laboratory services, there is potential to increase the laboratory capacity of both PHLs and obtain economies of scale when operating the laboratory.

“Capacity is [an] important criteria when you talk about regionalization, which is why smaller jurisdictions should regionalize because individually they may have limited capacity but collectively they have greater capacity, and it makes perfect sense to provide lab services for several smaller regions. That way it boils down to efficiency. It is cost effective in that matter.”—Dr. Wilma Wooten, San Diego HO.

Implementing one or more of options five through seven (amend the state PHLD requirements, consolidation through local efforts, and funding rural counties for laboratory services) in addition to the LabAspire program, will increase the PHLD pipeline and bolster the state’s PHL system capacity by ensuring an adequate supply of PHLDs to supervise PHLs and obtain economies of scale for provision of laboratory services.

Indicators of Success

One indicator of effectiveness that could be measured following implementation of options five through seven include quantification of the number of federally qualified PHLDs available to direct PHLs in California both pre and post implementation of the options. A second indicator would be to poll health departments in rural counties to assess whether county health departments are able to access affordable and timely PHL services. Lastly, it is important to assess the impact of the provision of laboratory services following formation of inter-organizational partnerships among county PHLs. Indicators for this assessment could whether 1) turn-around time for testing services has been affected, 2) there has been a decline in quality assurance of samples, 3) there has been an increase in erroneous test results, 4) there has been a decrease in services provided, and 5) there has been cost savings as a result of the strategic partnership.

Conclusion

California has a strong network of PHLs that provide testing for 37 million Californians. The laboratory is an essential health resource for the community. Given the large population and

expansive geography of California, there needs to be enough PHLs to provide adequate community disease surveillance to monitor the health and safety of California residents. The “typical” regionalization of PHLs - similar to the Laboratory Response Network (LRN), where there are 15 reference PHLs serving large catchment areas - is unlikely to occur in California. The LRN laboratories serve in circumstances of BT threat. These occurrences happen sporadically and do not occur on a daily basis. Samples of non- BT threats like rabies, influenza, sexually transmitted diseases, etc., are processed on a daily basis for disease surveillance. However, California may not need 37 local PHLs to accomplish this task. If counties decide to engage in inter-organizational strategies of cooperation resulting in fewer PHLs in California, there needs to be assurance that testing capacities and capabilities of the PHL system are not compromised. California has more than 100 years of history providing quality PHL services to the citizens of California. Action towards implementing the recommended policy options must be taken both at the state and local level to ensure that a strong and cohesive network of PHLs continues to provide PHL services to Californians for another century to come.

Chapter Six: Limitations and Conclusions

Limitations

This research has several limitations that need to be acknowledged. The case studies chosen for evaluation of PHL partnerships were limited to three examples. The inclusion of more cases would provide a broader picture of the factors necessary to engage in successful inter-organizational relationships. Documenting partnerships where one county has a PHL and one does not, such as Del Norte and Humboldt County, and Sutter and Yuba County might provide a different perspective on factors integral for a successful partnership. Documenting more cases would also allow more opportunities for cross case replication of information and greater validity of the findings. Additionally, case study findings are based on information reported by the interview participants. There is always the possibility that the information was not described correctly or completely. While this is not likely in the case of the individuals interviewed for the case studies, information could have been held back or re-interpreted due to concerns about the perceived response to the information shared.

Purposeful sampling was used for the selection of cases and the interview participants. This did not allow for statistical generalization of the data collected, as is the case for most qualitative research. That being said interviewing participants beyond the HOs and PHLDs that participated in the strategic partnership such as laboratory personnel would add broader insight and information to the development, maintenance and conclusion of the partnerships studied.

Due to limitations in funding and the necessity to keep the scope of this dissertation manageable within the allotted time frame, this dissertation reflects only a portion of the counties in California. Only HOs from counties that have a PHL were contacted for an interview. Obtaining information from the counties without PHLs could have resulted in a different perspective on the state's laboratory capacity. Furthermore, among the HOs that presided in counties with a PHL, only a portion was contacted for an interview, although an attempt was made to have regional representation of PHDs across California. Obtaining interviews from all 58 county HOs and the three city HOs could have generated a more complete picture of the feasibility of regionalizing PHLs and its impacts on provision of laboratory services and building laboratory capacity.

Of the nine PHLDs that supervise small sized PHLs (≤ 5 employees), four PHLDs did not participate in an interview. Obtaining their opinions would have provided in-sight into problems associated with small sized PHLs. Due to the lack of these data points, a bias toward the perspectives of medium to large sized PHLs may be inherent in the conclusions drawn for this dissertation.

Lastly, county administrators that are responsible for the financial oversight of county programs were not interviewed. The individuals working in counties that belong to the County Health Executives Association of California (CHEAC), who are responsible for the financial, organizational, and programmatic capacity to deliver local health services, might have contributed a different view on how to enhance the state's laboratory capacity. Incorporating the perspective of county CHEAC would have generated a more "complete" picture of issues and concerns relating to the PHL and provided an economically grounded perspective on methods to

enhance the state's PHL capacity. The findings and conclusions made in the dissertation are mainly representative of HOs and PHLDs who are responsible for providing oversight of the health of their community regardless of financial or programmatic efficiencies. Clearly, further research is needed to cover the issues not addressed by this project.

Conclusion/Future Direction

The economic downturn in California and at the federal level has created an extra layer of difficulty for the counties to continue provision of public health programs and services. The PHDs will be experiencing cuts to their county budgets over the next several years. This will result in reductions in programs and services across PHDs in California. The PHL is not exempt from these cuts and thus efficiencies and economies of scale with relation to provision of PHL services need to be considered.

The current system of 37 county PHLs was established in the 1950's and has proven to be an effective system for the delivery of PHL testing services. However, with changing technology, amendments to laboratory and personnel regulations and economic constraints change may be on the horizon. As the pool of PHLDs that were "grandfathered-in" continues to shrink, counties will need to find board certified, doctorate level PHLDs to supervise PHLs. The larger PHLs have the financial capability to offer competitive salaries for PHLD positions, but a smaller county with a limited budget may not have this ability. As the State moves into the future, counties will need to rethink how to adapt to the changes that are occurring. The data collected in this dissertation can be utilized to assess whether a strategic partnership between counties to provide PHL services is beneficial to pursue. Regionalization, and strategic alliances such as a consolidation effort between PHLs or a contractual agreement for joint power purchasing and centralization of testing among counties can function to address funding deficiencies, PHLD workforce shortage etc.. However, that being said, engagement in an inter-organizational form of cooperation among counties is not a one-size fits all solution. A well-developed strategic plan needs to be discussed among county administrators e.g. HOs, PHD director, health executives and PHLDs to ensure that the option chosen will create a stronger PHL system that has the capacity to protect the health, safety and well-being of Californians.

Future work beyond the scope of this dissertation might include 1) introduction of more policy options to address laboratory capacity, 2) utilization of the dissertation findings as a starting point to look into other forms of partnerships or strategies that will improve the state's laboratory capacity, 3) looking at programs outside of the PHL field to evaluate other solutions of obtaining economic efficiencies for delivering health services and 4) inclusion of the perspectives of CHEAC members to obtain a broader understanding of the fiscal requirements of enhancing laboratory capacity in California.

References:

- (AAFP) American Academy of Family Physicians- Proficiency Testing. (2010). *CLIA personnel requirements*. Retrieved March 5, 2010, from <http://www.aafp.org/online/en/home/practicemgt/pt/clia/requirements.html>
- Abbot D.D., and McGurk, J.S. (1998). *Department of Health Services: Authority and responsibility of local health officers in emergencies and disasters*. Retrieved April 5, 2011, from http://www.norcalbt.com/CountyShasta/Documents/hlthofficr_authorities.pdf.
- Adamek, R., and Lavin, B. (1975). *Inter-organizational exchange: A note on the scarcity hypothesis. An Inter-organization Theory*, ed. A. Negandhi, Kent, Ohio: Kent State University Press: pp. 196-209.
- Ahn, R., Gaylin, D.S., Keiller, A., Mendelson, D.N., Moiduddin, A. & Rubin, R.J. (1997). *Public Health Laboratories and Health System Change*. Retrieved July 15, 2009, from <http://aspe.hhs.gov/health/Reports/phlabs/front.htm>.
- Allen, M. (1974). *The structure of inter-organizational elite cooptation: Interlocking corporate directorates*. *American Sociological Review*, 39:393-406
- Aiken, M., and Hage, J. (1968). *Organizational Interdependence and Intra-organizational Structure*. *American Sociological Review*, 63: 912-930.
- (APHL) Association of Public Health Laboratories (2000). *Core Functions and Capabilities of State Public Health Laboratories*. Retrieved May 12, 2009, from http://www.aphl.org/aphlprograms/lss/publications/Documents/Core_Functions_PHLs.pdf.
- Ash, K. O. (1996). *Impact of Cost Cutting on Laboratories: New Business Strategies for Laboratories*. *Clinical Chemistry* 42(5):822-6.
- Baldwin, L.H., Camm, F.A., Moore, N.Y. (2001). *Federal Contract Bundling: A Framework for Making and Justifying Decisions for Purchased Services*. Santa Monica, CA: RAND Corporation. Retrieved May 16, 2011, from http://www.rand.org/pubs/monograph_reports/MR1224.
- Bangladesh Environmental Technology Verification (2009). *Laboratory Capacity Building*. Available: http://www.betv-sam.org/lab_capacity_building.htm [2009, July 2]
- (BDP) The Berkeley Daily Planet (2000). *\$1.1 billion sales tax cut announced by Davis*. Retrieved January 19, 2011, from <http://www.berkeleydailyplanet.com/issue/2000-10-26/article/1822?headline=-1.1-billion-sales-tax-cut-announced-by-Davis>.

- Beckman, C. and Haunschild, P. (2004). *Friends or strangers? Firm- specific uncertainty, market uncertainty, and network partner selection*. *Organization Science*, 15: 259-275.
- Beebe, James. (2006). *Public health and clinical laboratories: Partners in the age of emerging infections*. *Clinical Microbiology Newsletter*, 28(2):9-12.
- Benson, J.K. (1975). *The inter-organizational network as a political economy*. *Administrative Science Quarterly*, 20:229-249.
- Blau, P.M. (1964). *Chapter 1 in his Exchange and Power in Social Life*. New York: Wiley.
- California Department of Finance. (2010). *Governor's Budget Summary 2010-2011*. Retrieved January 19, 2011, from <http://www.dof.ca.gov/budget/historical/2010-11/governors/summary/documents/BSINTRO.pdf>.
- (CA-DoT) California Department of Transportation (2010). Division of Traffic Operations-Road Information – Area Maps. Retrieved November 1, 2010, from <http://www.dot.ca.gov/hq/roadinfo/statemap.htm>
- Cauley de la Sierra, M. (1995). *Managing Global Alliances: Key Steps for Successful Collaboration*. Addison-Wesley Publishing Company.
- Capener, M.A., Martins, M.J., Puffer, J. & Buck, E. (1992). *California Association of Public Health Laboratory Directors 1950-1990*.
- (CDC 2008) Centers for Disease Control and Prevention (2008). *Public Health Preparedness: Mobilizing State by State*. Retrieved May 31, 2009, from <http://www.bt.cdc.gov/publications/feb08phprep/>.
- (CDC 2009) Centers for Disease Control and Prevention. (2009). *National Centers*. Retrieved May 14, 2009, from <http://www.cdc.gov/about/organization/nationalcenters.htm>.
- (CDPH) California Department of Public Health (2009). *Laboratory Branches*. Retrieved August 1, 2009, from <http://www.cdph.ca.gov/search/results.aspx?k=laboratory%20branch>.
- Child, J. and Faulkner, D. (1998). *Strategies of Co-operation: Managing Alliances, Networks and Joint Ventures*. Oxford University Press.
- Church, D.L., Done-Joe, C., and Unger, B. (2000). *Effects of Restructuring on the Performance of Microbiology Laboratories in Alberta*. *Arch Pathol Lab Med*, 124: 357-61.
- Clark, B. (1965). *Inter-organizational Patterns in Education*. *Administrative Science Quarterly*, 10:224-237.

- CLIA (2003). *CLIA Part II: Perplexity about Personnel and Complexity*. Retrieved June 16, 2009, from <http://www.westgard.com/cliainfinalrule2.htm>.
- Cooney, J.P. Jr., and Stith, J.R. (1974). *Consolidation of Clinical Laboratory Facilities: An Evaluation Part Two*. Health Services Research Center of the Hospital Research and Educational Trust and Northwestern University.
- Cook, K.S. (1977). *Exchange and power in networks of inter-organizational relations*. The Sociological Quarterly, Special issue: Organization analysis: Critique and Innovation, Winter, 18(1): 62-82
- Cuellar, A.E. and Gertler, P.J. (2003). *Trends in Hospital Consolidation: The Formation of Local Systems*. Health Affairs, 22(6): 77-87.
- Cyert, R.M., and March, J.G. (1963). *A Behavioral Theory of the Firm*. Englewood Cliffs, N.J.: Prentice Hall.
- (DGS) Department of General Services, Commonwealth of Virginia. (2009). *Division of Consolidated Laboratory Services*. Retrieved May 12, 2009, from <http://www.dgs.state.va.us/DivisionofConsolidatedLaboratoryServices/tabid/453/Default.aspx>.
- Dictionary by Farlex (2009). *Joint Powers Agreement*. Retrieved May 30, 2009, from <http://legal-dictionary.thefreedictionary.com/joint+powers+agreement>.
- DiMaggio, P. and Powell, W. (1983). *The iron cage revisited: institutional isomorphism and collective rationality in organizational fields*. American Sociological Review, 48: 147-160.
- Dowdle, W.R. (1993). *The Future of the Public Health Laboratory*. Annual Review of Public Health 14: 649-664.
- Eccles, R.G. (1981). *The quasifirm in the construction industry*. Journal of Economic Behavior and Organization, 2: 335-357.
- Ehrmeyer, Sharon S., Laessig, Ronald H. (2004). *Has compliance with CLIA requirements really improved quality in US clinical laboratories?* Clinica Chimica, 346: 37-43
- El Dorado Public Health Laboratory (2009). *Laboratory Capacity*. Available: <http://www.co.el-dorado.ca.us/publichealthpreparedness/laboratorycapacity.html> [2009, July 3].
- Eldere, J. Van. (2005). *Changing Needs, Opportunities and Constraints for the 21st Century Microbiology Laboratory*. Clinical Microbiology and Infection, 11: 15-8.
- Elling, R.H. and Halebsky, S. (1961). *Organizational differentiation and support: a conceptual framework*. Administration Science Quarterly, 6:185-209.

- Emerson, R.M. (1976). *Social Exchange Theory*. Annual Review of Sociology, 2: 335-362
- Encyclopedia Britannica. (2009). *California*. Retrieved December 1, 2009, from <http://www.britannica.com/EBchecked/topic/89503/California>.
- Evan, W. (1965). *Toward a theory of inter-organizational relations*. Management Science, 11: 199-237.
- Fagg, K. L., et al. (1999). *Laboratory Restructuring in Metropolitan Edmonton: A Model for Laboratory Reorganization in Canada*. Clinica Chimica Acta: International Journal of Clinical Chemistry, 290(1): 73-91.
- Gausewitz, Philips L. (1999). *Organizing Hospital Laboratories for Efficiency and Quality*. Clinics in Laboratory Medicine, 19: 337-49
- Georgia Public Health Laboratory (2009). *Georgia Public Health Laboratory*. Retrieved May 12, 2009, from <http://health.state.ga.us/programs/.ab/>.
- Granovetter, Mark. (1985). *Economic action and social structure: the problem of embeddedness*. American Journal of Sociology, 91:481-510.
- Gray, L.D. (2001). *Practical Aspects of the Consolidation of Clinical Microbiology Services (Experiences and Recommendations): Part 1*. Clinical Microbiology Newsletter 23(14): 103-105
- Guetzkow, Harold. (1966). *Relations among organizations*. pg. 13-44 in Raymond V. Bowers (Eds.), *Studies on Behavior in Organizaitons*. Athens, Georgia: University of Georgia Press.
- Gueztkow, H. (1966). *Relations Among Organizations, in R. Bowers (Ed.), Studies on Behavior in Organizations*. Athens, Geogia; University of Georgia Press: 13-44
- Gulati, Ranjay. (1995). *Familiarity Breeds Trust? The implications of repeated ties for contractual choice in alliances*. Academy of Management Journal, 38: 85-112.
- Gulati, Ranjay (1998). *Alliances and Networks*. Strategic Management Journal, Special issue: Editor's Choice, 19(4): 293-317.
- Gulati, R. and Gargiulo, M. (1999). *Where do inter-organizational networks come from? The American Journal of Sociology*, 104(5): 1439-1438.
- Gulati, R. and Sytch, M. (2007). *Dependence asymmetry and joint dependence in inter-organizational relationship effects of embeddedness on a manufacturer's performance in procurement relationships*. Adminsrtrative Science Quarterly, 52(1): 32-69.
- Hardy, A.V. (1960). *The Public Health Laboratory--Looking to the Future*. Am. J. Public Health Nations Health, 50:927-932.

(HHS) Health and Human Services (2009). *Public Health Infrastructure and the Private Sector*. Retrieved May 13, 2009, from <http://aspe.hhs.gov/health/reports/phlabs/part2a.htm>.

Hill, Elizabeth G. (2003). *Overview of the Governor's Budget*. Legislative Affairs Office. Retrieved January 19, 2011, from http://www.lao.ca.gov/2003/budget_overview/03-04_budget_overview.pdf

Hirsch, P.M. (1975). *Organizational effectiveness and the institutional environment*. *Administrative Science Quarterly*, 20(3): 327-344

(HRSA) Health Resources and Services Administration (2005). *The Clinical Laboratory Workforce: The Changing Picture of Supply, Demand, Education and Practice*. Retrieved June 10, 2009, from <http://bhpr.hrsa.gov/healthworkforce/reports/clinical/default.htm>.

Infectious Diseases Society of America (2001). *Policy Statement on Consolidation of Clinical Microbiology Laboratories*. *Clinical Infectious Diseases: An Official Publication of the Infectious Diseases Society of America* (32)4: 604.

Inhorn, S.L., Astles, J.R., Gradus, Stephen, Malmberg, V., Snippes, P.M., Wilcke, B.W. Jr., White, V.A. (2010). *The State Public Health Laboratory System*. *Public Health Reports*, 2010 Supplement 2, 125:4-17

(IOM 1988) Institute of Medicine (1988). *The Future of Public Health*. National Academy Press.

(IOM 2003) Institute of Medicine (2003). *The Future of the Public's Health in the 21st Century*. The National Academies Press.

Jaffe, Ina. (2011). *No Hollywood Ending to Schwarzenegger's Term*. National Public Radio. Retrieved January 19, 2011, from <http://www.npr.org/2011/01/03/132445643/no-hollywood-ending-to-schwarzeneggers-term>.

Keister, L.A. (2001). *Exchange structures in transition: Lending and trade relations in Chinese Business Groups*. *American Sociological Review*, 66(3): 336-360.

Kelch, D.R. (2011). *The crucial role of counties in the health of Californians: An overview*. Prepared for California Healthcare Foundation. Retrieved April 5, 2011, from <http://www.chcf.org/publications/2011/03/crucial-role-counties>.

Kellogg, Wilfred H. (1931). *The Certification of Laboratories in California*. *American Journal of Public Health*, 21(9): 977-983.

Kim, O. and Walker, M. (1984). *The free rider problem: Experimental evidence*. *Public Choice*, 43(1): 3-24.

- Kogut, Bruce. (1988). *Joint ventures: Theoretical and empirical perspectives*. Strategic Management Journal, 9(4): 319-332.
- Kotter, J.P. & Schlesinger, L.A. (1979). *Choosing Strategies for Change*. Harvard Business Review (57)2:106-114.
- LabLink. (1995). *Laboratory Information from the Michigan Department of Public Health*. Retrieved June 1, 2009, from http://www.michigan.gov/documents/LabLinkvol1no2_7801_7.pdf.
- (LAO) Legislative Analyst's Office (2001) *Realignment Revisited: An Evaluation of the 1991 Experiment in State- County Relations*; Retrieved February 5, 2011, from http://www.lao.ca.gov/2001/realignment/020601_realignment.pdf.
- Larson, A. (1992). *Network dyads in entrepreneurial settings: A study of the governance of exchange relationships*. Administrative Science Quarterly, 37(1): 76-104
- Lawler, E.J., and Yoon, J. (1996). *Commitment in exchange relations: Test of theory of relational cohesion*. American Sociological Review, 61(1): 89-108
- Laumann, E.O., Galaskiewicz, J., Marsden, P.V. (1978). *Community Structure as Interorganizational Linkage*. Annual Review of Sociology, 4:455-484.
- Levine, S. and White, P.E. (1961). *Exchange as a conceptual framework for the study of inter-organizational relationships*. Administrative Science Quarterly, 5: 538-601.
- (LHC 2003) Little Hoover Commission (2003). *To Protect and Prevent: Rebuilding California's Public Health System*. Retrieved July 15, 2009, from <http://www.lhc.ca.gov/studies/170/report170.pdf>.
- (LHC 2009a) Little Hoover Commission (2009a). *About Us: The Little Hoover Commission*. Retrieved July 21, 2009, from <http://www.lhc.ca.gov/about/about.html>.
- (LHC 2009b) Little Hoover Commission (2009b). *First Year Checkup: Strategies for a Stronger Public Health Department*. Retrieved May 15, 2009, from <http://www.lhc.ca.gov/studies/194/report194.pdf>.
- Lincoln, J.R., Gerlach, M.L., Takahashi, P. (1992). *Keiretsu networks in the Japanese economy: A dyad analysis of intercorporate ties*. American Sociological Review, 57(5): 561-585.
- Los Angeles Times (2011). *GOP lawmakers issue plan to balance California budget*. Retrieved May 20, 2011, from <http://articles.latimes.com/2011/may/13/local/la-me-budget-republicans-20110513>.

- Marshall, Steven A., Brokopp, Charles D., Size, Tim (2010). *Leadership Principles for Developing a Statewide Public Health and Clinical Laboratory System*. Public Health Reports, Supplement 2 (125): 110-117.
- Maxwell, J. A. (2005). *Qualitative research design: An interactive approach* (2nd ed.). Thousand Oaks, CA: Sage.
- McDade, J.E. & Hausler, W.J., Jr. (1998). *Modernization of Public Health Laboratories in a Privatization Atmosphere*. Journal of Clinical Microbiology, (36)3:609-613.
- Meyer, J. and Rowan, B. (1977). *Institutionalized organizations: Formal structure as myth and ceremony*. American Journal of Sociology, 83: 340-363.
- Mizruchi, M.S. (1989). *Similarity of political behavior among large American corporations*. American Journal of Sociology, 95: 401-424.
- Nelson, R. and Winter, S. (1982). *An Evolutionary Theory of Economic Change*. Harvard University Press, Cambridge, MA.
- Oliver, Christine. (1990). *Determinants of inter-organizational relationships: Integration and future directions*. The Academy of Management Review, 15(2): 241-265.
- Passiment, E. (2006). *Update on the Laboratory Workforce-Shortage Crisis*. Retrieved June 25, 2009, from www.mlo-online.com/articles/0306/0306washreport.pdf.
- Patton, M. Q. (2002). *Qualitative research and evaluation methods* (3rd ed.). Thousand Oaks, CA: Sage.
- Pentella, M.A. (2009). *Defending the Public's Health*. Retrieved June 10, 2009, from http://www.aphl.org/policy/Documents/AAAS_APHL_2009_final.pdf.
- Peterson, L.R., Hamilton, J.D., Baron, E.J., Tompkins, L.S., Miller, J.M., Wilfert, C.M., Tenover, F.C. & Thomson Jr, R.B., Jr (2001). *Role of Clinical Microbiology Laboratories in the Management and Control of Infectious Diseases and the Delivery of Health Care*. Clinical Infectious Diseases: An Official Publication of the Infectious Diseases Society of America (32)4: 605-611.
- Pfeffer, Jeffrey. (1972). *Merger as a response to organizational interdependence*. Administrative Science Quarterly, 17:382-394.
- Pfeffer, J., and Nowak P. (1976). *Joint ventures and inter-organizational interdependence*. Administrative Science Quarterly, 21(3): 398-418.
- Pfeffer, J. and Salancik, G.R. (1978). *Chapter 3. External Control of Organizations*. Harper.

- Podolny, J.M. (1994). *A status based model of market competition*. American Journal of Sociology, 98:829-872.
- Powell, W.W., Koput, K.W., Doerr, L.S. (1996). *Interorganizational collaboration and the locus of innovation: Networks of learning in biotechnology*. Administrative Science Quarterly, 41(1):116-145.
- Prahalad, C.K. and Hamel G, (1990). *The Core Competence of the Corporation*. Harvard Business Review, Product 6528 (May-June): 1-15
- Provan, K.G. (1993). *Embeddedness, interdependence and opportunism in organizational supplier-buyer networks*. Journal of Management, 19: 841-856.
- Provan, G., Beyer, Janice M., Kruythbosch, Carlos. (1980). *Environmental linkages and power in resource dependence relations between organizations*. Administrative Science Quarterly, 25(2):200-225.
- Public Health Laboratory Issues in Brief. (2004). *Assessing America's Local Public Health Laboratory Capacity*. Retrieved August 5, 2009, from http://www.aphl.org/AboutAPHL/publications/Documents/Assessing_Americas_Local_PH_L_Capacity.pdf.
- Reid, W. (1964). *Interagency coordination in delinquency prevention and control*. Social Service Review. 38: 418-428.
- Richardson, Harold. (1999). *Laboratory Medicine in Ontario: Its Downsizing and the Consequences on Quality*. Clin.Chim.Acta, 290(1): 57-72.
- Ring, P.S. and Van De Ven, A.H. (1992). *Structuring Cooperative Relationships between Organizations*. Strategic Management Journal, 13(7):483-498.
- Schmidt, R. M., and M. A. Madoff. (1977). *The State and Territorial Public Health Laboratory: Program Activities, Organization and Prospects for the Future*. American Journal of Public Health 67(5): 433-8.
- Soman, L.A. (2010). *California's State Budget for Fiscal Year 2010-2011: Another Long Budget Year*. Center for Healthier Children, Families and Communities. Retrieved January 19, 2011, from http://www.cshcn-ca.org/files/State_Budget_Report_07-23-10.pdf
- Schaeffer, Morris. (1981). Ed. *Federal Legislation and the Clinical Laboratory*. Boston, Massachusetts: G.K. Hall Medical Publishers
- Schermerhorn, John R. Jr. (1975). *Determinants of inter-organizational cooperation*. The academy of management journal, 18(4): 846-856

- Schmidt, R.M. & Madoff, M.A. (1977). *The State and Territorial Public Health Laboratory: Program Activities, Organization and Prospects for the Future*. American Journal of Public Health (67)5: 433-438.
- Scott, W.R. (2004). *Institutional Theory: Contributing to a Theoretical Research Program*. Chapter prepared for Great Minds in Management: The Process of Theory Development. Ken G. Smith and Michael A. Hitt, (Eds). Oxford UK: Oxford University Press
- Selznick, P. (1949). *Conclusion chapter in his TVA and the Grass Roots*. University of California Press.
- Selznick, P.R. (1996). *Institutionalism old and new*. Administrative Science Quarterly, 41: 270-272
- Skeels, M.R. (1995). *Public Health Laboratories Build Health Communities*. Laboratory Medicine 26(9):588.
- Stake, R. E. (2006). *Multiple Case Study Analysis*. New York, NY: The Guilford Press.
- The Lewin Group. (1997). *Public Health Laboratories and Health System Change*. Retrieved October 21, 2010, from <http://www.lewin.com/content/publications/455.pdf>.
- Thompson, J. (1967). *Domains of organized actions*. Chapter 3 in Organizations in Action. McGraw.
- Thompson, J., and McEwen, W. (1958). *Organizational Goals and Environment: Goal-setting as an interaction process*. American Sociological Review, 23: 23-31.
- Tolbert, P. and Zucker, L. (1983). *Institutional sources of change in the formal structure of organizations: The diffusion of civil service reform*. Administrative Science Quarterly, 28: 22-39
- Trends Research (2010). *The Emerging U.S. Oligarchy*. Retrieved May 19,2011, from <http://www.trendsresearch.com/reports/oligarchies.pdf>.
- Turner, J.C., Brown, R.J. and Tajfel, J. (1979). *Social comparison and group interest in in-group favoritism*. European Journal of Social Psychology, 9: 187-204.
- Uzzi, Brian. (1996). *The sources and consequences of embeddedness for the economic performance of organizations: The network effect*. American Sociological Review, 61(4): 674-698.
- Walker, G., Kogut, B., and Shan, W. (1997). *Social capital, structural holes and the formation of an industry network*. Organization Science, 8:109-125.

Westphal, J.D., Gulati, R., Shortell, S.M. (1997). *Customization or conformity? An institutional and network perspective of the content and consequences of TQM adoption*. *Administrative Science Quarterly* 41:366-394

Wikipedia (2010a). *Napa County, California*. Retrieved August 10, 2010, from http://en.wikipedia.org/wiki/Napa_County,_California.

Wikipedia (2010b). *Solano County, California*. Retrieved August 10, 2010, from http://en.wikipedia.org/wiki/Solano_County,_California

Wikipedia (2010c). *Alameda County, California*. Retrieved August 10, 2010, from http://en.wikipedia.org/wiki/Alameda_County,_California.

Wikipedia (2010d). *Contra Costa County, California*. Retrieved August 10, 2010, from http://en.wikipedia.org/wiki/Contra_Costa_County,_California.

Wikipedia (2010e). *San Francisco County, California*. Retrieved August 10, 2010, from http://en.wikipedia.org/wiki/San_Francisco.

Wikipedia (2010f). *Mendocino County, California*. Retrieved August 10, 2010, from http://en.wikipedia.org/wiki/Mendocino_County,_California.

Wikipedia (2010g). *Mendocino County, California*. Retrieved August 10, 2010, from http://en.wikipedia.org/wiki/Sonoma_County,_California

Williamson, O.E. (1981). *The economics of organization: The transaction cost approach*. *American Journal of Sociology*, 87:548-577.

Wilson, Michael L., Gradus, Stephen, Zimmerman, Scott J. (2010). *The Role of Local Public Health Laboratories*. *Public Health Reports*, Supplement 2 (125): 118-125

Yin, R. K. (2009). *Case Study Research: Design and Methods* (4th ed.). Thousand Oaks, CA: Sage.

Young, R.C. and Larson, O.F. (1965). *The contribution of voluntary organizations to community structure*. *American Journal of Sociology*, 71(2): 178-186.

Yves L. Doz and Gary Hamel. (1998). *Alliance Advantage- The art of creating value through partnering*. Harvard Business School Press. Boston, Massachusetts.

Zaheer, A., McEvily, B. and Perrone, V. (1998). *Does trust matter? Exploring the effects of inter-organizational trust on performance*. *Organizations Science*, 9: 141-159.

Zajac, E.J., D'Aunno, T.A. & Burns, L.R. (2005). *Managing Strategic Alliances in Health_Care Management: Organization Design and Behavior pp. 356-381, (5th Edition)*. Clifton Park, NY: Thomson Delmar Learning.

Zeit, G. (1980). *Interorganizational Dialectics*. Administrative Science Quarterly, 25(1): 72-88.

Zucker, L.G. (1977). *The role of institutionalization in cultural persistence*. American Journal of Sociology, 42” 726-743

Appendix 1: State Laboratory Functions (Association of Public Health Laboratories 2000, Skeels 1995, McDade, Hausler 1998, Ahn et al. 1997)

- 1) Disease prevention, control and surveillance
 - a. Serve as experts for detection and identification of biologic agents
 - b. Provide access to specialized low incidence test, high risk diseases, provide data for epidemiologic surveillance, and detection of newly emerging infectious agents
 - c. Perform population screening for genetic metabolic disorders, community lead exposure and more.
- 2) Integrated data management
 - a. Serve as focal point of data collection in order to disseminate the latest and most accurate scientific information to support public health programs.
 - b. Link with federal agencies like the Center for Disease Control and Prevention (CDC) for national and global disease surveillance
 - c. Provide data to identify emerging health problems
- 3) Reference and specialized laboratory testing
 - a. Serve as the state's primary reference testing site
 - b. Perform tests not commercially profitable
 - c. Verification of result from other labs
- 4) Laboratory improvement and regulation
 - a. Laboratory training, proficiency testing etc. to help improve the quality of the laboratory environment
 - b. Quality assurance across laboratories
- 5) Environmental health and protection
 - a. Analysis of environmental samples and biological specimens to identify and monitor potential threats to human health
 - b. Ensure compliance with environmental regulations
- 6) Food safety assurance
 - a. Testing specimens implicated in foodborne illnesses
 - b. Monitoring radioactive contamination of water milk, shellfish and other foods
- 7) Policy development
 - a. Participate in the development of standards for all health related laboratories
 - b. Provide scientific and managerial leadership to aid the formulation of state and federal public health policies
- 8) Emergency response
 - a. Provide high volume laboratory support as a part of national disaster preparedness program
 - b. State PHL need to be able to handle unknown samples that may contain infectious, toxic, radioactive, and/or explosive materials
- 9) Public Health related research
 - a. Improve the practice of laboratory science
- 10) Training and education
 - a. Provide training and education for laboratory staff in the private and public sectors in the US and abroad
- 11) Partnerships and communication

- a. Establish partnerships and communication with public health colleagues and others to participate in state policy planning and to support the core functions of the state public health laboratory

Appendix 2: Laboratory Response Network Catchment Areas

Region of California	LRN Reference PHL	Catchment Area (Counties Served)
Upper Northern Coastal		
1.	Humboldt	Del Norte and Western slopes of the Trinity Alps
Lower Northern and Central Coastal		
2.	Sonoma	Mendocino, Lake, Napa and Solano
3.	State MDL and VRDL PHLs	Alameda, Contra Costa, Marin, Napa, San Francisco, and Berkeley
4.	Santa Clara	Monterey, San Benito, San Mateo, Santa Clara, and Santa Cruz
Northern Inland		
5.	Shasta	Glenn, Lassen, Modoc, Shasta, Siskiyou, Tehema, and Eastern Trinity
6.	Placer	Sierra, Nevada, Placer, El Dorado
7.	Sacramento	Butte, Colusa, Plumas, Sutter, Yolo, and Yuba
8.	San Joaquin	Alpine, Amador, Calaveras, Mariposa, Mono, Stanislaus, and Tuolumne
9.	Fresno	Madera and Merced
10.	Tulare	Kings and Kern
Southern Coastal		
11.	San Luis Obispo	Orange, Santa Barbara, Ventura,
12.	Los Angeles	Pasadena and Long Beach City
13.	Orange	Orange
Southern Inland		
14.	San Bernardino	Inyo, and Riverside
15.	San Diego	San Diego

Appendix 3: CLIA Requirements for Public Health Laboratory Directors

CLIA Personnel Requirements

The CLIA personnel requirements are found in Subpart M of the Code of Federal Regulations. This subpart addresses qualifications and responsibilities for Provider Performed Microscopy (PPM), Moderate and High Complexity laboratories. Laboratories performing only Waived testing do not have specific personnel qualifications. The PPM classification has requirements for the laboratory director and testing personnel; the Moderate Complexity classification has requirements for the laboratory director, clinical consultant, technical consultant and testing personnel; the High complexity classification has requirements for the laboratory director, clinical consultant, technical supervisor, general supervisor and testing personnel.

Moderate/High Complexity

A moderate/high complexity laboratory is required to have personnel who meet the following qualifications (in most situations, the laboratory director is qualified to full multiple roles):

LABORATORY DIRECTOR

Must possess a current license as a laboratory director issued by the State in which the laboratory is located, if such licensing is required.

AND

Be a doctor of medicine or osteopathy licensed to practice medicine or osteopathy in the State in which the laboratory is located and certified in anatomic or clinical pathology, or both by the American Board of Pathology or the American Osteopathic Board of Pathology or possess qualifications that are equivalent.

OR

Be a doctor of medicine or osteopathy or doctor of podiatric medicine licensed to practice medicine or osteopathy or podiatry in the State in which the laboratory is located and have laboratory training or experience consisting of: At least one year of directing or supervising non-waived laboratory testing, or Have at least twenty continuing medical education credit hours, commensurate with the director responsibilities, or Have laboratory training equivalent to twenty continuing medical education credit hours, commensurate with the director responsibilities, obtained during medical residency.

OR

Hold an earned doctoral degree in a chemical, physical, biological or clinical laboratory science from an accredited institution and:

Be certified by the American Board of Medical Microbiology, the American Board of Clinical Chemistry, the American Board of Bioanalysts or the American Board of Medical Laboratory Immunology, or Have at least one year experience directing or supervising non-waived testing.

OR

Have earned a master's degree in a chemical, physical, biological or clinical laboratory

science or medical technology from an accredited institution and:
Have at least one year of laboratory training or experience or both in non-waived testing, and In addition, have at least one year of supervisory laboratory experience in nonwaived testing.

OR

Have earned a bachelor's degree in a chemical, physical or biological science or medical technology from an accredited institution and: Have at least two years of laboratory training or experience or both in nonwaived, and In addition, have a least two years of supervisory laboratory experience in nonwaived testing

OR

Be serving as a laboratory director and must have previously qualified or could have qualified as a laboratory director on or before February 28, 1998.

OR

Qualified under State law to direct a laboratory in the state in which the laboratory is located (on or before February 28, 1992).

CLINICAL CONSULTANT

The clinical consultant must be qualified to consult with and render opinions to the laboratory's clients concerning the diagnosis, treatment and management of patient care. The qualifications include:

Be qualified as the laboratory director.

OR

Be a doctor of medicine, osteopathy or podiatric medicine and possess a license to practice medicine, osteopathy or podiatry in the State in which the laboratory is located.

TECHNICAL CONSULTANT

The laboratory must have a technical consultant qualified by education and either training or experience to provide technical consultation for each of the specialties and subspecialties tested in the laboratory. The qualifications include:

Possess a current license issued by the State in which the laboratory is located, if such licensing is required.

AND

Be a doctor of medicine or osteopathy licensed to practice medicine or osteopathy in the State in which the laboratory is located and certified in anatomic or clinical pathology, or both by the American Board of Pathology or the American Osteopathic Board of Pathology or possess qualifications that are equivalent.

OR

Be a doctor of medicine or osteopathy or doctor of podiatric medicine licensed to practice

medicine or osteopathy or podiatry in the State in which the laboratory is located and have at least one year of laboratory training or experience or both in non-waived testing, in the designated specialty or subspecialty areas of service for which the technical consultant is responsible.

OR

Hold a doctoral or master's degree in a chemical, physical, biological or clinical laboratory science or medical technology from an accredited institution, and have at least one year of laboratory training or experience or both in non-waived testing, in the designated specialty or subspecialty areas of service for which the technical consultant is responsible.

OR

Have earned a bachelor's degree in a chemical, physical or biological science or medical technology from an accredited institution and have at least two years of laboratory training or experience or both in non-waived testing, in the designated specialty or subspecialty areas of service for which the technical consultant is responsible.

TESTING PERSONNEL

The laboratory must have a sufficient number of individuals who meet the qualifications to perform the volume and complexity of tests performed. Qualifications include:

Possess a current license issued by the State in which the laboratory is located, if such licensing is required.

AND

Be a doctor of medicine or osteopathy or doctor of podiatric medicine licensed to practice medicine or osteopathy or podiatry in the State in which the laboratory is located or have earned a doctoral, master's or bachelor's degree in a chemical, physical, biological or clinical laboratory science or medical technology from an accredited institution

OR

Have earned an associate degree in a chemical, physical or biological science or medical laboratory technology from an accredited institution.

OR

Be a high school graduate or equivalent and have successfully completed an official military medical laboratory procedures course of at least 50 weeks duration and have held the military enlisted occupational specialty of Medical Laboratory Specialist (Laboratory Technician)

OR

Have earned a high school diploma or equivalent, and have documentation of training appropriate for the testing performed prior to analyzing patient specimens. Such training must ensure that the individual has:

The skills required for proper specimen collection, including patient preparation

if applicable, labeling, handling, preservation or fixation, processing or preparation, transportation and storage of specimens, and The skills required for implementing all standard laboratory procedures, and The skills required for performing each test method and for proper instrument use, and The skills required for performing preventive maintenance, troubleshooting and calibration procedures related to each test performed, and A working knowledge of reagent stability and storage, and The skills required to implement quality control policies and procedures of the laboratory, and An awareness of the factors that influence test results, and the skills required to assess and verify the validity of patient test results through the evaluation of quality control sample values prior to reporting patient test results.

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Appendix 4: County Personnel and Test/year (2010')

Alameda	Director	1	Humboldt	Director	1	Los Angeles	Director	1
	Sr. Micro/Micro	6		Sr. Micro/Micro	1.5		Asst. Director	1
	Lab Asst/Tech	2		Lab Asst/Tech	4		Sr. Micro/Micro	65
	Clerical	3		Total	6.5		Lab Asst/Tech/Clerical	54
	Total	12		Tests/yr	3000		Total	121
	Tests/yr	20,000					Tests/yr	451,000
Butte	Director	1	Imperial	Director	1	Madera	Director	1
	Sr. Micro/Micro	2		Sr. Micro/Micro	2		Sr. Micro/Micro	
	Total	3		Lab Asst/Tech	2		Lab Asst/Tech	
	Specimen/yr	7,000		Clerical	1		Clerical	
			Total	6	Total	N/A		
			Tests/yr	18,456	Tests/yr	N/A		
Contra Costa	Director	1	Kern	Director	1	Marin	Director	1
	Lab Manager	1		Sr. Micro/Micro	2		Sr. Micro/Micro	3
	Sr. Micro/Micro	9		Lab Asst/Tech	2.5/3 temp		Lab Asst/Tech	0.5
	Lab Asst/Tech	2		Clerical	2		Clerical	2
	Clerical	2		Total	10.5		Total	7.5
	Total	15		Tests/yr	50,000		Tests/yr	34,000
	Tests/yr	114,000						
El Dorado	Director	1	Kings	Director	1	Merced	Director	1
	Total	1		Sr. Micro/Micro	1		Sr. Micro/Micro	1
	Tests/yr	N/A		Lab Asst/Tech	1		Lab Asst/Tech	1
				Total	3		Total	3
			Tests/yr	13,000	Tests/yr	12,000		
Fresno	Director	1	Long Beach	Director	1	Monterey	Director	1
	Sr. Micro/Micro/Chemist	11		Sr. Micro/Micro	7		Sr. Micro/Micro	3
	Lab Asst/Tech	2		Lab Asst/Tech	5		Lab Asst/Tech	2
	Clerk	7		Clerical	4		Water Specialist	1
	Total	21		Chemist	1		Chemist	1
	Speciment Count	85,000		Total	18		Clerical	1
		Tests/yr	100,000	Total	9			
				Tests/yr	40,000			

Los Angeles	Director	1	Napa-Solano	Director	1	Sacramento	Director	1
	Asst. Director	1		Asst. Director	1		Sr. Micro/Micro	8
	Sr. Micro/Micro	65		Sr. Micro/Micro	5		Lab Asst/Tech	1
	Lab Asst/Tech/Clerical	54		Lab Asst/Tech	2		Clerical	3
	Total	121		Clerical	2		Total	13
Tests/yr	451,000		Total	11	Tests/yr	80,000		
			Tests/yr	25,000				
Madera	Director	1	Orange	Director	1	San Bernadino	Director	1
	Sr. Micro/Micro			Lab Manager	1		Sr. Micro/Micro	9
	Lab Asst/Tech			Sr. Micro/Micro	28		Lab Asst/Tech	5.5
	Clerical			Lab Asst/Tech	18		Clerical	2.5
	Total	N/A		Chemist	1		Total	18
Tests/yr	N/A	Clerical	4	Tests/yr	105,000			
			Total	53				
			Tests/yr	140,000				
Marin	Director	1	Pasadena	Director	1	San Diego	Director	1
	Sr. Micro/Micro	3		Lab Asst/Tech	1		Sr. Micro/Micro	18
	Lab Asst/Tech	0.5		Total	2		Lab Asst/Tech	8
	Clerical	2		Tests/yr	N/A		Clerical	10
	Total	7.5					Total	31
Tests/yr	34,000			Tests/yr	100,000			
Merced	Director	1	Placer	Director	1	San Francisco	Director	1
	Sr. Micro/Micro	1		Sr. Micro/Micro	4		Asst. Director	1
	Lab Asst/Tech	1		Lab Asst/Tech	3		Sr. Micro/Micro	11
	Total	3		Clerical	1.5		Lab Asst/Tech	10
	Tests/yr	12,000		Total	9.5		Clerical	3
			Tests/yr	25,000	Total	26		
					Tests/yr	75,000		
Monterey	Director	1	Riverside	Director	1	San Joaquin	Director	1
	Sr. Micro/Micro	3		Asst. Director	1		Sr. Micro/Micro	9
	Lab Asst/Tech	2		Sr. Micro/Micro	4		Lab Asst/Tech	2
	Water Specialist	1		Lab Asst/Tech	5		Courier	0.5
	Chemist	1		Clerical	3		Clerical	2
	Clerical	1		Lab Manager	1		Total	14.5
	Total	9		Total	15		Tests/yr	70,000
Tests/yr	40,000	Tests/yr	100,000					

San Luis Obispo	Director	1	Santa Cruz	Director	1	Tulare	Director	1	
	Sr. Micro/Micro	6		<i>*Emeline Branch</i>	Sr. Micro/Micro		3	Sr. Micro/Micro	5.5
	Lab Asst/Tech	3			Lab Asst/Tech		2	Lab Asst/Tech	5
	Clerical	2		<i>*Watsonville</i>	CLS		1	Clerical	2
	Total	12			Phlebotomist		1	Total	13.5
	Tests/yr	42,000			Total		8	Tests/yr	55,000
			Tests/yr	54,393					
San Mateo	Director	1	Shasta	Director		Ventura	Director	1	
	Asst. Director	1			Sr. Micro/Micro		3	Sr. Micro/Micro	5
	Post-Doc Trainee	1			Lab Asst/Tech			Lab Asst/Tech	2
	Sr. Micro/Micro	5			Clerical			Clerical	1
	Lab Asst/Tech	3			Total		<i>N/A</i>	Total	9
	Clerical	2			Tests/yr		<i>N/A</i>	Tests/yr	51,000
Total	13								
Tests/yr	80,000								
Santa Barbara	Director	1	Sonoma	Director	1	Yolo	Director	1	
	Sr. Micro/Micro	4			Sr. Micro/Micro		4	Sr. Micro/Micro	1
	Lab Asst/Tech	1			Lab Asst/Tech		3	Lab Asst/Tech	0.5
	Clerical	1			Clerical		1	Total	2.5
	Total	7			Total		9	Tests/yr	3500
	Tests/yr	27,235			Tests/yr		31,000		
Santa Clara	Director	1	Stanislaus	Director	1				
	Sr. Micro/Micro	6			Sr. Micro/Micro	3			
	Lab Asst/Tech	1			Lab Asst/Tech	1			
	BT Coordinator	1			Clerical	1			
	Clerical	2			Total	6			
	Courier	1			Tests/yr	20,000			
Total	12								
Tests/yr	30,000								
			Sutter	Director	1				
					Sr. Micro/Micro	1 (on call)			
					Lab Asst/Tech	1			
					Total	3			
					Tests/yr	300			

Appendix 5: Case Study Interview Guide (Napa/Solano)

General Questions:

1. What counties does the Napa/Solano lab serve?
2. How does Napa contribute to the merger?
3. How are the finances divided?
4. What size population do you serve?
5. How many personnel work in the lab?
 - a. PHM
 - b. Senior PHM
 - c. Assistant Director
 - d. Director
6. How many tests are run per year?
7. What testing capabilities do you have?
8. How are you dealing with the laboratory director shortage?
 - a. Are you having problems recruiting applicants?
9. Are you facing heavy competition from private labs?
10. Does Medicare/Medicaid reimbursements affect your laboratory?
11. Has the move to managed care in the hospital affected the laboratory?
12. Do you have relationships with clinical labs, or commercial labs? If so, what type of relationship?
 - a. If Yes: How are you dealing with the problem?
13. Do you have relationships with other labs in other counties?
 - a. Which one, and how close are you?
14. Can you describe the breakdown of the different sources of funding?

Initiation of the merger:

1. What criteria did you use to choose Napa and Solano for a merger?
 - a. Size
 - b. Testing capabilities
 - c. Location
2. Why did the merger occur?
 - a. Financial
 - b. Laboratory director shortage
 - c. Competition from private clinical labs
3. What year did the merger take place?
4. Who initiated the plan, and saw it through completion? One champion, multiple stakeholders?
5. Was there involvement outside of the laboratory from county officials to conduct the merger?
 - a. Who? And what was their role in the merger?
6. Who initiated the merger?
7. How was the merger initiated?
8. Why did you choose a joint powers agreement? What are the benefits of the JPA versus another form of partnership?
9. How did you come to an agreement to house the laboratory in Solano?

10. What were some initial problems that had to be dealt with during the initial merging of labs?
 - a. Were programs affected because the lab in Napa shut down
 - b. Were test results delayed?
 - c. Did the quality of services decrease in the laboratory?
11. How has elimination of a laboratory affected the community in Napa?
 - a. Did testing become unavailable to certain populations?
12. Who was brought to the table for the initial talks about the merger?
 - a. Laboratory personnel
 - b. County health officers
 - c. Community members
13. What was the negotiation process like? How did you agree to the terms that you abide by today?
14. What are the major struggles you faced during the initial phases of the consolidation?
15. How much did it cost to initiate the merger?

Maintenance of Merger

1. Has it been difficult trying to maintain the merger?
 - a. What are some of the obstacles faced?
2. How has this been a successful venture?
 - a. Why has this been successful?
 - i. Quicker turn around time for tests?
 - ii. Cost savings?
 - iii. Increased testing availability?
3. Who provides the major oversight of the laboratory? Solano? What role does Napa have?
4. How often is the JPA renewed? Are there changes to the JPA each time to reflect the changing environment?
5. How has this merger affected the county financially?
6. How has the current economic crisis affected the lab if at all?
7. How many tests did you run pre and post merger?
8. Why was a merger an ideal situation for your county?
9. Should other counties do the same thing? Why or why not?
10. Do you feel that consolidating labs in other counties is a feasible option?
11. If you could “redo” the merger what would you change? What would you keep the same?
12. Has this merger hindered your performance as a laboratory?
13. What services/programs have you gained or lost due to the merger?
14. Who funded the merger? Was this a “zero cost” merger?
15. Why do you think other counties are opposed to the idea of consolidation?

Outcome measures:

1. With consolidation is there an increase in the number of false test results?
 - a. Are there more errors with specimen processing due to larger amount of samples?
2. What activities decreased in quality when the laboratory first merged? i.e. testing protocol, people getting properly trained etc.
3. What are some of the affects of consolidation on quality assurance?
4. Are there increases in complaints regarding errors in resulting?

5. Do you outsource any lab testing? Why? i.e. cheaper to outsource? Don't have the technology?

Relationship with the State:

1. How often do you interact with the State lab? What type of relationship do you have?
 - a. Relatively independent of one another
 - b. Often shipping samples for testing
 - c. Does the state often utilize your lab for testing
2. What do you perceive as the role of the state lab?
3. What do you perceive to be your role in providing PH laboratory services in relation to the state lab?
4. Did the state laboratory increase their oversight of your laboratory following consolidation?

Wrap-Up:

1. Are there any other things that you would like to share that you did not feel was addressed during our conversation?
2. Can I call or email you for any follow up questions?

Appendix 6: Napa/Solano County Joint Powers Agreement

NAPA COUNTY AGREEMENT NO. 4092
SOLANO COUNTY AGREEMENT NO. 064092

JOINT EXERCISE OF POWERS AGREEMENT (NAPA-SOLANO COUNTY PUBLIC HEALTH LABORATORY)

THIS AGREEMENT is made and entered into as of this 1st day of July, 2010 by and between the COUNTY OF NAPA, a political subdivision of the State of California, hereinafter referred to as “Napa County”, and the COUNTY OF SOLANO, a political subdivision of the State of California, hereinafter referred to as “Solano County.”

RECITALS

WHEREAS, on or about July 1, 2000, by that joint powers agreement known as Napa County Agreement No. 4092/Solano County Agreement No. 064092, subsequently amended on four occasions, Napa and Solano created a joint public health lab known as the Napa-Solano Public Health Laboratory; and

WHEREAS, the joint powers agreement will be expiring on June 30, 2010; and

WHEREAS, Napa and Solano wish to continue to operate the joint public health lab pursuant to a new joint powers agreement, on the terms and conditions set forth below:

TERMS

NOW, THEREFORE, IT IS HEREBY AGREED by Solano County and Napa County as follows:

1. DESIGNATION AND FUNCTION OF JOINT LABORATORY.

A. Name. During the term of this Agreement, Solano County and Napa County shall continue to operate the joint public health testing laboratory created on July 1, 2000, which shall continue to be known as the Napa-Solano County Public Health Laboratory.

B. Address. Testing shall occur at the Napa-Solano County Public Health Laboratory site (the existing Solano County Public Health Laboratory site) located at 2201 Courage Drive, Fairfield, California 94533 or at such other location as mutually agreed to by the parties in writing.

C. Submission and delivery of specimens, Napa County specimens submitted for testing shall continue to be received at Napa County Public Health, a division of the Napa County Health and Human Services Agency, at 2344 Old Sonoma Rd., Bldg. G, Napa, California 94559. Solano County specimens submitted for testing shall be received at the Napa-Solano County Public Health Laboratory and/or at any existing or future intake locations designated by the Director of the NapaSolano County Public Health Laboratory. Solano County shall be responsible for

providing courier services to pick up and deliver to the Napa-Solano County Public Health Laboratory all Napa County specimens submitted to the Napa County Public Health Department as well as any Solano County specimens submitted at designated intake locations in Solano County other than the Napa-Solano County Public Health Laboratory.

2. OVERSIGHT OF NAPA COUNTY HIV/AIDS PROGRAMS. In accordance with the funding Napa receives from the California Department of Public Health, Office of AIDS, both counties agree, for their mutual benefit, that Solano County will provide oversight of the following Napa County AIDS programs:

A. Ryan White CARE Act Title II (“HIV Care”): Napa currently contracts with the Queen of the Valley Medical Center for case management services for this program. Solano County shall provide subcontractor oversight, conduct site visits, prepare biannual reports and the renewal application for funding for submission to the State Office of AIDS, and interface with the state consultant regarding the program.

B. Housing Opportunities for People with AIDS (HOPWA): Napa currently contracts with Queen of the Valley Medical Center for implementation of this program. Solano shall provide subcontractor oversight, conduct site visits, prepared biannual reports, and the renewal application for funding for submission to the State Office of AIDS, and interface with the state consultant regarding the program.

3. TERM OF AGREEMENT. The term of this Agreement shall be 36 months, beginning on July 1, 2010 and ending on June 30, 2013 except that either party may terminate this Agreement at any time for the convenience of that party upon giving the other party no less than six (6) months prior written notice.

4. PERIODIC REVIEWS.

A. Monthly statistical reports. During the term of this Agreement, the Napa-Solano County Public Health Laboratory shall prepare monthly statistical reports of the services provided (by county) in relation to specimens originating in Solano County and Napa County.

B. Annual performance evaluations. Evaluation of the performance of the services provided and other obligations required of the parties under this Agreement shall be conducted annually, during the Agreement. The annual evaluations shall include, but not be limited to, evaluation of the following: quality of performance, turnaround time and reporting of tests; timely submission of test and patient information to and from each county; billing procedures and collections results; and satisfaction level of the respective Health Officers of Solano and Napa counties with the services provided by the Napa-Solano County Public Health Laboratory.

C. Annual Fiscal review. Fiscal review of this Agreement shall be performed annually. Such review shall include review and recommendations for update of the third-party testing fee schedules adopted by the governing boards of each party to this Agreement.

D. Renewal review. All aspects of the Agreement shall be reviewed for purposes of negotiating renewal beginning during the 18th month of the Agreement, with the

results included in the performance evaluation completed during the 24th month.

5. FISCAL ASPECTS. As consideration for the benefits conferred on each party by this Agreement, the parties agree to share responsibility for the costs of operation of and to allocate any revenues collected by the Napa-Solano County Public Health Laboratory, as follows:

A. Compensation. Napa County shall provide Solano County \$115,360 annually to support the general operational costs of the Napa-Solano Public Health Laboratory and \$11,545 in salary support for Solano County personnel providing program oversight of Napa County AIDS programs. In years 2 and 3 the annual compensation to support the general operational costs of the Napa-Solano Public Health Laboratory will increase by an amount equal to the Consumer Price Index (CPI).

B. Cost of facilities, equipment supplies and support services. Solano County shall be solely responsible for all costs of providing and maintaining the facilities (including utility costs), equipment, supplies, and support services (including specimen courier services) necessary to operate the Napa-Solano County Public Health Laboratory for the benefit of both counties in a manner which does not reduce in scope, timeliness, or quality the public health testing services separately provided by each county prior to the original creation of the Napa-Solano County Public Health Laboratory. Napa County agrees to enter into discussions with Solano County if, at any time during the term of this Agreement, it becomes necessary to re-evaluate the facilities used by the Napa-Solano County Public Health Laboratory.

C. Billing for tests requested by Health Officers of Solano and Napa Counties. Solano County shall be responsible for the costs of all testing by the Napa-Solano County Public Health Laboratory when such tests are requested by either the Solano County Health Officer or the Napa County Health Officer.

D. Billing for tests requested by third parties, fee schedules. Solano County shall be responsible for billing third parties (public or private) for the costs of conducting at the Napa-Solano County Public Health Laboratory any tests requested by such third parties. Solano County and Napa County shall each be responsible for ascertaining and forwarding to the Napa-Solano County Public Health Laboratory at the time of specimen submission all information necessary to bill such third parties and for providing any necessary follow-up information upon request by the Napa-Solano County Public Health Laboratory. The amounts billed to such third parties shall be determined in accordance with fee schedules adopted by resolution of the governing board of Napa County (for specimens originating in Napa County) and Solano County (for specimens originating outside Napa County) which shall be updated periodically to reflect the operational costs of the facility as a whole as well as any specific expenses unique to the particular test billed. All amounts received from such third party billing shall be deposited in the treasury of Solano County for the support of the operations of the Napa-Solano County Public Health Laboratory.

6. TESTING PROCEDURES. Testing shall be performed in accordance with methods

approved by the following agencies:

A. State of California, Department of Health Services, Laboratory Field Services, State of California approved Public Health Laboratory #1349

B. Department of Health and Human Services, Health Care Financing Administration, Clinical Laboratory Improvement Amendments (CLIA)/CLIA ID#: 05D0601 176

C. State of California, Department of Health Services, Environmental Laboratory Certification (ELAP), Certificate #2396.

7. LIABILITY.

A. Hold harmless/Indemnification by Solano County. Solano County shall hold harmless and indemnify Napa County for any liability arising from the acts or omissions of the Director, and subordinate personnel of the Napa-Solano County Public Health Laboratory, any employee of Solano County involved with preparation or handling of specimens of Solano County origin at the intake location, or any courier employed or retained by Solano County to transport specimens from either county to the Napa-Solano County Public Health Laboratory, or from any defects in the facilities, equipment and supplies provided by Solano County under this Agreement. It is expressly acknowledged by the parties that any property transferred by Napa County to Solano County pursuant to this Agreement for use in the Napa-Solano County Public Health Laboratory is conveyed "as is", and Solano County shall be solely responsible and defend, indemnify, and hold harmless Napa County for any liability arising subsequent to the conveyance from defects in or use of such property. In support of this obligation of Solano County, Napa County hereby transfers to Solano County any warranties or guarantees acquired by Napa County in connection with such transferred property.

B. Responsibility for test result follow-up activity. Nothing in this Agreement shall be construed to require the Health Officers of Solano County or Napa County to provide follow-up services relating to information regarding communicable diseases and public health conditions reported to such Health Officers by the Napa-Solano County Public Health Laboratory except for information relating to specimens originating in each Health Officer's employing county.

8. PROCEDURES MANUAL. The Director shall maintain, in accordance with standards agreed to by the Health Officers of Napa County and Solano County, a written Procedures Manual to govern the operations of the Napa-Solano County Public Health Laboratory. The Procedures Manual shall prescribe the laboratory testing methodologies and schedules, test turnaround times, reporting procedures, courier schedules, requirements for designated off-site specimen intake locations, requisition forms, billing instructions, contact phone numbers, and the most current testing fee schedules adopted by the governing boards of Napa and Solano counties.

9. ACCESS TO AND RETENTION OF RECORDS. Solano County and Napa County or the duly authorized representatives of either, including their respective Health

Officers, shall have access to the records of the Napa-Solano County Public Health Laboratory for the purpose of audit and review. In exercising such access rights, the parties shall comply with all applicable laws and regulations pertaining to confidentiality of specific health records and individual privacy rights, including the Health Insurance Portability and Accountability Act ("HIPAA"). Except where longer retention is required by any federal or state law, the Napa-Solano County Public Health Laboratory shall maintain all required records for no less than seven (7) years after the date of creation of the records.

10. INSURANCE. Solano County and Napa County shall each obtain and maintain in full force and effect throughout the term of this Agreement, and thereafter as to matters occurring during the term of this Agreement, the following insurance coverage or equivalent self-insurance, satisfactory evidence of which shall be provided to each party upon request by the other party:

A. Workers' Compensation Insurance. To the extent required by law, workers' compensation insurance covering the respective performance of the obligations of each party and its employees under this Agreement, including but not limited to, workers' compensation and disability.

B. Liability Insurance.

1. General Liability. Commercial or comprehensive general liability insurance (or self-insurance) coverage (bodily injury and property damage) of not less than One Million Dollars (\$1,000,000) combined single limit per occurrence, covering liability for any personal injury, including death, to any person and/or damage to the property of any person for which that party is obligated to defend, indemnify and hold the other party harmless under Paragraph 7 of this Agreement.

2. Professional Liability. Professional liability insurance (or self-insurance) coverage for all activities of each party's employees who are providing services under this Agreement as licensed professionals, in an amount not less than One Million Dollars (\$1,000,000) combined single limit per claim.

3. Comprehensive Automobile Liability Insurance. Comprehensive automobile liability insurance (or self-insurance) coverage (Bodily Injury and Property Damage) on owned, hired, leased and non-owned vehicles used by the party's employees in conjunction with the performance of that party's obligations under this Agreement, in an amount not less than Three Hundred Thousand Dollars (\$300,000) combined single limit per occurrence.

C. Certificates of insurance. Where the foregoing obligations are satisfied with insurance rather than self-insurance the insured party shall obtain, maintain in its files, and provide to the other party upon request, certificate(s) of insurance which shall name the other party, its officers, employees, and agents as additional insureds; provide that the other party shall be given no less than thirty (30) days prior written notice of any non-renewal, cancellation, other termination, or material change; provide that the insurance provided is primary coverage to the other party with respect to any insurance or self-insurance programs maintained

by the other party, and provide that the inclusion of more than one insured shall not operate to impair the rights of one insured against another insured the coverage afforded applying as though separate policies had been issued to each insured, but the inclusion of more than one insured shall not operate to increase the limits of the company's liability.

D. Deductibles/Retentions. Upon request by either party, any deductibles or selfinsured retentions applicable to the coverage obtained by the other party shall be declared to, and approved by the requesting party and, upon request by that party, shall be reduced, eliminated, or other security provided for the amounts involved, including amounts relating to the costs of investigations, claims administration, and defense expenses.

11. NO WAIVER. Waiver by either party of any breach or violation of any requirement of this Agreement shall not be deemed to be a waiver of any such breach in the future, or of the breach of any other requirement of this Agreement.

12. NOTICES. Except where otherwise specified in this Agreement, all notices to either party required or authorized by this Agreement shall be in writing and shall be delivered in person or by deposit in the United States mail, by certified mail, postage prepaid, return receipt requested. Any mailed notice, demand, request, consent, approval or communication that either party desires to give the other party shall be addressed to the other party at the address set forth below. Either party may change its address by notifying the other party of the change of address. Any notice sent by mail in the manner prescribed by this paragraph shall be deemed to have been received on the date noted on the return receipt or five days following the date of deposit, whichever is earlier.

SOLANO COUNTY NAPA COUNTY

Solano County Napa County

Health & Social Services Department Health & Human Services

275 Beck Avenue, MS 5-240 2261 Elm Street

Fairfield, CA 94533 Napa, CA 94559-3721

13. AMENDMENT/MODIFICATION. Except as otherwise provided herein, this Agreement may be modified or amended only in writing with the prior written consent of the governing boards of both parties.

14. INTERPRETATION. The headings used herein are for reference. The terms of the Agreement are set out in the text under the headings. This Agreement shall be governed by the laws of the State of California. The venue for any legal action filed by either side in state court to enforce any provision of this Agreement shall be the County of Solano, California. The venue for any legal action filed by either side in federal court to enforce any provision of this Agreement lying within the jurisdiction of the federal courts shall be the Eastern District of California.

15. SEVERABILITY. If any provision of this Agreement, or any portion thereof, is found by any court of competent jurisdiction to be unenforceable or invalid for any reason, such provision shall be severable and shall not in any way impair the enforceability of any

other provision of this Agreement.

16. **AUTHORITY TO CONTRACT.** Solano County and Napa County each warrant to the other that they are legally permitted and otherwise have the authority to enter into and perform this Agreement.

17. **THIRD PARTY BENEFICIARIES.** Nothing contained in this Agreement shall be construed to create any rights in third parties and the parties to do not intend to create such rights.

18. **ATTORNEY’S FEES.** In the event of legal action by either party to enforce the provisions of this Agreement or to obtain damages for breach thereof, each party shall be responsible for its own costs and attorney’s fees incurred in connection with such action.

19. **ENTIRETY OF CONTRACT.** This Agreement constitutes the entire agreement between the parties relating to the subject of this Agreement and supersedes all previous agreements, promises, representations, understandings and negotiations, whether written or oral, among the parties with respect to the subject matter hereof.

IN WITNESS WHEREOF, this Agreement was executed by the parties hereto as of the date first above written.

COUNTY OF NAPA, a political subdivision of the State of California

By _____
DIANE DILLON, Chair of the Napa ,
County Board of Supervisors

“County of Napa”

ATTEST: GLADYS I. COIL ATTEST:
Clerk of the Napa County Board of Supervisors

By _____

APPROVED AS TO FORM: ROBERT WESTMEYER, Napa County Counsel

By P.Tyrrell (by e-signature)

APPROVED BY THE NAPA COUNTY

COUNTY OF SOLANO, a political subdivision of the State of California

By _____
Chair of the Solano County Board of Supervisors

"County of Solano"

ATTEST: MICHAEL D. JOHNSON
Clerk of the Solano County Board of Supervisors

By _____

APPROVED AS TO FORM:
DENNIS BUNTING, Solano County
Counsel Counsel

By _____

BOARD OF SUPERVISORS

Date: _____

Processed By: : _____

Appendix 7: Considerations for Strategic Partnerships

In choosing a partner organization whether it is a regionalization or strategic alliance, one must consider the 3 C's: compatibility, capability and commitment (Cauley de la Sierra, M., 1995). It is always wise to examine partners with which you have had previous relationships with and you know how they operate. Compatibility is important in a successful relationship and thus an organization must consider a partner's operating strategies, decision making styles, organizational culture, organizational structure, size, resource contribution, their strengths and weaknesses, management practices, internal support/personnel commitment, finances and many more. Assessing the capability of a partner is important because every organization needs to really understand what their "mate" has to offer with regards to their strengths and resources. Each organization needs to critically examine whether their partner is able to contribute to the alliance in such a way that it will help both organizations achieve their goals and business objectives. Different strategies of cooperation can include one where partners bring similar resources to achieve economies of scale, enhance capacity, and share knowledge. This is a form of additive or scale strategy. On the other hand, there are complementary alliances where organizations contribute different resources, which will allow them to build on their own strengths (Child and Faulkner, 1998). Lastly, an organization needs to assess whether their partner will be committed to a strategic form of cooperation because everyone needs to dedicate their time, energy and resources to ensure success of a strategic cooperation. Commitment from all parties involved is critical in keeping the partnership strong and focused on obtaining the goals and objectives proposed. This was demonstrated in the case of the Napa and Solano County PHL consolidation and is a major factor attributing to its success.

It will be important to assess the risk of joining in any strategic cooperation and to analyze the expected benefits or detriments of a cooperative strategy such as improved financial performance, organizational learning and the cost of withholding from a partnership or merger (Zajac, D'Aunno & Burns, 2005). An initial stimulus, such as challenges from the environment or within the organization can help push an organization like a county PHL to assess what type of partnership will be most beneficial (Child, Faulkner 1998). A list of critical questions that should be asked of PHLs contemplating engaging in a partnership is provided below.

When PHLs choose to engage in some form of strategic cooperation and are undergoing the initial phases of restructuring and reorganization, core functions of the laboratory need to be established to ensure that the laboratory has direction and is providing the necessary services suitable for the community (Association of Public Health Laboratories, 2000). There are three measures of core competence 1) provide potential access to a wide variety of markets and clients, 2) make significant contributions to the perceived customer benefits of the end product and 3) be difficult for competitors to imitate (Prahalad and Hamel, 1990). When developing the core functions of the PHL one should incorporate the needs of the community it is serving. There needs to be open communication with laboratory clients to determine what the needs of the community are. A few questions that PHLs should be asking clients who utilize their services include (Association of Public Health Laboratories, 1999):

1. Are the laboratory services meeting the needs of the DPH?
2. How well is laboratory information communicated to the department?

3. What would the department like to get from the laboratory that the department has not gotten and conversely, what does the laboratory provide that the department has no need for?
4. Are there immediate hot button laboratory or departmental issues that demand immediate attention?
5. Is there any planning done by department and laboratory staff to determine future direction and needs of each?

While there are significant obstacles that must be overcome when engaging in a strategic cooperation of PHLs there are a few solutions to help smooth the transition process which include (Gausewitz, 1999):

1. All stages of planning and implementation need to have champions who are dedicated to accomplishing the task.
2. Mutual trust, common goals, and excellent communication between everyone involved are needed.
3. When it comes to starting operations start small and proceed deliberately
4. Location where tests are performed needs to be considered a key component of operational issue analysis.
 - a. The laboratory facility that will provide the most space and accessibility for clients and couriers may be the better location for the PHL

Critical questions to ask when you are choosing a partner [(Cauley de la Sierra, M., 1995) pg. 25]

The following checklist of key issues may assist organizations in finding partner's that satisfies the three C's: compatibility, capability, commitment.

1. What are you looking for-technology, market access, testing capabilities, distribution channels, financial support?
2. Can an existing relationship be extended?
3. Have you examined a number of potential candidates?
4. How will you go about determining compatibility? Focus on compatibility, not similarity.
5. Is there any "chemistry" between your senior and middle management?
6. Are your working cultures compatible? If cultures are significantly different, could you successfully blend the two cultures? How?
7. Does your partner have previous experience in collaborative ventures? How does its' track record stack up?
8. Are there any conflicts of interest? Does your partner have any alliances with some of your competitors? Can they affect you? How will you come with that situation?
9. Do you and your partner have complementary capabilities in technology, market access, testing services and so on?
10. Does the candidate have strengths that might benefit more than one section of your laboratory?
11. Have you thoroughly researched your partner's capabilities? Some companies have been burned when a partner's technology or market prowess proved considerable weaker than originally expected.
12. How committed will each partner be to the venture?

13. Does the partner appear willing to contribute the resources and skills that are necessary to make the alliance a success?
14. Is the activity central to your laboratory? If not, what are the chances the venture will be relegated to the sidelines by one of you?
15. Are you trying to forge too many alliances at the same time and consequently overlooking critical issues and problems that may disrupt the relationships? Is your emphasis on the quality, not the quantity of alliances?
16. How difficult will it be for your partner to withdraw from the venture?
17. What benefits will the partner derive from the venture? Are they greater than yours? How can you keep them equal?
18. What are the partner's direct costs?
19. How much can you learn from your partner's? How do you plan to transfer any new knowledge, technology and/or skills acquired from partners and the venture to the parent laboratory?
20. How much does the partner need to alliance to meet its tactical or strategic objectives?
21. Is the venture needed for the partner to have growth or survival purposes?
22. How willing and able will the partner be to devote additional resources-capital, human, technologies, time-to the venture?
23. What are the alternate strategies available to your lab, and to the potential partners?
24. What are the internal and external barriers to the partner's participation?
25. What is the price of failure?

In addition to the questions mentioned above, Ms. Holly Maag, the Imperial County PHLD have suggested additional questions and considerations when counties are contemplating engaging in a form of inter-organizational partnership.

1. The first and foremost thing is that you don't lose PH assets i.e. employees, space, equipment, institutional knowledge, experience, vision, technical expertise it includes everything. If you can regionalize and include all that, that would be the first thing to look at.
2. The second thing would be to look at; are the populations homogenous enough that you could have everybody well served; so that you can have one location to provide PHL services.
3. Is an expanded testing menu possible? Will this be an opportunity for better pricing, better volumes, expanded testing numbers, do more tests, and more frequent and rapid turn around time.
4. How is the consolidation or regionalization effort going to fit in with the PH infrastructure? If you are going to close a level B (LRN) lab then that doesn't make sense. If you are going to consolidate a level B lab with a lab that isn't a level B then that might make sense. Also is it going to be able to protect the strategic infrastructure with respect to addressing emerging or reemerging pathogens or with respect to bioterrorist agents following a regionalization effort?
5. Does it make economic sense. Is the county's individual retirement system and salary systems different? If you then regionalize and have one lab and in lab A people make \$15/hr while people working in lab B may make \$18/hr, what does the economics look

like in terms of the salary scaling , benefits, sick leave, retirement, and merging and consolidating county policies that may be very disparate even though they are neighboring counties.

6. You need to consider commuting distances. Are you going to build a new lab, whose going to run it? Will it be under the jurisdiction of where the lab sits or will it be under joint jurisdiction. Who is going to provide the personnel policy and what County is going to do it? There are a lot of questions. Are the county ordinances going to allow this, how are you going to do this through a memorandum of understanding (MOU), or another form of agreement? You will probably also need to have county council involved from the beginning of the negotiation processes.

“I am not a huge fan of a regionalization model because unless you show me evidence of the model and the hypothetical from which the model would work very well I don’t believe that regionalization is the best option for California PHLs. I think that regionalization may have to happen in this economic climate because of the decline of funding overall for the nation for public health, but it really is too bad that the infrastructure for public health in California goes to the wind to whatever administration is in power. While this may not be the best solution, it might have to happen, but it does need to be looked at very carefully because you can’t undo it when it is done.” – Holly Maag, Imperial County PHLD.

Appendix 8: Public Health Laboratory Director Interview Guide

Laboratory Background Information:

1. How many personnel work in the lab?
 - a. PHM
 - b. Senior PHM
 - c. Assistant Director
 - d. Director
3. What counties do you serve?
4. What size population do you serve?
5. How long have you been a laboratory director?
6. How many tests are run per year?
7. What type of laboratory do you run? High Complexity? Low Complexity?
8. What testing capabilities do you have?

PHL Projections (financial, personnel, etc):

9. Do you anticipate a problem finding a successor for your position?
 - a. If yes, how are you dealing with this issue?
 - b. Are you having problems recruiting applicants?
10. Are you facing competition from private or clinical labs?
 - a. How are you dealing with the problem?
11. Describe the relationships you have with other labs in other counties?
 - a. Which one, and how close are you?
12. Can you describe the breakdown of the different sources of funding your lab receives?
13. What is your definition of an adequate size for an economically viable lab?
 - a. How big should the lab be in terms of employees to provide adequate testing services?
 - b. How many tests should be run per year?
14. How would you define laboratory capacity? How can it be enhanced?
15. What are your opinions on the impact of CA's budget constraints on PHL's?
 - a. How has it affected your laboratory?
 - b. Have there been discussions about your laboratory or neighboring laboratories closing?
16. What would be the impact on your county if the laboratory closed down?
17. How should the laboratory shortage be addressed if CLIA laws could not be changed?
18. What are some reasons that PHL's close i.e Mendocino?
19. What would be involved in closing a lab?
 - a. Would hearings need to take place or can the health officer just shut it down?
20. Do you think laboratory directors are against the idea of partnerships? Why or why not?
21. How significant is the health officer and health administrators in impacting the activities of your laboratory?
22. What are the major problems your lab is facing if any?
 - a. Financial
 - b. Lack of Personnel
 - c. Laboratory Director retiring
 - d. Other

23. Do you think that PHLs will be obsolete in the future?
24. What do you foresee in the next 5-10 years for PHLs?

Strategies of Cooperation:

25. Should PHL's engage in partnerships like the Napa/Solano lab? Why or why not?
 - a. Under what conditions should labs consider partnering?
26. Would you be willing to participate in discussions regarding a partnership or any other form of strategic cooperation with another county?
 - a. Why or why not?
27. How would a partnership/strategic alliance affect your county?
 - a. Financially?
 - b. Programs/tests offered?

Wrap-Up:

28. Are there any other things that you would like to share that you did not feel was addressed during our conversation?
29. Can I call or email you for any follow up questions?

Appendix 9: PHLD and HO Interview Participants

D/P= Laboratory Directors Declined Participation for Interview

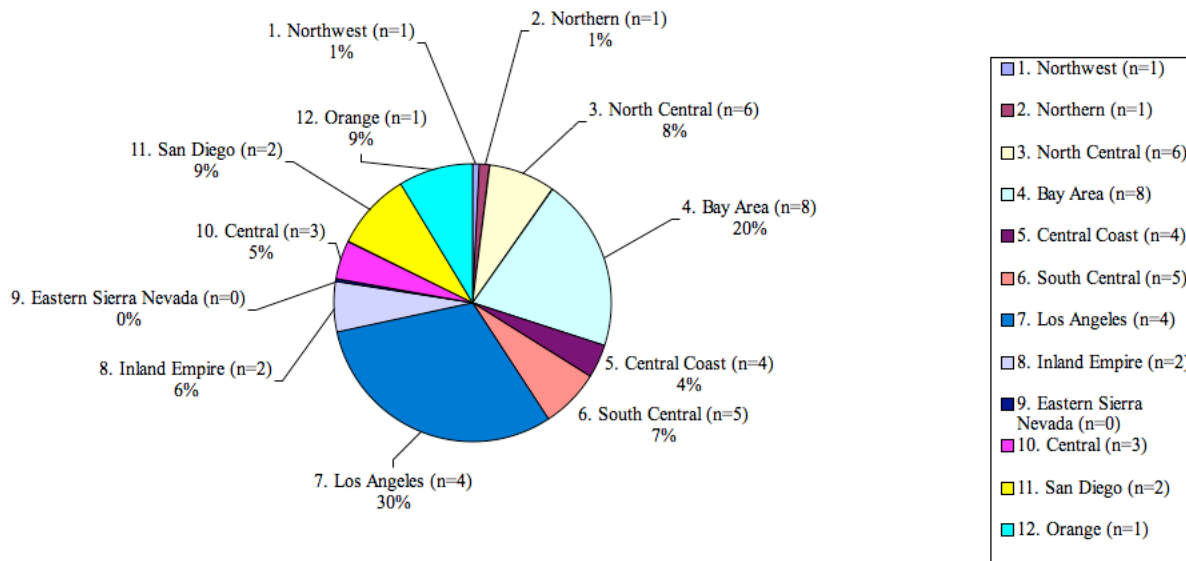
PT= Part-time PHLD

	County	Participating PHLDs	D/P	Participating HOs
1.	Alameda	James R. Carlson, Ph.D		Dr. Muntu Davis
2.	Butte and Sutter	Greg Costo (PT)		
3.	Contra Costa and Orange County	Rick Alexander (PT)		Dr. David Souleles (Orange County—Deputy Director)
4.	El Dorado	Michael R. Deatherage	D/P	Dr. Olivia Kasirye
5.	Fresno and Merced	James Spolsdoff (PT)		Dr. Timothy Livermore (Merced County)
6.	Humboldt and Stanislaus	Mark Miller (PT)		Dr. Ann Lindsay (Humboldt County) Dr. John Walker (Stanislaus County)
7.	Imperial	Holly Maag		
8.	Kern	Michael Lancaster, Ph.D		
9.	Kings	Robert Koelewyn		Dr. Michael McLean
10.	Long Beach	Mimi Lachica		
11.	Los Angeles	Mary Beth Duke		Dr. Jonathan Fielding
12.	Madera	Jerry Peterson	D/P	
13.	Marin	Lynn Murrin		Dr. Anju Goel
14.	Monterey	Gerry Guibert		Dr. Hugh Stallworth
15.	Napa/Solano	Al Shabandi		Dr. Karen Smith (Napa County)
16.	Pasadena City	Caroline Bautista	D/P	Dr. Eric Walsh
17.	Placer	Masau WaKabongo Ph.D		
18.	Riverside	William Lawrence (PT)		Dr. David Herfindahl (Deputy Health Officer)
19.	Sacramento	Anthony Gonzalez, Ph.D.		Dr. Glennah Trochet
20.	San Bernardino	Linda Ward		
21.	San Diego	Particia McVay, M.D.		Dr. Wilma Wooten
22.	San Francisco	Sally Liska, Dr.P.H		
23.	San Joaquin	Stephen Willis		
24.	San Luis Obispo	James Beebe, Ph.D.		Dr. Penny Borenstein
25.	San Mateo	Bruce Fujikawa, Dr.P.H.		Dr. Scott Morrow
26.	Santa Barbara	Debra Ann Palacio		Dr. Takashi Wada
27.	Santa Clara	Patricia Dadone		Dr. Martin Fenstersheib
28.	Santa Cruz	Duncan Gillies (PT)		Dr. Poki NamKung
29.	Shasta	Dale Dondero (PT)	D/P	
30.	Sonoma	Mike Ferris		Dr. Mark Netherda (Deputy HO)
31.	Tulare	Robin Purves		
32.	Ventura	Brett Austin		Dr. Robert Levin
33.	Yolo	Stanley Kwan (PT)		Dr. Joseph Iser

Appendix 10: Public Health Laboratory Breakdown by Regions Demarcated by the California Department of Transportation

*denotes LRN reference laboratory								
1. Northwest		Population	5. Central Coast		Population	9. Eastern Sierra Nevada		Population
	Del Norte	29,100		Monterey	408,238		Inyo	17,136
	Humboldt*	129,100		San Benito	54,699		Mono	12,774
	Lake	65,279		San Luis Obispo*	265,297			
	Mendocino	86,211		Santa Barbara	405,396			
				Santa Cruz	253,137			
2. Northern		Population	6. South Central		Population	10. Central		Population
	Lassen	35,574		Fresno*	909,153		Alpine	1061
	Modoc	9,184		Kern	800,458		Amador	38,238
	Plumas	20,275		Kings	156,289		Calaveras	46,843
	Shasta*	180,214		Madera	143,333		Mariposa	17,976
	Tehama	61,550		Tulare*	426,276		Merced	245,321
	Trinity	14,317					San Joaquin*	672,388
	Siskiyou	44,542					Stanislaus	510,694
							Toulumne	55,644
3. North Central		Population	7. Los Angeles		Population	11. San Diego		
	Butte	220,337		Long Beach City			Imperial	163,972
	Colusa	21,204		Los Angeles*	9,862,049		San Diego*	3,001,072
	El Dorado	178,447		Pasadena City				
	Glenn	28,237		Ventura	797,740			
	Nevada	97,118						
	Placer*	341,945						
	Sacramento*	1,394,154						
	Sierra	12,437						
	Sutter	92,207						
	Yolo	197,658						
	Yuba	73,067						
4. Bay Area		Population	8. Inland Empire		Population	12. Orange		
	Alameda	1,474,368		Riverside	2,100,516		Orange*	3,010,759
	Berkeley City			San Bernardino*	2,015,355			
	Contra Costa	1,029,703						
	Marin	248,794						
	Napa	133,433						
	San Francisco	808,976						
	San Mateo	712,690						
	Santa Clara*	1,764,499						
	Solano	407,515						
	Sonoma*	466,741						

Percentage of California's Population Served



Appendix 11: Health Officer Interview Guide

1. What is your position at the county?
2. How long have you been in this position?
3. Do you anticipate any difficulty replacing the laboratory director if he/she retires?
 - a. How do you plan to deal with this issue?
4. How does your county view the PHL and its importance in providing testing services within the county?
5. Do you work closely with the PHL director?
6. What influences your decision regarding issues relating to the PHL?
7. Do you have direct influence over decisions relating to the PHL? What does the organization chart look like for your county with regards to the board of supervisors, health officer and PHL?
8. How has the CA budget constraints impacted your decisions regarding the PHL's?
9. What are your thoughts regarding consolidation/regionalization of public health laboratories?
 - a. Are there discussions among the HO's about regionalizing services?
 - b. Do you feel that consolidating labs with other counties is a feasible option?
 - c. Is there a certain criteria the labs should meet for consolidation?
10. Do you know if other county health officers share your same view or a different view on the issue of consolidation?
11. Is there currently discussion in your county to shut down or minimize PHL services?
 - a. If there is, how do you plan on dealing with the specimens?
 - b. What factors/criteria do you consider when closing down a PH service?
12. What is your opinion of the CLIA requirements for the LD?

Wrap Up:

13. Are there any other things that you would like to share that you did not feel was addressed during our conversation?
14. Can I call or email you for any follow up questions?

Appendix 12: County Public Health Laboratory Director Salary Range

* denotes small sized PHLs <5 personnel							
1. Northwest		Minimum	Maximum	7. Los Angeles		Minimum	Maximum
	Humboldt	\$79,080	\$96,540		Los Angeles	\$106,989	\$161,937
					Long Beach	\$77,276	\$115,914
					Pasadena*	\$70,241	\$87,801
					Ventura	\$75,984	\$106,377
2. Northern		Minimum	Maximum	8. Inland Empire		Minimum	Maximum
	Shasta*	\$63,840	\$81,492		Riverside	\$72,677	\$99,829
					San Bernardino	\$76,419	\$97,718
3. North Central		Minimum	Maximum	9. Eastern Sierra Nevada			
	Butte*	\$67,524	\$90,492		No PHLs		
	El Dorado*	\$76,814	\$93,392				
	Placer	\$88,088	\$107,099				
	Sacramento	\$92,478	\$101,936				
	Sutter*	\$76,282	\$103,221				
	Yolo*	\$81,132	\$98,616				
4. Bay Area		Minimum	Maximum	10. Central		Minimum	Maximum
	Alameda	\$85,675	\$99,341		Merced*	\$76,690	\$93,267
	Contra Costa	\$91,429	\$111,133		San Joaquin	\$86,382	\$105,019
	Marin	\$89,752	\$108,805		Stanislaus	N/A	N/A
	Napa/Solano	\$94,707	\$115,117				
	San Francisco	\$102,648	\$124,774				
	San Mateo	\$102,461	\$128,086				
	Santa Clara	\$95,462	\$116,087				
	Sonoma	\$97,051	\$117,964				
5. Central Coast		Minimum	Maximum	11. San Diego		Minimum	Maximum
	Monterey	\$78,876	\$107,676		Imperial	\$74,388	\$94,980
	San Luis Obispo	\$91,790	\$111,571		San Diego	\$86,570	\$105,206
	Santa Barbara	\$80,099	\$97,784				
	Santa Cruz	\$88,067	\$117,478				
6. South Central		Minimum	Maximum	12. Orange		Minimum	Maximum
	Fresno	\$59,526	\$106,328		Orange	\$92,227	\$154,170
	Kern	\$86,940	\$106,128				
	Kings*	\$73,299	\$89,461				
	Madera*	\$70,525	\$85,723				
	Tulare	\$76,761	\$93,551				

Appendix 13: Senate Joint Resolution No. 15

Senate Joint Resolution No. 15

RESOLUTION CHAPTER 46

Senate Joint Resolution No. 15—Relative to public health laboratories.

[Filed with Secretary of State June 28, 2010.]

Legislative Counsel's Digest

SJR 15, Alquist. Public health laboratories.

This measure would encourage the Centers for Medicare and Medicaid Services to amend the Clinical Laboratory Improvement Amendments regulations to, and the Congress and the President of the United States to enact legislation that would, allow qualified nondoctoral, nonboard certified persons to serve as laboratory directors of local public health laboratories, if they are qualified to direct those laboratories under the law of the state in which the laboratory is located, with the express goals of ensuring adequate local public health laboratory support for response to communicable disease events, ensuring an adequate supply of local public health laboratory directors, and ensuring protection for the balance of the nation by increasing national security through adequate disease identification. This measure would encourage specified federal entities to also encourage CMS and the Congress and President of the United States to accomplish these goals in this manner.

WHEREAS, The federal Centers for Medicare and Medicaid Services (CMS) has adopted the Clinical Laboratory Improvement Amendments (CLIA) regulations related to laboratory director qualifications that are unreasonable for the California local public health laboratory system and have led to the closure of needed local public health laboratories in California; and

WHEREAS, CMS fails to recognize the unique responsibility and authority of local public health laboratories in response to disasters, both naturally occurring and man made; and

WHEREAS, The California local public health laboratory system has been recognized internationally for decades, is considered exemplary in quality of service and accuracy of testing, has responded to both naturally occurring and manmade disasters, and has protected California's citizens for decades; and

WHEREAS, The California local public health laboratory system is an important element of the public health system that forms the triad, along with law enforcement and fire officials, in protecting our communities; and

WHEREAS, California's many immigration gateways, without adequate local public health laboratory resources, can be an entry point for the spread of infectious diseases with potential national impact; and

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WHEREAS, The loss of local public health laboratory support in any community creates a national security concern that must not be ignored; and

WHEREAS, Congresswoman Doris Matsui has drafted federal legislation to provide states with the authority to permit local public health laboratories to operate in accordance with minor changes in CLIA language regarding laboratory director qualifications; and

WHEREAS, The California Conference of Local Health Officers, the California Association of Public Health Laboratory Directors, and the County Health Executives of California have all requested administrative relief from the onerous regulation without success; now, therefore, be it

Resolved by the Senate and the Assembly of the State of California, jointly, That the Legislature of the State of California encourages CMS to amend the CLIA regulations to, and the Congress and the President of the United States to enact legislation that would, allow qualified nondoctoral, nonboard certified persons to serve as laboratory directors of local public health laboratories, if they are qualified to direct those laboratories under the law of the state in which the laboratory is located, with the express goals of ensuring adequate local public health laboratory support for response to communicable disease events, ensuring an adequate supply of local public health laboratory directors, and ensuring protection for the balance of the nation by increasing national security through adequate disease identification; and be it further

Resolved, That the Legislature of the State of California encourages the federal Secretary of Health and Human Services, the Department of Homeland Security, and other relevant federal regulatory authorities to encourage CMS to amend the CLIA regulations, and the Congress and President of the United States to enact legislation, to accomplish these policy goals in this manner; and be it further

Resolved, That the Secretary of the Senate transmit copies of this resolution to the President and Vice President of the United States, the Speaker of the House of Representatives, the Majority Leader of the Senate, and to each Senator and Representative from California in the Congress of the United States.

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Res. Ch. 46 — 2 —

Appendix 14: Dr. James Beebe Letter to CAPHLD

Colleagues

Since I came to California in 2007 and became Director of the San Luis Obispo County Public Health Laboratory, I have enjoyed the discourse and company of fellow laboratory directors and have benefited from communications and technical advice from many. In return, I have provided assistance wherever and whenever called upon by fellow directors. CAPHLD meetings have been a technically valuable and friendly forum where a non-California bred scientist can get more of an inside view of laws, regulations, practices and politics.

Until this time I have abstained from engagement in discussion of the effort of CAPHLD leadership to change the CLIA credentials requirements for laboratory directors. However, I find it necessary to now publically dissent. You may be interested in the reasons know why.

It is claimed that the shortage of qualified public health laboratory directors for local public health laboratories is artificial—and that eliminating the requirement for a doctoral degree and board certification would solve the problem. I agree that it is artificial, but not for the reason of a credentials barrier.

I feel that the requirement that doctoral-level board-certified laboratory directors obtain public health microbiologist certification by passing the PHM exam is a significant artificial and unnecessary barrier.

I have had numerous conversations with out-of-state doctoral peers, who in busy professional lives expressed incredulous surprise that California would require them to pass an exam for bench-level scientist. Several simply looked elsewhere.

Before I came to California I asked Kathy Williams why there was no directors exam—as there is for clinical scientists, but only an exam that dealt with subject matter that I have largely forgotten after thirty years; knowledge that--- after cramming and taking the exam, I would forget again.

Some of you may feel that the subject matter of the exam is something a laboratory director should have in forefront of his mind. I would say that budgets, cost analyses, safety challenges, quality, new technology and equipment, marketing lab services and remodeling this ancient building are in the forefront of my mind. And they had better be. Besides, I have a group of fine public health microbiologists that use PHM exam knowledge on a daily basis with distinction.

Recently I learned of the efforts of the one of the most important local public health laboratories of California —Los Angeles-- to recruit a laboratory director. Several experienced, fully qualified, doctoral level scientists from outside California have corresponded with management regarding the position but expressed reticence to take time to study, laboriously prepare and take an exam for a bench scientist. (Dr Robert Kim-Farley, personal communication). It seems to me that the public health management of Los Angeles should have an opportunity to select from the most experienced and proven professionals of the nation for the challenging and singularly important position of Public Health Laboratory Director of the City-County of Los Angeles. The leaders of LA Public Health and the people of the city of Los Angeles have every right to select

from a cadre of the most qualified laboratory directors.
It appears they will be denied this opportunity—for an artificial reason.

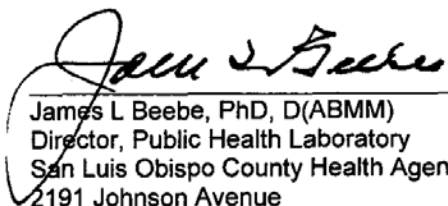
For me the requirement didn't make much sense in 2007, but for personal reasons I felt a director position at a California local public health laboratory was a good place to be at this stage of my career. So I studied for four months, took and passed the exam, interviewed and was offered positions at Santa Cruz and San Luis Obispo, and accepted the latter. Dr Tom Maier happily passed the baton to me; my colleague Duncan Guillies appears to be still looking for that opportunity.

This may be difficult to accept but doctoral-level scientists are the standard for director-level positions through out virtually all scientific fields. Both the public and Public Health can be expected to desire the standard of the field. CLIA 1988 and its amendments recognized that issue and set that standard, but not without providing a clause that would allow a transition period for states like California. Nearly two decades have passed since the grandfather clause was enacted.

Since that time, many of you have effectively directed public health laboratories. But a time will come when each you will need to pass the baton as well. Will your health officer have a choice of who succeeds you? Lab Aspire is the new model for the nation and with support it will provide candidates. But there are still many professionals throughout the nation who have the credentials and who could serve. I urge you to remove the barrier and allow them to join the candidate list from which your health officer can select.

It is my sincere hope that all of you will allow me to express my opinion and not resent me for the position I have taken. I value the contributions of my CAPHLD colleagues and the deference and good will that you have afforded me.

I strongly suggest that CAPHLD sponsor a resolution to change state regulations allowing board certification (ABMM, HCLD, etc) to exempt candidates from the requirement for PHM certification.



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Appendix 15: CAPHLD Statement



California Association of Public Health Laboratory Directors

Responding to the Crisis in City and County Public Health Laboratory Services in California August 2010

Introduction: Public Health has its roots in the philosophy that the public's best interest is to protect itself from diseases. Established public policy indicated that citizens accept this philosophy and support the need for organized public health services, including the public health laboratory. In the United States, a network of federal, state, and local public health laboratories (PHLs) carry out the mission of providing essential laboratory services to protect their respective communities from infectious diseases, both naturally occurring and manmade. Unlike the highly visible protective services provided by law-enforcement and fire agencies, PHL services go largely unrecognized by the public because their work is accomplished behind the scenes until a major event occurs such as the anthrax attacks of 2001 or the influenza pandemic of 2009. Without local PHLs, California would not have had the capacity to respond to these events! Local PHLs are clearly key to early detection and fast response to infectious disease. Over the decades, these laboratories have saved countless lives from a multitude of past, current, reemerging, and adapting infectious diseases.

As directed by State Law, local PHLs structure their programs to meet the priorities and resources of their jurisdictions to rapidly and accurately detect and identify communicable diseases in their respective communities. Public Health Labs serve their local environmental health programs, public health nursing, epidemiologists, and Public Health Officers, etc. Local PHLs, staffed by Public Health Microbiologists (PHMs) with unique and specialized training, provide expertise in a wide range of microbiological disciplines. Local PHLs test human, animal, environmental, and food specimens, providing immediate and accessible results to detect and identify infectious diseases ranging from rabies to multiple drug resistant tuberculosis, and to assure the safety of our beach and drinking waters, and foods. This information lets the local Public Health Officer know the disease potential in their jurisdiction, plan a response, decide proper treatment, educate the public with current and relevant scientific information, prepare epidemiological data to help target limited resources, and interact effectively with local elected and emergency response officials.

California, with its size and population, faces unique challenges in the provision of public health laboratory services. The State continues to face financial problems that have resulted in reduced capacity and expertise in its State Laboratory. Fortunately, California's network of local (City and County) PHLs have continued to provide services, and in many cases with upgraded, state of the art technology, and increased capacity. Such successes have been made possible through the vision of the California Association of Public Health Laboratory Directors and via collaboration with the State and local emergency preparedness staff to secure federal and local funding. Without a doubt, local jurisdictions continue to value the availability and access they have to services provided by their local PHL.

Problem: Local jurisdictions face the loss of laboratory services through the closure of their local PHLs, and less control of their unique local program efforts. California faces the probable degradation of its network of local PHLs at the very time the State laboratory has greatly reduced services.

The primary reason PHLs are facing closure is a growing artificial shortage of "qualified" Public Health Laboratory Directors. The Federal Clinical Laboratory Improvement Amendments (CLIA-1988) changed qualification requirements for Public Health Laboratory Directors (PHLD). These requirements have caused a shortage of qualified candidates to direct public health laboratories at both the state and local levels. This shortage of qualified PHLD has resulted in the utilization of part-time retired laboratory directors and the closure of some county public health laboratories. Ten years ago, 40 local PHLs were licensed in California. Of the current 37 local public health laboratories, 10 (27%) are directed by part-time directors and at least another two part-time directors will be added in the next 12 months.

Qualifications to direct Public Health Laboratories in California are specified in Title 17, California Code of Regulations, Chapters 2 and 3. These regulations include academic preparation, training, and experience requirements. Local PHLs, under these directors have been successfully providing quality testing services in California for more than six decades. CLIA-1988 requires a lab director to be a MD or Board-certified PhD. This CLIA requirement is not only problematic by the crisis it has created, but it has no empirical basis. In research by Michael Kenney (1) examining the relationship between academic degrees and the quality of public health laboratory testing, Kenney came to a number of conclusions. Kenney states, "Laboratory structural and process quality assurance standards should have an empirical base and should rest upon measurable levels of public health protection afforded by those standards rather than upon assumed levels of protection thought to accompany formal requirements". Further, "Medicare regulation...should be amended to allow non-doctoral directors to direct Medicare-certified laboratories in those states that have comprehensive clinical laboratory regulatory programs which have demonstrated effectiveness, in meeting acceptable outcome measures of laboratory quality". Kenney found that education above the bachelor's level for director did not equate to quality. Education, training, and experience at the bench level are related to high quality testing.

The Association of Public Health Laboratories (APHL) states, "the infectious disease training provided in the vast majority of pathology residency programs has little or no public health training or emphasis" and "none of these board certifications really examine for the type of training and experience required to effectively direct a state PHL". (2) when CLIA was passed into law, there was an inadequate supply of such CLIA qualified laboratory directors. In order to

prevent the immediate shutdown of numerous public health laboratories at all levels (state as well as local) the law provided a grandfather clause. Now, however, the pool of grandfathered scientists is reaching retirement age, and the pool of “CLIA qualified” laboratory directors who wish to direct public health laboratories remains extremely inadequate.

Currently only four such CLIA laboratory directors exist in California’s 37 local PHLs, the others have been “grandfathered” in. APHL documented the shortage of CLIA qualified laboratory directors in their Position/Policy Statement of June 2006 (3). There has been little progress, if any, since then. APHL further states, “individuals who have spent several years pursuing the specialty certifications provided by the current CMS-approved boards generally expect to command high salaries and are rarely willing to take a direct position in a PHL where salaries may be only marginally competitive and laboratory directors will be required to spend most of their time working outside their specialty area”. (2) Post Doctoral programs at UCLA, UC Berkeley, and UC Davis, intended to address this problem have, to this date, have produced only a few local public health laboratory directors in California. Competition for these individuals by the private sector and academia is stiff and many health jurisdictions will have little chance of attracting these individuals.

In all other CLIA requirements, California’s PHLs meet or exceed CLIA standards. Of particular significance is the education and training requirement for California bench level scientists (PHMs), which exceeds CLIA standards.

Solution: Amend 42 Code of Federal Regulations 493.1443 by adding the underlined:

(6) For the subspecialty of oral pathology, be certified by the American Board of Oral Pathology, American Board of Pathology, the American Osteopathic Board of Pathology, or possess Qualifications that are equivalent to those required for certification or,

(7) For California local Public Health Laboratories, be qualified under state law to direct a laboratory in California.

Conclusion: California Public Health Laboratories have operated successfully for over 60 years without doctoral-level directors in most of its laboratories. Their track record demonstrates that the proposed solution will not negatively affect the quality of testing in California and will enable cities and counties to continue to provide local public health laboratory services to their citizenry.

Failing to resolve this crisis amounts to a failure to serve and protect the citizens of California. The solution proposed has no new costs associated with it and preserves the necessary and highly successful network of local Public Health Laboratories.

References:

(1) Kenney, Michael L. Laboratory Quality and Director Qualifications: An Empirical Assessment of the Medicare Requirement That Directors of Independent Clinical Laboratories Possess Earned Doctorates. Dr.PH Dissertation. University of California, Berkeley. 1984.

(2) Association of Public Health Laboratories (APHL). Priming the Pipeline of Future Public Health Laboratory Directors and Technical Supervisors: CLIA Certification in Public Health Microbiology.

(3) APHL. APHL Position/Policy Statement, Public Health Laboratory Workforce Shortage. June 2006.

Appendix 16: National Response to CAPHLD



December 7, 2007

The Honorable Doris Matsui
U.S. House of Representatives
Washington, DC 20515

Dear Congresswoman Matsui:

On behalf of the Association of Public Health Laboratories (APHL), the American Society for Clinical Pathology (ASCP) and the College of American Pathologists (CAP), we commend your support for public health and your strong interest in making improvements to the public health laboratory workforce shortage. WE are also deeply appreciative of the interest that your staff has shown, especially Kevin Whittlesey and John Young, in engaging in a dialogue with us on public health laboratory matters. It is with profound regret then that we strongly oppose your draft legislation that would lessen the academic requirements for directors of local public health laboratories performing high complexity testing. If enacted, these provisions would dramatically threaten patient safety by putting quality in jeopardy- an outcome we cannot support or endorse.

The proposed legislation would weaken the Clinical Laboratory Improvement Amendments of 1988 (CLIA-88) requirements for the directors of laboratories performing high complexity testing. The requirement of a doctoral degree as a qualification for a laboratory director is a standard in the pharmaceutical, biotechnology, veterinary and plant pathology fields. To lessen the academic requirements for directors of laboratories performing human testing cannot be rationally argued in any arena of laboratory practice and would be indefensible to the general public who rightly expects that our laboratories maintain the highest quality standards in personnel.

Like our many colleagues throughout healthcare, we believe that the best strategies to address the workforce shortages are through recruitment and retention activities and not through the lessening of academic qualifications. The workforce shortage is one of APHL's highest priorities in our strategic plan. The nursing workforce shortages and the strategies of recruitment and retention are well documented (*The Nursing Workforce Shortage: Causes, Consequences,*

Proposed Solutions, Patrician Keenan, The Commonwealth Fund, April 2003) and there is no suggestion to lessen the educational requirements for nurses.

IN their statement: Personnel Standards for Laboratory Professionals (Policy Number 06-01), the American Society for Clinical Pathology has indicated that without proper laboratorian training, the likelihood of erroneous laboratory test results increases substantially. Further, ASCP found that with medical diagnosis highly dependent on laboratory tests results, erroneous test results can have a significant impact on patient care. Directors of clinical and public health laboratories must have sufficient training to be responsible for all aspects of laboratory activities. WE are sure that this is the standard of quality in laboratory testing that you want for the citizens of California.

One alternative strategy that we respectfully suggest for your consideration, the State of California recently initiated a new program, “Lab Aspire”, that is specifically designed to address the shortage of qualified public health laboratory leaders. California has committed substantial state funding to it which is an extraordinary development given the lean budget in California. Briefly, Lab Aspire was created to fill the gap in preparedness for public health laboratory director positions. Lab Aspire is only one mechanism to bring California’s local public health laboratory directors into compliance with the regulations, and it may take a few years to complete this process. Interim solutions such as several small county laboratories contracting with a qualified director for oversight of their clinical operations, or detailing directors from the state laboratory or large county/city laboratories should also be considered.

In summary, we are strong supporters of your introduction of public health workforce legislations that could be the companion bill to S. 1882, and we pledge to support that effort in every possible way. However, we cannot support regulations that lessen the qualifications for directors of laboratories performing high complexity testing.

We appreciate the opportunity to offer these comments. We will continue to make our staff and experts available to you and your staff to that end.

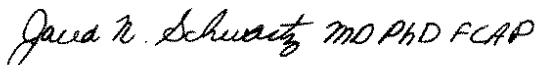
Thank you for your consideration.



William J. Becker, DO, MPH
President, APHL



Lee H. Hilborne, MD, MPH, FASCP, DLM
President, ASCP



Jared N. Schwartz, MD, PhD, FCAP
President, CAP