Table of Contents

Key Points of Report

A Review of Management Controls at the Department of Health's Immunization Program

December 1999

Overall Conclusion

Incomplete immunization data, gaps in provider monitoring, and the inconsistent reporting of information makes it difficult to determine if resources provided by the State of Texas and the federal government have been efficiently and appropriately used by the Department of Health's Immunization Program (Program). The Department of Health (Department) has received more than $300 million in cash and vaccines for the Program over the past four years.

Immunization rates for school age children are high, and incidence of childhood disease is stable, which may indicate that the Program has been successful in getting children immunized. Our main areas of concern are the underutilization of the statewide immunization registry, the lack of information regarding performance of providers, and the inconsistent reporting of vaccine supplies.

Key Facts and Findings

- Fewer than half of Texas' 5.5 million children are being tracked by the statewide immunization registry. The objectives of a centralized statewide registry are to keep track of whether a child has received immunizations, to help remind parents when immunizations are due, and to provide a centralized immunization history for healthcare providers to use. Because the data is so incomplete, these benefits have not been realized to the extent intended. Texas has invested more than $10 million in this registry to date, with annual expenditures to maintain the system exceeding $1 million.

- The Department has not adequately documented provider monitoring activities necessary to ensure that vaccines and cash given to healthcare providers have been used as intended. Policies, procedures, and criteria that would provide for consistent programmatic monitoring have not been documented. Additionally, the Program has not implemented a consistently applied risk assessment methodology to determine high-risk providers.

- Reporting of vaccine inventory information is inconsistent, increasing the risk that decision makers do not have accurate information. The Department has not developed written policies and procedures to direct consistent statewide reporting of immunization and vaccine inventory information.

Contact

Susan A. Riley, CPA, Audit Manager, (512) 479-4700

Office of the State Auditor

Lawrence F. Alwin, CPA

This audit was conducted in accordance with Government Code, Section 321.0132, 321.0133, and 321.0134.

Executive Summary

Incomplete immunization data, gaps in provider monitoring, and inconsistent reporting of vaccine inventory makes it difficult to determine if resources provided by the State of Texas and the federal government have been efficiently and appropriately used by the Department of Health's Immunization Program (Program). The Department of Health (Department) has received more than $300 million in cash and vaccines for the Program over the past four years.

Texas spent over $100 million from the State's General Revenue Fund between 1995 and 1998 to implement various initiatives aimed at increasing the immunization rates in Texas. These initiatives seek to properly immunize 5.5 million Texas children to prevent outbreaks of childhood diseases and avoid the cost associated with treating those diseases.

Immunization rates for school age children are high, and incidence of childhood disease is stable, which may indicate that the Program has been successful in getting children immunized. Our main areas of concern are underutilization of the statewide immunization registry, the lack of information regarding performance of providers, and the inconsistent tracking of vaccine supplies.

- Texas does not realize the benefits of an immunization registry, as fewer than half of Texas' 5.5 million children are being tracked. The State has spent more than $6 million implementing the immunization registry. An additional $4.3 million from Program funds has been spent upgrading the Integrated Client Encounter System (ICES). These upgrades enabled ICES to capture and provide immunization information to the immunization registry. Funds exceeding $1 million annually are being spent to maintain the registry. The registry is surrounded by public controversy over consent and confidentiality, which has resulted in limited provider participation. The Program has been unable to keep key staff positions filled.

- The Department has not followed up to make sure that vaccines and cash given to healthcare providers for immunizations have been used as intended. Monitoring policies, procedures, and criteria have not been documented. A systematic risk assessment methodology, though developed, has not been implemented. In many instances, monitoring visits are not consistently documented. As a result, they provide little useful information to Program managers. Over 6,000 providers receive vaccines and/or financial assistance from the Program. Federal, state, and Department guidelines or regulations require monitoring of providers.

- Decision makers may not have accurate vaccine inventory information, as reporting policies and procedures are not documented. Reporting inconsistencies were noted in the preparation of vaccine inventory reports. Over half of the Program's resources are provided in the form of vaccines.

Summary of Management's Response

Management generally agrees with the recommendations. Although TDH differs with certain specific findings of the state auditor, we are nevertheless in the process of revising operations to address many of the concerns noted.

Summary of Objective and Scope

The primary objective of this project was to evaluate the management processes and control systems within the Program. The scope of the project included consideration of management of information, performance, and resources.

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Section 1:

Benefits of a Statewide Immunization Registry Have Not Been Fully Realized

Since 1994 Texas has invested over $10 million in an immunization tracking registry (ImmTrac) that remains incomplete, underutilized, and surrounded by public controversy. Of this amount, more than $6 million was spent on personnel, ongoing operations, and equipment. Another $4.3 million was invested in equipment to upgrade the Integrated Client Encounter System (ICES). This upgrade enabled ICES to capture and subsequently provide immunization information to the registry. Appendix 5 breaks down the use of funding related to ImmTrac.

Benefits of an Immunization Registry

An immunization registry serves as a centralized resource for immunization information in our increasingly mobile society. As families move, change insurance coverage, and change medical providers, medical and immunization records become scattered among different care givers, clinics, and offices, resulting in missed opportunities to immunize. The risk that individuals will not be properly immunized increases the risk that states will bear a larger burden of treating rather than preventing childhood diseases.

Immunization registries benefit parents, providers, communities, and public health offices. Appendix 3 details benefits identified by the National Vaccine Advisory Committee.

Source: National Vaccine Advisory Committee - Centers for Disease Control - 1999

ImmTrac tracks less than 45 percent of the targeted population, individuals age 18 and younger. In addition, representation of younger children in ImmTrac is slightly worse. Individuals born in 1997 who are now ages 16 to 24 months have a better chance of being included in the ImmTrac database due to their continuing contact with immunization providers. Representation of this population in ImmTrac is slightly less, at 44.5 percent. The Department indicates that after completion of our fieldwork, a 16-month backlog of immunization data was added to the registry, raising the representation rate to 61.8 percent. This assertion has not been evaluated to determine its accuracy. See Appendix 6 for a calculation of the representation note.

ImmTrac is not widely used by Program staff due to the lack of representation of children in the system. Program staff indicated that it is improbable that a given individual's immunization record would be in the ImmTrac system. Even when records are found in ImmTrac, the immunization history is often incomplete. The low rate of representation in ImmTrac is caused by various factors, including the following:

- Due to regulations regarding consent, parents must consent, or "opt in," before providers can submit immunization information into the ImmTrac System. This places additional paperwork burdens on hospital registrars, nurses, and other healthcare providers who must obtain parental consent for each of the more than 5.5 million individuals represented in the target population.

  In addition, the "opt in" nature of the system requires that there be training programs directed at individuals responsible for obtaining consent from

parents. When parents are not convinced of the merits of the immunization registry, consent is not gained, and their children are not included in the registry.

An alternative to the "opt in" system would be an "opt out" system. In this system, all children would automatically be included in the system unless a parent chose otherwise. This type of system would typically have higher participation, as the consent issue would be eliminated. The administrative burden may be reduced with the "opt out" system, as only those few individuals that did not want their children tracked in the registry would require consent-type paperwork.

- Consent requirements affect how other Department systems, including the Bureau of Vital Statistics (BVS); the Integrated Client Encounter System (ICES); Women, Infants, and Children (WIC) systems; and the Medicaid billing system share information with ImmTrac. These systems and others, such as private providers and insurance companies, require system enhancements in order to obtain and track consent for inclusion in ImmTrac. Enhancements are in the process of being implemented; however, insurance companies and private providers are making little progress.

- The ImmTrac database has not been routinely maintained. Database maintenance, including the investigation of duplicate records, deletion of erroneous records or records outside the target population, and importing of records from other contributing systems, has not been routinely performed. At the time of fieldwork, the Program was experiencing a 16-month maintenance backlog.

- Public controversies surrounding confidentiality further hamper the full implementation of ImmTrac. The idea of a statewide database tracking all individuals age 18 and under alarmed various parent groups. As a result, laws were amended to clarify which individuals receive immunization information from the Department. Several Program staff members indicated that they hesitate to use the ImmTrac system because they fear the consequences of breaking the confidentiality of patient records.

- Public healthcare providers are using ICES instead of ImmTrac. Many of the public healthcare providers surveyed found ICES more reliable than ImmTrac as an immunization registry. However, ICES was not designed to track services provided by private healthcare providers.

- Private providers are not actively entering information into ImmTrac. Of over 4,000 private providers currently giving immunizations in partnership with the Department, only 54 private providers had ImmTrac installed on site. It is not required that providers install ImmTrac in order to participate. However, if the system is not installed, providers must submit paper copies. This method is time consuming and labor intensive.

  Immunization-tracking registries have typically had problems getting private providers to participate. Currently, only six of sixty-four immunization

tracking projects across the nation have active participation from a significant portion of private providers.

- The Program has not been able to keep sufficient staffing to maintain ImmTrac. Eight of eleven positions allocated to the ImmTrac project, including the director, have been vacant for more than a year. The Program has re-evaluated staffing requirements and is in the process of filling some positions.

- ImmTrac is not compatible with other established immunization registries. Municipal health departments are unable to transfer their immunization information into the ImmTrac system. Initial expectations were that ImmTrac would receive data from existing tracking systems. However, the "opt in" nature and consent requirements for ImmTrac hinder transferring the data from these systems into ImmTrac.

  Tarrant County, the City of San Antonio, and Houston/Harris County maintain immunization registries. The San Antonio registry, in operation for more than 20 years, does not require consent and contains all children given immunizations through public health clinics as well as many private providers. The Houston/Harris County registry requires consent to be included in the registry. However, this registry does not word the consent to include consent for ImmTrac.

The Department recognizes the many issues and opposing opinions surrounding ImmTrac. To address the various concerns, the Department has held meetings with various interested parties and has revised rules and policies. However, because of the differing opinions of interested parties, this has been a slow process.

Existing enabling legislation for ImmTrac appears to give the Department sufficient rule-making authority to partially implement and maintain the ImmTrac system. However, some changes to the enabling legislation would most likely be necessary in order to fully implement the ImmTrac project.

Recommendation:

We recommend that the Department, with input from oversight groups, consider available options and determine which option is best for the State. The Department should document the reasons for its choices, including cost/benefit analysis.

Several available options include:

- Fully implement the ImmTrac system.
- Leave the ImmTrac system as is.
- Retain the ImmTrac System focusing efforts on public healthcare providers.
- Abandon the ImmTrac System.

Additional information regarding each option is included in Appendix 4.

Management's Response:

Much of the report accurately reflects many of the barriers that the Program faces in order to implement the registry. In response to the previously shared findings in the draft report, TDH staff have addressed several of the issues. For instance, the backlog of records has been imported, and San Antonio and Tarrant County have implemented a consent policy for data to be included in the Department's immunization registry. TDH will continue to focus on other deficiencies identified in the report to work toward the goal of having a fully implemented registry system in accordance with existing state laws and our federal immunization grant requirements. We point out that although ICES does provide some immunization data, it is an outdated system that will soon be replaced with a successor. Furthermore, ICES does not allow tracking of populations that migrate from one public care provider to another, nor does it include patients who access private health care.

Section 2:

Program Managers Do Not Have the Information They Need to Determine if Providers Are Using Resources, Money, and Vaccine Inventories as Intended

Information necessary to measure the performance and use of Program resources is not readily available to Program managers. As a result, the Program is at risk of not being in compliance with Department, state, and federal guidelines and regulations.

In addition, inconsistencies in the manner that vaccine inventories are reported could result in inaccurate information. As a result, decision makers may not have accurate and necessary information to make sure waste, abuse, and fraud are minimized.

Section 2-A:

Information About Provider Performance Necessary to Determine the Appropriate Use of Program Resources Is Not Readily Available to Program Managers

Monitoring is the periodic observation and systematic collection of data to determine whether the organization is getting what it paid for at a reasonable price and whether the usage of resources is in accordance with the requirements of the applicable program.

Provider monitoring and oversight functions are not providing readily accessible information to determine whether the providers are meeting performance expectations and using taxpayer funds as intended. Our review of the monitoring function found that:

- Monitoring responsibilities, including monitoring of subrecipients required by Department guidelines, as well as state and federal regulations, are not adequate.
- Current monitoring activities are not providing readily accessible results to Program managers.
- Current monitoring activities are not based on written policies and procedures with documented monitoring criteria.

- Current monitoring activities are not based on a standardized, consistently applied risk assessment methodology.

- Current monitoring activities tend to focus on reconciling data self-reported by providers that is seldom independently verified.

- Current monitoring activities rely upon undocumented institutional knowledge and provider experience, neither of which can be easily duplicated by those unfamiliar with the intricacies of the Program.

The aforementioned deficiencies are due to various factors, including the following:

- Program managers are not aware of the differences between ongoing administration of the Program and programmatic monitoring responsibilities. These monitoring responsibilities are used to ensure that state and federal resources are appropriately used and safeguarded. Although the Department may be in contact with many providers on a day-to-day basis, procedures are not in place to address programmatic performance monitoring. Monitoring should be designed to ensure that providers are complying with Program requirements.

  The Program has delegated private provider monitoring responsibilities to regional offices and local health departments within their jurisdictions. However, the results of these activities are not readily accessible or consistently reported to the Program. Actual monitoring documentation and/or summaries were not locally available to Program managers ultimately responsible for Program decisions.

- Monitoring visits are poorly documented. Therefore, they yield little information that can be used to determine the performance of providers or indicate whether they are following Program rules and regulations.

  Monitoring activities for over four 4,000 private providers receiving vaccines is random and is provided primarily during the Program's initial contact with providers. While setting up a new provider, Program staff will educate the provider on current guidelines, reporting requirements, vaccine ordering and storage, and other information.

  Complaints against a private provider occasionally result in return visits from Program staff. However, in many instances Program employees address provider problems via telephone. While telephone calls to address immediate problems or answer questions are necessary day-to-day functions of the Program, these functions do not represent the spirit of monitoring as addressed in guidance offered by the authoritative bodies.

  Some public providers are monitored through a partnership formed with the Department's Quality Assurance Division (QA). This has resulted in successful performance monitoring of eligible public providers. However, this partnership does not include all of the public providers receiving taxpayer funds.

QA monitors immunizations programs of various public provider groups that receive funding from WIC, Title V, X, or XX. However, not all eligible public providers have received monitoring visits. In addition, public provider groups receiving only Program assistance are not monitored by QA. In all, the Program gave nearly $7.5 million, in addition to providing vaccine inventories, to public providers in 1998.

- The Program has developed a risk assessment tool to aid in the selection of providers that need to be monitored. However, this tool has not been implemented statewide, and there is confusion within the Program concerning who is responsible for using the tool. The risk assessment tool would enable the Program to target providers that need additional guidance and training, while using Program staff and other resources in the most efficient manner.

Monitoring enables the Program to identify healthcare providers that may be misusing assistance received from the Program. It provides further assurance of the quality of services being provided by healthcare providers. Monitoring also helps to provide assurance that taxpayer funds, both state and federal, are used appropriately.

Managers should perform ongoing monitoring activities (1) to determine whether control systems can be relied upon to provide reasonable assurance that financial and compliance goals can be accomplished, and (2) to address new risks.

Examples of monitoring include: review of financial and other reports for propriety and trends; evaluation of trends; review of reconciliations; ensuring that reconciling items are investigated; verification of supporting documentation; periodic asset counts; on-site inspection and observation visits; and follow-up on complaints, rumors, and allegations.

While the Program staff does review providers' reports and documents, reviews of reports and documents seldom provide information necessary to determine whether Program objectives are being met and whether Program resources are being used appropriately. Additionally, reviews of reports and documents self-prepared by providers without test and verification of data provide little evidence that Program resources are being used appropriately.

A documented monitoring methodology is necessary to ensure compliance with applicable Department, state, and federal requirements and to ensure that performance goals are being achieved. In addition to being good business practice, various authoritative bodies and documents either require or recommend monitoring activities. These bodies and documents include:

- Office of Management and Budget
- Federal Inspector General
- *Immunization Grant Application Guidance*
- Department of Health's *Contracting Guide for Client Services*

- State Appropriations Act Special Provisions Relating to All Health and Human Services Agencies
- Grants Management Common Rule (45CF92.40(a))
- Uniform Grant Management Standards – Office of the Governor, Office of Budget and Planning, *Guidelines and Instructions for State Agencies*.

Section 2-B:

Reporting Inconsistencies Increase the Risk That Decisions Are Being Made With Inaccurate Information

Reports of vaccine inventories that are inconsistently prepared increases the possibility that Program decisions are being made with inaccurate information. During the 1998 fiscal year, vaccine inventories valued at $35 million were received from the Centers for Disease Control. In addition, more than $12 million in state funds was used to purchase vaccine inventories.

Regional staff members have indicated that they do not have sufficient instructions on how to document inventory receipts, distributions, or returns. Throughout the regions, different procedures may be used to track and report vaccine inventories to the central office. We found that different regions used varying methods to prepare reports for the central office. For example, the Monthly Biological Report is one report for which different procedures were used. Some regional offices were confused about whether the inventory information should or should not include subregional office balances. We observed both practices on our visits to different regions.

The lack of written procedures can lead to inconsistencies in tracking and reporting inventory balances, which results in information that is not comparable, complete, or accurate.

Written policies and procedures promote consistency in performance. This is especially important in an organizational structure such as the Department where there are regional and subregional offices located throughout the State operating autonomously.

Section 2-C:

Organizational Structure Hinders Accountability for Program Resources

The organizational structure of the Department hinders accountability of individual programs. Individual regional offices do not report directly to Program managers at the Department. Regional staff report to a separate associateship within the Department.

This autonomous relationship between Program managers in the central office and regional staff decreases accountability for Program requirements. Essentially, the individual programs are funding services without the ability to direct the delivery of

the services. As a result, the Program cannot be sure that immunization funding is used for immunization services.

Recommendation:

We recommend that:

- The Department seek appropriate guidance in determining its programmatic monitoring responsibilities associated with requesting and receiving taxpayer funds. The Department should develop and document standard policies, procedures, and tools for monitoring Program providers, both public and private. The risk assessment tool should be re-evaluated and implemented as appropriate. The policies and procedures should be clearly communicated to those responsible for monitoring providers to make certain that monitoring activities are consistently applied. Results of monitoring activities should be documented and used in the decision-making process.

- The Department prepare written policies and procedures over all inventory processes. These policies and procedures should be clearly communicated to all responsible staff to make sure that processes are consistent throughout the State.

- The Department consider how to make sure the regions are accountable for Program objectives and that Program funding is spent according to Program budgets within the framework of recent legislation (House Bill 2085, 76th Legislative Session.)

Management's Response:

The findings outlined in Section 2 point out a need for the Program to have consolidated and consistent policies and procedures guiding Program activities. We agree that policies and procedures need to be better defined and articulated, and we have begun a process to pull together existing policies and procedures and identify gaps where additional policies and procedures need to be developed and implemented.

We agree that current monitoring activities, while being accomplished as indicated in Attachment A, require standardization. Standard documentation, uniform monitoring tools, and questionnaires will be developed and utilized. It should be pointed out that the Immunization Program has consistently met or exceeded Performance Measures, especially doses administered. For FY 1999, the Annual Targeted Performance was 5,172,914 doses; the actual number of doses administered was 5,454,776.

Although it is true that not all providers are monitored on a yearly basis, Attachment A indicates that we are not only meeting but exceeding our federal requirements of quality assurance reviews. The Program will investigate innovative ways to further enhance this monitoring activity within the legislative travel cap and cost restrictions. We agree that we have not adequately utilized the risk assessment tool. This tool will

be re-evaluated and will be utilized by regional Program staff during FY 2000 to target those providers needing guidance and training.

Vaccine inventory activities require a collaboration between the Immunization Division and the Pharmacy Division. The pharmacy inventory system is antiquated and, in collaboration with the Centers for Disease Control and Prevention, is in the process of being re-designed. In the interim, the Immunization Division will work with the Pharmacy Division to better standardize and improve inventory activities including tracking, distribution, reporting, and returns. Our policies and procedures will be reviewed, revised as needed, and emphasized to guide regional and local staff in inventory monitoring and reporting.

We do not agree that the organizational structure of the Department hinders the accountability of individual Programs. Certainly, this structure requires an ongoing exchange of communication between Program managers in Austin and their counterparts in the regions. As already stated, we believe that standardized policies and procedures will improve the function of the Program across the state and will overcome any challenges that might be posed by the structure of the Department.

State Auditor's Follow-up Comment:

The State Auditor's Office requested documentation that supported the Department's assertions regarding monitoring and monitoring coverage. The documentation provided by the Department was a compilation of information including site visit listings, travel voucher excerpts, day-timer notations, and other extraneous documentation. The documentation does represent ongoing Program administration, technical assistance, and training activities. These activities are necessary; however, they are not activities that address the responsibilities of programmatic monitoring. Therefore, the foundation of the Department's assertion that it exceeds federal requirements for quality assurance reviews is unclear.

Section 3:

Federal Grants and Awards Were Understated in the Department's *Annual Financial Report*

The Department's *Annual Financial Report* understated the value of vaccine serum received through the Centers for Disease Control by more than $31 million. The Department did report some non-monetary assistance. However, the amount did not include the value of all non-monetary assistance received in the form of vaccines.

The Comptroller of Public Accounts' reporting guidelines, in compliance with *Office of Management and Budget Circular A-133*, state that the, "Schedule of Expenditures of Federal Awards reports total expenditures…and non-monetary assistance for all federal awards by federal program."

Recommendation:

We recommend that all federal awards, including non-monetary assistance, be reported in accordance with the Comptroller of Public Accounts' reporting guidelines.

Management's Response:

We agree that all federal awards including non-monetary assistance be reported in accordance with the Comptroller's Reporting Guidelines.

Appendix 1:

Objective, Scope, and Methodology

Objective

The objective of this audit was to evaluate the management processes and control systems within the Immunization Program at the Department of Health.

Scope

The scope of this audit covered the operations and administration of the Program, including a review of the information and associated systems used by the Program to perform daily operations.

Methodology

Conventional audit procedures, including interviews with management and staff of the Department, were applied to collect information. Audit testing and analysis included review of Program files, user surveys, and reviews of Program measures. Our work will not necessarily reveal all of the Program's internal control weaknesses.

Information collected including the following:

- Prior reports related to the Department
- Documentary evidence such as:
  - Texas Health Code
  - Various audit reports
  - Department and Program documents, memoranda, and publications, including the *Department Strategic Plan* and Legislative Appropriation Requests
  - Review of the Department and Program's on-line reference materials
  - Policy and procedures manuals
- Interviews with management and staff
- Field visits to the following public health regional offices:
  - San Antonio
  - Temple
  - El Paso
  - Fort Worth
- Survey of ImmTrac users

Procedures and tests conducted:

- Review of documentation related to Department and Program operations
- Review of Program expenditures
- Review of contracts and grants

Analysis techniques used:

- Control review
- Trend analysis of budgets, expenditures, and performance statistics
- Review of performance measures
- Risk assessment of Program controls
- Population forecasting
- Comparison of target populations to ImmTrac representation

Criteria used:

- State Auditor's Office Methodology Manual
- *Comptroller Reporting Requirements for Annual Financial Reports of State Agencies*
- *Office of Management and Budget Circular A-133*
- General Appropriations Act, 75th Legislative Session
- Texas Administrative Code
- Vaccines for Children Training Manual
- Financial Administrative Procedures Manual for Department of Health Contracts
- Code of Federal Domestic Assistance
- Code of Federal Regulations
- Department of Health's *Contracting Guide for Client Services*
- Information received from the Centers for Disease Control
  - Immunization Registry Clearing House
  - National Immunization Program
  - National Vaccine Advisory Committee
- Information received from the Robert Woods Foundation - All Kids Count Project - works to address issues surrounding immunization registries.
- The Joint General Investigating Committee Report on State Contracting, October 14, 1996

- *Audits of State and Local Governmental Units, American Institute of Certified Public Accountants* (including references to SOP 98-3)
- Inspector General documents
- Other standard audit criteria established during fieldwork

Fieldwork was conducted from March 1999 to June 1999. The audit was conducted in accordance with *Government Auditing Standards*.

The following members of the State Auditor's Office performed the audit work:

- Dennis Ray Bushnell, CPA (Project Manager)
- Leslie Ashton, CPA
- Sandra Queen, MPA
- Stacey Williams
- Angelica Martinez
- Earl Wells
- Anthony Chavez
- Matthew Martinez
- Bruce Truitt, MPAff (Quality Control Reviewer)
- Susan A. Riley, CPA (Audit Manager)
- Deborah Kerr, Ph.D. (Director)

Appendix 2:

Program Mission

The mission of the Program is to improve the quality and longevity of life for people in Texas by achieving and maintaining a "vaccine-preventable disease free environment." This will add to the State's economic base by avoiding substantial health care costs. This mission will be achieved through the utilization of cost-effective immunization programs and efficient epidemiology applied in quality partnerships with public and private participants (local, state, and national) who share the common vision of community well-being.

Staffing – Full-Time Equivalent (FTEs) Employees:

Central Office	70
Region Staff	188
Total	**258**

Table 1

Available Resources 1995-1998			
Year	**Budgeted Financial Funding***	**Non-Monetary Assistance (Vaccine)****	**Total Available Resources**
1995	$ 51,655,229	$ 33,374,607	$ 85,029,836
1996	41,186,067	36,633,132	77,819,199
1997	44,687,619	43,104,337	87,791,956
1998	35,955,310	43,381,164	79,336,474
Total	**$ 173,484,225**	**$ 156,493,240**	**$ 329,977,465**
*Budgeted Financial Funding September 1, 1994, to August 31, 1998 **Non-Monetary Assistance January 1, 1995, to December 31, 1998			

Source: Department of Health Immunization Program Accountant

Table 2

Incidence of Disease				
Disease	**1995**	**1996**	**1997**	**1998***
Measles	14	49	7	0
Mumps	43	44	75	42
Pertussis	217	151	233	287
Rubella	8	8	12	89
Tetanus	3	3	6	4
Varicella (Chickenpox)	22,568	20,322	26,688	20,484
Hepatitis A	3,001	3,460	4,511	3,537
Hepatitis B	1,211	1,258	1,245	1,960
* Some 1998 data may change as the Department receives updated information.				

Source: Department of Health Immunization Program

Appendix 3:

Benefits of Immunization Registries

Obtained from "Development of Community and State-Based Immunization Registries," *Report of the National Vaccine Advisory Committee* - Centers for Disease Control, January 12, 1999

Source: www.cdc.gov/nip/registry/i_recs.pdf

For parents, immunization registries:

- Consolidate in one site all immunizations a child has received
- Provide an accurate, official copy of a child's immunization history for personal, day care, school, or camp entry requirements
- Help ensure that a child's immunizations are up to date
- Provide reminders when an immunization is due
- Provide recalls when an immunization has been missed
- Help ensure timely immunization for children whose families move or switch health-care providers
- Prevent unnecessary (duplicative) immunization

For communities, immunization registries:

- Help control vaccine-preventable diseases
- Help identify high-risk and under-immunized populations
- Help prevent disease outbreaks
- Link (where supported by legislation) with other health databases, such as newborn and lead screening, or other state registries
- Provide information on community and state coverage rates
- Streamline vaccine management

For providers, plans, and purchasers, immunization registries:

- Consolidate immunizations from all providers into one record
- Provide a reliable immunization history for any child, whether a new or continuing patient
- Provide definitive information on immunizations due or overdue
- Provide current recommendation and information on new vaccines
- Produce reminders and recalls for immunizations due or overdue
- Complete required school, camp, and day-care immunization records
- May reduce a practice's paperwork
- Facilitate introduction of new vaccines or changes in the vaccine schedule
- Help manage vaccine inventories
- Generate coverage reports for managed-care (e.g., HEDIS) and other organizations
- Reinforce the concept of the medical home

For public health officials, immunization registries:

- Provide information to identify pockets of need, target interventions and resources, and evaluate Programs
- Promote reminder and recall of children who need immunizations
- Ensure that providers follow the most up-to-date recommendation for immunization practice
- Facilitate introduction of new vaccines or changes in the vaccine schedule
- Integrate immunization services with other public health functions
- Can help monitor adverse events

Appendix 4:

Immunization Registry Options

- Fully implement the ImmTrac system. The cost to fully implement the system as currently legislated cannot be determined. Savings from reduced childhood disease incidence and treatment may offset the cost of operating the registry.

  - The Department would need to establish policies that require internal use of the ImmTrac system. Even if the staff uses ICES as a tracking system, ICES only contains information from public sector providers. ICES would not report information on immunizations administered in the private sector. Circumventing the ImmTrac system provides little assurance that the information obtained is complete.

  - The Department would need to actively support the immunization registry. Only with strong support and conviction from the Department will ImmTrac become a viable and effective immunization registry.

  - The Legislature may wish to consider:

    - Requiring healthcare providers, both public and private, to actively participate in immunization reporting. Appropriate enforcement capabilities would be necessary.

    - Enabling or requiring transfer of data between systems maintained within the Department and by third parties.

    - Clarifying or changing the "opt in" nature of ImmTrac.

    - Clarifying or changing the confidentiality of ImmTrac information.

- Leave the ImmTrac system as is. The cost to the State would continue at more than $1 million annually. Complete and reliable immunization information would be unavailable for more than half of Texas children.

- Retain the ImmTrac System and focus efforts on public healthcare providers. Savings would be negligible.

  - Texas would continue to track immunization information for individuals who receive immunizations from public healthcare providers. The ImmTrac system would become less useful, tracking fewer individuals as service delivery moves toward the private sector.

  - ImmTrac would continue to duplicate information in other Department systems, specifically, ICES.

- Legislative action would be necessary to clarify the targeted population.

- Abandon the ImmTrac System. Abandoning the ImmTrac system would result in annual savings exceeding $1 million annually.

  - Texas would not have an operational immunization tracking system.

  - Texas parents would be totally responsible for tracking vaccination schedules.

  - Reduced immunization rates could result in increased costs to the State to treat individuals who contract preventable diseases.

  - The State could be declared in noncompliance with federal grant guidelines that require an immunization registry. Failure to implement and maintain a registry could place federal immunization grant funding at risk.

  - Legislative action would be necessary to repeal registry requirements.

Appendix 5:

Immunization Registry Expenditures

Table 3

Fiscal Year	Salaries & Wages	Other Personnel Costs	Operating Costs	Equipment	Total*
1994	$ 36,488.00	$ 0.00	$ 836,645.81	$ 152,928.19	**$ 1,026,062.00**
1995	103,280.95	337.47	99,214.00	4,606,159.25	**4,808,991.67**
1996	267,254.89	10,348.07	1,038,504.51	103,161.88	**1,419,269.35**
1997	308,555.62	19,101.60	777,443.87	144,893.89	**1,249,994.98**
1998	255,949.90	16,500.00	969,569.76	11,160.00	**1,253,179.66**
1999**	108,641.92	6,411.45	548,184.45	0.00	**663,237.82**
Total*	**$ 1,080,171.28**	**$ 52,698.59**	**$ 4,269,562.40**	**$ 5,018,303.21**	**$ 10,420,735.48**

* In evaluating how an immunization registry system (ImmTrac) would operate in the State of Texas, it was determined to utilize the existing integrated client eligibility system (ICES). In order for ImmTrac to be installed into local clinics, those clinics needed to have upgraded computers and ICES. To accomplish this, immunization funds in the amount of $4,326,059 were to supplement the implementation of ICES in local and regional clinic sites.

** Expenditures as of April 20, 1999

Source: Department of Health Immunization Program Accountant

Appendix 6:

Calculation of ImmTrac Representation Rate

As of March 31, 1999

Total Records in ImmTrac Database	3,460,999
Questionable Match Records - Probable Duplicates	-341,385
Records for Individuals over 18 Years of Age	-643,565
Total Non-Questionable Records in ImmTrac Database for Individuals 18 Years of Age and Under	**2,476,049**

Source: Department of Health Training Specialist and Acting Program Director - ImmTrac Program

Population Projections of Individuals 18 and Younger:		**Representation Rate**
Centers for Disease Control	5,584,604	44.34%
Department of Health - Bureau of Vital Statistics	5,558,775	44.54%

NOTE: Subsequent to the completion of fieldwork, the ImmTrac Program reports that it has imported 16 months of backlogged data. Using the Program supplied totals, the representation rate, after importing the backlogged data, would be 61.6 percent. This assertion has not been evaluated to determine its accuracy.

Appendix 7:

Department of Health Response

Texas Department of Health

William R. Archer III, M.D.
Commissioner of Health

Patti J. Patterson, M.D., M.P.H.
Executive Deputy Commissioner

1100 West 49th Street
Austin, Texas 78756-3199
(512) 458-7111
http://www.tdh.state.tx.us

December 2, 1999

Mr. Lawrence F. Alwin, CPA
State Auditor
P.O. Box 12067
Austin, Texas 78701

Dear Mr. Alwin:

This letter is in response to the draft report entitled *Management Controls at the Texas Department of Health's (TDH) Immunization Program*, which we received November 22, 1999. We do believe that much of the auditor's report identifies areas that we can focus on to provide better immunization services to the State of Texas, and we believe that we can work with your office to achieve this goal.

Section 1: Benefits of A Statewide Immunization Registry Have Not Been Fully Achieved

Much of the report accurately reflects many of the barriers that the program faces in order to implement the registry. In response to the previously shared findings in the draft report, TDH staff have addressed several of the issues. For instance, the backlog of records has been imported, and San Antonio and Tarrant County have implemented a consent policy for data to be included in the Department's immunization registry. TDH will continue to focus on other deficiencies identified in the report to work toward the goal of having a fully implemented registry system in accordance with existing state laws and our federal immunization grant requirements. We point out that although ICES does provide some immunization data, it is an outdated system that will soon be replaced with a successor. Furthermore, ICES does not allow tracking of populations that migrate from one public care provider to another, nor does it include patients who access private health care.

Section 2: Program Managers Do Not Have The Information They Need To Determine If Providers Are Using Resources, Money And Vaccine Inventories, As Intended

The findings outlined in Section 2 point out a need for the program to have consolidated and consistent policies and procedures guiding program activities. We agree that policies and procedures need to be better defined and articulated, and we have begun a process to pull together existing policies and procedures and identify gaps where additional policies and procedures need to be developed and implemented.

We agree that current monitoring activities, while being accomplished as indicated in Attachment A, require standardization. Standard documentation, uniform monitoring tools, and Mr. questionnaires will be developed and

utilized. It should be pointed out that the Immunization Program has consistently met or exceeded Performance Measures, especially doses administered. For FY 1999, the Annual Targeted Performance was 5,172,914 doses; the actual number of doses administered was 5,454,776.

Although it is true that not all providers are monitored on a yearly basis, Attachment A indicates that we are not only meeting but exceeding our federal requirements of quality assurance reviews. The program will investigate innovative ways to further enhance this monitoring activity within the legislative travel cap and cost restrictions. We agree that we have not adequately utilized the risk assessment tool. This tool will be re-evaluated and will be utilized by regional program staff during FY 2000 to target those providers needing guidance and training.

Vaccine inventory activities require a collaboration between the Immunization Division and the Pharmacy Division. The pharmacy inventory system is antiquated and, in collaboration with the Centers for Disease Control and Prevention, is in the process of being re-designed. In the interim, the Immunization Division will work with the Pharmacy Division to better standardize and improve inventory activities including tracking, distribution, reporting, and returns. Our policies and procedures will be reviewed, revised as needed, and emphasized to guide regional and local staff in inventory monitoring and reporting.

We do not agree that the organizational structure of the Department hinders the accountability of individual programs. Certainly, this structure requires an ongoing exchange of communication between program managers in Austin and their counterparts in the regions. As already stated, we believe that standardized policies and procedures will improve the function of the program across the state and will overcome any challenges that might be posed by the structure of the Department.

Section 3: Federal Grants And Awards Were Understated In The Department's Annual Financial Report

We agree that all federal awards including non-monetary assistance be reported in accordance with the Comptroller's Reporting Guidelines.

In conclusion, we appreciate the insights provided by the report. If you have any further questions or concerns, please have a member of your staff contact Doctor Sharilyn Stanley, Acting Associate Commissioner for Disease Control and Prevention, at 512-458-7729.

Sincerely,

William R. Archer III, M.D.
Commissioner of Health

Attachment

Attachment A:

Immunization Division
Random sampling of VFC site visits excluding vaccine deliveries
for the period 9/1/98 - 8/31/99

	Nbr of VFC site	Nbr of sites visited	Total nbr of visits
Region 1	169	90	215
Region 2/3	165	70	98
Region 4/5	285	127	267
Region 6	74	37	118
Region 7	92	28	42
Region 8	209	152	227
Region 9/10	106	33	38
Region 11	126	73	250
Austin-Travis CHD	22	7	39
Bell CHD	14	19	38
Dallas CHD	250	86	117
El Paso CHD	109	45	55
Harris CHD	114	39	51
Hidalgo CHD	140	13	13
Houston City HD	390	248	335
Laredo City HD	51	16	25
Tarrant CHD	162	19	34
	2,478	1,102	1,962
# of TVFC sites	3,866	44%	% of sites visited
% of sites polled	64%		

The 1999 Grant Guidance states:

Vaccine Management:

National Objective: Conduct Quality Assurance Reviews (QARs) in 25 percent of public and private sites in 1999. (Proposed)

Required Activities: Conduct annual QARs, including a review of vaccine handling practices, in a minimum of 25 percent of public and private provider sites

Vaccines for Children (VFC) Program:

National Objective: Conduct VFC-monitoring visits annually to at least 25 percent of the provider sites enrolled in the VFC Program. (Proposed)

Required Activities: Conduct VFC-monitoring visits to enrolled public and private providers. During these visits, grantees should ensure that providers are screening all patients to determine VFC eligibility and retaining records for all VFC-eligible patients, review vaccine storage and handling practices, verify provider profile information and provide appropriate educational interventions, as necessary.

The 2000 Grant Guidance states:

Program Management:

Required Activities: Conduct QARs in public clinics based on the Standards for Pediatric Immunization Practices.