The Cost of Doing Business: Cost Structure of Electronic Immunization Registries

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Objective. To predict the true cost of developing and maintaining an electronic immunization registry, and to set the framework for developing future cost-effective and cost-benefit analysis.
Data Sources/Study Setting. Primary data collected at three immunization registries located in California, accounting for 90 percent of all immunization records in registries in the state during the study period.
Study Design. A parametric cost analysis compared registry development and maintenance expenditures to registry performance requirements.
Data Collection/Extraction Methods. Data were collected at each registry through interviews, reviews of expenditure records, technical accomplishments development schedules, and immunization coverage rates.
Principal Findings. The cost of building immunization registries is predictable and independent of the hardware/software combination employed. The effort requires four man-years of technical effort or approximately $250,000 in 1998 dollars. Costs for maintaining a registry were approximately $5,100 per end user per three-year period.
Conclusions. There is a predictable cost structure for both developing and maintaining immunization registries. The cost structure can be used as a framework for examining the cost-effectiveness and cost-benefits of registries. The greatest factor effecting improvement in coverage rates was ongoing, user-based administrative investment.

Key Words. Immunization registry, cost structure, parametric cost analysis

Success in immunizing the pediatric population has progressed to the point that disease burden is essentially zero for many of the childhood vaccine preventable diseases; however, reaching this level has required substantial resources in the form of time, personnel, and financing, raising concern about our ability to maintain this degree of disease protection (Centers for Disease Control and Prevention 1998, 2000a; Herrera et al. 2000; Wood et al. 1999; Zimmerman and Burns 2000). These concerns have been voiced by the National Vaccine Advisory Committee (NVAC), Institute of Medicine (IOM), and the Centers for Disease Control and Prevention (CDC). All have identified electronic immunization registries (defined as confidential, computerized information systems that contain the immunization history and status of patients) as a critical component in the long-term strategy to maintain these historically high levels of coverage rates (National Vaccine Advisory Committee 1999; Shefer et al. 1999).

Although registries have primarily focused on immunization of children aged 0–2, the potential to serve a larger population has not been lost on developers. Indeed, some are using registries to monitor immunizations for all age groups and for other public health data such as tuberculin skin tests. A registry, in combination with a geographic information system (GIS) (Clarke, McLafferty, and Tempalski 1996), would permit identification of population-based pockets of need, could be used to guide public health policy, and could serve as a core for development of population-based electronic medical records. The use of a registry to perform epidemiological analysis takes on great importance in light of the events of September 11, 2001, and the potential need to monitor vaccination for agents of bioterrorism, such as anthrax and smallpox.

The belief is that registries should be able to generate an individual's unified immunization record from multiple providers, identify when a child is eligible for immunization and when they may be post-due, create population-level coverage rates, as well as provide reports to individual providers about their clientele's coverage rates in a far less costly and more timely manner than any present system (Linkins and Feikema 1998). To be successful, however, registries must be widely available and easy to use, yet capable of protecting individual privacy. While some of these factors have been investigated, it is unclear what the cost of meeting these goals will be, who incurs the costs and who may benefit. As important is the need to investigate whether the defined policy objectives and the proposed methods for meeting these objectives (i.e., registries) will correspond.

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The importance of understanding the capitalization requirements was clearly stated by NVAC: "The barriers to creating a national system of state-based registries are mainly political and financial rather than technical" (National Vaccine Advisory Committee 1999, p. 24). The NVAC further stated that the "Centers for Disease Control and Prevention (CDC) should pursue immediately further study to completely characterize start-up and maintenance costs of registries and compare these to costs of alternative systems" (National Vaccine Advisory Committee 1999, p. 8). This study attempts to meet this information need.

We are not the first to try. As of September 1997, more than three hundred registries were in development, supported by at least $142 million in 317d Federal categorical immunization grant funds and more than $200 million in other public, private, and foundation funds (Centers for Disease Control and Prevention 2000b; Wood et al. 1999). Early research using data from some of these registries found costs ranging from as low as $0.65 to as high as $217 per child per year (Rask et al. 2000a; Slifkin, Freeman, and Biddle 1999). Other authors' findings fell erratically within this range (Horne, Saarlas, and Hinman 2000; Urquhart 1999). In examining each of these studies it was evident that different components, different time periods, and different processes were evaluated. Consequently, comparison of results between studies and generalization of findings to a national level was unrealistic. What was needed was a method for converting the collective experiences in such a way as to permit "comparing apples with apples."

Yet medical informatics is not the first industry to be confronted with the need to anticipate the cost of development and deployment of an application. Such diverse industries as banking, manufacturing, shipping, and retailing have been confronted with the need to predict costs, anticipate benefits, and develop a realistic capitalization plan for large distributed computer applications (Cost Estimating Group 1999; International Society of Parametric Analysts 1998).

In the case of immunization registries, the numerous applications being developed provide enough data to deconstruct expenditure data (such as personnel and equipment costs) and examine how performance issues (such as expected database size, number of end users, communication and record retrieval speed, and reliability) and application objectives (such as reminder/recall notifications, identification of duplicate records, and assuring patient confidentiality) are related (see Table 1). In doing so, a cost model emerges that permits comparison of alternative methods for accomplishing the same policy objectives. In other words, it becomes possible to answer the questions:

Table 1: Sample Breakdown of Registry Components

Expenditures *Personnel*	*Application Objectives* *Perform CDC Registry* *Core Functions*	*Performance Criteria*
		Dependability
• Administrative	• Link electronically with birth records	Reliability
• Technical	• Submit/retrieve information at encounter	Number of end users
• Data entry	• Determine immunizations needed	Expected database size
• Time required for task completion	• Identify individuals late/due for reminder/recall notification	Growth rate of the database
	• Recover lost data	Response time and record retrieval speed
Equipment	• Protect confidential medical information	Theoretical capacity of each registry
• Central server	• Produce coverage level reports	Millions of instructions per second (MIPS)
• Telecommunication services	• Produce authorized immunization records	Source lines of code (SLOC)
• PCs or dumb terminals	• Exchange information with other registries via HL7 (Health Level Seven 2001)	Anticipated costs to meet future demand (Hornstein 1995)
• Printers	• Identify duplicate records	
	• Consolidate records from providers	
Software		

What does it cost? What do I get? Is it worth it (Rask et al. 2000b; Slifkin, Freeman, and Biddle 1999)?

In the nonmedical world, "parametric cost analysis" is the standard procedure for developing robust and dynamic cost models. Used by both commercial and military technology contractors, parametric cost analysis is able to delineate the relationship between performance criteria and cost. Parametric cost analysis is a prescribed set of steps for: (1) converting personnel and equipment costs into standard metrics, and (2) mathematically relating these cost metrics to the functional requirements of a project.

Commercially available and widely used parametric models include PRICE (Lockheed-Martin) and SEER (Galorath Associates). In the public domain, alternatively, are well-liked models such as COCOMO (Boehm 1981) and military standard DOD MIL SPEC 881-B (Department of Defense

1993). Because DOD MIL SPEC 881-B can be used during the investigative stage, it was selected for this project.

Calibration Standard: DOD MIL SPEC 881-B

The DOD MIL SPEC 881-B is commonly used in parametric analysis of systems whose functional requirements are not fully understood. First drafted in 1992 (since project, updated to MIL-HDBK-881) (International Society of Parametric Analysts 1998), DOD MIL SPEC 881-B is anchored in a relatively universal format for collecting and converting technical and cost information to common denominators. This format is called a work breakdown structure, or WBS (see Figure 1).

A WBS is essentially a detailed framework that describes hardware, software, services, data, and facilities as defined by the technical objectives of a proposed application in preparation for the parametric transformation used to create a model of the application's cost structure, and in identifying key predictors of costs (referred to as cost estimating relationships or CERs) (Albrecht and Gaffney 1983; Cochran 1976).

Objectives

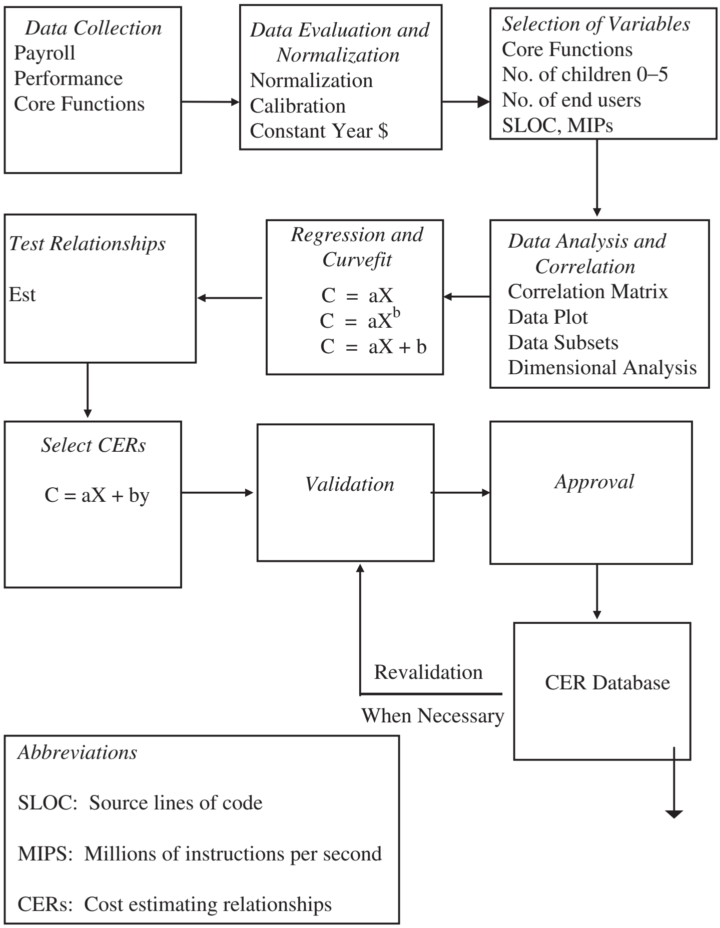
This article describes the application of DOD MIL SPEC 881-B in the parametric cost analysis of three functioning electronic immunization registries in order to: (1) predict true cost of developing, using, and maintaining a registry, (2) set the framework for developing future cost-effective and cost-benefit analysis, and (3) identify the necessary and sufficient conditions to assure alignment between policy objectives and registries.

Methodology

Setting

This study was performed as part of a larger project at the University of California, San Diego, School of Medicine, Division of Community Pediatrics. The San Diego Project is, in essence, a health services delivery engineering laboratory addressing the real-life problems of those who serve maternal and child health needs in vulnerable populations.

Figure 1: The Work Breakdown Structure (WBS)



This study examined three very different electronic immunization registries. Together, they accounted for more than 90 percent of all children in the state of California who had records entered into a registry. Table 2 compares the registries by organization type, funding source, location, software/hardware application, number of records, and availability to providers. The diversity of these registries was considered to be a requirement because it reduced the likelihood of identifying cost structures that reflect specific, nongeneralizable population or architectural constraints. All three

Table 2: Characteristics of Registries A, B, and C as Compared in this Study

	Organization	*Funding Source*	*Location*	*Application*	*Records*	*Availability*
A	Large, nonprofit, staff-modeled HMO	Internal operations	Southern California	Mainframe (IBM S390) using DB2 as a database	17 million records on 6 million patients	More than 60,000 terminals (dumb and P.C.)
B	County public health department	California State Immunization Information Systems	Urban county in northern California	Client-server architecture, using ORACLE 7 as its database	78,000 active records	13 public health clinics, 3 hospitals, 15 private providers contracted for managed Medical services
C	County public health department	California State Immunization Information Systems	Rural county in central California	"Off the shelf" registry software compatible with county's VAX-based systems	More than 23,000 active records	County hospitals and 23 private provider offices

were recognized within the state as well-managed entities, actively improving immunization rates within their respective populations.

Data Analysis

The project followed the guidelines in DOD MIL SPEC 881-B in developing an immunization registry work breakdown structure based upon functional requirements including those outlined by the CDC (National Immunization Program 2000). Components previously listed in Table 1 are also used in the WBS. Additional parameters such as growth rate of the database, theoretical capacity of each registry, and anticipated costs to meet future demand were calculated (Hornstein 1995). These WBS elements were "branched" to types of personnel (administrative, technical, data entry) and amount of time required for task completion, types of equipment (central server, telecommunication services, PCs or dumb terminals, printers), and types of software. Each of these elements was further subdivided and associated with direct costs and indirect costs. Direct costs included items such as direct labor costs, direct operating costs, travel costs associated with deployment and maintenance, professional services, direct material costs, and capital acquisition (to the extent that these capital acquisitions formed part of the service delivery). Indirect costs included employee benefits, volunteer time, reporting to funding sources, and any approval process required by local, state, or federal regulating bodies.

Cost elements were obtained for the first three years of each registry's operation. All data were collected and maintained in a manner that provided a complete audit trail, and expenditure dates were recorded so those dollar-valued costs could be adjusted for inflation. Data were collected in person at each registry's administrative office and didacted from business records. The data were summarized and submitted to each administrative team for confirmation or correction. Two consulting medical economists reviewed all financial data and constructions of the financial components of the WBS and subsequent financial analysis. Two consulting system engineers reviewed all operational and technical data and conversion of these data into the WBS for analysis.

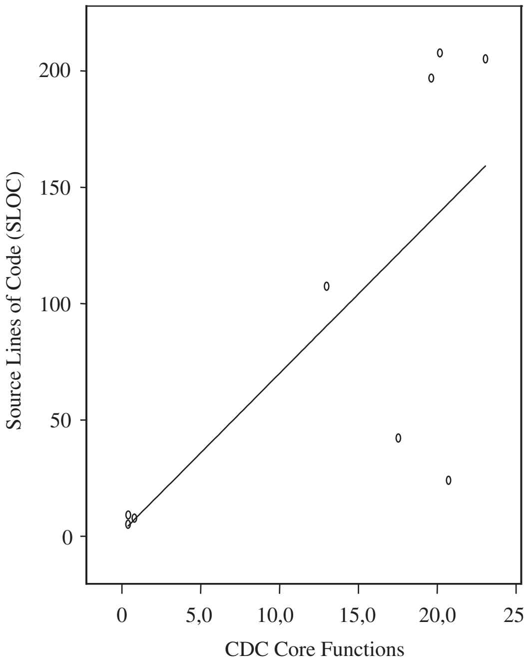
Normalization. Once the raw data were confirmed, it underwent a series of transformations in preparation for analysis. The first was normalization of the data. Normalization involved the identification and then elimination of anomalies and inconsistencies in data that did not have a bearing on the project itself. These exclusions included one-time, nonrecurring events such as loss of key personnel or loss of a vendor-supplied product due to a buyout or bankruptcy. While a "real" cost, such setbacks are not a cost driver directly linked to registry development; rather, they reflect the exigencies of any large undertaking and are not "predictable." The normalization process also took into account how expenditures were adjusted to reflect actual date of expenditure rather than funding dates. Expenditures for conferences involving best practices, legal requirements, or funding organization priorities materially affecting development were included. Other anomalies included funding of personnel who were used for nonregistry tasks. Only time spent on the project (liberally defined) was included in the cost figures.

Calibration. Following normalization, the data were calibrated using standard business and information technology reporting conventions. Personnel were coded as to type of personnel (technical analyst, programmer, administrator, secretary, clerk, and so forth) and their efforts were described as either full-time equivalents (FTEs) or man-hours/man-years to task. Software and hardware platforms and database design or architecture were calibrated according to such industry standards as processing capacity (millions of instructions per second or MIPS), transaction times (reported in milliseconds), telecommunication capacity (short transaction transmissions measured as TRANSUMs), dependability quotient (reported as percent of availability during a year), and storage requirements (reported in gigabytes). Sequence of development and time to completion for each of the functional requirements were part of the calibration process. When a population-derived metric was required, a cost per 100,000 population was used as the unit of measure.

Regression. Fully normalized and calibrated data initially underwent simple linear regression to search for unidimensional CERs. Standard regression analysis found that some relationships were linear (e.g., monthly phone billing based on minutes of usage), some were curvilinear (e.g., per-minute costs if the same phone bill was based on a flat monthly service fee), while others were quadratic (e.g., base rates for predetermined amounts of phone time with additional charges if the base rate is exceeded). The regressions were used to determine if a model of the registry cost structures could be developed.

Once CERs were identified, their ability to predict registry costs was assessed using a statistical technique called the mean absolute deviation (MAD). The MAD essentially evaluates how well a parametric model estimates its own database. For example, a MAD score of 20 percent means that the parametric equation estimates its own database accurately within plus or minus 20 percent (Cost Estimating Group 1999).

Figure 2: Mean Average Deviation (MAD) of SLOC for the CDC Core Functions



RESULTS

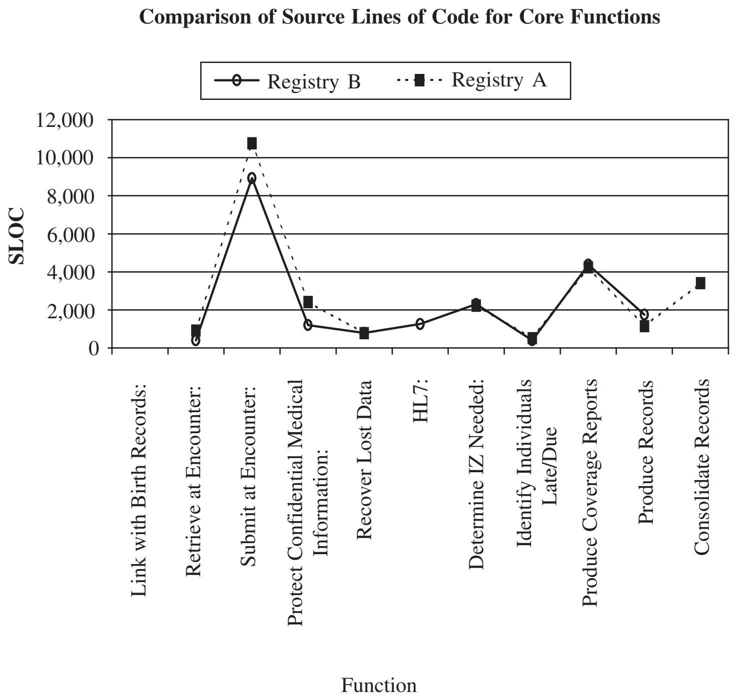
Despite such widely divergent platforms, populations, and funding streams, the three registries produced remarkably convergent development cost structures. The parametric analysis and CERs yielded a MAD score of 8 percent, suggesting that the identified cost structures are, indeed, accurate and that the CERs are valid predictors of registry costs (Figure 2). Furthermore, the analysis was able to derive a specific CER with a very high coefficient accounting for 93 percent of a registry's three-year costs.

Cost Structures

Technical Personnel Cost Structures

The functional requirements tightly constrained the logical structure of all three registries independent of the architecture used. Three-year technical costs were remarkably well predicted. For example, the cost for technical staff

Figure 3: SLOC to Complete Core CDC Functions



(once normalized and calibrated) was 4 man-years (or 4 FTEs) for planning and developing the application with an additional three-quarter man-years (or .75 FTE) for annual maintenance. Even more striking was the fact that all three registries essentially rewrote the application code after three years at a cost of 1.5 man-years (or 1.5 FTEs). The rewrite of the application code was in response to new legislation, immunization schedules, and a better understanding of ways to use the information and/or to improve operational performance.

Underscoring the fact that registry architectural logic is narrowly constrained by the functional requirements is the remarkably tight grouping of source lines of code (SLOC) used to accomplish both specific registry functions and standard reports. The two registries that developed their own applications did so using essentially the same number of SLOC despite very different platforms. Registry B, running on a client server platform, had 45,553 SLOC compared to Registry A, running on an IBM mainframe environment, with 49,901 SLOC. Registry B needed 26,388 SLOC to accomplish 10 of 12 CDC core functions while Registry A needed 26,848 to complete 10 of the core functions (see Figure 3). This remarkably tight "clustering" also suggests these are benchmark SLOC standards for each function. Dividing number-of-SLOC-written by man-hours-spent yielded a cost of roughly $5.00 per completed SLOC, which is in the bottom quartile of industry standards (Hall and Schick 1998; Hornstein 1995). In addition, "learning curve" analysis (Department of Defense 1993) was conducted to determine if programmers were capable of writing more SLOC by the end of the study period as compared to the first six months. The results indicated a 20 percent increase in productivity.

The economic significance of this finding is that the technical costs for registry development are fixed (at approximately $250,000 in 1998 dollars) regardless of the size of the cohort covered. Concomitantly, the unit cost per record will be inversely proportional to the size of the population covered. Clearly, the significance from a cost offset standpoint is that a minimum population size is required if one of the goals of the registry is to be cost-effective.

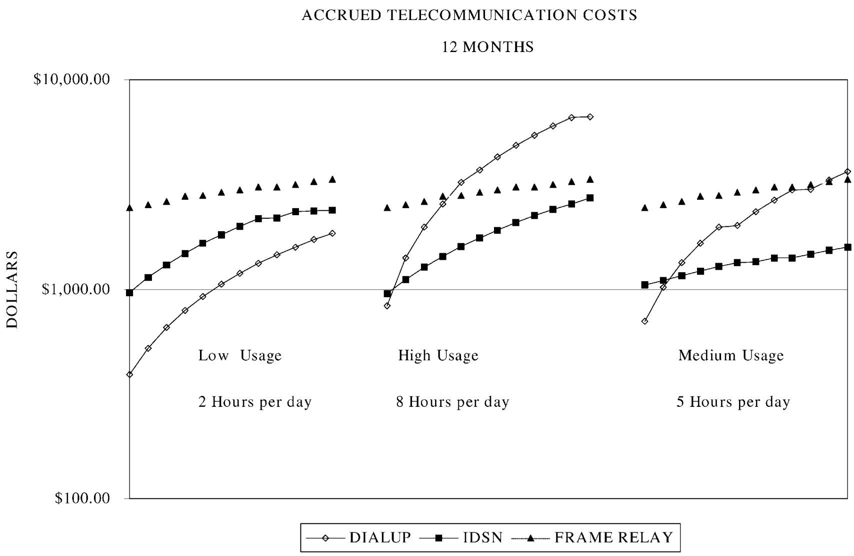
Technical Infrastructure Cost Structures

Technical infrastructure costs were comprised of two basic units: telecommunications and hardware. Speed, dependability, expandability, and costs were the constraints analyzed.

Telecommunications. Telecommunications proved to be a variable cost and exhibited a linear relationship with performance. This would be almost tautological if it were not for the fact that lower unit costs were incurred for the higher-usage, initially more expensive, telecommunications systems. Dialup modem, ISDN, Frame-relay, and T-1 systems were analyzed. The higher capacity Frame-relay and T-1 lines were found to be more cost-effective for medium and high utilization users. Dial-up modem and ISDN lines, though initially cheaper to install, proved far more costly over the study period than their higher-speed counterparts. This relationship was true even before performance (measured in TRANSUMS) was factored.

For example, the registry that depended solely on dialup-modems incurred a one-month telecommunications cost in excess of $4,100 with fewer than 450 records entered the entire month at an average of three minutes per inquiry. In comparison, during the same month the registry that exclusively employed T-1 lines spent $12,300 for 74,000 record entries with an average

Figure 4: Comparison between Performance and Telecommunications Cost



response time of 35 milliseconds. Figure 4 shows the relationship between cost and performance.

Hardware/software. Central Repository. Despite different hardware used by each registry, computation and storage costs were tightly grouped at roughly $5,000 per MIP. However, there was an inverse relationship between speed, dependability, and cost per transaction. In part, this is an artifact of the largest registry using the most dependable hardware. The registry using client-server architecture was very close to the mainframe registry's dependability/cost per transaction ratio.

End-User Processor. The registries using PCs at the user level produced a yearly "per seat" cost of $1,400. This incorporated all end-user needs including the PC, printers, software, and telecommunication devices. This proved to be at or below the median for industry standards (Gale Group).

Administrative Cost Structures

Administrative cost structures provided both the most dramatic example of why cost studies need to be rooted in performance criteria, and the means for examining the conditions necessary to meet policy objectives. Each registry allocated approximately 28 percent of their total budget to administrative costs (range 27–31 percent). However, one of the registries experienced less than a 2-point increase in coverage rates while the other two experienced 28- and 33-point increases, respectively, during the same time period. When the administrative costs were associated with number of end users (proxied by number of access terminals), the registry with no significant improvement had spent only $177 per year per end user while the two with significant increases spent between $1,700 and $1,800. While a functioning registry is a necessary condition in meeting national policy objectives, it alone is not sufficient in improving rates. Significant administrative efforts (approximately $5,100 per end user per three-year period) are required in "re-engineering" the organization's immunization practices using the functions of registries.

Data entry. Data entry costs were fixed and linear. Expressed in man-hours, data entry required 82.7 man-hours per 1,000 record entries. This appears to be the primary cost-driver incurred by the end user. The registry that used solely data entry personnel rather than more expensive nurses and physicians experienced a per chart entry cost of only $0.11. This compares favorably with industry standards for data entry.

Cost Estimating Relationships

Administrative costs per end user emerged as the dominant CER in predicting three-year registry costs, accounting for 94 percent of total costs. The "hard" cost proved to be $5,100. Administrative cost is a far more dynamic estimator than cost-per-child-per-year (which proved to be a very poor predictor, with cost ranges of $0.39 to $27.02, accounting for less than 48 percent of the three-year costs). Web-based strategies, use of cheaper "appliance" terminals for accessing central database records, or other strategies for decreasing costs will have minimal impact on this figure as it represents ongoing administrative oversight, audit and feedback, end-user support, and training activities.

DISCUSSION

Parametric cost analysis is a powerful method for examining cost structures, and the necessary and sufficient conditions for policy objectives to be met by strategies. It also provides a sound basis for performing further cost-effective, cost-benefit, and benchmarking studies.

Chief among the findings in this study was that database development costs are fixed and tightly constrained by the CDC's core functions. These costs are incurred regardless of the size of the population covered, the platform used for development, or the telecommunication strategies used in connecting users with the registry. This suggests there is some minimum population base below which it is unlikely a registry can be sustained from an economic standpoint.

The average cost per SLOC ($5) is well below industry standards and suggests that programmers involved in this study may have been underpaid relative to industry standards. Such a complex endeavor cannot risk the loss of technically skilled and knowledgeable staff.

When appropriate telecommunication infrastructure is developed, the overall contribution to registry costs over a three-year period becomes negligible. Inappropriate, albeit cheap, connectivity in the form of dial-up modems produces expensive and nonuser-friendly results. It is unclear how internet-based communication strategies will affect long-term communication, performance, and security costs.

Data entry costs show a similar pattern in terms of strategies employed. Clinical staff is commonly used to perform routine data entry tasks (again it may be the only option, initially). The consequence is expensive, error-prone data entry, and clinical staff who may perceive "new" registry tasks as a hindrance to their "real" job of providing clinical services. When personnel are hired specifically for data entry, the cost becomes relatively insignificant.

CONCLUSION

The real costs and the real opportunity to convert an electronic database into a functional registry that aligns with policy objectives are dependent upon the adequate allocation of resources to administrative efforts. If a registry is administratively viewed solely as an alternative to the paper chart, and business processes are not reengineered, then overall costs may be quite low. However, if the registry is to serve its intended purpose of improving immunization coverage rates, then adequate administrative time and money must be allocated to reexamine and redesign organizational practices.

This is simply the cost of doing business.

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