effectiveness of some control measures which might work in other regions.

First, the dog is a utilitarian part of Navajo life and is therefore desirable; in the more rural areas of the reservation the dog is typically used for herding sheep, while in the more populous community areas it functions as a household protector. The question then becomes "How many dogs are needed to carry out the job?", not "Should there be any dogs at all?". Many Navajos readily agree that they have too many dogs, and, unfortunately, abandonment has become a major control practice, my data show. Second, there may be an aversion to spaying or neutering dogs on the reservation for three reasons: (*a*) it may be too costly; (*b*) it is often believed that castration alters a dog's behavior, making it less likely to be protective; and (*c*) it eliminates any choice on the part of the owner to supplement his or her own dog population as the situation warrants.

Each of these reasons needs to be and can be addressed within the framework of an effective dog control program. For instance, given the ratio of males to females, spay programs should receive a higher priority than neutering males. Although a single spay operation is more expensive than a single castration, spaying will be more cost effective. As an example, one male can inseminate any number of females in the area of his homesite, and, unless all the males in that area are neutered, the probability of the female becoming pregnant remains high. Since neutering every male is practically impossible, targeting the fewer females makes more sense.

In all, the dog-bite problem is not insurmountable, and reasonable steps can be taken to reduce the health impact on the human population.

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Incorporating Outcome Standards into Perinatal Regulations

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Synopsis

State and local governments license and monitor hospitals to ensure that a minimum acceptable level of care is present as one means of improving the outcomes and health status of patients served. Standards developed to achieve these purposes, however, have focused almost exclusively on the inputs and processes believed to be necessary for quality care and optimal services. Even when the overwhelming consensus of professionals and providers is that such standards impact positively on outcomes, direct evidence of such causal relationships is often lacking.

In 1983, the Chicago Department of Health began incorporating direct measurement of outcomes into its mandated regulatory functions for one operating unit of hospitals—the maternity and newborn services. Crude perinatal and neonatal mortality rates for Chicago hospitals are adjusted using an indirect standardization process that controls for both race and birth weight. This process allows for the calculation of adjusted mortality

rates and standardized mortality ratios (SMRs) that are used as an initial screening instrument. Additional evaluation and investigation activities are then directed to hospitals identified through the initial screening process as meriting further study.

Hospitals are also evaluated for compliance with the traditional standards and requirements. Information derived from both outcome and compliance evaluations is used to determine monitoring and regulatory activities such as penalties, waivers, and periodicity of future inspections.

Use of this Outcome-Oriented Perinatal Surveillance System appears to be an objective, understandable, and acceptable basis for establishing monitoring, evaluation, and regulatory strategies for hospitals with maternity and newborn units.

After more than 3 years of study and discussion, the Chicago Department of Health (CDOH) adopted updated standards and regulations for hospital maternity and newborn services (*1*) effective January 1, 1982. These revised standards were adapted from and modeled on the recommendations of the appropriate local and national professional organizations. The standards delineated two levels of hospital maternity and newborn care, quite consistent with the Levels II and III described by the National Committee on Perinatal Health (*2*), the Committee on Fetus and Newborn of the American Academy of Pediatrics (*3*), and other widely representative professional organizations. Virtually all of the provisions of the Chicago 1982 Perinatal Standards relate to structure (inputs) and process requirements, and not to outcome standards.

It is worth noting that the 1982 Perinatal Standards called for upgrading all so-called Level I (primary level) maternity units to Level II capabilities, ostensibly to address the high rates of infant and perinatal mortality persisting in Chicago (*4*). Authority for the revision of these standards and regulations was provided by a Perinatal Enabling Ordinance (*1*) which was adopted by the Chicago City Council in mid-1981. The 1982 Perinatal Standards also called for the execution of a formal letter of agreement between all hospitals with maternity services and their respective perinatal centers. This letter of agreement describes the roles, responsibilities, and operational interactions between each hospital maternity and newborn unit and the perinatal center which coordinates all such activities within a regional perinatal network. (There are six such centers in Chicago.) Another important feature of these standards is that each hospital is required to participate in morbidity and mortality review activities.

During 1982 and 1983, Chicago hospitals providing maternity and newborn care were assessed for their compliance with the newly revised regulations. Self-assessment questionnaires were followed by onsite inspections by professional survey teams from the CDOH. Hospitals were notified of noncompliance with any provision of the 1982 Perinatal Standards and were revisited following submission and acceptance of plans for correction of the noncompliance.

By early 1983, only about one-third of the city's hospitals had been approved as being in full compliance with the new standards. Approximately 40 percent of the hospitals had not yet completed their letter of agreement. Forty-five percent also had a variety of other violations, including inadequate square footage in certain units (but especially in nurseries), improperly credentialed professional staff, lack of medical protocols, and inadequate equipment.

Requests to CDOH for exemptions and waivers increased as a result of the high rate of noncompliance. Often, hospital administrators, as well as professional medical staff, argued that such waivers should be granted since the unmet requirements did not necessarily equate with quality of care or optimal outcomes.

The department of health, in concert with its Chicago Maternal and Child Health Advisory Committee, developed an outcome oriented surveillance system for hospital maternity and newborn units in early 1983. As part of this new approach, the department proposed that outcomes replace input and process measures as the prime standard against which maternity services of hospitals would be measured. Outcome standards would serve as the prime focus of regulatory activities for maternity and newborn care. These proposals, as well as specific provisions for standards of risk-adjusted perinatal and neonatal outcomes, were adopted by the Chicago Board of Health in August 1983 and implemented beginning in 1984 (*5*).

All hospitals were evaluated during 1984 and 1985 for compliance with both the newly approved outcome standards and the existing structure and process standards. This evaluation was done as part of

each hospital's requirements for continued licensure by the city.

Statistical Methods

The primary data source for the Outcome-Oriented Perinatal Surveillance (OOPS) System is the vital records system and, specifically, recorded live births, fetal deaths, and neonatal deaths. The department of health is the local registrar for all births and deaths which occur within the city. The birth and death records are edited both manually and by computer, processed, and several computer files created. In Chicago, records of all deaths of infants under 1 year are immediately linked with the corresponding birth certificates. This process creates a linked birth and death file.

Death certificates for neonatal deaths occurring outside the city among infants born alive in Chicago are not registered with the CDOH, although they are necessary to complete this file. These records are obtained through cooperative arrangements that have been established with the Cook County Department of Public Health and the Illinois Department of Public Health.

From the linked file and the fetal death file, birth weight, race, and hospital of birth (or fetal death) become available for all infant and fetal deaths among Chicago births. The matching process for 1981–83 was 95 percent complete. Because of selected improvements introduced into the process, it is anticipated that the match process for 1982–84 will be close to 97 percent successful. These files allow for calculation of birth weight specific perinatal (20 weeks gestation through 28 days after birth) and neonatal mortality rates by race for each hospital. They also provide for computation of birth weight distributions for each institution. Six weight categories were used to describe the distribution: less than 751 grams, 751–1,000 grams, 1,001–1,500 grams, 1,501–2,000 grams, 2,001–2,500 grams, and more than 2,500 grams.

Birth weight distribution and birth weight specific mortality rates are the essential components of risk-adjusted mortality rates using either direct or indirect standardization methodologies (*6–11*). The advantages and disadvantages of both techniques have relevance for this type of application.

In the direct standardization process, each hospital's birth weight specific perinatal and neonatal mortality rates are applied to the birth weight distribution of a standard population. The birth weight adjusted rate is the total calculated by summing the contributions from each of the weight categories. Use of a standard birth weight distribution controls for many of the social, demographic, and health-risk factor differences existent among the various population groups served by the 38 hospitals with maternity and newborn services units operating in Chicago (*6,7*). The direct standardization methodology provides information on how each hospital might be expected to perform if all hospitals served the same population. Differences between adjusted rates for individual hospitals are at least partially attributable to differences in the medical care provided in the various hospital maternity and newborn units (*8,9*).

Adjusted perinatal and neonatal mortality rates for each hospital located in Chicago are calculated using this methodology. The absolute values of these adjusted rates are not necessarily meaningful in themselves, since they are based on a hypothetical population.

The indirect standardization method applies a standard set of birth weight specific mortality rates to the actual birth weight distribution of each hospital. Use of the hospital's birth weight distribution together with a standard mortality experience provides a measure of the expected number of deaths that would have occurred at each hospital if it had birth weight specific mortality rates equal to those of the standard.

The indirect standardization process allows for a standardized mortality ratio (SMR) to be calculated. This is a ratio of the observed to the expected number of deaths multiplied by 100. Again, differences in SMRs are at least partially attributable to differences in the medical care provided.

The direct and indirect standardization techniques both attempt to adjust for differences in risk by controlling for birth weight as an important risk factor. There are other risk factors that influence perinatal outcome at a given birth weight, including race, sex, gestation, and plurality. Since there are such significant differences in weight-specific mortality between blacks and nonblacks in virtually all weight categories, it is especially important to use separate birth weight distributions and birth weight specific mortality rates for these racial groups in developing a composite indicator.

The advantages and disadvantages of both techniques have relevance for this type of application. In adjusting for both race and birth weight, the direct standardization technique encounters limitations with unstable weight-specific rates due to the small number of events (*11*). The indirect standardization technique is less affected by these limitations and is preferable from this perspective.

Table 1. Distribution of selected perinatal health statistics by hospital

Hospital	Rate for births less than 2,500 g	Perinatal mortality rate [1]		Standard mortality ratio (SMR) [3]
		Observed	Adjusted [2]	
1	7.3	19.4	48.3	210.9
2	7.4	17.7	31.3	136.4
3	7.4	20.1	29.0	126.4
4	4.7	12.1	27.7	120.9
5	5.5	16.2	26.8	117.0
6	6.4	11.0	26.5	115.7
7	9.3	26.9	26.3	114.9
8	6.1	15.4	26.2	114.3
9	9.1	25.5	26.1	113.9
10	4.8	17.4	26.0	113.8
11	11.7	18.1	25.5	111.4
12	12.5	20.5	25.3	110.5
13	7.0	17.5	25.3	110.4
14	8.0	20.9	24.8	108.2
15	6.6	20.7	24.8	108.2
16	17.8	41.5	24.7	107.9
17	13.5	26.1	24.6	107.5
18	15.4	24.4	24.4	106.7
19	7.6	22.0	24.3	105.9
20	9.1	9.7	24.0	104.9
21	14.8	22.9	23.5	102.7
22	8.1	13.8	23.5	102.6
23	6.3	10.4	23.0	100.4
24	14.3	32.5	23.0	100.0
25	13.6	32.7	22.7	98.9
26	13.7	26.8	22.6	98.4
27	5.2	11.5	22.5	98.2
28	6.9	13.8	22.4	97.7
29	11.3	15.8	22.1	97.0
30	4.5	12.4	21.5	93.5
31	4.6	9.0	21.3	92.8
32	6.7	12.0	21.2	92.6
33	5.9	10.7	20.9	91.2
34	11.2	26.3	20.5	89.5
35	4.9	8.7	20.0	87.3
36	16.5	21.2	19.8	86.5
37	13.3	21.2	19.5	85.1
38	12.7	14.5	12.0	52.2

[1] (Neonatal + fetal deaths) ÷ (live births + fetal deaths) × 1,000.
[2] Adjusted by indirect method using City of Chicago 1981–83 race- and weight-specific rates as standard.
[3] SMR is the ratio of expected to observed perinatal deaths × 100.

However, the direct standardization concept is easily understood and accepted by hospital administrators and professional staff. They perceive that the use of their institution's mortality rates against a standard population produces a more understandable yardstick for comparison of outcomes for different hospitals.

Despite the initial usefulness of the direct standardization techniques in promoting and explaining the OOPS concept, the indirect standardization process has been used in the implementation of the program. In the remaining sections of this paper we will use the results of the indirect standardization techniques (mortality rates adjusted for both weight and race and SMRs).

The city-wide race and birth weight specific mortality rates were used to calculate the expected number of deaths for that race and birth weight distribution, and SMRs were computed for each hospital. SMRs are then ranked from highest to lowest as in table 1. The SMR becomes an extremely useful summary statistic for measuring the difference between the expected and observed rates for each hospital. The difference between a hospital's SMR and the standard of 100 reflects the percentage difference between the hospital's adjusted rates and the overall city rate.

Three years' data are aggregated into the database in order to ensure that each hospital has an adequate number of events to permit statistical analysis. This step will limit, to the extent possible, differences due to spurious fluctuations. Additionally, the most recent year's data are also reviewed separately to allow for analysis of current outcomes as well as trends, although the limitations of a single year's events for a hospital with few births are recognized.

Various biostatistical techniques can be applied to the adjusted rates to determine which hospitals have birth weight- and race-adjusted rates that are significantly different from the standard. The SMR, together with traditional tests of statistical significance, such as the Standard Normal Deviate of Z-Scores, are useful in identifying those hospitals with potentially unsatisfactory perinatal outcomes, as well as in quantifying and analyzing observed differences.

Surveillance and Analytical Methods

The utilization of SMRs as a performance or outcome standard for hospital maternity and newborn units establishes a screening tool to target hospitals that may have unsatisfactory or unfavorable outcomes. Outcome criteria specified in the Chicago 1984 Perinatal Standards are employed to determine which hospitals merit more intensive evaluation and investigation:

1. hospitals with an SMR for perinatal mortality more than 15 percent above the city standard of 100;
2. hospitals with an SMR for neonatal mortality more than 15 percent above the city standard of 100.

Adjusted rates for the 3-year base period and the most current year available are analyzed. Hospitals with adjusted SMRs within these criteria are considered to have satisfactory outcomes. As outlined in the chart, those hospitals with SMRs 15 percent

or more above the city-wide figure are targeted for further evaluation and investigation to determine if there were unusual circumstances or referral patterns which resulted in those apparently high SMRs. Only after further studies are performed will a hospital's outcomes be considered unsatisfactory. Hospitals with SMRs above the criteria just described will be rated satisfactory only if more intensive evaluation and investigation activities provide explanations for the high SMRs that are unrelated to the quality of care provided at the institutions. These more intensive evaluation and investigation activities may include application of statistical tests of significance to differences in SMRs; examination of differences in gestational age, plurality, and sex among birth weight categories; and thorough examination of birth weight specific mortality rates by race for all weight categories.

It is possible that certain hospitals might have high SMRs based upon unusual referral patterns for certain clinical conditions. For example, a hospital specializing in second trimester abortions may have an increased number of liveborn fetuses in weight categories between 500 and 1,500 grams and, as a result, have high birth weight specific mortality rates for those weight categories. Or a hospital specializing in genetic and congenital conditions may have many mothers referred for delivery of infants whose severe problems place them at a greater risk of mortality than other infants in the same weight category. Examination of these situations could document that high SMRs were due to these circumstances rather than inadequate medical care. A review of individual cases is necessary to establish these facts.

The fetal death and linked birth and death file can provide the names and other identifiers of fetal and neonatal deaths (and the mothers) so that specific hospital records can be readily retrieved and reviewed by CDOH staff at the time of onsite inspections. This facilitates monitoring of medical management and documentation of unusual referral patterns as described previously. Also, the birth and death records on file can be readily reviewed to determine if errors in completion or editing of the records themselves explain any of the differences noted.

In addition to the outcome surveillance activities cited previously, compliance with the input and process measures of the perinatal requirements is also assessed by CDOH staff during onsite visits. Noncompliance with any standard or requirement is presented to the hospital after the outcome evaluation and onsite inspection activities are completed.

'As part of this new approach, the department proposed that outcomes replace input from process measures as the prime standard against which maternity services of hospitals would be measured. Outcome standards would serve as the prime focus of regulatory activities for maternity and newborn care. These proposals . . . were adopted by the Chicago Board of Health . . . and implemented beginning in 1984.'

Plans for correction are requested for all noncompliant provisions. However, hospitals with satisfactory outcomes may request waivers from any of these requirements except the letter of agreement and required reports. Reasonable requests are approved by CDOH. Hospitals with unsatisfactory outcomes, however, must comply with all provisions of the perinatal regulations or face aggressive regulatory actions ranging from fines to closure of their maternity and newborn services. Hospitals in this category are scheduled for inspections at more frequent intervals than those with satisfactory outcomes, as outlined in the chart.

Finally, the compilation of extensive information on risk characteristics and outcomes for each hospital allows for the development and dissemination of ongoing reports that are sent back to each facility. The reports can be used in fulfilling the mortality and morbidity review responsibilities required of each hospital's staff.

All statistical reports and surveillance studies are shared with the community hospitals and their respective perinatal centers. The results section of this paper presents some of the information and reports that are generated.

Results

In table 1 are examples of crude and adjusted mortality indicators computed using the information sources and indirect technique previously described. Included are crude perinatal mortality rates, low birth weight rates, and race- and birth weight-adjusted rates using the indirect standardization technique and its accompanying SMR. These

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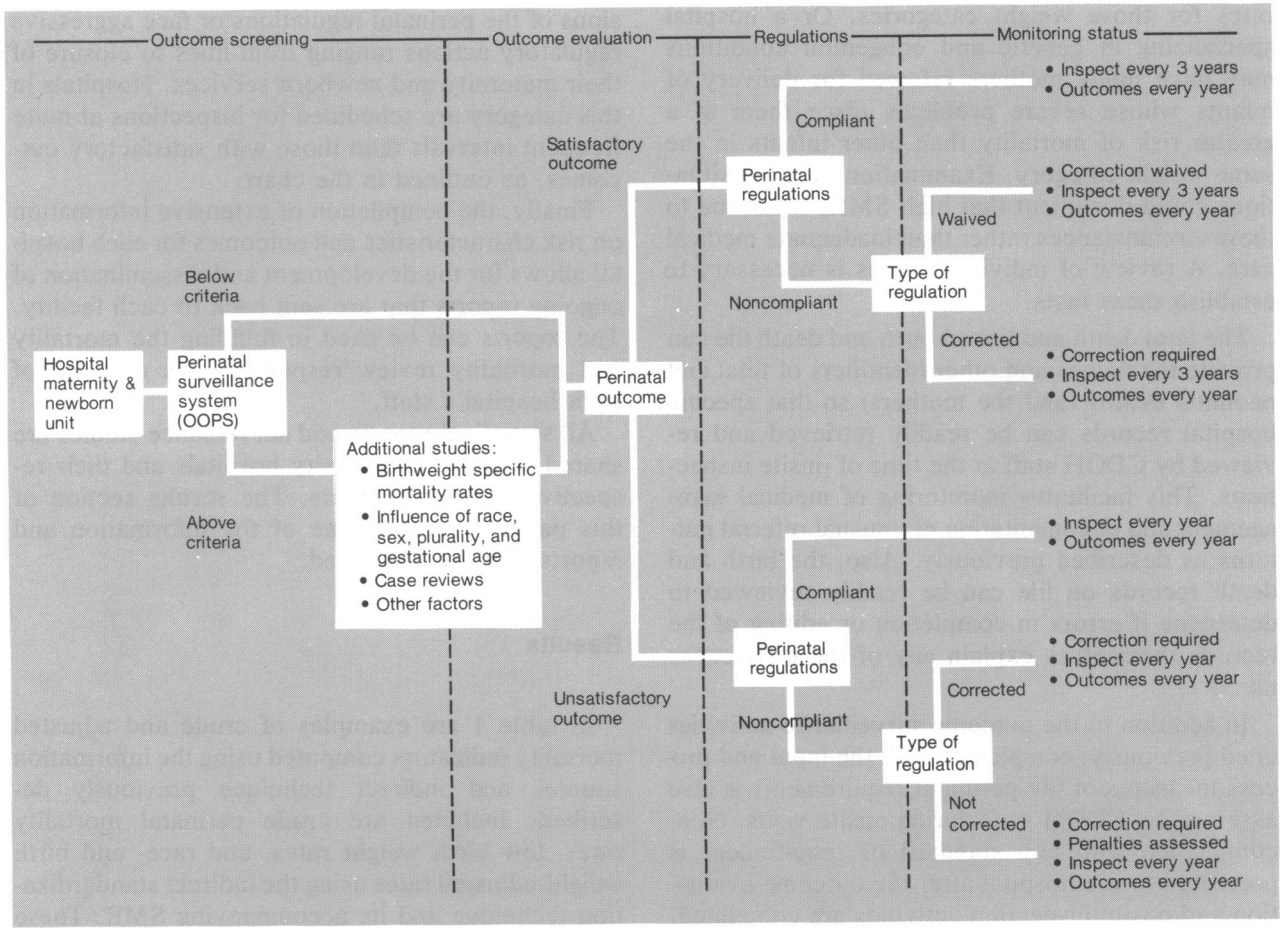
indicators are provided for all births at Chicago hospitals during 1981, 1982, and 1983, and they are derived from reports generated for the use of CDOH regulatory staff in assessing hospital outcomes.

Six hospitals have SMRs 15 percent or more above the city-wide figure of 100 (table 1). None of these hospitals would have been identified by their crude perinatal rates alone. Thirteen hospitals have SMRs 10 percent or more above the city-wide figures, but only 1 of the 13 had a crude perinatal mortality rate among the 15 worst. Similar analyses of SMRs can be performed for 3-year adjusted neonatal mortality rates or for most recent year-adjusted perinatal and neonatal mortality rates.

Further review for contributing factors, including a thorough review of the medical records concerning each death, was conducted for each of the six hospitals. As a result of those additional studies, each one was found to have unsatisfactory outcomes with no extenuating or explaining circumstances. Three of the six highest SMRs were significant at the .05 level using standard normal deviations. While levels of statistical significance contribute additional information, all high SMRs are of concern to the surveillance program.

Four of the six hospitals with high SMRs also had one or more noncompliant provisions of the traditional standards and were required to correct each

Integrated approach to monitoring perinatal outcomes



deficiency cited. No waivers were considered for these hospitals. They will be inspected at least annually until outcomes become satisfactory. The other two institutions were found to be fully compliant but will also be monitored and inspected annually.

A review of weight-specific mortality rates by race was conducted as part of the additional studies of the six hospitals with unsatisfactory outcomes. This review used reports generated regularly by the outcome-oriented surveillance system. Table 2 demonstrates differences between one hospital's weight-specific rates for blacks and the overall city experience for blacks in all weight categories for perinatal deaths except the lowest weight grouping. Those differences were largely responsible for that hospital's composite SMR exceeding the 15 percent screening criteria for perinatal outcomes. Reports similar to table 2 are provided annually to each hospital for all births as well as for both races separately. In addition, reports describing other risk characteristics of the population served are provided to each hospital regularly; seven different reports are developed for each institution. Three provide data on weight-specific mortality rates as compared with the city-wide experience. Four others describe risk factors such as maternal age, race, and birth weight categories. An analysis of crude and adjusted mortality rates, birth weight distribution, and weight-specific rates is provided to each hospital with these reports. These data and information are useful in internal morbidity and mortality review activities as well as in joint reviews with each hospital's perinatal center.

Among the 32 institutions with satisfactory outcomes as a result of the initial outcome evaluation, 10 were found to be noncompliant with other requirements. All 10 were requested to submit plans of correction. The Chicago Department of Health would consider justifiable requests for waivers for hospitals in this category. Although only two such requests had been received as of April 1985, more are anticipated later in 1985. The remaining 22 hospitals were found to be compliant with all provisions of the 1984 Perinatal Standards, including the outcome criteria.

Discussion

Few would argue with the premise that health providers and institutions exist primarily to improve outcomes. Similarly, health agencies regulating providers and institutions also exist to improve outcomes through health protection, promotion, and prevention strategies. Yet both providers and regulators have traditionally limited themselves to standards that focus on inputs and processes believed to result in better care and improved outcomes. A more comprehensive framework for monitoring and regulating such services would include tools that focus on outcomes as well as structure and process measures.

'One important feature of this surveillance program is the capability to measure and monitor differences in the ratio of fetal to neonatal deaths in various weight categories. Hospitals which underreport fetal deaths may be identified through such techniques. Knowledge that the health agency has the data and the capability to identify potential underreporters should serve as a deterrent to the practice.

Techniques designed to control for differential risk characteristics among populations served have been used in recent years for research and evaluation efforts in perinatal health care delivery (*7–9*). The application of such methodologies to establish regulatory standards, however, has not been given much attention. There may be many reasons that explain this situation, such as different focuses of planners, evaluators, and regulators within State and local health agencies. The unavailability of adequate data sets such as linked birth and death files can be another reason. Further, there may be a general philosophical inertia among regulators based on perceptions that their prime roles are those of counters (of nurses, square footage, sponges, and so forth) and documentors (of credentials, protocols, committee meetings, and other items). None of these factors appears especially persuasive or prohibitory, although some limitations and constraints are readily apparent.

Certain limitations of this unique application that we have described are directly related to the source of the data, that is, the vital records system.

The quality and completeness of vital records data have been described both for Chicago and for other parts of the country (*12*). While data related to hospital of birth, race, and birth weight are among the more reliable and complete items on the birth

records, there is some concern that fetal and neonatal deaths may be underreported. The perinatal mortality rate is the best single descriptor of pregnancy outcome, and its use controls for differences in classification of fetal and neonatal deaths, but it still does not fully address differences resulting from the misclassification and subsequent underreporting of fetal deaths. The practice of misclassifying fetal deaths has legal as well as evaluation implications. SMRs for hospitals that underreport fetal deaths will be somewhat lower than those reporting completely and accurately. One important feature of this surveillance program is the capability to measure and monitor differences in the ratio of fetal to neonatal deaths in various weight categories. Hospitals which underreport fetal deaths may be identified through such techniques. Knowledge that the health agency has the data and the capability to identify potential underreporters should serve as a deterrent to the practice.

Some concerns over the validity of standardization techniques in general have been raised (*13*). Much of the bias inherent in standardization techniques relates to the practice of considering together populations with different birth weight distribution. Separate standardization for blacks and nonblacks reduces such bias and has been employed in this system.

The use of adjusted rates that are not further partitioned by sex, plurality, and gestational age also requires further elaboration. Certainly all of these factors are related to survival at a given birth weight, yet incorporation of one or more of these into the initial screening process poses serious problems for this particular application. Conceptually, there are two general approaches to addressing these concerns. The first approach would require the inclusion of additional cells or categories for plurality, gestational age, or other factors within each race and birth weight category for the initial evaluation. A second approach would use further examination of these other factors only for hospitals which fail the initial screening process. The second approach was preferred because it provided for the development of a screening instrument from which additional evaluations and investigations can be generated. Problems of small numbers that are associated with doubling or tripling the number of categories or cells can be avoided with this approach.

A further refinement of adjusted mortality rates might be to exclude certain nonpreventable or unavoidable deaths. Various diagnostic categories and clinical conditions could be defined as nonpreventable. These categories might include all deaths under 500 grams, prehospital and antepartum demises, and congenital anomalies incompatible with life. Such exclusions would result in a more sensitive measure of potentially preventable mortality.

Valid and objective outcome information allows regulators to focus on patient care and patient outcomes. With outcomes as the prime focus, inputs and processes that are believed to be consistent with optimal care can be viewed as a means to

Table 2. Comparison of selected perinatal statistics of hospital A and Chicago for black infants, by birth weight; provisional data for 1981–83

Perinatal indicator	*Under 751 g*	*751–1,000 g*	*1,001–1,500 g*	*1,501–2,000 g*	*2,001–2,500 g*	*Over 2,500 g*	*Total*[1]
Fetal deaths	6	3	2	2	4	8	25
Live births	22	5	8	43	173	2,297	2,551
Hebdomadal deaths[2]	17	1	3	2	0	3	26
Neonatal deaths	18	3	4	3	1	7	36
Infant deaths	18	3	4	3	5	18	51
Perinatal deaths[3]	24	6	6	5	5	15	61
Hebdomadal rate:							
Hospital A	772.7	200.0	375.0	46.5	0.0	1.3	10.2
Chicago	790.4	255.6	63.9	17.9	4.6	1.8	12.1
Neonatal rate:							
Hospital A	818.2	600.0	500.0	69.8	5.8	3.0	14.1
Chicago	825.8	346.7	93.4	25.8	7.4	2.9	14.8
Infant rate:[4]							
Hospital A	818.2	600.0	500.0	69.8	28.9	7.8	20.0
Chicago	849.9	431.1	139.6	49.4	19.6	8.9	23.1
Perinatal rate:[5]							
Hospital A	857.1	750.0	600.0	111.1	28.2	6.5	23.7
Chicago	892.9	463.5	188.3	72.4	23.6	5.2	28.0

[1] Totals do not add because weights are not known for some events.
[2] Hebdomadal deaths include all deaths of liveborn infants in first 7 days.
[3] Neonatal + fetal deaths.
[4] Rates per 1,000 live births for hebdomadal, neonatal, and infant deaths.
[5] (Neonatal + fetal deaths) ÷ (Live births + fetal deaths) × 1,000.

an end. This approach is especially applicable if unsatisfactory outcomes exist alongside noncompliance with inputs and processes.

Further, the use of outcome measures allows for administrative and professional discretion to guide all actions. Unusual circumstances or conditions can result in apparently unsatisfactory outcomes unrelated to the quality of care and services. These circumstances and conditions can and must be examined more carefully than would be customary if only an initial screening process is employed. The criteria for further review, as well as the comparison standards and norms, are key elements left to the judgment of those directly responsible for such efforts. There is little doubt that integration of structure, process, and outcome standards provides for more complete and comprehensive information as to what is happening and why. It is important to note that this integral approach establishes a framework for additional investigation and possible remedial activities.

This integrated approach has already served to reverse at least one major public policy decision made earlier in Chicago, namely the elimination of Level I hospital and maternity newborn units. It is apparent that the system described in this paper would allow a hospital not fully complying with the previous Level II requirements to operate under waivers as long as outcomes are found to be satisfactory. This stance appears to be a complete reversal of earlier policy assumptions that improved outcomes would result from elimination of Level I units. Direct measurement of outcomes now provides public policy makers with more certainty in allowing for primary level services to continue if outcomes are demonstrably satisfactory.

The availability, reliability, and completeness of the birth and death record files undoubtedly make perinatal outcome surveillance an achievable end. Race- and birth weight-specific categories are especially well suited as a basis for comparison of outcomes in different institutions. Comparable data sets and methodologies have not been available for other hospital operating units. However, with the further refinement of tracer methodologies for specific clinical conditions, and development and implementation of diagnosis-related groupings for all hospitals, extension and expansion of outcome-oriented surveillance systems appear both plausible and promising in the near future.

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