Electronic Medical Record and Adherence to Guidelines for the Prevention of Group B Beta-hemolytic Streptococcus Disease in Neonates

By

Carmen Strickland, MD

A Master's Paper submitted to the faculty of
The University of North Carolina at Chapel Hill
In partial fulfillment of the requirements for
The degree of Master of Public Health in
The Public Health Leadership Program.

Chapel Hill

2004

Advisor

Second Reader

4/8/04

Date

Abstract

Background:

Group B beta-hemolytic streptococcal (GBS) disease causes significant neonatal morbidity and mortality in the United States. Universal screening and use of intrapartum prophylaxis for women identified to be at risk has been promoted through recent Centers for Disease Control (CDC) national guidelines. Despite the recommendation for universal screening, many women present in labor with unknown GBS status. Interventions that decrease rates of unknown GBS status may improve providers' ability to effectively implement the GBS prevention guideline.

Research Question:

Does electronic access to GBS screening results reduce the rates of both unknown GBS status and subsequent delivery of inappropriate care for the prevention of GBS disease?

Study Design:

A retrospective cohort study using data from an extensive perinatal database is described. Included subjects are women delivering babies at University of North Carolina (UNC) Women's Hospital between 1996 and 2003,

who received care at a university managed or affiliated prenatal care site. Rates of delivery of appropriate care based on GBS status are assessed and the effect of access to an electronic medical record on rates of inappropriate care is examined.

Results:

A total of 7102 births were eligible for assessment of adherence to GBS prevention guidelines. 28.3% of women had unknown GBS status and 24.8% of the entire sample received inappropriate care. Lack of an electronic medical record (EMR) was significantly associated with both a higher rates of both unknown GBS status (OR 1.54, 95%CI 1.34-1.71) and inappropriate care (OR 1.12, 95% CI 1.11-1.13).

Conclusions:

Results of prenatal GBS screening, required in order to correctly implement GBS preventive measures, are often missing on admission to the hospital for delivery. Access to an electronic medical record improves the ability of providers to maximize the protective effect of GBS prevention measures.

Background:

Group B Streptococcal disease (GBS)

Group B beta streptococcal (GBS) disease is the leading cause of preventable neonatal sepsis in developed countries, causing approximately 1600 illnesses and 80 deaths annually.[1] In 2002, the nationally projected rate of early-onset disease was 0.4/1,000 persons < 1 year of age.[2] Though the number of surviving infants is increasing, devastating neurologic damage often results in lifelong care needs.[3, 4] Ten to thirty percent of the population of child-bearing women are colonized with GBS in either the gastrointestinal or genitourinary tract.[5] Exposure to GBS occurs during labor as the neonate passes through the birth canal.[6] Early onset GBS disease typically manifests in the first 24-48 hours of life, presenting as pneumonia and, less frequently, as meningitis.[1]

GBS prevention guidelines

In 1996, based on evidence that the use of prophylactic antibiotics in at risk women during labor reduces the number of affected newborns, the Centers for Disease Control (CDC) published a national guideline for the prevention of GBS disease. This initial guideline promoted the identification of at risk women by either screening in the third trimester or assessment of risk factors during labor. In 2002, a prospective study comparing the two identification methods demonstrated greater reduction of affected neonates with universal screening.[7]

The CDC subsequently revised the guideline in 2002 to recommend that prenatal care providers screen all pregnant women at 35-37 weeks of pregnancy and administer prophylactic antibiotics during labor to all women with evidence of GBS colonization.[8]

Implementation of guidelines

Guidelines such as these published by the CDC are playing an increasingly important role in attempts to improve the quality of health care delivery in the U.S. ([9]) Implementation of guidelines is challenging, however, in the context of complex and varied care delivery systems. Research has identified a number of barriers to full implementation of guidelines. These include lack of provider knowledge or acceptance, lack of data required to follow the recommended algorithms, lack of access to diagnostic or treatment modalities, and inaccessibility. [10, 11]. In the absence of full adherence to recommendations, clinical practice often falls short of reaching desired goals; the case of GBS prevention provides a striking example.

Full implementation of the GBS prevention guideline involves the completion and integration of several distinct tasks. First, women receiving prenatal care must be screened between 35-37 weeks gestation. The results of this testing must be readily available when they present to labor and delivery. Finally, using outpatient GBS culture data, the inpatient provider must correctly institute therapy for women at risk. Rigorous assessment of adherence to this guideline,

then, requires evaluation of the degree to which each of these components is accomplished.

Assessment of GBS prevention guideline

The ultimate outcome of interest, rate of affected neonates, has been closely followed in the wake of the CDC guidelines, largely through the Active Bacterial Core Surveillance (ABCs) program.[1] Rates of intrapartum antibiotic prophylaxis to GBS + women, [12-15] rates of anaphylaxis and other maternal medical outcomes, [16-19]and effect of the new guidelines on length of hospital stay and rate of laboratory testing for neonates[7, 17, 20-24] have all been assessed. In addition, the CDC has followed the rates of adoption of the guidelines at both the provider and hospital level.[25] [26]

Fewer studies have rigorously assessed the specific processes associated with adherence to the guideline; the available data suggests that several components of the guideline leave room for substantial improvement in the delivery of care. [27, 28] Most notably, a 2003 multi-state study showed that, while 89% of GBS positive women received intrapartum antibiotic prophylaxis (IAP), screening results were documented in only 52% of pregnancies across an eight state surveillance area. This raises concern for a high rate (48%) of women whose GBS status remained unknown at the onset of labor. [29]

Potential of electronic medical record system to improve care

The methods by which GBS culture results are made available in the inpatient setting and rates of availability of this data have not been assessed, despite their importance in allowing for full guideline implementation. Clinical care of pregnant women is often shared between distinct prenatal and delivery care providers. Given the unpredictable timing of onset of labor, and fact that much of labor care is delivered during after hours, the systems in place for transferring updated prenatal information are often complex and time-intensive. Common strategies include repeated photocopying and faxing of prenatal records at weekly intervals during the last month of pregnancy. Under these circumstances, the potential for missing or lost data is significant, with implications for both overuse and underuse of IAP.

Shared Care

In shared clinical care systems, the electronic medical record (EMR) holds promise to improve outcomes by making data available across providers and geographic sites. Branger and colleagues implemented an electronic medical record among primary and specialty clinicians sharing the care of diabetic patients and demonstrated increased availability of data and slightly improved clinical outcomes.[30] More recently, electronic access to clinical data was studied in an emergency department (ED) setting. Researchers found a reduction in cost and improved physician satisfaction associated with enhanced access to clinical data.[31]

In the case of a patient admitted in labor, the presence of an electronic medical record system linking outpatient records with inpatient clinical care allows immediate access to accurate GBS results, thus reducing the likelihood of error in adhering to guidelines for GBS prevention. This study will test whether EMR access to GBS results is associated with a decreased number of women with an unknown GBS status at entry to labor and delivery and will look at the relationship between EMR access and rates of appropriate care. Implications regarding quality of care will be discussed.

(Addendum A: EMR and Improved Clinical Outcomes in Shared Care Settings: Review of the Literature)

Research Setting

The University of North Carolina Women's Hospital provides primary, secondary and tertiary obstetric services to pregnant women in eastern and central North Carolina. This large system comprises a number of outpatient prenatal care sites managed by the Departments of Obstetrics and Gynecology (OBGYN) or Family Medicine (FM). In addition, a number of independent sites providing prenatal care services are affiliated with UNC Hospitals (UNCH). These sites contract with the above departments for obstetric services for their patients and, as such, are subject to UNCH policies and procedures relating to pregnancy care. In all, 7 prenatal care sites are managed by the FM department, 16 by the OBGYN department, and 1 site has care delivered by both departments. The hospital

averaged approximately 2,600 deliveries/year between May 1996 and September 2003.

UNC Electronic Medical Record History

All outpatient sites providing prenatal care for patients delivering at UNC Women's Hospital use a paper medical record for prenatal care. Beginning in 1991, the University of North Carolina Hospitals adopted an electronic medical record known as the Clinical Information System (CIS). This system was used on Labor and Delivery from its inception. A subsequent transition to a web-based medical record system (WebCIS) occurred in April 2002. Results of laboratory tests performed at the UNC McLendon Laboratory have been available to clinicians via the electronic medical record since 1991 with the original CIS system. Through these systems, providers on the labor and delivery unit have had electronic access to any clinical data generated by the McLendon Laboratory since 1991.[32]

History of UNC GBS Prevention Policies

Three written policies for GBS prevention were identified from 1994-present. Since 1994, UNC has promoted a policy of universal screening of women for GBS colonization. Women have been identified as candidates for intrapartum antibiotic prophylaxis (IAP) if culture positive on screening between 33-37 weeks, if a urine culture was positive for GBS or if they had a positive

history of a previously affected newborn. All policies have advocated empiric treatment of women with unknown GBS status.[15, 33-35]

Suggested regimens for IAP at UNCH have shifted in accordance with changes in the CDC guidelines between 1996 and 2002. The 1998 UNCH report recommends penicillin G and ampicillin for IAP, and suggests clindamycin, or erythromycin for penicillin-allergic patients. The revised 2001 UNCH policy includes the above except erythromycin, and adds cefazolin for patients with mild penicillin allergies. In addition, vancomycin is listed for use in the setting of identified resistance to clindamycin for penicillin-allergic patients.

Methods

We developed a retrospective cohort study using the University of North Carolina (UNC) Department of OBGYN perinatal database. Since 1996, one to two full time employees have abstracted data from perinatal charts and maintained the database. They review all available antepartum and intrapartum records of women delivering at UNC Women's Hospital within approximately one week of discharge. Abstraction forms and protocols have been in place and unchanged since the inception of this database. Data has been primarily used to generate comprehensive discharge summaries for distribution back to referring physicians. [36, 37]

Study participants

The population studied included all women receiving care at prenatal care (PNC) sites either operated by or affiliated with UNC Hospitals who delivered at UNCH from April 1996 through September 2003. These PNC sites are all subject to UNCH policies and procedures regarding GBS prevention. Women referred from outside sites were excluded. Women were also excluded if they delivered at a gestational age of <37 weeks as they may not yet have been screened. Women delivered by elective or otherwise planned cesarean section were excluded as the CDC guideline for intrapartum antibiotic prophylaxis (IAP) use applies only to women who experience labor. Finally, women with an intrauterine fetal demise (IUFD) or terminating pregnancy for anomalies were also excluded, as were women whose deliveries occurred prior to admission. These exclusion criteria were applied to limit participants to women who were candidates to receive full implementation of the guidelines for GBS prevention.

For purposes of more clearly determining use of IAP intended for the prevention of GBS, a decision rule was developed to select a population of women whose antibiotic regimen likely represented IAP for GBS. Accordingly, women who received more than one antibiotic during labor were excluded. From the remaining women, those whose single antibiotic during labor was not one indicated for IAP according to the UNCH GBS or CDC prevention policies were excluded.

Demographic and Clinical Characteristic

The following demographic information was obtained: age, race, marital status, type of prenatal care site, and specialty management of prenatal care site (OBGYN or FM). Clinical data included parity (dichotomized into primiparous, multiparous), estimated gestational age at delivery (in weeks), APGAR scores at 1 and 5 minutes, neonatal death, type of delivery (vaginal, cesarean) and birthweight. Results of GBS screening were coded as positive or negative and cases with missing values were coded as unknown. Use of an antibiotic during labor was treated as a categorical variable (none, a specific IAP antibiotic) and subsequently dichotomized into GBS intrapartum antibiotic prophylaxis administered or not.

Independent variables

Access to lab result via electronic record was used as the primary independent variable. For each prenatal care site, laboratory services have been provided by either UNC McLendon Laboratory or by an independent commercial laboratory.[38] McLendon laboratory results have been automatically available in the UNC electronic medical record since 1991.[39] For each birth, based on prenatal care site, access to laboratory results via the electronic record was dichotomized.

Outcome measures

A dichotomous outcome describing use and nonuse of IAP during labor as appropriate or inappropriate was applied using decision rules from the UNC

School of Medicine GBS prevention guideline (approved 5/30/01, revised 10/02). Intrapartum antibiotic prophylaxis was defined as use of a single IAP antibiotic during labor. Appropriate care included use of IAP for women who had a GBS positive screen, met criteria for automatic prophylaxis or had unknown GBS status. Appropriate care also included withholding IAP for women with negative GBS screening tests. Women for whom these conditions were met were combined into the appropriate care category.

Inappropriate care included non-use of IAP for women who had a GBS positive screen, met criteria for automatic prophylaxis, or had unknown GBS status. Use of IAP in women with negative GBS screening tests was also considered inappropriate care.

Statistical analysis

Descriptive statistics were used to characterize the study sample. Categorical variables were compared using the chi-square statistic. T-tests were used to test for differences in the means for continuous variables. Odds ratios were calculated to assess the strength of significant associations. For all statistical tests, significance was set at 0.05 using two-tailed tests. All analyses were performed using SPSS statistical software. (SPSS 11.5 for Windows)

Study Approval

The UNC SOM institutional review board approved this study and a HIPAA waiver of informed consent was granted.

Results:

Study Population

Data were available for 18,652 births. Application of all exclusion criteria reduced eligible births to 8,426. (Figure 1) Of these, a further 1,324 were excluded for missing drug data or multiple antibiotic administration, leaving 7,102 cases for the final analysis. (Figure 2)

The mean age of the sample was 26 years. Women in the sample were white (40.1%), Hispanic (35.3%), or black (20.5%) with 4.2% identified as other/unspecified for racial or ethnic group. Just under half of the women in the sample were married and 43.7% were primiparous. Vaginal delivery was documented for 90% of the sample. Most of the prenatal care was provided in the UNC OB sites, community health centers, or local health departments. Mean birthweight for this sample of women with term deliveries was 3407 grams. Electronic laboratory record access was available to providers of 48.4% (n= 3436) of women in the sample. (Table 1)

Rates of GBS status and inappropriate care

In the study sample, 19.4% of women were GBS positive, 52.3% GBS negative and 28.3% of the sample had unknown GBS results. Approximately one third of the sample received IAP. Overall, one quarter of the sample received inappropriate care (n=1761). The rate of inappropriate care was highest among women with unknown GBS status (60.1%). Known GBS positive and GBS

negative women had low rates of inappropriate care (8.7% and 8.1%, respectively). (Figure 2)

Factors associated with rates of GBS status and inappropriate care

Lack of electronic laboratory record access was associated with an increased rate of inappropriate care (OR=1.12, 95% CI 1.11-1.13). Bivariate analysis demonstrated a significantly increased risk for unknown GBS status in the setting of no EMR access (OR= 1.54, 95%CI 1.34-1.71). Relative to women with known positive GBS results, OR for inappropriate care in women with unknown GBS status was 8.70 (95% CI 7.14-10.00).

Discussion:

Rate of unknown GBS status

One quarter of women eligible for GBS prophylaxis at this single, large academic institution between 1996 and 2003 received inappropriate care relative to the current institutional guideline for the prevention of GBS disease. Twenty-eight percent of this sample had an unknown GBS status. This rate is expected to underestimate the actual rate of unknown status in the general population of women presenting to UNCH in labor. Since data is abstracted several days after admission, allowing time for chart retrieval, greater availability of results than observed at the time of admission is anticipated. Rates of unknown status as high as 48% in unselected populations have been reported previously.[29] The high rate of unknown GBS status demonstrated in this population clearly poses an important barrier to full implementation of GBS prevention guidelines.

Explanations for an unknown GBS status on admission to labor and delivery include lack of screening and lack of available results to the inpatient provider. The data did not allow for a direct assessment of these subsets. In this population of women at gestational age >37 weeks, the likelihood of prenatal screening is optimized. We believe that poor availability of GBS screening results on labor and delivery explains the high rate of unknown GBS status.

In practice, labor and delivery providers' access to patients' GBS results is limited under two circumstances. First, prenatal care providers may not clearly and accurately document the result in the prenatal chart. Second, hospital providers may not have access to a copy of the prenatal chart. For patients with laboratory data directly entered into an EMR, a backup system exists to overcome both of these obstacles. The fact that EMR access was associated with a lower rate of unknown status supports our clinical experience that unknown GBS status results primarily from limitations in data availability rather than from lack of screening.

Rate of inappropriate care

Unknown GBS status was strongly associated with receipt of inappropriate care. Compared to women with positive GBS cultures, women with an unknown GBS result were eight times as likely to receive inappropriate care, defined as lack of IAP under UNCH policy. Rates of inappropriate care were much lower among women with either positive or negative results.

The 1996 CDC guideline and subsequent 2002 revision promote treatment of women with unknown GBS status based on an assessment of risk factors at the time of labor. Risk factors include maternal temperature greater than or equal to 100.4, rupture of membranes greater than 18 hours, and fetal prematurity. The presence of risk factors was not analyzed for this project since UNCH GBS prevention policies have promoted a more conservative approach, recommending empiric treatment of all GBS unknown women.

Effect of EMR access on delivery of care

Our hypothesis, that access to GBS results in an EMR would decrease the rate of women receiving inappropriate care was supported in this analysis. The strong relationship between EMR access and lower rates of unknown GBS status suggests a primary mechanism through which EMR access affects the rate of inappropriate care. Information on specific systems of prenatal record data transfer from the included PNC sites to the hospital was not available for this project. It is possible that site-specific systems play a similarly large role in determining the rate of women with unknown GBS status.

Strengths

The high quality of the data analyzed in answering the research question lends great strength to this study. The data is felt to be truly representative of the population and services provided for several reasons. At this institution, data have been collected by a total of 5 trained full time employed abstractors over the

6-year study period, using a standardized protocol.[40] Data collection occurs at the point of service on an ongoing basis, decreasing chances for error or missing data. The large number of cases increases the power to detect differences. The use of data from a single institution decreases error due to heterogeneous clinical protocols and practices for GBS prevention. Last, the nature of the fixed relationships between practices and laboratory services is such that the presence or absence of access to electronic laboratory results is clear.

In addition, the number of conservative assumptions made in case selection and subsequent analysis strengthens results. The likelihood for bias has been greatly reduced by eliminating cases not eligible for full implementation of screening and treatment according to the guideline.

Considerations

GBS status

In the process of data abstraction, GBS status was not derived directly from or checked against actual laboratory results. Instead, GBS status was determined from either the prenatal record laboratory results section, or from inpatient admission notes in which GBS status is almost universally noted.[36] In cases where the prenatal record had no documented GBS result but laboratory results are electronically available, (prenatal care source is affiliated with the UNC McLendon Laboratory), providers are able to access the result and document the woman's GBS status in the admission note. As such, GBS results for women with electronic access reflect both accurately documented, available

results of screening as well as undocumented, but electronically available results. This specific aspect of data collection allows for an accurate assessment of the effect of EMR access on rate of unknown GBS status.

One further note relating to GBS status is that the coding for this variable does not allow a separate category for women meeting predefined criteria for IAP prophylaxis (GBS bacteruria, previous GBS-affected neonate). Women meeting these criteria automatically receive IAP and do not require GBS cultures in the third trimester. When documentation in the prenatal and inpatient records for these women clearly indicates the anticipated need for GBS prophylaxis, even in the absence of GBS cultures, they are classified as GBS positive in the dataset.[36] Since these women are ultimately classified as either positive or unknown, with the same recommendation of IAP, final analysis of appropriate care is unaffected.

Bias may have been introduced in the delineation of medication regimens consistent with intrapartum antibiotic prophylaxis. Medication administration is well documented in the database but indications for medical therapy are left to interpretation. Both the CDC and UNCH guidelines have advocated only single antibiotic regimens for the prophylaxis of GBS disease. As such, women receiving multiple antibiotics during labor were excluded.

The potential exists for missed cases of appropriately treated women in the setting of both GBS risk and a concurrent infectious process requiring treatment. Any such bias would serve to diminish our ability to detect a difference between those receiving appropriate and inappropriate care. Given the absence of any

intrapartum infectious process routinely treated with a single agent, and the fact that differential misclassification of these women based on EMR access is unlikely, the risk of serious confounding is low.

Last, further analysis of any significant differences between patients with EMR access and those without would allow an understanding of any additional factors that could confound our results.

Conclusion

This study adds to our understanding of the need to assess processes associated with the implementation of guidelines. One goal of any GBS prevention effort is to minimize the number of women with unknown GBS status at the time of labor in order to maximize benefit and limit risk for both women and their newborns. Maternity care systems characterized by high rates of unknown GBS status face important challenges to both the quality and cost of care.

We have identified a high rate of unknown GBS status at a large academic center with multiple external sites referring patients for delivery. Future efforts to track rates of unknown status in a variety of settings and to better understand systems that support the availability of accurate GBS results in the hospital are essential. Rates of GBS unknown status were reduced in the setting of access to an EMR. EMR access was also associated with lower rates of inappropriate care. Expansion of EMR availability to surrounding outpatient sites is currently being considered at UNCH. Prospective assessment of outcomes such as those

examined in this study at individual PNC sites before and after instituting EMR access is recommended to further our understanding of the effect of this intervention.

A growing body of research seeks to demonstrate clinical benefit associated with technologies such as electronically available clinical data. Shared care settings in which multiple providers require access to the same clinical data are uniquely suited to demonstrate the potential benefit of EMR access. Rigorous assessment of such technologies faces substantial challenges given the tremendous resources involved in developing such systems, and the difficulty in creating settings for randomized, controlled trials.[41] Settings such as that described for this study may provide practical opportunities to better understand the impact of EMRs. Future prospective study should consider the even greater potential effect of computerized decision support in which electronic clinical data is linked in real time with recommendations for care from accepted guidelines.

Acknowledgements

The author would like to thank Carol Porter for her assistance with the database, Chris Bowes and Kris Silver for their clarification of the data abstraction process, Dennis Rodriguez for his work in managing the database, Merry K Moos for invaluable historical information regarding UNCH policies for

GBS prevention, Jon Hussey, MPH for assistance with data analysis and Valerie King, MD, MPH, for her assistance in the development of the project.

Figure 1.

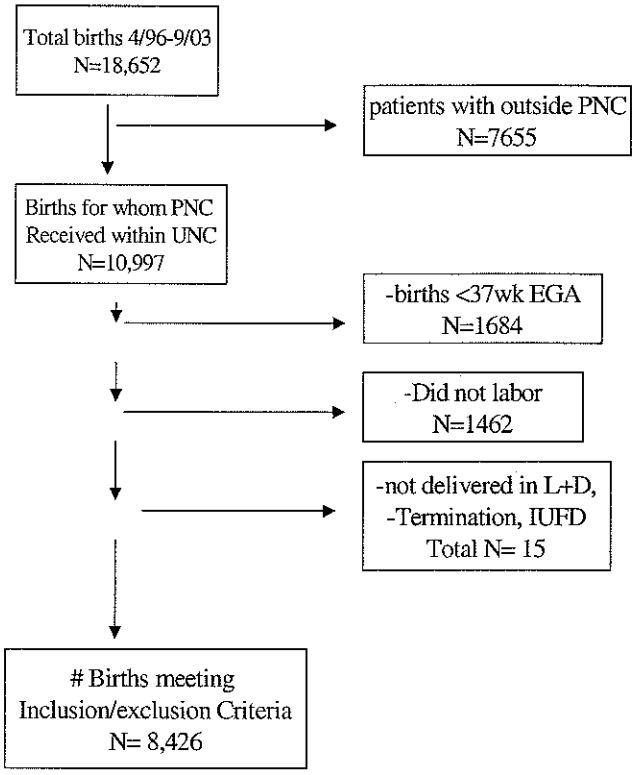
Total births 4/96-9/03
N=18,652
patients with outside PNC
N=7655
Births for whom PNC
Received within UNC
N=10,997
-births <37wk EGA
N=1684
-Did not labor
N=1462
-not delivered in L+D,
-Termination, IUFD
Total N= 15
Births meeting
Inclusion/exclusion Criteria
N= 8,426

Figure 2.

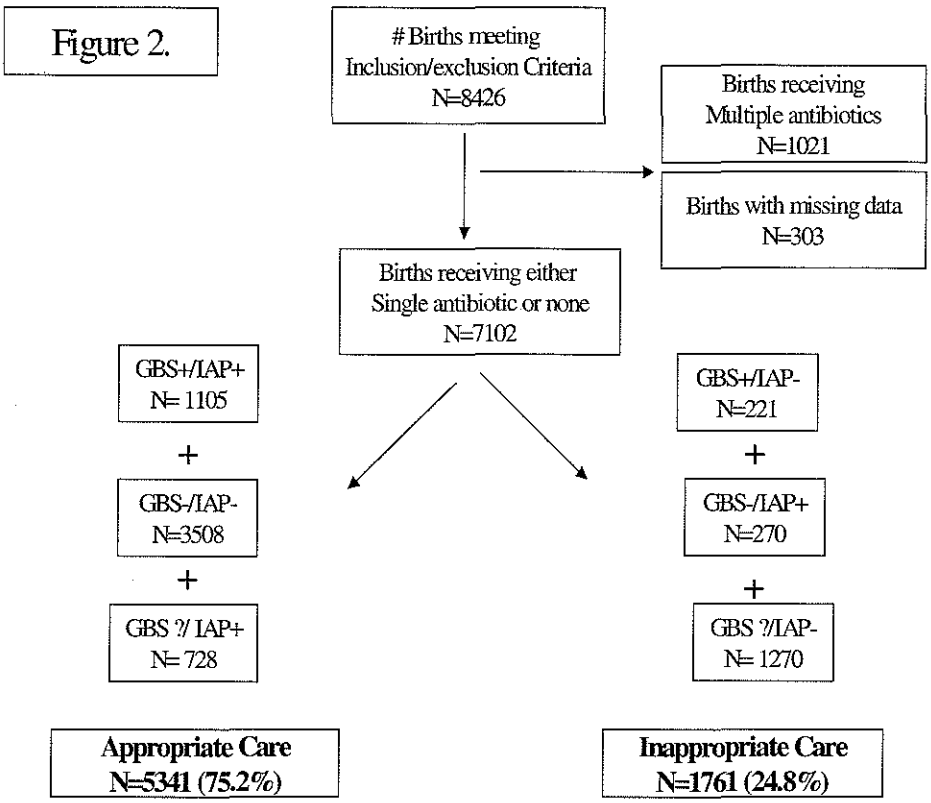
Births meeting Inclusion/exclusion Criteria N=8426
Births receiving Multiple antibiotics N=1021
Births with missing data N=303
Births receiving either Single antibiotic or none N=7102
GBS+/IAP+ N= 1105
+
GBS-/IAP- N=3508
+
GBS ?/ IAP+ N= 728
GBS+/IAP- N=221
+
GBS-/IAP+ N=270
+
GBS ?/IAP- N= 1270
Appropriate Care N=5341 (75.2%)
Inappropriate Care N=1761 (24.8%)

Table 1. Demographics

	Appropriate Care N= 5341 (75.2%)		Inappropriate Care N=1761 (24.8%)		Total N=7201
Age (years)	26.15		26.06		
<20	802	(74.5)	274	(25.5)	1076
20-35	4152	(74.5)	1350	(25.5)	5502
> 35	386	(73.8)	137	(26.2)	523
Race					
White	2110	(74.1)	735	(25.9)	2845
Black	1068	(73.5)	386	(26.5)	1454
Hispanic*	1931	(76.9)	577	(23.1)	2508
Other	232	(78.6)	63	(21.4)	295
Marital Status (%single)*#	2350	(73.7)	838	(26.3)	3188
Parity (% primiparous)*	2375	(76.4)	730	(23.6)	3105
Type of Delivery					
Total vaginal deliveries	4887	(76.2)	1525	(23.8)	6412
Total Cesarean section	454	(65.8)	236	(34.2)	690
Specialty of PNC site *					
FM	556	(69.1)	249	(30.9)	805
OB	4785	(75.9)	1512	(24.1)	6297
Gestational Age at Delivery (mean weeks)**	39.36		39.13		
Birthweight (grams)*	3419.02		3372.35		
APGAR 1	7.99		8.03		
APGAR 5	8.84		8.85		
Neonatal Death/Stillborn-combined (%)	6	(75)	2	(25)	8

* Indicates statistically significant at the 0.05 level
** sample includes GA≥ 37 weeks
# N= 7087

Table 2. GBS status by EMR access

	GBS known (+ or -)	GBS unknown
EMR access	2622	814
No EMR access	2482	1184

OR for unknown GBS (no EMR/EMR)
$\frac{1184/814}{2482/2622} = 1.54$ (CI 1.34-1.71)

Table 3. Type of Care by GBS status

	Appropriate Care		Inappropriate Care		Total	OR for appropriate care (95% CI)
GBS positive	1105	(83.3)	221	(16.7)	1326	1
GBS negative	3508	(92.9)	270	(7.1)	3778	2.60 (2.15- 3.14)
GBS unknown	728	(36.4)	1270	(63.6)	1998	0.12 (0.10-0.14)
Total	5341	(75.2)	1761	(24.8)	7102	

Appropriate care for GBS unknown relative to positive:
OR= 0.115, 95% CI 0.10-0.14
Inappropriate care for GBS unknown relative to positive:
OR= 8.69, 95% CI 7.14-10.00

Table 4. IAP use by GBS status

	IAP	No IAP	Total
GBS positive	1211 (91.3%)	115 (8.7%)	1326
GBS negative	306 (8.1%)	3472 (91.9%)	3778
GBS unknown	797 (39.9%)	1201 (60.1%)	1998
Total	2314 (32.6%)	4788 (67.4%)	7102

Table 5. Type of care by EMR access

	Appropriate Care	Inappropriate Care
EMR access	2621	815
No EMR access	2720	946
Total	5341 (75.2%)	1761 (24.8%)

OR for inappropriate care (no EMR/EMR)
946/2720 x 2621/815
= 1.12, 95% CI = 1.11-1.13

Addendum

EMR and Improved Clinical Outcomes in Shared Care Settings: Review of Literature

Information technology has been touted as one means by which error in the U.S. health care system can be dramatically reduced. The potential for wider dissemination and use of evidence-based guidelines and the associated impact on clinical outcomes has received increasing attention in recent years with mixed results.[42] At the level of individual patient care, improving the accuracy of and access to data in the medical record are important goals. Limitations of paper medical records have been demonstrated.[43, 44] Electronic medical records (EMRs) may enhance patient care by putting more organized, easy to access clinical data in the hands of providers. [44, 45] To date, however, evidence of actual clinical benefit linked to the use of an EMR is limited.

The potential added utility of an EMR in directly linking providers sharing the care of an individual patient has been explored in several areas of medical practice. Given the increasingly fragmented nature of medical care in the U.S., this potential for benefit deserves rigorous assessment. A review of the literature yielded a limited number of studies attempting to assess the value of an electronic record system to patients and providers in the setting of shared medical care.

Shared Care: Diabetes

In 1999, Branger, et al reported results of a non-randomized controlled trial conducted in the Netherlands over a one year period assessing the impact

of improved communication between general practitioners (GPs) and specialists in the care of diabetic patients [30]. The intervention consisted of an inter-physician communication feature added to a pre-existing electronic medical record system. Control GPs communicated with specialists by the traditional paper-based manner. The primary outcome of interest was the number of messages exchanged by the providers. In addition, documentation of a number of diabetes parameters in the medical record was measured and hemoglobin A1C levels were compared as a clinical outcome measure.

Results of this study showed a significant increase in messages between providers (in both directions), over the study period. They also showed significantly more data in the patient record for 6 of 10 diabetes parameters. Comparison of the mean differences in HgbA1C did not yield a significant difference between intervention and control groups. Several features of the study design limit interpretation of results. Most notably, the non-random selection of intervention and control groups introduces bias that may lead to an overestimate of effect since intervention GPs were identified by higher numbers of referred diabetics and may have provided care differently. The authors, however, used an analysis of covariance allowing for a distinction to be made between effects due to baseline differences and those due to exposure to the intervention.

The short study period and small number of diabetic patients with HgbA1C testing in the pre and post intervention periods (intervention, n=123, control n= 32) may have limited the power of this study to demonstrate a

difference in mean HbgA1C levels. Despite the lack of benefit in clinical outcomes, this study is important in demonstrating improved process outcomes as a result of an electronic system for sharing data among providers.

Shared Care: Emergency Departments

The emergency room provides an example of another care system in which access to important clinical data is often limited. Two papers have originated from Wishard Memorial Hospital and Health Services (Wishard) at Indiana University using the Regenstrief Medical Record System (RMRS) to assess the impact of electronic access to patient data on both processes and outcomes of care. The first, in 1982, demonstrated that internists caring for patients in an inner-city hospital emergency department (ED) order fewer laboratory tests when given a printed summary of clinical data from that hospital compared with when they did not receive this summary.[46].

Recently, Overhage, et al completed a randomized controlled trial to more rigorously assess the hypothesis that improving emergency physician's access to clinical information from another institution would result in less expensive evaluations and improved quality and efficiency of care. This pilot study is part of the larger Indianapolis Network for Patient Care (INPC) project whose goal is to link 12 of 14 EDs and hospitals in Indianapolis via the RMRS to improve access to patients' clinical data. [31]

From 1995-1996, data from the RMRS was made available to physicians in the ED at two different local hospitals. Upon patient registration

in the ED, an electronic copy of the face sheet was sent to the RMRS and the presence of a match in the database was determined. Patients identified as matches were randomized (by random number generator) to intervention or control, notification of eligibility for the study was sent back to the ED, and the patient was consented for entry into the trial.

For intervention patients at either ED, physicians had access to RMRS data by two means. A printed clinical abstract generated from the most recent data in the RMRS was attached to the patient's chart in the ED for review. Direct online access for 24 hours was also available for physicians caring for intervention patients. For control patients, the computer generated an "empty" clinical abstract to signal that the patient's registration had been received.

The primary outcome of interest was mean ED charge for a single encounter. In addition, researchers measured the ordering rates for several specific laboratory tests and assessed the frequency of hospital admission. Last, a physician survey questionnaire was administered to assess perceptions of the system.

The authors demonstrated a statistically significant reduction in charges by $26 per encounter at one of the two hospitals. The other hospital showed no difference in mean charges. They observed no difference in ordering rates of laboratory tests, or hospital admission between intervention and control patients. The response rate for the survey was 50%. Seventy percent of respondents indicated that they would "like to receive a printed summary for all patients". Less than 0.5% of encounters at each study hospital

were associated with online access. Almost half of respondents cited forgetting their password and the time required to search for information as the top two barriers to use of the online system.

That this well-conceived study of the effect of electronic access to clinical data did not yield notable differences between intervention and control patients is disappointing. A number of limitations in study processes may explain the absence of effect; they provide valuable examples of difficulties that need to be overcome in future studies.

First, and most significant, is the context in which the study was performed. The authors note that the primary medical record at both hospitals is a traditional paper chart and that this was rarely retrieved in either location for ED care. Limited online resources for clinical data were available to physicians at the two hospitals and few physicians made use of them. Use of an electronic system for access to patient data in this setting would represent a striking change in work practice for these physicians. The short time frame for this project further limits physician familiarity and comfort with such a new and different system.

Barriers to use of online access such as forgotten passwords and time required to locate desired data would be substantially reduced if the time period for the study were extended. Similarly, if the study occurred in a setting characterized by greater familiarity with use of electronic clinical data, results may have differed substantially.

In addition to contextual issues, the exact processes comprising the study protocol were not fully implemented, particularly at one of the two hospital sites. Printed abstracts were not available to physicians in 39% of cases at Methodist for a variety of reasons including difficulty using the printer and human error in attaching to the chart.

The potential utility of shared electronic clinical data for patients receiving care across institutions is highlighted by data collected during the course of this study. Researchers report that more than 32,000 patients seen at the two study sites had data available in the RMRS system for more than 50,000 encounters during the study year. Moreover, 6% of these patients visited more than one ED during that single year.

Shared Care: GBS Prevention

Implementation of GBS prevention guidelines in most settings requires shared care between an outpatient prenatal care site and an inpatient labor and delivery setting. Even if a single provider is involved across the two settings, access to the patient's clinical data is often compromised in the setting of a paper record system by time and labor intensive processes required to transfer paper records. The use of an electronic record with shared access across sites may improve the accuracy of GBS status awareness with subsequent improvement in the delivery of care according to the guideline. This effect has yet to be rigorously assessed in trials.

A report from a large West Coast HMO, in which an automated system is likely to link outpatient and inpatient components of care, could provide an example of an efficacy trial of guideline implementation. Unfortunately, the goals in this paper were to assess the rates of implementation and important data (GBS unknown/negative rate and numbers associated with IAP use in all GBS categories) are not provided. [17]

Bibliography

1. *From the Centers for Disease Control and Prevention: early-onset group B streptococcal disease--United States, 1998-1999.* Jama, 2000. **284**(12): p. 1508-10.
2. Schuchat, A., et al., *Active bacterial core surveillance of the emerging infections program network.* Emerg Infect Dis, 2001. **7**(1): p. 92-9.
3. *Prevention of perinatal group B streptococcal disease: a public health perspective. Centers for Disease Control and Prevention.* MMWR Recomm Rep, 1996. **45**(RR-7): p. 1-24.
4. Logsdon, B.A. and D.T. Casto, *Prevention of group B Streptococcus infection in neonates.* Ann Pharmacother, 1997. **31**(7-8): p. 897-906.
5. Regan, J.A., M.A. Klebanoff, and R.P. Nugent, *The epidemiology of group B streptococcal colonization in pregnancy. Vaginal Infections and Prematurity Study Group.* Obstet Gynecol, 1991. **77**(4): p. 604-10.
6. Regan, J.A., et al., *Colonization with group B streptococci in pregnancy and adverse outcome. VIP Study Group.* Am J Obstet Gynecol, 1996. **174**(4): p. 1354-60.
7. Schrag, S.J., et al., *A population-based comparison of strategies to prevent early-onset group B streptococcal disease in neonates.* N Engl J Med, 2002. **347**(4): p. 233-9.
8. Schrag, S., et al., *Prevention of perinatal group B streptococcal disease. Revised guidelines from CDC.* MMWR Recomm Rep, 2002. **51**(RR-11): p. 1-22.
9. Woolf, S.H., *Practice guidelines: a new reality in medicine. I. Recent developments.* Arch Intern Med, 1990. **150**(9): p. 1811-8.
10. Wolff, M., et al., *US family physicians' experiences with practice guidelines.* Fam Med, 1998. **30**(2): p. 117-21.
11. Keffer, J.H., *Guidelines and algorithms: perceptions of why and when they are successful and how to improve them.* Clin Chem, 2001. **47**(8): p. 1563-72.
12. Cheon-Lee, E. and M.S. Amstey, *Compliance with the Centers for Disease Control and Prevention antenatal culture protocol for preventing group B streptococcal neonatal sepsis.* Am J Obstet Gynecol, 1998. **179**(1): p. 77-9.
13. Hafner, E., et al., *Group B streptococci during pregnancy: a comparison of two screening and treatment protocols.* Am J Obstet Gynecol, 1998. **179**(3 Pt 1): p. 677-81.
14. Schuchat, A., et al., *Integrated monitoring of a new group B streptococcal disease prevention program and other perinatal infections.* Matern Child Health J, 2002. **6**(2): p. 107-14.
15. Katz, V.L., et al., *Group B streptococci: results of a protocol of antepartum screening and intrapartum treatment.* Am J Obstet Gynecol, 1994. **170**(2): p. 521-6.

16. Gilson, G.J., et al., *Prevention of group B streptococcus early-onset neonatal sepsis: comparison of the Center for Disease Control and prevention screening-based protocol to a risk-based protocol in infants at greater than 37 weeks' gestation.* J Perinatol, 2000. **20**(8 Pt 1): p. 491-5.
17. Davis, R.L., et al., *Introduction of the new Centers for Disease Control and Prevention group B streptococcal prevention guideline at a large West Coast health maintenance organization.* Am J Obstet Gynecol, 2001. **184**(4): p. 603-10.
18. Dunn, A.B., J. Blomquist, and V. Khouzami, *Anaphylaxis in labor secondary to prophylaxis against group B Streptococcus. A case report.* J Reprod Med, 1999. **44**(4): p. 381-4.
19. Locksmith, G.J., P. Clark, and P. Duff, *Maternal and neonatal infection rates with three different protocols for prevention of group B streptococcal disease.* Am J Obstet Gynecol, 1999. **180**(2 Pt 1): p. 416-22.
20. Pylipow, M., M. Gaddis, and J.S. Kinney, *Selective intrapartum prophylaxis for group B streptococcus colonization: management and outcome of newborns.* Pediatrics, 1994. **93**(4): p. 631-5.
21. Wiswell, T.E., B.J. Stoll, and J.M. Tuggle, *Management of asymptomatic, term gestation neonates born to mothers treated with intrapartum antibiotics.* Pediatr Infect Dis J, 1990. **9**(11): p. 826-31.
22. Mercer, B.M., R.D. Ramsey, and B.M. Sibai, *Prenatal screening for group B Streptococcus. II. Impact of antepartum screening and prophylaxis on neonatal care.* Am J Obstet Gynecol, 1995. **173**(3 Pt 1): p. 842-6.
23. Peralta-Carcelen, M., et al., *Impact of maternal group B streptococcal screening on pediatric management in full-term newborns.* Arch Pediatr Adolesc Med, 1996. **150**(8): p. 802-8.
24. Fargason, C.A., Jr., et al., *The pediatric costs of strategies for minimizing the risk of early-onset group B streptococcal disease.* Obstet Gynecol, 1997. **90**(3): p. 347-52.
25. *From the Centers for Disease Control and Prevention. Adoption of perinatal group B streptococcal disease prevention recommendations by prenatal-care providers--Connecticut and Minnesota, 1998.* Jama, 2000. **283**(18): p. 2384-5.
26. *From the Centers for Disease Control and Prevention. Adoption of hospital policies for prevention of perinatal group B streptococcal disease--United States, 1997.* Jama, 1998. **280**(11): p. 958-9.
27. Nemunaitis-Keller, J. and P. Gill, *Limitations of the obstetric group B Streptococcus protocol.* J Reprod Med, 2003. **48**(2): p. 107-11.
28. Brozanski, B.S., et al., *Effect of a screening-based prevention policy on prevalence of early-onset group B streptococcal sepsis.* Obstet Gynecol, 2000. **95**(4): p. 496-501.
29. Schrag, S.J., et al., *Prenatal screening for infectious diseases and opportunities for prevention.* Obstet Gynecol, 2003. **102**(4): p. 753-60.

30. Branger, P.J., et al., *Shared care for diabetes: supporting communication between primary and secondary care.* Int J Med Inf, 1999. **53**(2-3): p. 133-42.
31. Overhage, J.M., et al., *A randomized, controlled trial of clinical information shared from another institution.* Ann Emerg Med, 2002. **39**(1): p. 14-23.
32. Thompson, K., *History of electronic medical record at UNC.* 2004: Chapel Hill, NC. p. Information Systems Department.
33. *UNC Group B Beta Strep Ambulatory Protocol.* 1994, University of North Carolina Hospital: Chapel Hill, NC.
34. McMahon MJ, M., MK, *Reducing the Risk of Early-Onset Neonatal Group B Streptococcal Infection.* 1998, University of North Carolina Hospital: Chapel Hill, NC.
35. *GBS Algorithm.* 2001, University of North Carolina at Chapel Hill School of Medicine: Chapel Hill, NC.
36. Bowes, C., *Department of OBGYN, UNCH.* 2004: Chapel Hill, NC. p. Abstraction of perinatal data.
37. Silver, K., *Department of OBGYN, UNC.* 2004: Chapel Hill, NC. p. Perinatal database data entry.
38. Learning, L., *Information Systems Department, UNCH.* 2004: Chapel Hill, NC. p. Access to McLendon Laboratory results.
39. Morris, D., *Information Systems Department, UNCH.* 2004: Chapel Hill, NC. p. Availability of McLendon Laboratory results in WebCIS.
40. *OB Database Procedure Manual.* 1996.
41. Tierney, W.M., J.M. Overhage, and C.J. McDonald, *Demonstrating the effects of an IAIMS on health care quality and cost.* J Am Med Inform Assoc, 1997. **4**(2 Suppl): p. S41-6.
42. Sintchenko, V., et al., *Comparative impact of guidelines, clinical data, and decision support on prescribing decisions: an interactive web experiment with simulated cases.* J Am Med Inform Assoc, 2004. **11**(1): p. 71-7.
43. Deeb, L.C., et al., *Interventions among primary-care practitioners to improve care for preventable complications of diabetes.* Diabetes Care, 1988. **11**(3): p. 275-80.
44. Tang, P.C., M.P. LaRosa, and S.M. Gorden, *Use of computer-based records, completeness of documentation, and appropriateness of documented clinical decisions.* J Am Med Inform Assoc, 1999. **6**(3): p. 245-51.
45. Hippisley-Cox, J., et al., *The electronic patient record in primary care--regression or progression? A cross sectional study.* BMJ, 2003. **326**(7404): p. 1439-43.
46. Wilson, G.A., C.J. McDonald, and G.P. McCabe, Jr., *The effect of immediate access to a computerized medical record on physician test ordering: a controlled clinical trial in the emergency room.* Am J Public Health, 1982. **72**(7): p. 698-702.