Aggregated Complication Measure for Neonatal Quality of Care. R40 MC 05474
Final report

I. Introduction

A. Nature of the research problem

Every year in the United States, over 57,000 infants are born at least two months premature. Many of these infants die or are severely disabled as a result of their prematurity. While some outcomes are an unavoidable consequence of prematurity, increased cost and long-term disabilities associated with chronic conditions such as cerebral palsy, mental retardation, and asthma may result from the care these infants received in the neonatal intensive care unit (NICU). Differences in the quality of care delivered by hospitals should explain much of the variation in short and long-term outcomes of these infants. However, no validated measure of neonatal quality of care has been developed or consistently used by state agencies and public health organizations, particularly for the older premature infants who encompass the majority of admissions to any NICU. With the increase in the deregionalization of care for these infants, more of the intensive care to premature infants is being provided at smaller community hospitals and without a validated, easy-to-use measurement of neonatal quality, premature infants in this current environment are at increased risk of receiving suboptimal quality of care, resulting in increased costs and long-term disability.

B. Purpose, scope, and methods of investigation

This project developed, and validated a quality measurement that has sufficient power to assess the quality of care for all premature infants cared for at a given hospital. This measure, the "aggregate complication measure" (ACM), is easy to calculate using data typically collected by state and local agencies; it combines individual complications into a single measure based on the impact each complication has on one of a number of well established outcomes; it is adjusted for differences in the severity of illness using direct standardization methods; and it reflects the frequency and severity of complications occurring at the hospital.

This study initially was designed to use a retrospective cohort design on the population of infants delivered in Pennsylvania, California, or New York between 1993 and 2003. It includes information on older premature infants who are not typically included in databases such as the Vermont Oxford Network. This multi-state, population-based cohort study offers the strongest design to fulfill the specific aims of this project. However, New York data were not available during the time frame listed above. Thus, Missouri was substituted for New York in this analysis. Also, additional data from 2004-2005 were available from California and Pennsylvania to improve the power of the study. In the end, infants from 621 hospitals were included in this study; 347 delivered more than 50 premature infants over the time frame of the study.

The eligible population is all infants with a gestational age $\leq$ 37 weeks, whose mothers reside and deliver in Pennsylvania, California, or New York. The population of each state has a diverse ethnic and socioeconomic background that allows for further analysis of our results after stratification by race or socioeconomic status. Infants were excluded from the study if they were transferred to a NICU outside of one of these three states prior to discharge. These three states were chosen because of their large populations and presence of many major academic medical centers.

C. Nature of the findings

II. Review of the literature

The literature revealed that many commonly used measures of neonatal quality do not meet the characteristics of an ideal outcome measure as we listed them in the grant proposal. Mortality rate, the most commonly used measure, is of limited utility because of low baseline rates in many hospitals, the few studies that show an association between high mortality rates and "poor quality hospitals" , and regional variations in the definition of a live birth. Rates of individual complication have been used in prior studies as a measure of quality when mortality is rare. However, many of the "common" neonatal complications suffer from small numbers, particularly at individual hospitals, and the hospitals' rank orders vary between different complications. Neurodevelopmental outcome is poorly recorded in administrative data and influenced by the care received by the infant after discharge from the NICU. Finally, none of these measures focus on conditions that are prevalent in infants born at gestational ages between 32 and 36 weeks.

III. Study Design and Methods

A. Study Design

In the conceptual model for this project is the location of treatment determines the quality of care received by the neonate. The quality of care, in turn, helps determine the ultimate outcome of the infant. When many infants are treated at each hospital, we can use the interhospital variation in these outcomes as a surrogate marker for the quality of care received by the children at each individual hospital. In order for this model to hold true, we must first control for factors other than quality that may influence outcome. These factors include baseline characteristics of the infant, such as gestational age and birth weight; maternal conditions present at the time of delivery, such as mode of delivery and age; and area-level socioeconomic factors (SES) acting through access to care. The selected outcome must occur with enough frequency that differences between hospitals are not the result of chance. Individual complication rates and differences in mortality are infrequent enough that hospital rankings based on these factors could be unstable. For this reason, we have proposed the ACM models to serve as the measure of outcome for this study. The weights assigned to each complication should not be arbitrary, but should reflect the complication's relationship to a relevant, validated, and widely accepted outcome measure. To measure the quality of care at an individual hospital we adjusted for differences in casemix or severity of illness, using direct standardization of the outcome measure for each hospital, based on patient risk as the primary stratification variable. Hospital-specific scores on the aggregate complication measure for patients in each strata of risk were applied to a standardized population of patients. The hospital-level values obtained after direct standardization allowed for comparison of hospitals by assuming that all of the hospitals treated the same population of premature infants. This project defined the standardized population as the actual population of infants in all three states included in the project. This population has large numbers of patients of various SES and racial groups and provides a realistic distribution of infants.

B. Population studied

The primary data sets were comprised of patient-level data from 1995 to 2007 from hospital administrative datasets in California, Missouri, and Pennsylvania, linked to birth and death certificate records of newborns.

C. Sample selection

From the population above we selected all premature infants, when prematurity is defined as a delivery at less than or equal to 37 weeks gestation, where a term gestation is on average 40 weeks in length. We also selected a sub population of the premature infants, those born at ≤ 32 weeks gestation because of their unique impact on costs and resource use. Older infants between 32 and 37 weeks gestation, though, are also important because they constitute a large proportion of admissions to a NICU. Hospital ranks were developed for all premature infants and for these two groups separately to highlight differences in the quality of care between these two groups of premature infants at various hospitals.

D. Instruments used

A total of 27 complications were studied. All outcomes and control factors were identified using either ICD-9CM data from the infant or mother's hospital discharge record or specific fields in the linked birth certificate record. The outcome of death was validated using linked death records from the department of vital statistics in each state.

E. Statistical Techniques employed

To compare the rates of various complications, Pearson's correlation coefficients were calculated. To compare the rank ordering of various complications, Kendall's tau correlation coefficients were calculated. To develop the aggregated complication measure, we used factor analysis. This multivariate method allows for the grouping of individual complications that explain a specific latent factor that we cannot directly measure. Although multiple latent factors can be identified with this technique, we included only factors with an eigenvalue greater than 1, as per standard convention. These factors have sufficient variance for the outcome studied. Factor loadings from this analysis weighted individual complications in our final measure. For risk adjustment, we constructed multivariable logistic regression models and predicted the probability of each relevant outcome measure. Then, using the mortality model, we stratified the population into 10 deciles of mortality. For each hospital, we used the rate of complications within each decile of mortality to calculate the number of complications that would have occurred if the entire population of premature infants had received care at that individual hospital. This direct standardization method controls for the fact that hospitals have vastly different casemixes, and that many hospitals do not care for the sickest children.

IV. Detailed Findings

A. Choice of Outcomes and Delivery Hospitals

A.1. Impact of Obstetric Unit closures on Maternal and Neonatal Outcomes[50]

Between 1997 and 2005, 9 of 19 obstetric units in Philadelphia county closed, resulting in a 40% reduction in the number of obstetric beds and a 31% average increase in the number of deliveries at the remaining hospitals. The prior literature on hospital closures could not estimate how this degree of obstetric unit closure would influence pregnancy outcomes, because prior work has focused primarily on the reasons for hospital or unit closures, not the impact on patients' health. Using birth certificate data linked to maternal and neonatal hospital discharge records for all births between 1/1/1995 and 6/30/2005,

Table 1: Relative change in pregnancy outcomes in Philadelphia County in post-closure years

	1997-1999	2000-2002	2003-2005
Newborn Mortality			
Neonatal deaths	**1.39 (1.08-1.78)**	1.09 (0.82-1.45)	1.16 (0.92-1.46)
All fetal deaths	1.51 (0.95-2.40)	1.19 (0.76-1.86)	0.77 (0.28-2.14)
All fetal deaths + neonatal deaths	**1.43 (1.10-1.86)**	1.11 (0.86-1.42)	0.96 (0.62-1.48)
Possibly preventable fetal deaths*	1.40 (0.67-2.90)	1.19 (0.65-2.19)	0.78 (0.27-2.32)
Possibly preventable fetal + neonatal deaths*	**1.38 (1.06-1.79)**	1.09 (0.84-1.43)	1.06 (0.78-1.43)
Cesarean Sections			
All deliveries	**0.87 (0.75-1.00)**	0.99 (0.84-1.18)	0.91 (0.76-1.07)
All deliveries with GA 37-42 weeks	**0.86 (0.75-0.98)**	0.97 (0.82-1.16)	0.88 (0.74-1.06)
Premature Delivery			
23-32 week preterm	1.08 (0.94-1.23)	1.10 (0.87-1.39)	0.98 (0.77-1.24)
23-37 week preterm	**0.92 (0.85-0.98)**	1.02 (0.89-1.17)	0.89 (0.72-1.10)
Complications			
Any infant complication	1.28 (0.89-1.85)	1.12 (0.78-1.59)	1.27 (0.84-1.93)
Any maternal complication	0.96 (0.78-1.17)	1.13 (0.95-1.34)	1.18 (0.95-1.47)

we constructed a difference-in-differences model to compare pregnancy outcomes in Philadelphia and eight other urban counties in the United States: Alameda, CA (Oakland); Allegheny, PA (Pittsburgh); Lehigh, PA (Allentown); Los Angeles, CA; Sacramento, CA; San Diego, CA; San Francisco, CA; and San Jose, CA. Relative to the pre-closure years, in 1997-1999 the relative difference in neonatal and all neonatal and fetal mortality increased for Philadelphia residents compared to the other eight urban areas (odds ratio (OR) for neonatal mortality 1.39, 95% CI 1.08-1.78, OR for neonatal+fetal mortality 1.43, 95% CI 1.10-1.86). The relative difference in Cesarean section deliveries declined in Philadelphia, as did deliveries of infants between 23 and 37 weeks gestation. These results demonstrate the use of a difference-in-differences study design for interventions that cannot be randomized, similar to the analysis proposed in this study.

A.2. Fetal deaths may bias assessment of neonatal intensive care (NICU) quality [55]

Using linked birth certificate and hospital admission records from the mother and infant in Missouri between 1993 and 2003, an evaluation of risk adjusted neonatal death (ND) rate compared to fetal death (FD) rate and neonatal +fetal deaths was performed. At individual hospitals, adjusted rates of all three measures showed wide variations; hospitals with level I NICUs had the worst average rates for each measure. Risk-adjusted Cesarean section rates were not associated with risk-adjusted ND, FD, or ND+FD rates (r=0.02-0.04). When ND are used to assess NICU technical quality, higher-level NICUs show improved outcomes, but the size of the effect is smaller than when ND+FD are used. Because current methods cannot distinguish FD that result from poor care by the neonatal service from FD that are inevitable, these data suggest that overall mortality rates may not be the ideal measure to assess the

quality of neonatal care. These results were presented at the 2008 Pediatric Academic Societies meeting, the 2008 AcademyHealth national meeting, and a manuscript is under preparation for submission.

B. Principal Findings of Project

1. Correlation of complication rates and choice of complications for measure

The first finding of the study was to determine the correlations between individual complication rates. Preliminary data from 5 NICUs at Kaiser Permanente suggested that rank ordering between 7 common complications of premature birth were not well correlated, suggesting that these complications may be measuring different facets of the quality sphere of these hospitals. Complications that are poorly correlated with other complications may either be (1) too noisy for inclusion in an aggregated measure or (2) may not measure any aspect of the quality sphere. To define complications for possible inclusion in the aggregate measure complication, we determined the correlation of our complications first among individual patients, and then between individual hospitals.

1.1 Kappa correlations of complications in individual patients

The kappa correlations between individual complications are shown in the table below. Kappa correlation coefficients control for the fact that most complications are rare; patients who do not have either complication will not be included in the kappa measure and thus artificially increase the correlation between complications because of their rare occurrence.

	bpdi	ivh_any_gradei	neci	fungal_sepsisi	bacterial_sepsisi	ropi	surgery_ropi
pneumoniai	0.1581	0.0663	0.0517	0.0835	0.0729	0.1243	0.1498
pneumothoraxi	0.1341	0.1254	0.0548	0.0476	0.0734	0.0882	0.0965
pulmonary_hemorrhagei	0.0341	0.064	0.0254	0.0171	0.0204	0.0228	0.0493
rdsi	0.2071	0.1453	0.0466	0.0359	0.1916	0.1799	0.0343
bpdi		0.2035	0.0955	0.1132	0.2256	0.3429	0.1588
perinatal_asphyxiai	0.0168	0.0286	0.0077	0.004	0.0064	0.0099	0.0086
ivh_any_gradei	0.2035		0.0721	0.0606	0.1416	0.1805	0.0847
neonatal_seizuresi	0.0775	0.1051	0.0529	0.0471	0.049	0.0596	0.1086
neci	0.0955	0.0721		0.0583	0.1039	0.0816	0.062
intestinal_perforationi	0.0453	0.0456	0.2424	0.0534	0.0444	0.0388	0.0866
pdai	0.2743	0.1897	0.0809	0.0688	0.2159	0.2808	0.0828
cardiovascular_shocki	0.0183	0.026	0.0481	0.022	0.0247	0.0085	0.031
fungal_sepsisi	0.1132	0.0606	0.0583		0.0707	0.084	0.0778
bacterial_sepsisi	0.2256	0.1416	0.1039	0.0707		0.2045	0.0697
meningitisi	0.0214	0.0251	0.0242	0.0204	0.0239	0.0165	0.0241
urinary_tract_infectioni	0.0563	0.0277	0.0441	0.0569	0.0678	0.0521	0.0874
dici	0.0265	0.0546	0.0921	0.0329	0.0317	0.024	0.0461
renal_failurei	0.0468	0.0568	0.0618	0.0451	0.0293	0.0294	0.0737
any_fracturei	0.003	0.001	0.0022	0.0017	0.0013	0.0027	0.0099
ropi	0.3429	0.1805	0.0816	0.084	0.2045		0.2014
hearing_lossi	0.0014	0.0002	0.0016	0.0002	0.0007	0.0011	0.0036
surgery_ropi	0.1588	0.0847	0.062	0.0778	0.0697	0.2014	
surgery_pdai	0.1965	0.131	0.1015	0.0953	0.0976	0.173	0.2054
placement_of_chest_tubei	0.0551	0.0561	0.0183	0.0221	0.0303	0.0347	0.0589
laparotomyi	0.0585	0.0481	0.3696	0.0587	0.0571	0.0466	0.0902
vpsi	0.0175	0.0406	0.007	0.0119	0.0103	0.0167	0.0483
airway	0.0281	0.0117	0.0097	0.0169	0.0121	0.0186	0.0428

1.2. Pearson's correlation of unadjusted and adjusted hospital complication rates

A similar set of correlations are seen for unadjusted and adjusted hospital complications rates shown in the Table below. The adjustment is made using the direct standardization method outlined below in section 2.1.

Ungrouped small hosp	bpdi	ivh_any_gradei	neci	fungal_sepsisi	bacterial_sepsisi	ropi	surgery_ropi
Neonatal Death	0.1483	0.1664	0.1017	0.17	0.1739	0.1212	0.1222
Death Both	-0.1573	-0.1479	-0.124	-0.0836	-0.1195	-0.139	-0.1373
pneumoniai	0.5803	0.4683	0.366	0.5185	0.5221	0.5837	0.5509
pneumothoraxi	0.611	0.5684	0.4826	0.5187	0.5077	0.5151	0.5371
pulmonary_hemorrhagei	0.5778	0.6278	0.5467	0.5069	0.4902	0.5595	0.5577
rdsi	0.7837	0.7572	0.5887	0.6084	0.7015	0.7114	0.629
bpdi	1	0.752	0.5528	0.6393	0.6448	0.6758	0.6813
SGS	0.2576	0.2271	0.151	0.1703	0.2238	0.2589	0.298
TBM	0.3554	0.3566	0.2553	0.2729	0.3115	0.4133	0.3281
Vocal Cord Paralysis	0.3536	0.3571	0.2772	0.2528	0.314	0.4099	0.3144
perinatal_asphyxiai	0.2069	0.148	0.2056	0.2157	0.2021	0.1527	0.1087
ivh_any_gradei	0.752	1	0.5436	0.6092	0.6444	0.7464	0.7041
IVH Grade III/IV	0.5735	0.6178	0.4019	0.4025	0.5064	0.5708	0.6024
PVL	0.3385	0.3808	0.2369	0.2789	0.2872	0.3361	0.3554
neonatal_seizuresi	0.5328	0.5255	0.3722	0.4263	0.6041	0.5435	0.48
neci	0.5528	0.5436	1	0.5121	0.5557	0.5023	0.4365
intestinal_perforationi	0.4661	0.4778	0.5941	0.4688	0.4856	0.4333	0.3918
pdai	0.7039	0.7255	0.5865	0.5873	0.6716	0.7869	0.6833
cardiovascular_shocki	0.3013	0.3063	0.4117	0.2914	0.1826	0.2284	0.2551
fungal_sepsisi	0.6393	0.6092	0.5121	1	0.5198	0.6055	0.5431
bacterial_sepsisi	0.6448	0.6444	0.5557	0.5198	1	0.6057	0.5783
meningitisi	0.4404	0.4084	0.3858	0.3335	0.445	0.3844	0.3334
urinary_tract_infectioni	0.3097	0.2632	0.3015	0.3191	0.3977	0.2986	0.2778
dici	0.3482	0.3306	0.3064	0.345	0.3719	0.334	0.3245
renal_failurei	0.5675	0.5186	0.4789	0.4942	0.5616	0.4968	0.4799
any_fracturei	0.1193	0.1259	0.0626	0.1314	0.1482	0.1105	0.0967
ropi	0.6758	0.7464	0.5023	0.6055	0.6057	1	0.8063
hearing_lossi	0.062	0.0887	0.074	0.1678	0.0188	0.0688	0.0725
surgery_ropi	0.6813	0.7041	0.4365	0.5431	0.5783	0.8063	1
surgery_pdai	0.5685	0.6105	0.4212	0.4423	0.5359	0.6721	0.6376
placement_of_chest_tubei	0.4541	0.443	0.3138	0.3592	0.4151	0.3773	0.3911
tracheostomy	0.3634	0.3757	0.2906	0.2254	0.3336	0.2949	0.2655
laparotomyi	0.5076	0.5484	0.5473	0.4851	0.5124	0.4817	0.4326
vpsi	0.3634	0.3863	0.2346	0.2271	0.3032	0.3921	0.3703
airway	0.4634	0.4621	0.3523	0.3208	0.43	0.4854	0.4112
infection	0.6948	0.6848	0.6033	0.6413	0.9851	0.647	0.6049
infection 1	0.6967	0.6877	0.6049	0.6412	0.9846	0.648	0.6067

grouped small hosp	bpdi	ivh_any_gradei	neci	fungal_sepsisi	bacterial_sepsisi	ropi	surgery_ropi
Neonatal Death	-0.1333	-0.0704	-0.1545	-0.0932	-0.1263	-0.1616	-0.0697
Death Both	-0.4172	-0.4188	-0.387	-0.3377	-0.3832	-0.3904	-0.319
pneumoniai	0.5475	0.4438	0.4197	0.5389	0.5275	0.559	0.5324

pneumothoraxi	0.6282	0.6309	0.5271	0.4902	0.493	0.5182	0.5798
pulmonary_hemorrhagei	0.5285	0.6193	0.5019	0.4875	0.4159	0.5042	0.5233
rdsi	0.7749	0.7361	0.6257	0.5812	0.6514	0.669	0.5878
bpdi	1	0.7042	0.5636	0.6118	0.5798	0.5761	0.6194
SGS	0.3035	0.2839	0.2496	0.2549	0.2441	0.3111	0.2853
TBM	0.2843	0.2898	0.2396	0.2257	0.2437	0.3569	0.2575
Vocal Cord Paralysis	0.3462	0.3549	0.3	0.2689	0.2653	0.4027	0.3128
perinatal_asphyxiai	0.2199	0.1519	0.1786	0.2403	0.1979	0.1502	0.0963
ivh_any_gradei	0.7042	1	0.5754	0.6127	0.5707	0.7052	0.6659
IVH Grade III/IV	0.5049	0.5807	0.4139	0.3628	0.4453	0.501	0.5589
PVL	0.2589	0.3156	0.2076	0.2291	0.2066	0.2585	0.2856
neonatal_seizuresi	0.5058	0.5187	0.4239	0.3984	0.6178	0.5129	0.4738
neci	0.5636	0.5754	1	0.4696	0.569	0.511	0.4446
intestinal_perforationi	0.5995	0.6032	0.6512	0.5058	0.5873	0.6312	0.5637
pdai	0.6109	0.6433	0.5989	0.5376	0.5903	0.7444	0.6254
cardiovascular_shocki	0.4002	0.3677	0.3529	0.3982	0.1936	0.2709	0.3164
fungal_sepsisi	0.6118	0.6127	0.4696	1	0.4514	0.5771	0.5281
bacterial_sepsisi	0.5798	0.5707	0.569	0.4514	1	0.5244	0.5092
meningitisi	0.405	0.369	0.4909	0.3428	0.4695	0.3361	0.2886
urinary_tract_infectioni	0.3571	0.3349	0.4297	0.4024	0.4623	0.3374	0.3391
dici	0.4395	0.4034	0.4227	0.3964	0.4618	0.4402	0.4286
renal_failurei	0.546	0.5108	0.499	0.4757	0.5671	0.4894	0.461
any_fracturei	0.085	0.0935	0.0373	0.1191	0.1264	0.0756	0.062
ropi	0.5761	0.7052	0.511	0.5771	0.5244	1	0.7865
hearing_lossi	0.023	0.0535	0.0595	0.1734	-0.0311	0.0322	0.0395
surgery_ropi	0.6194	0.6659	0.4446	0.5281	0.5092	0.7865	1
surgery_pdai	0.5101	0.5713	0.4498	0.443	0.4792	0.6502	0.6416
placement_of_chest_tubei	0.5127	0.496	0.4486	0.3976	0.4162	0.3701	0.4068
tracheostomy	0.3224	0.329	0.3042	0.1855	0.2547	0.2441	0.2098
laparotomyi	0.524	0.5381	0.5914	0.4713	0.4903	0.5268	0.465
vpsi	0.4625	0.5181	0.3692	0.3165	0.4259	0.5305	0.5162
airway	0.4395	0.4409	0.3861	0.3306	0.3611	0.4594	0.3705
infection	0.6367	0.6281	0.6149	0.5816	0.9854	0.5703	0.5445
infection 1	0.6392	0.6322	0.6179	0.582	0.9846	0.5716	0.5468

1.3. Implications

Several complications were removed because of poor correlation between other complications and limited frequency within the dataset. These complications included the four airway complications (subglottic stenosis, tracheostomy, vocal cord paralysis, and tracheobronchomalacia); meningitis and urinary tract infection; hearing loss; and any fracture. Severe IVH and PVL were removed because of limited data, as these complications were not consistently coded through ICD-9 codes until 2001. RDS was removed because of this complication was felt to be related to obstetric care rather than neonatal care.

2. Construction of Aggregate Measure using unadjusted and adjusted complication rates

2.1. Development of Direct Standardization Mortality Model

The first step to developing an aggregated complication model is the development of a direct standardization model. Using a logistic regression model for mortality we calculated 10 deciles of mortality for the entire population. We then used them to stratify a given hospital's complication rate according to these deciles.

2.2. Use of Factor Analysis for unadjusted complication rates

Factor analysis was then used to determine latent aggregated factors that may underlie hospital complication rates. Two analyses were performed: one for unadjusted hospital complication rates, one for risk-adjusted rates. In each case, we only included latent factors with an eigenvalue > 1, and where the predicted variance was improved by the inclusion of an additional latent factor. Rotation of the factor analysis was performed if multiple latent factors were identified.
For the unadjusted complication rates, 2 metrics were calculated: one with mortality as an option, one without. Mortality made little effect on the factors and loadings attached to each factor. Both scores found 3 latent variables with eigenvectors above 1. Rotation provided more concise factors.
With mortality:

```
Factor analysis/correlation                          Number of obs    =      611
    Method: principal factors                        Retained factors =        3
    Rotation: orthogonal varimax (Kaiser off)        Number of params =       54

    --------------------------------------------------------------------------
         Factor  |     Variance   Difference        Proportion   Cumulative
    -------------+------------------------------------------------------------
        Factor1  |      2.92367      0.34244            0.3435       0.3435
        Factor2  |      2.58123      0.14555            0.3033       0.6468
        Factor3  |      2.43567            .            0.2862       0.9330
    --------------------------------------------------------------------------
    LR test: independent vs. saturated: chi2(171) = 4738.10 Prob>chi2 = 0.0000

Rotated factor loadings (pattern matrix) and unique variances

    -------------------------------------------------------------
        Variable |  Factor1   Factor2   Factor3 |   Uniqueness
    -------------+------------------------------+--------------
    bacterial_~t |   0.0361    0.3834    0.4099 |      0.6837
    bpdi_percent |   0.0856    0.4885    0.4768 |      0.5267
    death_perc~t |   0.4356    0.0302    0.0223 |      0.8088
    dici_percent |   0.0722    0.1860    0.2790 |      0.8824
    fungal_sep~t |   0.1404    0.1304    0.5150 |      0.6980
    intestinal~t |   0.0216    0.0131    0.6336 |      0.5979
    ivh_any_gr~t |   0.5102    0.6374    0.0057 |      0.3335
    laparotomy~t |  -0.0004    0.0584    0.5647 |      0.6777
    neonatal_s~t |   0.8762    0.0603    0.0386 |      0.2271
    pdai_percent |   0.0184    0.7877    0.1825 |      0.3459
    placement_~t |   0.8883    0.0315   -0.0203 |      0.2096
    pneumoniai~t |   0.0020    0.1759    0.2847 |      0.8880
    pneumothor~t |   0.8937    0.1074    0.0817 |      0.1831
    rdsi_percent |   0.2563    0.6308    0.2270 |      0.4849
    renal_fail~t |   0.0962    0.1645    0.3569 |      0.8363
    ropi_percent |   0.0465    0.3172    0.4576 |      0.6878
    surgery_pd~t |   0.0007    0.6551   -0.0803 |      0.5644
    surgery_ro~t |   0.0751    0.2337    0.6008 |      0.5787
    urinary_tr~t |   0.0320    0.2374    0.3126 |      0.8449

Without mortality:
Factor analysis/correlation                          Number of obs    =      611
    Method: principal factors                        Retained factors =        3
    Rotation: orthogonal varimax (Kaiser off)        Number of params =       51

    --------------------------------------------------------------------------
         Factor  |     Variance   Difference        Proportion   Cumulative
    -------------+------------------------------------------------------------
        Factor1  |      2.74620      0.20119            0.3351       0.3351
        Factor2  |      2.54501      0.09236            0.3105       0.6456
        Factor3  |      2.45265            .            0.2993       0.9449
    --------------------------------------------------------------------------
    LR test: independent vs. saturated: chi2(153) = 4567.64 Prob>chi2 = 0.0000
```

Rotated factor loadings (pattern matrix) and unique variances

Variable	Factor1	Factor2	Factor3	Uniqueness
bacterial_~t	0.0439	0.3758	0.4156	0.6842
bpdi_percent	0.0937	0.4799	0.4834	0.5272
dici_percent	0.0908	0.1755	0.2827	0.8810
fungal_sep~t	0.1615	0.1166	0.5173	0.6927
intestinal~t	-0.0004	0.0197	0.6277	0.6056
ivh_any_gr~t	0.5100	0.6388	0.0085	0.3318
laparotomy~t	-0.0121	0.0632	0.5607	0.6815
neonatal_s~t	0.8695	0.0587	0.0360	0.2393
pdai_percent	0.0102	0.7876	0.1902	0.3433
placement_~t	0.8920	0.0272	-0.0230	0.2030
pneumoniai~t	0.0141	0.1687	0.2874	0.8888
pneumothor~t	0.8930	0.1024	0.0805	0.1857
rdsi_percent	0.2664	0.6245	0.2332	0.4847
renal_fail~t	0.1058	0.1550	0.3611	0.8344
ropi_percent	0.0593	0.3089	0.4597	0.6897
surgery_pd~t	-0.0047	0.6614	-0.0763	0.5568
surgery_ro~t	0.0665	0.2304	0.6007	0.5816
urinary_tr~t	0.0384	0.2307	0.3168	0.8449

Interpretation: Factor analysis led to 3 factors. Factor 2 clusters mainly "early" factors, such as PDA, RDS, and any surgery. Factor 3 clusters some later conditions, such as severe GI issues (perf, laparotomy), ROP surgery, and fungal sepsis. BPD and other types of infection, such as bacterial sepsis, appear in both groups, possibly showing the importance of both complications. Factor 1 places the more "random" complications that don't go well with other complications, but do appear to be associated with mortality: IVH, pneumothorax/chest tube, and seizures. There was no big difference in scores whether we included death or excluded death from the factor analysis.

2.3. Use of Factor Analysis for adjusted complication rates

Different results were seen when we used risk-adjusted complication rates. Now, only one latent factor was found, with a strong variance. No effect was found when we dropped the 274 hospitals with less than 50 preterm deliveries over the 11 year period of the study.

*** All hospitals

Factor analysis/correlation — Number of obs = 621
Method: principal factors — Retained factors = 1
Rotation: (unrotated) — Number of params = 18

Factor	Eigenvalue	Difference	Proportion	Cumulative
Factor1	9.38527	8.45811	0.8781	0.8781

Factor loadings (pattern matrix) and unique variances

Variable	Factor1	Uniqueness
pneumoniai~l	0.6626	0.5610
pneumothor~l	0.6944	0.5179
pulmonary_~l	0.6690	0.5525
bpdi_total	0.8317	0.3083
ivh_any_gr~l	0.8419	0.2911

```
    ivh_gr_iii~l |   0.6504 |      0.5770
    neonatal_s~l |   0.6480 |      0.5801
      neci_total |   0.6720 |      0.5484
    intestinal~l |   0.6528 |      0.5738
      pdai_total |   0.8691 |      0.2446
    fungal_sep~l |   0.7046 |      0.5035
    bacterial_~l |   0.7650 |      0.4148
    renal_fail~l |   0.7056 |      0.5021
      ropi_total |   0.8399 |      0.2945
    surgery_ro~l |   0.7950 |      0.3679
    surgery_pd~l |   0.7414 |      0.4504
    laparotomy~l |   0.7045 |      0.5036
      vpsi_total |   0.4206 |      0.8231
    -------------------------------------


*** Only large hospitals

Factor analysis/correlation                       Number of obs    =      347
    Method: principal factors                     Retained factors =        1
    Rotation: (unrotated)                         Number of params =       17

    --------------------------------------------------------------------------
         Factor  |   Eigenvalue   Difference        Proportion   Cumulative
    -------------+------------------------------------------------------------
        Factor1  |      9.24902      8.57119            0.8716       0.8716


Factor loadings (pattern matrix) and unique variances

    -------------------------------------
        Variable |  Factor1 |   Uniqueness
    -------------+----------+--------------
    pneumoniai~l |   0.6994 |      0.5108
    pneumothor~l |   0.7462 |      0.4431
    pulmonary_~l |   0.6338 |      0.5983
      bpdi_total |   0.7838 |      0.3857
    ivh_any_gr~l |   0.8099 |      0.3441
    neonatal_s~l |   0.6749 |      0.5445
      neci_total |   0.7038 |      0.5047
    intestinal~l |   0.8151 |      0.3356
      pdai_total |   0.8216 |      0.3250
    fungal_sep~l |   0.6809 |      0.5364
    bacterial_~l |   0.7156 |      0.4879
    renal_fail~l |   0.7212 |      0.4799
      ropi_total |   0.8002 |      0.3597
    surgery_ro~l |   0.7651 |      0.4146
    surgery_pd~l |   0.7393 |      0.4534
    placement_~l |   0.6273 |      0.6064
    laparotomy~l |   0.7611 |      0.4208
    -------------------------------------
```

2.4. Validation of adjusted complication rates using interclass correlation coefficients

The final aspect of the study was to validate an individual aggregated measure. One method was to calculate the interclass correlation coefficient between the single latent factor identified in the risk adjusted complication measure. The table below demonstrates a high Cronbach's alpha of 0.899, with the omission of no one factor that improved this value. Item-test correlation averaged 0.61-0.85, while item-rest correlation ranged from 0.52-0.82.

```
                                                      average
```

Item	Obs	Sign	item-test correlation	item-rest correlation	inter-item covariance	alpha
pneumoniai~l	621	+	0.6637	0.6405	3.51e+07	0.8953
pneumothor~l	621	+	0.7059	0.6730	3.38e+07	0.8920
pulmonary_~l	621	+	0.6632	0.6513	3.61e+07	0.8983
bpdi_total	621	+	0.8501	0.8073	2.90e+07	0.8829
ivh_any_gr~l	621	+	0.8548	0.8191	2.98e+07	0.8829
neonatal_s~l	621	+	0.6661	0.6438	3.51e+07	0.8955
neci_total	621	+	0.6801	0.6487	3.42e+07	0.8932
intestinal~l	621	+	0.6155	0.5995	3.60e+07	0.8980
pdai_total	621	+	0.9003	0.8477	2.47e+07	0.8892
fungal_sep~l	621	+	0.7146	0.6875	3.42e+07	0.8928
bacterial_~l	621	+	0.8300	0.7448	2.59e+07	0.8973
renal_fail~l	621	+	0.6913	0.6786	3.59e+07	0.8975
ropi_total	621	+	0.8535	0.8082	2.85e+07	0.8830
surgery_ro~l	621	+	0.7872	0.7764	3.54e+07	0.8960
surgery_pd~l	621	+	0.7439	0.7204	3.42e+07	0.8926
placement_~l	621	+	0.5450	0.5199	3.57e+07	0.8975
laparotomy~l	621	+	0.6710	0.6511	3.53e+07	0.8959
Test scale					3.29e+07	0.8989

3. Association of Aggregate Measures with other measures of neonatal quality: Unadjusted measure

3.1. Association with other outcomes

For the unadjusted measure, there were 3 factors identified in the analysis. This lead to 3 separate scores, taken from the factor analysis loading weights, and a total score that was calculated by multiplying each of the 3 individual scores by the proportion of variation explained by each score.

Kendall's tau and Pearson's correlation coefficients showed a moderate correlation with death and readmission; a strong correlation with costs and lengths of stay, and modest difference in correlations when individual factors were analyzed.

	All deaths	Neonatal Deaths	Readmits	Cost	LOS
Total - No death Ktau	.1551 (<.001)	.0055 (.84)	.094 (.013)	.315 (<.001)	.4612 (<.001)
Total - No death Pearson's	.2424 (<.001)	.0343 (.43)	.1557 (.0059)	.17 (.0001)	.54 (<.001)
F1 - No death Ktau	.1444 (<.001)	.0099 (.73)	.046 (.22)	.256 (<.001)	.4151 (<.001)
F1 - No death Pearson's	.2258 (<.001)	.0456 (.29)	.1194 (.03)	.1411 (.0013)	.4976 (<.001)
F2 - No death Ktau	.1733 (<.001)	.009 (.76)	.1186 (.0019)	.3005 (<.001)	.4253 (<.001)
F2 - No death Pearson's	.2929 (<.001)	.0559 (.20)	.161 (.0044)	.1827 (<.001)	.5193 (<.001)
F3 - No death Ktau	.1247 (<.001)	-.0259 (.37)	.0651 (.09)	.3526 (<.001)	.5091 (<.001)
F3 - No death Pearson's	.2096 (<.001)	-.0068 (.88)	.1132 (.046)	.1871 (<.001)	.6002 (<.001)

Similar results were found when we stratified hospitals into quartiles based on the total complication score and examined the difference in the observed-expected rates of each validating outcome listed above. The reported p-value is the overall group difference, whereas the Diff row shows the statistical difference between specific pairs of quartiles. These data suggest that the greatest difference between hospitals came between the lowest complication quartile and the remaining 3 quartiles.

	All deaths	Neonatal Deaths	Cost	LOS	Readmissions
Quartile					
Lowest	-.022 (.089)	.003 (.055)	-474 (1280)	-.25 (.23)	.004 (.047)

2nd	.017 (.054)	.007 (.032)	5.92 (1597)	-.08 (.14)	0 (.024)
3rd	.019 (.044)	.009 (.026)	34.8 (639)	-.04 (.15)	.006 (.025)
Highest	.023 (.047)	.006 (.033)	-39.0 (327)	.004 (.22)	.013 (.034)
p-value	< 0.001	0.63	0.004	< 0.001	0.12
Diff	1 v. all	None	1 v. all	1 v. all 2 v. 4	None
Quintile					
Lowest	-.028 (.093)	-.001 (.055)	-598 (1203)	-.28 (.24)	.004 (.049)
2nd	.013 (.062)	.010 (.040)	21.2 (1933)	-.11 (.16)	.001 (.028)
3rd	.019 (.039)	.008 (.025)	67.3 (628)	-.03 (.08)	.006 (.025)
4th	.025 (.049)	.010 (.026)	-69.3 (433)	-.05 (.20)	.007 (.031)
Highest	.018 (.046)	.004 (.035)	0 (321)	.02 (.21)	.011 (.031)
p-value	< 0.001	.21	< 0.001	< 0.001	0.57
Diff	1 v. all	None	1 v. all	1 v all 2 v. 3, 5 4 v. 5	None

V. Discussion and Interpretation of Findings

A. Conclusions to be drawn from findings (with reference to data supporting each)

1. Individual complication measures track poorly with one another, as demonstrated by the kappa correlations on individual patient data and correlations of rates and ranks for individual hospital data.
2. Complications can be aggregated to improve the validity of a complication measure. However, issues of censoring by death and risk-adjustment are important to include in any aggregated measure.

B. Explanation of study limitations

Assessing quality via complications ran into several unexpected issues. First, many complications were "censored by death", particularly those complications that occur or are measured late in the hospital course. Thus, hospitals with high mortality rates may falsely appear as high quality facilities without accounting for this issue. We are currently investigating whether hospital-level mortality rates need to be included in the measure, or whether an aggregated complication measure may serve as an adjunct marker of quality, in addition to the risk-adjusted mortality rate. Also, several potential measures of quality, such as fractures and airway complications, had to be eliminated because of their rare occurrence and poor assessment of mild occurrences of each complication that were not diagnosed by the hospitals.

C. Comparison with findings of other studies and application of findings to MCH health care delivery situations

This is the first study of complications as a measure of either neonatal performance or neonatal quality. Studies of adult care suggest that patient factors are more highly associated with the occurrence of complications compared to hospital factors. However, this situation occurs because of the large number of coexisting conditions that adults have upon admission to the hospital. With appropriate risk-adjustment and consideration of particular issues such as the censoring by death issue discussed above, complications may serve as an additional method of assessing the care delivered by neonatal intensive care units, either from state public health departments, in publicly-reported measures of care (as has already begun in the state of Pennsylvania, who is reporting quarterly infection rates at individual hospitals).

E. Policy implications

With further validation of an aggregated complication measure, policy makers will have additional tools to assess the care delivered at neonatal intensive care units.

F. Suggestions for further research:

1. Bayesian analysis for risk-adjusted hospital complication rates
2. Impact of Omitting Congenital Anomaly Patients from models
3. Comparison of different methods of weighting complications in aggregate complication measure
4. Final use of aggregate complication measure in assessing neonatal quality

VI. List of products (peer reviewed articles, books, chapters in books, master and doctoral dissertations, conference presentations, etc.).

Conference presentations:

Lorch SA. "Assessing the Quality of Pediatric Care: Moving into the Mainstream of Clinical Care," State-of-the-Art Symposium, Pediatric Academic Societies Annual Meeting, Baltimore, MD. May 2009

Lorch SA, Silber JH, Fager C, Ross R, Even-Shoshan O: Fetal Deaths may bias the assessment of neonatal intensive care quality. Platform presentation, Pediatric Academic Societies Annual Meeting, Honolulu, HA, May 2008.

Lorch SA, Silber JH, Fager C, Ross R, Even-Shoshan O: Fetal Deaths may influence the assessment of neonatal intensive care quality. Poster presentation, Academy Health Annual Meeting, Washington, DC, June 2008.

Lorch SA, Srinivas SK, Fager C, Small D: The impact of obstetric unit closures on maternal and neonatal outcomes of pregnancy. Platform Presentation, Pediatric Academic Societies Annual Meeting, Baltimore, MD, May 2009.

Lorch SA, Srinivas SK, Fager C, Small D: The impact of obstetric unit closures on maternal and neonatal outcomes of pregnancy. Poster Presentation, AcademyHealth Annual Meeting, Chicago, IL, June 2009.

Srinivas SS, Fager C, Lorch SA. Risk-adjusted Cesarean section rates as a measure of obstetric quality. Poster Presentation, Society for Maternal-Fetal Medicine, January 2009.

In press publications:

Srinivas SS, Fager C, Lorch SA. Risk-adjusted Cesarean section rates as a measure of obstetric quality. In press, Obstetrics and Gynecology.

In submission publications:

Lorch SA, Srinivas SS, Fager C, Small DS. The public health impact of obstetric unit closures on perinatal outcomes.

Lorch SA, Fager C. Individual complications as a measure of neonatal intensive care quality.

In preparation publications:

Lorch SA, Fager C, Barfield W. The importance of risk adjustment and fetal deaths in assessing neonatal intensive care quality with mortality rates.

Lorch SA, Fager C, Small DS. The impact of censoring by death on hospital rates of individual complications.

Lorch SA, Fager C. An aggregated complication measure of neonatal intensive care quality.

Lorch SA, Dennis E, Fager C. Racial and gender differences in complication rates in premature infants.

Dennis E, Fager C, Lorch SA. The impact of treatment hospital on racial disparities in rates of pregnancy complications.