## Trending Infection Rates in the NICU

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## Hypothesis:

We hypothesize that a policy of targeted surveillance of infants transferred to the CHONY NICU will not increase the rate of infection or colonization with antibiotic resistant organisms in the general NICU population. Targeted infants will be those transferred at greater than 7 days of life.

#### Scientific Abstract:

Surveillance cultures for antibiotic resistant organisms in the NICU at Columbia are routinely performed on all infants who are transferred from outside institutions. Our protocols have been extrapolated primarily from data in adult hospital units and patients. More recent studies have indicated that it may be safe and cost effective to perform targeted admission surveillance for antibiotic resistant organisms in transported infants based on certain risk factors such as age at transfer and co-morbid conditions. For this reason, the practice of screening all transported infants for MRSA, VRE and AR-GNB upon admission to the NICU will be changed to perform surveillance for these organisms in infants who are admitted at or after 7 days of life. Our objectives are to examine how this practice change impacts infection rates in the general NICU population (both transferred and inborn infants) caused by AROs. To perform this study, we will review clinical and microbiologic data of infants in the NICU that has been collected as standard of care or for previously IRB approved studies, and describe the epidemiology of antibiotic resistant organisms before and after our policy change. This research may aid in the development of more appropriate protocols and surveillance strategies to prevent the acquisition and transmission of potentially life threatening pathogens.

#### Lav abstract:

Surveillance cultures involve swabbing non-sterile body sites to determine if a patient is colonized with drug resistant bacteria. Appropriate infection control policies can then be applied to protect other patients from spread of these organisms. The Morgan Stanley Children's Hospital performs surveillance cultures for drug resistant bacteria upon admission to the NICU for any infant transported from an outside hospital. Our policy has been extrapolated from data in adults and is not specific to neonates. A recent study in our NICU showed a low colonization rate in infants transported from outside institutions if infants were transferred at less than 7 days of life. Based on this data, our policy will change, and infants transferred from outside institutions will have surveillance cultures only if they are transferred after 7 days of life. The aim of this study will be to monitor the effect this change in policy has on the rate of infection with drug resistant bacteria in the entire NICU population. To study this we will use laboratory and general patient data that is collected as part of ordinary care of infants in the NICU.

## **Study Description:**

We will describe the types and rates of colonization and infection with drug resistant organisms from the start of the policy change (July 1, 2013) until 2 years after this change (June 30, 2015). These data will be compared with rates of colonization and infection from the years 2009- 2013, using previously collected data from IRB approved protocols IRB-AAAC6366, ("Antimicrobal Prescribing in the NICU") and IRB-AAAE1315 ("Surveillance Cultures in the NICU). Cochrane-Armitage Test for trend and Poission regression with Generalized Estimating Equations will be used to describe changes in rates and trends over time. Risk factors for colonization and infection will be explored using Student's T- Test or Wilcoxon Rank Sum test for continuous outcomes, and Chi Squared or Fisher's Exact Test for categorical data as appropriate. The effect of multiple risk factors and covariates will be explored using logistic regression. Organism spread may be hypothesized using Bayesian models such as Markov Chain Monte Carlo. The success of and compliance with the policies of admission surveillance procedures will be described.

# **Study Procedure:**

A list of infants transferred to the NICU from other institutions from June 30, 2012 to June 30, 2015 will be generated from existing NICU census data. This list will supply the name, medical record number and referring institution. All patients will be assigned a unique study number. The electronic medical record of these infants will be reviewed to determine if surveillance cultures were performed upon admission and the results of these and any other cultures performed for the standard of care during the infant's admission; demographic data such as sex, birth weight, and admitting diagnosis (e.g., congenital anomalies, respiratory failure, retinopathy of prematurity) will also be generated. This list will be supplemented by data previously collected for the previously approved IRB-AAAE1315 ("Surveillance Cultures in the NICU). This will allow us to determine compliance and yield for surveillance cultures performed on infants transferred to the NICU and potentially determine risk factors and trends for ARO colonization among transferred infants.

We will determine the baseline trends of infections (e.g., bloodstream infections, skin and soft tissue infections, urinary tract infections and meningitis) and colonization caused by AROs among infants transferred to the NICU in comparison to an inborn population. To do so, data on transported infants will be compared with rates of colonization and infection in the general NICU population from the years 2009- 2013, using previously collected data from the IRB approved protocol IRB-AAAC6366, ("Antimicrobial Prescribing in the NICU") and IRB-AAAE1315 ("Surveillance Cultures in the NICU.

To study the effect of the change in surveillance policy on rates on infection and colonization with AROs in NICU population, a list of all positive cultures for infections caused by AROs during the 2-year study period will be generated from the Clinical Microbiology Laboratory's computerized information system. Pathogens of interest will mirror those pathogens sought on surveillance cultures of transferred infants and include MRSA, VRE and AR-GNB. From these data, rates of infection caused by different AROs in transferred vs. inborn infants will be calculated. All cultures, including admission surveillance cultures, were performed as the standard of care in the NICU, and were not done specifically for this study.

## **Study Drugs or Devices**

None

## **Study Instruments**

None

## Study Subjects.

This will be a chart review of all subjects who were transported to the NICU from outside institutions, and of all infants (inborn and transferred) admitted to the NICU who had positive clinical cultures for any ARO from January 1, 2009 until June 30, 2015.

#### Recruitment

Not applicable

## Confidentiality of Study Data

The medical records of infants will be collected and linked to a unique study identification number. The link between the infants' medical record numbers and the study identification number will be kept on a password protected, encrypted computer and stored in the PI's office. Only the study staff will have access to the link between the infants' medical record number and study identification number. The link between the study number and the patients' record number will be destroyed at the conclusion of the study after data analysis has been completed.

## **Privacy Protections**

Individual patient demographic and clinical information will be kept in confidence and stored on a password encrypted computer in locked offices and will not be shared with anyone or any organization outside the study team except as mandated by the institutional review board.

#### Potential Risks

The only risk for collection of existing demographic and clinical data is the loss of confidentiality.

#### Data and Safety Monitoring

As this study is an observational study with collection of existing medical data, safety monitoring is not applicable.

## **Potential Benefits**

There are no potential benefits to the study population. Potential benefits to society include the development of more appropriate protocols and surveillance strategies, and a greater

understanding of the epidemiology of AROs. This study may result in clinical practice changes that could prevent the acquisition and transmission of potentially life threatening pathogens in a vulnerable population.

Alternatives
Not applicable.