iNICQ 2018 and VON Day Quality Audit : Choosing Antibiotics Wisely

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Section 1

iNICQ 2018 and VON Day Quality Audit: Choosing Antibiotics Wisely

Introductory Letter to Collaborative Participants

To: Vermont Oxford Network iNICQ 2018: Choosing Antibiotics Wisely Participating Centers

From: Vermont Oxford Network

Re: Sample IRB letter for participation in the iNICQ 2018 Collaborative and the VON Day Audit / Choosing Antibiotics Wisely

Vermont Oxford Network (VON) has prepared a sample letter that may be used to communicate with your local IRB to determine what reviews and approvals are required prior to participation in the Vermont Oxford Network Internet-Based Newborn Intensive Collaborative for Quality (iNICQ) titled "Choosing Antibiotics Wisely and the associated VON Day Audit.

The materials presented in the iNICQ Choosing Antibiotics Wisely Quality Collaborative and the associated VON Day Audit are not intended as human subjects' research. The Vermont Oxford Network does not collect any personal identifiers on audited patients. However, you must select whether you will or will not collect individual identifiers for specific patients on your paper forms in order to have the ability to audit more deeply for quality improvement. This information will be for local use only and will not be transmitted to the Vermont Oxford Network. No specific interventions are being tested or promoted. However, as a result of involvement in this iNICQ series and your self-assessments regarding the status of current clinical outcomes or alarm safety metrics, your team may choose to alter clinical practices in the unit based on ideas they hear from faculty or other participants. The aggregated results of the collaborative and various improvement stories from participating sites may be presented or published.

The Committee on Human Research at the University of Vermont has reviewed the protocol for conducting the VON Day audit and the plans for the iNICQ Collaborative. They have determined that the role of Vermont Oxford Network in these activities is not Human Research. However, that determination solely addresses the role of the Vermont Oxford Network in sponsoring and supporting the VON Day audits and iNICQ Collaborative.

The approval from the University of Vermont Committees on Human Research does not cover any activities conducted by institutions or staff participating in the VON Day audits or iNICQ Collaborative. Each site participating in the VON Day audits and/or the iNICQ Collaborative must obtain any and all necessary Human Subjects reviews and approvals from their own institutional review boards before participating.

We have included materials related to the iNICQ Collaborative and the VON Day Audit in this package and will post the materials on our website. A sample letter that can be modified and used to request a determination from your local IRB is included as a Word document. We have also provided a link to the U.S. Department of Health and Human Services website regarding quality improvement activities and human subjects' protection.

The modifiable sections of the sample letter are highlighted in yellow. In those sections, please remove the text for the option you will not follow. Additionally, please remove all of the highlighting before submission to your IRB.

Section 2

iNICQ 2018 and VON Day Quality Audit: Choosing Antibiotics Wisely

Sample IRB Letter

[To the Institutional Review Board]/ or / [Appropriate Authority to Conduct Quality Improvement Projects and Audits] / at your institution]

To those concerned,

We are writing regarding [a new quality initiative / our continued involvement] in the quality improvement series iNICQ 2018: Choosing Antibiotics Wisely. This internet-based quality improvement collaborative (iNICQ) is designed to assist hospitals in improving the quality, safety and value of clinical care.

Vermont Oxford Network (VON) has partnered with the Centers for Disease Control and Prevention (CDC) to focus on antibiotic overuse in hospital newborn care units using the CDC's Core Elements of Hospital Antibiotic Stewardship Programs (ASP) as a guide. The broader curriculum, created by neonatal medicine experts from around the world, will help healthcare centers initiate or expand upon their existing antibiotic stewardship activities specific to the newborn care. Areas of focus will include:

- Improved communications, both within healthcare teams and between healthcare providers and patients.
- Increased monitoring of infections and antibiotic use deploying center level data to inform best practices via VON Day Quality Audits.
- The establishment of appropriate indications for, dose of and duration of therapy for antibiotics prescriptions.

The program will include both a series of internet-based educational sessions as well as two audits focused on institutional policies, guidelines and infant management.
For centers that participated in iNICQ 2017: [Our center has previously participated in two antibiotic stewardship activities in 2017.] Or For centers that are first time participants [no text needed].

The 2018 Collaborative will offer a prelaunch web seminar, 6 core web sessions and 4 intensive web sessions

These web based sessions will include but not be limited to the following topics:

- Promoting the rapid-cycle uptake of new AAP and ACOG guidelines.
- Encouraging the goal of becoming a VON Center of Excellence.
- Encouraging collaboration in your own organization to assure your NB unit and OB teams are also engaged in the ASP learning and improvement cycles .
- Scaling up in the region – with the tertiary and quaternary centers reaching out to Level 1 and 2's to engage them in the concept of ASP, to encourage them to join the national collaborative and to being to learn, measure, share and improve together – with a goal of standardizing practices.
- Engaging the Department of Health (DOH)/Hospital Acquired Infections (HAI) Division to let them know this is important work and garner expertise and support to joining the Choosing Antibiotics Wisely Collaborative.

- Engaging the state and perinatal quality improvement collaboratives –to make this a statewide project to both improve ASP capacity.
- Addressing the CDC Core elements and to begin to make progress on managing the microbiome of the entire state – given sharing of patients and populations and the opportunity to become a VON State of Excellence.
- Building the data knowledge and local capacity to aim for the National Healthcare Safety Network (NHSN) Antibiotic Utilization Rate (AUR) / Resistance modules in the future – so that we have good data to drive outcomes and create sustainable improvement for the future.

A "Toolkit" that details the supporting evidence, provides a Driver Diagram, key potentially better practices and change ideas that centers may consider will be provided. A subset of centers [including our center OR not including our center] will participate in the iNICQ intensive, which includes sessions on health information technology and how to translate data into actionable policy and practice. The majority of the sessions will be delivered via web-based seminars throughout 2018; centers engaged in the Intensive Curriculum will also participate in a face-to-face learning event at the NICQ Symposium in Chicago (Fall 2018).

In conjunction with this educational program we plan to participate in two quality improvement audits. The VON Day Audit: Choosing Antibiotics Wisely includes an assessment of specific policies and guidelines regarding antibiotic stewardship assessing alignment with the CDC Core Elements for antibiotic stewardship. In addition to a review of policies, the management of individual infants treated with antibiotics will be evaluated to better understand our center's practice regarding the use of antibiotics in the newborn population.

The specific data elements for the audit are included with these materials. The audit does not involve any specific intervention nor does it involve direct physical contact with any individual or patient; however, the local data collector - will need to review unit logs, review patient paper charts and/or electronic medical records and approach the infant's bedside to determine eligibility and review specific chart orders, management plans and laboratory values. [Select one: In order to follow up on any quality concerns brought out by the audit, our unit has chosen to record identifying data on specific infants OR we will not have identifying data on specific infants]. Should we chose to collect MRN, or patient identifiers, this data will not be submitted to VON.

No aspect of the infant's care will be directly affected by the auditing process and no individually identifiable data or protected healthcare information will be transmitted to VON; further, the website will not accept any data of this nature. Our center [select one: will OR will not] collect identifying data on specific infants on the paper form for internal quality improvement review; however, this data will not be transmitted to VON.

Shortly after completion of the VON data audit, our center will receive an electronic report highlighting key measures and results at our center. A more comprehensive report summarizing the aggregated results of all VON centers (de-identified by site) will be shared with all participants and in the future may be submitted for publication in the peer-reviewed literature. In each step of these efforts, no specific data regarding the center or the individuals

will be identifiable. In additional to the VON Day Audits, our local team may elect to perform serial quality improvement audits to measure improvements in care over time.

The iNICQ Collaborative and the VON Day Audit have been reviewed by the University of Vermont Institutional Review Board, who have determined that, with respect to the role of the Vermont Oxford Network, that this activity is "not human subjects research", as recognized by 45CFR46.102(F) and OHRP's guidance on research involving coded private information or biological specimens. However, that determination is solely about the role of the Vermont Oxford Network in sponsoring and supporting iNICQ Collaborative and the VON Day Audits. The approval from the University of Vermont Committees on Human Research does not cover any activities conducted by institutions or staff participating in the VON Day Audits or iNICQ Collaborative.

Each site participating in the VON Day audits and/or the iNICQ Collaborative must obtain any and all necessary Human Subjects reviews and approvals from their own institutional review boards, or appropriate local governing bodies, before participating.

We are interested in participating in these quality improvement opportunities. This letter is a request to our local IRB to determine if any reviews or approvals are needed prior to our center's participation in these projects.

Thank you for consideration of this project. Please feel free to contact us with any questions.

Sincerely,

(Local Investigator)

See Attachments below

Attachments:

VON Day Audit: Choosing Antibiotics Wisely Data Items

VON Day Audit: Choosing Antibiotics Wisely Data Items: Checklist

University of Vermont Committee on Human Subjects Determination Letter for iNICQ Choosing Antibiotics Wisely Quality Improvement Collaborative, and the VON Day Audit: Choosing Antibiotics Wisely

Section 3

iNICQ 2018 and VON Day Quality Audit: Choosing Antibiotics Wisely

University of Vermont Committees on Human Subjects

Determination Letters

The UNIVERSITY of VERMONT
Committees on Human Subjects
Serving the University of Vermont
and Fletcher Allen Health Care

RESEARCH PROTECTIONS OFFICE
213 Waterman Building
85 South Prospect Street
Burlington, Vermont 05405
(802)656-5040 ph
www.uvm.edu/irb/

Certification

Not Human Subjects Determination

TO: Madge Buus-Frank
FROM: Gale Weld, Research Review Administrator
DATE OF CERTIFICATION: 11-Sep-2014
SUBJECT: CHRMS: 15-118
iNICQ Quality Improvement Collaboratives

The IRB has determined that IRB review of the project is **not** required because it does not constitute human subjects research as described below and recognized by 45 CFR 46.102(f) and OHRP's Guidance on Research Involving Coded Private Information or Biological Specimens.

The definition of "human subject" includes, but is not limited to, human organs, specimens, and body fluids from living individuals, as well as private graphic, written, or recorded information about living individuals, if

(1) there is interaction or intervention with a living individual to obtain the data or specimens for research purposes, or

(2) the identity of the subjects can be readily ascertained by the investigator or other members of the research team.

The UNIVERSITY of VERMONT
Committees on Human Subjects
Serving the University of Vermont
and the UVM Medical Center

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Certification

Not Human Subjects Determination

TO:	Roger Soll, M.D.
FROM:	Gale Weld, Research Review Analyst, CIP
DATE OF CERTIFICATION:	19-Dec-2016
SUBJECT:	CHRMS: 17-0285 VON Days Quality Audits: Antibiotic Stewardship

The IRB has determined that IRB review of the project is **not** required because it does not constitute human subjects research as described below and recognized by 45 CFR 46.102(f) and OHRP's Guidance on Research Involving Coded Private Information or Biological Specimens.

The definition of "human subject" includes, but is not limited to, human organs, specimens, and body fluids from living individuals, as well as private graphic, written, or recorded information about living individuals, if

(1) there is interaction or intervention with a living individual to obtain the data or specimens for research purposes, or

(2) the identity of the subjects can be readily ascertained by the investigator or other members of the research team.

Note: If this project is the study of cancer or is cancer-related, it may require review by the University of Vermont Cancer Center prior to any research activities.

Section 4

iNICQ 2018 and VON Day Quality Audit: Choosing Antibiotics Wisely

Process Checklist

Vermont Oxford Network
VON Day Quality Audit / Choosing Antibiotics Wisely Checklist

DIRECTIONS: The following materials are time sensitive and **require immediate action**. Please read the contents carefully as there are multiple steps to complete in early January 2018 before you can participate fully in the collaborative.

☐ Convene your multidisciplinary improvement team to review the sample customizable IRB letter, the VON IRB determination letter, and the VON Day Quality Audit / Choosing Antibiotics Wisely data collection forms.

☐ Contact your local IRB.

- **If this is your initial Choosing Antibiotics Wisely VON Day Audit:**
  Obtain appropriate forms / materials/ applications from your local Institutional Review Board or comparable relevant human subjects' research committee or other governing body. Prepare a proposal for review by your local IRB or other relevant human subjects research committee and obtain all necessary approval and submit before target deadlines.
- **For continuing centers:**
  Write to your local IRB about your **continued** participation and plans to audit infants in the coming year. Your IRB will direct you as to what materials they need from you.

☐ Identify an individual to serve as the VON Day Data Collector for the two Choosing Antibiotics Wisely audits.

☐ Assure that the VON Day Data Collector has all of the appropriate access privileges to access policies, procedures, and charts locally.

☐ VON Day Data Collectors will need access to the VON Member's Area Home Page and the LMS. That access is granted by the VON Champion at your center. Furthermore, anyone at your center that has a web services login (access to the VON Member's Area Home Page) will be able to view the results of the VON Day Quality Audit once the audit has been completed.

☐ Assure that you have explored local requirements for human subjects training for the VON Day Data Collector (if required by your local IRB). **This step is required before data collection can begin at your site.**

☐ Data will need to be submitted **on two separate occasions** during the Collaborative. Audit 1 will take place in the 1st quarter of 2018 and Audit 2 will take place in the 4th quarter of 2018.

*NOTE: Data submission closes at 12 midnight Eastern Time on the final date of each audit. This is a hard stop deadline. The system will not accept your data after this date and time. Online and phone support will be available until **5:00 PM ET** on the last day of the audits (email: vondays@vtoxford.org).

Section 5

iNICQ 2018 and VON Day Quality Audit: Choosing Antibiotics Wisely

Protocol and Manual of Operations

VON Day Quality Audit
iNICQ 2018: Choosing Antibiotics Wisely
Protocol and Manual of Operations

I. Background:

Infections that were once lethal are now readily treatable. In neonatal-perinatal medicine, the prompt initiation of antibiotics has reduced morbidity and mortality for once common and potentially fatal infections. However, 20-50% of all antibiotics prescribed in U.S. acute care hospitals are either unnecessary or inappropriate. [1-6] Patients who are unnecessarily exposed to antibiotics are placed at risk for serious adverse events with no clinical benefit. The misuse of antibiotics has also contributed to the growing problem of antibiotic resistance, which has become one of the most serious and growing threats to public health. Unlike other medications, the potential for spread of resistant organisms means that the misuse of antibiotics can adversely impact the health of patients who are not directly exposed to the agent. The Centers for Disease Control and Prevention (CDC) estimates more than two million people are infected with antibiotic-resistant organisms, resulting in approximately 23,000 deaths annually. [7]

A growing body of evidence demonstrates that hospital-based programs dedicated to improving antibiotic use can both optimize the treatment of infections and reduce adverse events associated with antibiotic use.[8-9] These "antimicrobial stewardship" programs are coordinated interventions designed to improve and measure the appropriate use of antimicrobials by promoting the selection of the optimal antimicrobial drug regimen, dose, duration of therapy, and route of administration. Antimicrobial stewardship programs seek to achieve optimal clinical outcomes related to antimicrobial use, minimize toxicity and other adverse events related to antimicrobial use, reduce the costs of health care for infections, and limit the selection for antimicrobial resistant strains. [10]

Vermont Oxford Network (VON) has partnered with the Centers for Disease Control and Prevention (CDC) to focus on antibiotic overuse in hospital neonatal care units using the CDC's Core Elements of Hospital Antibiotic Stewardship Programs as a guide.[7] The broader curriculum, created by neonatal medicine experts from around the world, will help healthcare centers initiate or expand upon their existing antibiotic stewardship activities with an emphasis

on the newborn population and common sites of care where antibiotics are prescribed and administered. Areas of focus will include:

• Improved communications, both within healthcare teams and between healthcare providers, infants and their families.

• The establishment of policies and practices that will support appropriate prescription, dosage and length of treatment for antibiotic prescriptions.

• Increased monitoring of infections and antibiotic use utilizing center level data to inform best practices via VON Day Quality Audits.

There are significant gaps between the CDC recommendations and current NICU antibiotic stewardship capacity and practices [(11)]. In the first of our VON Day audits of 143 NICUs taking part in the Vermont Oxford Network iNICQ Quality Improvement Collaborative 2016: Choosing Antibiotics Wisely, few units had addressed the key items linked to CDC Core Elements. Centers reported limited capacity for leadership commitment (15%), accountability (55%), drug expertise (62%), oversight of prescribing (22%), tracking of antibiotic use (15%), reporting and team feedback (7%) and team-based education (33%).

Antimicrobial stewardship interventions have been proven to improve individual patient outcomes, reduce the overall burden of antibiotic resistance, and save healthcare dollars. Implementation of an antimicrobial stewardship program in a healthcare facility – regardless of inpatient setting – will help ensure that hospitalized patients receive the right antibiotic, at the right dose, at the right time, and for the right duration.

II. Goals:

- To assist member hospitals in performing a standardized quality audit of antibiotic stewardship practices in their Neonatal Intensive Care Unit (NICU) or other chosen newborn unit.

- To provide member hospitals with benchmarking comparisons of antibiotic stewardship practices at a wide range of Neonatal Intensive Care Units or other chosen newborn units.

III. Methods:

Vermont Oxford Network will provide paper data collection forms and will operate a password protected web-based secure data portal that will allow for electronic data entry and transfer of this data without identification of individual participants.

There are several steps that your center must do in order to participate.

1. Assign an audit coordinator/data collector. The audit coordinator/data collector will be in charge of the audit process regarding communication with your center's local institutional review board or governing body, as well as serve as the key contact for the VON Day Audit with Vermont Oxford Network. The audit coordinator may or may not be the individual who will conduct the audit. If the coordinator is not the person who will conduct the audit, also assign a separate "data collector".

2. Address any local Human Subjects Research concerns. The Committee on Human Research at the University of Vermont has reviewed the protocol for conducting the VON Day Quality Audit: Choosing Antibiotics Wisely and the plans for the iNICQ Quality Improvement Collaborative. They have determined that the role of Vermont Oxford Network in these activities is not Human Research (as recognized by 45 CFR 46.102(f) and OHRP's Guidance on Research Involving Coded Private Information or Biological Specimens). However, that determination pertains solely to the role of Vermont Oxford Network. Each site participating in the VON Day Quality Audit and/or the iNICQ Collaborative will need to present the protocol and appropriate materials to their local Institutional Review Board (IRB) or governing body to determine whether any necessary human subject reviews and approvals are needed. These materials can be found on the public VON website and on the VON Learning Mananagement System under this collaborative.

3. Conduct the audit.

Vermont Oxford Network will choose two weeks in the first quarter of 2018 and two weeks in the fourth quarter of 2018 during which the VON Day Quality Audit: Choosing Antibiotics Wisely will occur. Your center will choose a single day during those 2 weeks to perform the audit locally. We anticipate that the audit will take no more than 4 to 6 hours to complete on the chosen day.

Additionally, your center must choose a single unit to audit. The audit was designed with a typical Neonatal Intensive Care Unit (NICU) in mind. That said, depending on your hospitals size, shape and level of care offered, you may choose to audit a Neonatal Step-down Unit or your Newborn Nursery (Mother/Baby Unit). Choose only one unit to audit and plan on re-auditing the same unit in the follow up audit in November.

- Determine infant eligibility: On the selected day, assess the eligible infants in your unit of interest. Eligible infants are any infant on any antibiotic therapy at the time of the audit regardless of gestational or chronological age.

- Data Collection and Analysis: Data will be collected regarding the guidelines and policies regarding antibiotic stewardship in place at individual units (Unit Data Form, Appendix 1) and

evaluation of the practices regarding antibiotic use in individual patients (Individual Patient Data Form, Appendix 2). Data will come both from chart review and interview with staff or parents.

Individual centers will receive feedback regarding their own practices and compliance with their own local guidelines. Information regarding the aggregate group's policies and procedures will be presented at the upcoming iNICQ internet-based educational sessions. Measures used for this quality improvement effort are detailed in Appendix 3. VON Day Quality Audit results will be shared during subsequent iNICQ sessions and will be published in the aggregated form; no patient identifiable data are ever collected, and only aggregate center-level data (not center-identifiable data) will be shared.

In addition to the VON Day Quality Audits in March and November, where data are submitted to VON, we are recommending that centers perform regular local audits of their antibiotic utilization rates (AUR), and further that they "plot the AUR dot" regularly in an effort to measure the impact of local antibiotic stewardship interventions.

IV. Antibiotic Utilization Audit: Unit Level Questionnaire

Below are the detailed questions and definitions for the unit policy data items. Answer the questions as specifically applied to the singular unit you are choosing to audit.

The following questions address the resources that potentially lead to a successful antibiotic stewardship program.

[Modified from the CDC "Checklist for Core Elements of Hospital Antibiotic Stewardship Program" (7)]

This audit is designed primarily for Neonatal Intensive Care Units (NICUs) of all levels, from community NICUs to quaternary NICUs. As noted above, you may answer the questions in relation to policies and guidelines in your step-down unit or newborn nursery, but you may find the questions less relevant. You must choose only one unit to audit. A copy of the audit form is located in Appendix 1.

We are planning to audit our: (choose only one location)
a. NICU b. Neonatal Step-Down Unit c. Newborn Nursery (Mother/Baby Unit)

Organizational Commitment and Culture:

1. **Does your NICU** *[or chosen unit]* **have a formal written project plan that engages senior leadership in efforts to improve antibiotic use (antibiotic stewardship)? Yes / No / Unknown**

   Select "Yes" if your NICU [or chosen unit] has a formal written project plan that engages senior leadership in efforts to improve antibiotic use (antibiotic stewardship).

Select "No" if your NICU [or chosen unit] does not have a formal written project plan that engages senior leadership in efforts to improve antibiotic use (antibiotic stewardship).

Select "Unknown" if after performing due diligence and consulting with other key team members you are unable to determine whether your NICU [or chosen unit] has a formal written project plan that engages senior leadership in efforts to improve antibiotic use (antibiotic stewardship).

A "formal written project plan that engages senior leadership" is a plan that dedicates the necessary human, financial and information technology resources towards improving antibiotic stewardship.

"Antimicrobial stewardship" refers to coordinated interventions designed to improve and measure the appropriate use of antimicrobials by promoting the selection of the optimal antimicrobial drug regimen, dose, duration of therapy, and route of administration.

In order to answer "Yes" these activities must be specifically oriented to your NICU or chosen unit.

2. Does your NICU *[or chosen unit]* **receive any budgeted financial support for antibiotic stewardship activities (e.g. support or salary, training, or IT support)? Yes / No / Unknown**

Select "Yes" if your NICU [or chosen unit] receives budgeted financial support specifically for antibiotic stewardship activities, including salary support, training or information technology support.

Select "No" if your NICU [or chosen unit] does not receive any budgeted financial support specifically for antibiotic stewardship activities, including salary support, training or information technology support.

Select "Unknown" if after performing due diligence and consulting with other key team members you are unable to determine whether your NICU [or chosen unit] receives any budgeted financial support specifically for antibiotic stewardship activities, including salary support, training or information technology support.

3. Is there a physician leader responsible for the outcomes of stewardship activities in your NICU *[or chosen unit]***? Yes / No / Unknown**

Select "Yes" if there is a physician leader who is responsible for the outcomes of stewardship activities in your NICU [or chosen unit].

Select "No" if there is not a physician leader who is responsible for the outcomes of stewardship activities in your NICU [or chosen unit].

Select "Unknown" if after performing due diligence and consulting with other key team members you are unable to determine whether there is a physician leader responsible for the outcomes of stewardship activities in your NICU [or chosen unit].

4. Is there a pharmacist leader responsible for working to improve antibiotic use in your NICU *[or chosen unit]***? Yes / No / Unknown**

Select "Yes" if there is a pharmacist leader responsible for working to improve antibiotic use in your NICU [or chosen unit].

Select "No" if there is not a pharmacist leader responsible for working to improve antibiotic use in your NICU [or chosen unit].

Select "Unknown" if after performing due diligence and consulting with other key team members you are unable to determine whether there is a pharmacist leader responsible for working to improve antibiotic use in your NICU [or chosen unit].

5. Does your NICU *[or chosen unit]* **have a multidisciplinary team responsible for antibiotic stewardship? Yes / No / Unknown**

Select "Yes" if your NICU [or chosen unit] has a multidisciplinary team of individuals responsible for antibiotic stewardship in your NICU [or chosen unit]. Proceed to question 5a.

Select "No" if your NICU [or chosen unit] does not have a multidisciplinary team responsible for antibiotic stewardship in your NICU [or chosen unit]. Proceed to question 6.

Select "Unknown" if after performing due diligence and consulting with other key team members you are unable to determine whether your NICU [or chosen unit] has a multidisciplinary team responsible for antibiotic stewardship activities in your NICU [or chosen unit]. Proceed to question 6.

5a. If yes to 5, Which of the following are members of the multidisciplinary team?

If you selected "Yes" to question 5, please detail which disciplines are represented in your NICU [or chosen unit] multidisciplinary team responsible for antibiotic stewardship.

- Neonatologist(s) Yes / No / Unknown
- Pharmacist(s) Yes / No / Unknown
- Infection Prevention and Health Care Epidemiologist(s) Yes / No / Unknown
- Infectious Disease Specialist(s) Yes / No / Unknown
- Quality Improvement Specialist(s) Yes / No / Unknown
- Microbiology Laboratory Technician(s) Yes / No / Unknown
- Information Technologist(s) (IT) Yes / No / Unknown
- Nurse(s) Yes / No / Unknown
- Nurse Practitioner(s) / Physician Assistant(s) Yes / No / Unknown
- Parent(s) / Consumer Advisor(s) Yes / No / Unknown

6. Does your NICU *[or chosen unit]* **provide education to clinicians and other relevant staff on improving antibiotic prescribing? Yes / No / Unknown**

Select "Yes" if your NICU [or chosen unit] provides education to clinicians and other relevant staff (including but not limited to nurses, nurse practitioners, physician assistants, respiratory therapists) on improving antibiotic prescribing.

Select "No" if your NICU [or chosen unit] does not provide education to clinicians and other relevant staff on improving antibiotic prescribing.

Select "Unknown" if after performing due diligence and consulting with other key team members you are unable to determine whether your NICU [or chosen unit] provides education to clinicians and other relevant staff on improving antibiotic prescribing.

Example: In the context of an antibiotic stewardship program, education could include regular updates on antibiotic prescribing, antibiotic resistance, and infectious disease management that address both national and local issues. Sharing facility-specific information on antibiotic use is a tool to motivate improved prescribing, particularly if wide variations in the patterns of use exist among similar patient care locations.

There are many options for providing education on antibiotic use such as didactic presentations which can be done in formal and informal settings, messaging through posters and flyers and newsletters or electronic communication to staff groups. Reviewing de-identified cases with providers where changes in antibiotic therapy could have been made is another useful approach. A variety of web-based educational resources are available that can help facilities develop education content. Education has been found to be most effective when paired with corresponding interventions and measurement of outcomes.

Policies, Protocols, and Guidelines

7. Does your NICU *[or chosen unit]* **have a policy that requires prescribers to document in the medical record or during order entry the dose, duration and indication for all antibiotic prescriptions?**
Yes / No / Unknown

Select "Yes" if your NICU [or chosen unit] has a policy that requires prescribers to document in the medical record or during order entry all of the above characteristics of antibiotic prescription, including dose, duration and indication for all antibiotic prescriptions.

Select "No" if your NICU [or chosen unit] does not have a policy that requires prescribers to document in the medical record or during order entry all of the necessary features of antibiotic prescriptions, including dose, duration and indication for all antibiotic prescriptions.

Select "Unknown" if after performing due diligence and consulting with other key team members you are unable to determine whether your NICU [or chosen unit] has a policy that requires prescribers to document in the medical record or during order entry all of the necessary features of antibiotic prescriptions, including dose, duration and indication for all antibiotic prescriptions.

Specify the dose, duration and indication for all courses of antibiotics so they are readily identifiable.

8. Is there a formal procedure or process prompting the NICU *[or chosen unit]* **care team to review the appropriateness of all antibiotics prescribed for infants in the NICU** *[or chosen unit]* **48 to 72 hours after the initial order (e.g. "antibiotic time out")? Yes / No / Unknown**

Select "Yes" if there is a formal procedure or process prompting the NICU [or chosen unit] care team to review the appropriateness of all antibiotics prescribed for infants in the NICU [or chosen unit] 48 to 72 hours after the initial order.

Select "No" if there is no formal procedure or process prompting the NICU [or chosen unit] care team to review the appropriateness of all antibiotics prescribed for infants in the NICU [or chosen unit] 48 to 72 hours after the initial order.

Select "Unknown" if after performing due diligence and consulting with other key team members you are unable to determine whether there is a formal procedure or process prompting the NICU [or chosen unit] care team to review the appropriateness of all antibiotics prescribed for infants in the NICU [or chosen unit] 48 to 72 hours after the initial order.

"Antibiotic time out": Antibiotics are often started empirically in hospitalized patients while diagnostic information is being obtained. However, providers often do not revisit the

selection of the antibiotic after more clinical and laboratory data (including culture results) become available. A policy-mandated antibiotic "time out" prompts a reassessment of the continuing need and choice of antibiotics when the clinical picture is clearer and more diagnostic information is available.

9. Do specified antibiotic agents need to be approved by a physician (such as an infectious disease specialist) or a pharmacist prior to dispensing (i.e. pre-authorization)? Yes / No / Unknown

Select "Yes" if you have policies and procedures that require specific antibiotic agents be approved by a physician (such as an infectious disease specialist) or a pharmacist prior to dispensing.

Select "No" if you do not have policies and procedures that require specific antibiotic agents be approved by a physician (such as an infectious disease specialist) or a pharmacist prior to dispensing.

Select "Unknown" if after performing due diligence and consulting with other key team members you are unable to determine whether your unit has policies and procedures that require specific antibiotic agents be approved by a physician (such as an infectious disease specialist) or a pharmacist prior to dispensing.

Note: Prior authorization/approval restricts the use of certain antibiotics based on the spectrum of activity, cost, or associated toxicities to ensure that use is reviewed with an antibiotic expert before therapy is initiated. This intervention requires the availability of expertise in antibiotic use and infectious diseases and authorization needs to be completed in a timely manner.

10. Does a physician or pharmacist review courses of therapy for specified antibiotic agents (e.g. prospective audit with feedback)? Yes / No / Unknown

Select "Yes" if your NICU [or chosen unit] has policies or procedures that require a physician or pharmacist review courses of antibiotic therapy for specified antibiotic agents.

Select "No" if your NICU [or chosen unit] does not have policies or procedures that require a physician or pharmacist review courses of antibiotic therapy for specified antibiotic agents.

Select "Unknown" if after performing due diligence and consulting with other key team members you are unable to determine whether your NICU [or chosen unit] has policies or procedures that require a physician or pharmacist review courses of antibiotic therapy for specified antibiotic agents.

Example: Prospective audit and feedback- External reviews of antibiotic therapy by an expert in antibiotic use have been highly effective in optimizing antibiotics in critically ill patients and in cases where broad spectrum or multiple antibiotics are being used.

Prospective audit and feedback is different from an antibiotic "time out" because the audits are conducted by staff other than the treating team. Audit and feedback requires the availability of expertise and some smaller facilities have shown success by engaging external experts to advise in *post hoc* case reviews.

NICU Specific Policies and Guidelines

11. Does your NICU *[or chosen unit]* **have specific policies, protocols or guidelines for the diagnosis and antibiotic treatment (including antibiotic choice, dose and duration) for the following conditions?**

a. Maternal risk factors **Yes / No / Unknown**

Select "Yes" if your NICU [or chosen unit] has specific policies, protocols or guidelines for the diagnosis and antibiotic treatment (including antibiotic choice, dose and duration) of infants who have specific maternal risk factors.

Select "No" if your NICU [or chosen unit] does not have specific policies, protocols or guidelines for the diagnosis and antibiotic treatment (including antibiotic choice, dose and duration) of infants who have specific maternal risk factors.

Select "Unknown" if after performing due diligence and consulting with other key team members you are unable to determine whether your NICU [or chosen unit] has specific policies, protocols or guidelines for the diagnosis and antibiotic treatment (including antibiotic choice, dose and duration of infants who have specific maternal risk factors.

"Maternal risk factors" may include fever, rupture of membranes, known group B streptococcal carriage, and use of intrapartum antibiotics.

b. Suspected or proven early onset sepsis or meningitis **Yes / No / Unknown**

Select "Yes" if your NICU [or chosen unit] has specific policies, protocols or guidelines for the diagnosis and antibiotic treatment of infants with suspected or proven early onset sepsis or meningitis.

Select "No" if your NICU [or chosen unit] does not have specific policies, protocols or guidelines for the diagnosis and antibiotic treatment of infants with suspected or proven early onset sepsis or meningitis.

Select "Unknown" if after performing due diligence and consulting with other key team members you are unable to determine whether your NICU [or chosen unit] has specific policies, protocols or guidelines for the diagnosis and antibiotic treatment of infants with suspected or proven early onset sepsis or meningitis.

c. Suspected or proven late onset sepsis or meningitis **Yes / No / Unknown**

Select "Yes" if your NICU [or chosen unit] has specific policies, protocols or guidelines for the diagnosis and antibiotic treatment of infants with suspected or proven late onset sepsis or meningitis.

Select "No" if your NICU [or chosen unit] does not have specific policies, protocols or guidelines for the diagnosis and antibiotic treatment of infants with suspected or proven late onset sepsis or meningitis.

Select "Unknown" if after performing due diligence and consulting with other key team members you are unable to determine whether your NICU [or chosen unit] has specific policies, protocols or guidelines for the diagnosis and antibiotic treatment of infants with suspected or proven late onset sepsis or meningitis.

d. Suspected or proven ventilator associated pneumonia **Yes / No / Unknown**

Select "Yes" if your NICU [or chosen unit] has specific policies, protocols or guidelines for the diagnosis and antibiotic treatment of infants with suspected or proven ventilator associated pneumonia.

Select "No" if your NICU [or chosen unit] does not have specific policies, protocols or guidelines for the diagnosis and antibiotic treatment of infants with suspected or proven ventilator associated pneumonia.

Select "Unknown" if after performing due diligence and consulting with other key team members you are unable to determine whether your NICU [or chosen unit] has specific policies, protocols or guidelines for the diagnosis and antibiotic treatment of infants with suspected or proven ventilator associated pneumonia.

e. Suspected or proven central venous line infection Yes / No / Unknown

Select "Yes" if your NICU [or chosen unit] has specific policies, protocols or guidelines for the diagnosis and antibiotic treatment of infants with suspected or proven central venous line infection.

Select "No" if your NICU [or chosen unit] does not have specific policies, protocols or guidelines for the diagnosis and antibiotic treatment of infants with suspected or proven central venous line infection.

Select "Unknown" if after performing due diligence and consulting with other key team members you are unable to determine whether your NICU [or chosen unit] has specific policies, protocols or guidelines for the diagnosis and antibiotic treatment of infants with suspected or proven central venous line infection.

f. Suspected or proven urinary tract infection Yes / No / Unknown

Select "Yes" if your NICU [or chosen unit] has specific policies, protocols or guidelines for the diagnosis and antibiotic treatment of infants with suspected or proven urinary tract infection.

Select "No" if your NICU [or chosen unit] does not have specific policies, protocols or guidelines for the diagnosis and antibiotic treatment of infants with suspected or proven urinary tract infection.

Select "Unknown" if after performing due diligence and consulting with other key team members you are unable to determine whether your NICU [or chosen unit] has specific policies, protocols or guidelines for the diagnosis and antibiotic treatment of infants with suspected or proven urinary tract infection.

Note: "Suspected or proven urinary tract infection" does not include the prophylactic use of antibiotics to prevent urinary tract infection (see question 11i)

g. Suspected or proven necrotizing enterocolitis Yes / No / Unknown

Select "Yes" if your NICU [or chosen unit] has specific policies, protocols or guidelines for the diagnosis and antibiotic treatment of infants with suspected or proven necrotizing enterocolitis.

Select "No" if your NICU [or chosen unit] does not have specific policies, protocols or guidelines for the diagnosis and antibiotic treatment of infants with suspected or proven necrotizing enterocolitis.

Select "Unknown" if after performing due diligence and consulting with other key team members you are unable to determine whether your NICU [or chosen unit] has specific policies, protocols or guidelines for the diagnosis and antibiotic treatment of infants with suspected or proven necrotizing enterocolitis.

h. Suspected or proven surgical site infection **Yes / No / Unknown**

Select "Yes" if your NICU [or chosen unit] has specific policies, protocols or guidelines for the diagnosis and antibiotic treatment of infants with suspected or proven surgical site infection.

Select "No" if your NICU [or chosen unit] does not have specific policies, protocols or guidelines for the diagnosis and antibiotic treatment of infants with suspected or proven surgical site infection.

Select "Unknown" if after performing due diligence and consulting with other key team members you are unable to determine whether your NICU [or chosen unit] has specific policies, protocols or guidelines for the diagnosis and antibiotic treatment of infants with suspected or proven surgical site infection.

i. Prophylaxis for urinary tract infection **Yes / No / Unknown**

Select "Yes" if your NICU [or chosen unit] has specific policies, protocols or guidelines for the use of prophylactic antibiotic therapy to prevent urinary tract infection in high risk infants.

Select "No" if your NICU [or chosen unit] does not have specific policies, protocols or guidelines for the use of prophylactic antibiotic therapy to prevent urinary tract infection in high risk infants.

Select "Unknown" if after performing due diligence and consulting with other key team members you are unable to determine whether your NICU [or chosen unit] has specific policies, protocols or guidelines for the use of prophylactic antibiotic therapy to prevent urinary tract infection in high risk infants.

j. Prophylaxis for surgery **Yes / No / Unknown**

Select "Yes" if your NICU [or chosen unit] has specific policies, protocols or guidelines for the prophylactic use of antibiotics in infants immediately before or after surgery.

Select "No" if your NICU [or chosen unit] does not have specific policies, protocols or guidelines for the prophylactic use of antibiotics in infants immediately before or after surgery.

Select "Unknown" if after performing due diligence and consulting with other key team members you are unable to determine whether your NICU [or chosen unit] has specific policies, protocols or guidelines for the prophylactic use of antibiotics in infants immediately before or after surgery.

k. Prophylaxis for fungal sepsis **Yes / No / Unknown**

Select "Yes" if your NICU [or chosen unit] has specific policies, protocols or guidelines for the use of prophylactic antifungal therapy to prevent fungal sepsis in high risk infants.

Select "No" if your NICU [or chosen unit] does not have specific policies, protocols or guidelines for the use of prophylactic antifungal therapy to prevent fungal sepsis in high risk infants.

Select "Unknown" if after performing due diligence and consulting with other key team members you are unable to determine whether your NICU [or chosen unit] has specific policies, protocols or guidelines for the use of prophylactic antifungal therapy to prevent fungal sepsis in high risk infants.

l. Methicillin resistant *Staphylococcus aureus* (MRSA) colonization?
Yes / No / Unknown

Select "Yes" if your NICU [or chosen unit] has specific policies, protocols or guidelines for the diagnosis and antibiotic treatment of infants with suspected or proven Methicillin resistant Staphylococcus aureus (MRSA) colonization.

Select "No" if your NICU [or chosen unit] does not have specific policies, protocols or guidelines for the diagnosis and antibiotic treatment of infants with suspected or proven Methicillin resistant Staphylococcus aureus (MRSA) colonization.

Select "Unknown" if after performing due diligence and consulting with other key team members you are unable to determine whether your NICU [or chosen unit] has specific policies, protocols or guidelines for the diagnosis and antibiotic treatment of infants with suspected or proven Methicillin resistant Staphylococcus aureus (MRSA) colonization.

m. Other

Other condition:_____

12. Does your NICU *[or chosen unit]* **routinely use any of the following electronic systems to prescribe, dispense, or administer medications?**

a. Computerized provider order entry or an order management system (CPOE or CPROM) Yes / No / Unknown

Select "Yes" if your NICU [or chosen unit] routinely uses a computerized physician order entry or an order management system to prescribe or dispense medication.

Select "No" if your NICU [or chosen unit] does not routinely use a computerized physician order entry or an order management system to prescribe or dispense medication.

Select "Unknown" if after performing due diligence and consulting with other key team members you are unable to determine whether your NICU [or chosen unit] routinely uses a computerized physician order entry or an order management system to prescribe or dispense medication.

A "computerized provider order entry (CPOE)" or "order management system (CPROM)" refers to any system in which clinicians directly enter medication orders into a computer system, which then transmits the order directly to the pharmacy.

b. Electronic medication administration record (eMAR) Yes / No / Unknown

Select "Yes" if your NICU [or chosen unit] routinely uses an electronic medication administration record (eMAR) to dispense or administer medication.

Select "No" if your NICU [or chosen unit] does not routinely use an electronic medication administration record (eMAR) to dispense or administer medication.

Select "Unknown" if after performing due diligence and consulting with other key team members you are unable to determine whether your NICU [or chosen unit] routinely uses an electronic medication administration record (eMAR) to dispense or administer medication.

An electronic medication administration record (eMAR) is defined as a technology that automatically documents the administration of medication into certified EHR technology

using electronic tracking sensors (for example, radio frequency identification (RFID)) or electronically readable tagging such as bar coding).

c. Bar coded medication administration (BCMA) **Yes / No / Unknown**

Select "Yes" if your NICU routinely uses a bar coded medication administration system (BCMA) to dispense or administer medication.

Select "No" if your NICU does not routinely use a bar coded medication administration system (BCMA) to dispense or administer medication.

Select "Unknown" if after performing due diligence and consulting with other key team members you are unable to determine whether your NICU routinely uses a bar coded medication administration system (BCMA) to dispense or administer medication.

Barcoded Medication Administration (BCMA) is an inventory control system that uses barcodes to prevent human errors in the distribution of prescription medications at hospitals. BCMA makes sure that patients are receiving the correct medications at the correct time by electronically validating and documenting medications. The information encoded in barcodes allows for the comparison of the medication being administered with what was ordered for the patient.

13. Does your NICU routinely use the Neonatal Early-Onset Sepsis Calculator to evaluate the risk of early-onset infection among infants born at or above 34 weeks gestation?

Select "Yes" if your NICU [or chosen unit] routinely uses the Neonatal Early-Onset Sepsis Calculator (currently located at https://neonatalsepsiscalculator.kaiserpermanente.org/) to evaluate the risk of early-onset infection among infants born at or above 34 weeks gestation?

Select "No" if your NICU [or chosen unit] does not routinely use the Neonatal Early-Onset Sepsis Calculator (currently located at https://neonatalsepsiscalculator.kaiserpermanente.org/) to evaluate the risk of early-onset infection among infants born at or above 34 weeks gestation?

Select "Unknown" if after performing due diligence and consulting with other key team members you are unable to determine whether your NICU [or chosen unit] routinely use the Neonatal Early-Onset Sepsis Calculator (currently located at https://neonatalsepsiscalculator.kaiserpermanente.org/) to evaluate the risk of early-onset infection among infants born at or above 34 weeks gestation?

Pharmacy driven interventions to assure appropriate antibiotic treatment

14. Does your NICU *[or chosen unit]* **have policies or guidelines for:**

a. Dose adjustment in cases of organ dysfunction Yes / No / Unknown

Select "Yes" if your NICU [or chosen unit] has policies or guidelines for dose adjustment in the case of organ dysfunction.

Select "No" if your NICU [or chosen unit] does not have policies or guidelines for dose adjustment in the case of organ dysfunction.

Select "Unknown" if after performing due diligence and consulting with other key team members you are unable to determine whether your NICU [or chosen unit] has policies or guidelines for dose adjustment in the case of organ dysfunction.

Example: Dose adjustments in cases of organ dysfunction (e.g. renal adjustment)

b. Dose adjustment or customization based on gestational or chronological age Yes / No / Unknown

Select "Yes" if your NICU [or chosen unit] has policies or guidelines for dose adjustment or customization based on gestational or chronological age.

Select "No" if your NICU [or chosen unit] does not have policies or guidelines for dose adjustment or customization based on gestational or chronological age.

Select "Unknown" if after performing due diligence and consulting with other key team members you are unable to determine whether your NICU [or chosen unit] has policies or guidelines for dose adjustment or customization based on gestational or chronological age.

Example: Dose adjustments based on gestational age (in cases of extreme prematurity) or chronological age.

c. Dose optimization (pharmacokinetics/pharmacodynamics) to optimize the treatment of organisms with reduced susceptibility Yes / No / Unknown

Select "Yes" if your NICU [or chosen unit] has policies or guidelines for dose optimization to optimize the treatment of organisms with reduced susceptibility.

Select "No" if your NICU [or chosen unit] does not have policies or guidelines for dose optimization to optimize the treatment of organisms with reduced susceptibility.

Select "Unknown" if after performing due diligence and consulting with other key team members you are unable to determine whether your NICU [or chosen unit] has policies or guidelines for dose optimization to optimize the treatment of organisms with reduced susceptibility.

Example: Dose optimization including dose adjustments based on therapeutic drug monitoring, optimizing therapy for highly drug-resistant bacteria, achieving central nervous system penetration, extended-infusion administration of beta-lactams, etc.

d. Automatic alerts in situations where therapy might be unnecessarily duplicative Yes / No / Unknown

Select "Yes" if your NICU [or chosen unit] has policies or guidelines for automatic alerts in situations where therapy might be unnecessarily duplicative.

Select "No" if your NICU [or chosen unit] does not have policies or guidelines for automatic alerts in situations where therapy might be unnecessarily duplicative.

Select "Unknown" if after performing due diligence and consulting with other key team members you are unable to determine whether your NICU [or chosen unit] has policies or

guidelines for automatic alerts in situations where therapy might be unnecessarily duplicative.

Example: Automatic alerts in situations where therapy might be unnecessarily duplicative including simultaneous use of multiple agents with overlapping spectra e.g. anaerobic activity, atypical activity, Gram-negative activity and resistant Gram-positive activity.

e. Time sensitive automatic stop orders for specified antibiotic prescriptions
Yes / No / Unknown

Select "Yes" if your NICU [or chosen unit] has policies or guidelines for time sensitive automatic stop orders for specified antibiotic prescriptions.

Select "No" if your NICU [or chosen unit] does not have policies or guidelines for time sensitive automatic stop orders for specified antibiotic prescriptions.

Select "Unknown" if after performing due diligence and consulting with other key team members you are unable to determine whether your NICU [or chosen unit] has policies or guidelines for time sensitive automatic stop orders for specified antibiotic prescriptions.

Example: Time-sensitive automatic stop orders for specified antibiotic prescriptions, especially antibiotics administered for surgical prophylaxis or "rule out" diagnoses.

Regular monitoring or reporting on antibiotic use and resistance

15. Does your NICU *[or chosen unit]* **monitor and report prescriber adherence to specific treatment recommendations?** **Yes / No / Unknown**

Select "Yes" if your NICU [or chosen unit] monitors and reports prescriber adherence to specific treatment recommendations.

Select "No" if your NICU [or chosen unit] does not monitor and report prescriber adherence to specific treatment recommendations.

Select "Unknown" if after performing due diligence and consulting with other key team members you are unable to determine whether your NICU [or chosen unit] monitors and reports prescriber adherence to specific treatment recommendations.

Example: The CDC recommends that units perform periodic assessments of the use of antibiotics or the treatment of infections to determine the quality of antibiotic use. Examples include determining if prescribers have: accurately applied diagnostic criteria for infections; prescribed recommended agents for a particular indication; documented the indication and planned duration of antibiotic therapy; obtained cultures and relevant tests prior to treatment; and modified antibiotic choices appropriately to microbiological findings.

In addition, periodic assessments might include whether antibiotics are being given in a timely manner and assess compliance with hospital antibiotic use policies such as the documentation of dose, duration and indication or the performance of reassessments of therapy ("antibiotic time out").

For interventions that provide feedback to clinicians, it is also important to document interventions and track responses to feedback (e.g., acceptance).

16. Does your NICU *[or chosen unit]* **monitor and report adherence of prescribing providers to documentation of the 3 key components for every antibiotic order / prescription (dose, duration, and indication)? Yes / No / Unknown**

Select "Yes" if your NICU [or chosen unit] monitors and reports adherence of prescribing providers to documentation of dose, duration and indication for every antibiotic order or prescription.

Select "No" if your NICU [or chosen unit] does not monitor and report adherence of prescribing providers to documentation of dose, duration and indication for every antibiotic order or prescription.

Select "Unknown" if after performing due diligence and consulting with other key team members you are unable to determine whether your NICU [or chosen unit] monitors and reports adherence of prescribing providers to documentation of dose, duration and indication for every antibiotic order or prescription.

Antibiotic use and outcome measures

17. Does your NICU *[or chosen unit]* **participate in the National Healthcare Safety Network (NHSN) Healthcare-Associated Infection (HAI) tracking system? Yes / No / Unknown**

Select "Yes" if your NICU [or chosen unit] participates in the National Healthcare Safety Network (NHSN) Healthcare-Associated Infection (HAI) tracking system.

Select "No" if your NICU [or chosen unit] does not participate in the National Healthcare Safety Network (NHSN) Healthcare-Associated Infection (HAI) tracking system.

Select "Unknown" if after performing due diligence and consulting with other key team members you are unable to determine whether your NICU [or chosen unit] participates in the National Healthcare Safety Network (NHSN) Healthcare-Associated Infection (HAI) tracking system.

The CDC's National Healthcare Safety Network provides facilities, states, regions, and the nation with data needed to identify problem areas, measure progress of prevention efforts, and ultimately eliminate healthcare-associated infections.
http://www.cdc.gov/nhsn/index.html

18. Does your NICU *[or chosen unit]* **participate in the National Healthcare Safety Network (NHSN) Antibiotic Use (AU) and Resistance Module? Yes / No / Unknown**

Select "Yes" if your NICU [or chosen unit] participates in the National Healthcare Safety Network (NHSN) Antibiotic Use (AU) and Resistance Module.

Select "No" if your NICU [or chosen unit] does not participate in the National Healthcare Safety Network (NHSN) Antibiotic Use (AU) and Resistance Module.

Select "Unknown" if after performing due diligence and consulting with other key team members you are unable to determine whether your NICU [or chosen unit] participates in the National Healthcare Safety Network (NHSN) Antibiotic Use (AU) and Resistance Module.

The CDC's National Healthcare Safety Network (NHSN) Antibiotic Use (AU) and Resistance Module automatically collects and reports monthly days of DOT data, which can be analyzed in aggregate and by specific agents and patient care locations.

Centers that participate in the National Healthcare Safety Network (NHSN) Healthcare-Associated Infection (HAI) tracking system do not necessarily participate in the National Healthcare Safety Network (NHSN) Antibiotic Use (AU) and Resistance Module.

19. Does your NICU *[or chosen unit]* **monitor antibiotic utilization rate (AUR) [either as days of antibiotic therapy / patient OR days of antibiotic therapy / 1000 patient days]? Yes / No / Unknown**

Select "Yes" if your NICU [or chosen unit] monitors antibiotic utilization rate (AUR), calculated either as days of antibiotic therapy per patient OR as days of antibiotic therapy per 1000 patient days.

Select "No" if your NICU [or chosen unit] does not monitor antibiotic utilization rate (AUR), calculated either as days of antibiotic therapy per patient OR as days of antibiotic therapy per 1000 patient days.

Select "Unknown" if after performing due diligence and consulting with other key team members you are unable to determine whether your NICU [or chosen unit] monitors antibiotic utilization rate (AUR), calculated either as days of antibiotic therapy per patient OR as days of antibiotic therapy per 1000 patient days.

The antibiotic utilization rate (AUR) is calculated either as days of antibiotic therapy per patient OR as days of antibiotic therapy per 1000 patient days.

20. Does your NICU *[or chosen unit]* **monitor and report antibiotic use for > 48 to 72 hours in infants with negative blood, cerebral spinal fluid, or urine cultures? Yes / No / Unknown**

Select "Yes" if your NICU [or chosen unit] monitors and reports antibiotic use for > 48 to 72 hours in infants with negative blood, cerebral spinal fluid, or urine cultures.

Select "No" if your NICU [or chosen unit] does not monitor and report antibiotic use for > 48 to 72 hours in infants with negative blood, cerebral spinal fluid, or urine cultures.

Select "Unknown" if after performing due diligence and consulting with other key team members you are unable to determine whether your NICU [or chosen unit] monitors and reports antibiotic use for > 48 to 72 hours in infants with negative blood, cerebral spinal fluid, or urine cultures.

21. Does your NICU *[or chosen unit]* **share NICU** *[or chosen unit]* **-specific reports on antibiotic use with prescribers? Yes / No / Unknown**

Select "Yes" if your NICU [or chosen unit] shares NICU [or chosen unit] -specific reports on antibiotic use with prescribers.

Select "No" if your NICU [or chosen unit] does not share NICU [or chosen unit] -specific reports on antibiotic use with prescribers.

Select "Unknown" if after performing due diligence and consulting with other key team members you are unable to determine whether your NICU [or chosen unit] shares NICU [or chosen unit] -specific reports on antibiotic use with prescribers.

22. Does your NICU *[or chosen unit]* **share NICU** *[or chosen unit]* **-specific reports on antibiotic use with families? Yes / No / Unknown**

Select "Yes" if your NICU [or chosen unit] shares NICU [or chosen unit] -specific reports on antibiotic use with families.

Select "No" if your NICU [or chosen unit] does not share NICU [or chosen unit] -specific reports on antibiotic use with families.

Select "Unknown" if after performing due diligence and consulting with other key team members you are unable to determine whether your NICU[or chosen unit] shares NICU [or chosen unit] -specific reports on antibiotic use with families.

23. Is a current antibiogram (cumulative antibiotic susceptibility report) available to prescribers at your NICU *[or chosen unit]***? Yes / No / Unknown**

Select "Yes" if a current antibiogram (cumulative antibiotic susceptibility report) is available to prescribers at your NICU [or chosen unit].

Select "No" if a current antibiogram (cumulative antibiotic susceptibility report) is not available to prescribers at your NICU [or chosen unit].

Select "Unknown" if after performing due diligence and consulting with other key team members you are unable to determine whether a current antibiogram (cumulative antibiotic susceptibility report) is available to prescribers at your NICU [or chosen unit].

24. Do prescribers in the NICU *[or chosen unit]* **receive direct personalized communication about how they can improve their antibiotic prescribing? Yes / No / Unknown**

Select "Yes" if prescribers in your NICU [or chosen unit] receive direct personalized communication about how they can improve their antibiotic prescribing.

Select "No" if prescribers in your NICU [or chosen unit] do not receive direct personalized communication about how they can improve their antibiotic prescribing.

Select "Unknown" if after performing due diligence and consulting with other key team members you are unable to determine whether prescribers in your NICU [or chosen unit] receive direct personalized communication about how they can improve their antibiotic prescribing.

V. Antibiotic Utilization Audit: Status of NICU on day of audit

NICU *[or chosen unit]* **Census**

1. Enter date of audit: _____ / _____ / _____ (month / day / year)

Please enter the month, day and year that you are auditing your NICU [or chosen unit].

2. Enter Census on the day of the audit

Please enter the total number of patients managed in your NICU [or chosen unit] on the day of audit. This includes infants both on and off antibiotic therapy.

3. Do you have any patients to enter? Yes / No

Select "Yes" if you have patients in your NICU [or chosen unit] who are receiving antibiotic therapy. This includes any patient who received antibiotic therapy on the calendar day of the audit.

Select "No" if you do not have any patients in your NICU [or chosen unit] who are receiving antibiotic therapy on the day of the audit.

Go to Patient Data Entry Form

VI. Antibiotic Utilization Audit: Patient Data

This audit is for any infant in your NICU *[or chosen unit]* currently receiving antibiotics. Antibiotic agents include any systemic antibacterial or antifungal agents (please refer to Appendix 4 regarding eligible antibiotics for consideration).

If the infant is currently receiving antibiotics, please answer the following questions:

Patient Identification

Case number: _____

The case number is a unique sequential number (starting with "1" for the first case) assigned by the data collection program (on-line audit tool). Data forms provided by VON will be sequentially numbered and should be entered into the program in sequence.

Infant Demographics

2. Enter infant's gestational age at birth in weeks and days
Weeks: _____ Days: _____

Please enter the infant's gestational age at birth in weeks and days.

3. Enter infant's birth weight in grams: _____ (grams)

Please enter the infant's birth weight in grams.

4. Enter infant's chronological age (day of life): _____ (day of life)
* Date of birth counts as calendar day 1.

Please enter the infant's chronological age. The date of birth counts as one calendar day. For example, an infant who was born on Monday and is being audited on Wednesday would be noted as 3 days of life.

5. Enter current support infant is receiving (select one only):

Please enter the current support that the infant is receiving. Only one selection is valid for support. Whatever the highest support that the infant was on for the calendar day of the audit should be entered.

- **Assisted ventilation via endotracheal tube or tracheostomy (HFV or CMV)**
  Select "Assisted ventilation via endotracheal tube or tracheostomy (HFV or CMV)" if the infant is intubated or has a tracheostomy in place and receiving either high frequency ventilation (IMV $\geq$ 240/minute) or conventional ventilation (intermittent positive pressure ventilation with a conventional ventilator with an IMV rate of <240/minute).

- **Continuous Positive Airway Pressure or Noninvasive Ventilation**
  Select "Continuous Positive Airway Pressure (via nasal prongs, nasal mask, or tracheostomy) or Noninvasive Ventilation" if the infant is receiving continuous positive airway pressure via nasal prongs, nasal pharyngeal tube, nasal mask or tracheostomy or is receiving intermittent mandatory ventilation (IMV) via nasal prongs, nasal pharyngeal tube or nasal mask.

- **High flow nasal cannula**
  Select "High flow nasal cannula" if the infant is on nasal cannula with a flow rate of ≥ 1 L/min.

- **Oxygen only**
  Select "Oxygen only" if the infant is on supplemental oxygen (FiO_2 > 0.21) at the time of the audit. Oxygen can be given by low flow cannula or head box.

- **No support**
  Select no respiratory support if the infant is on none of the devices listed above.

Antibiotic Exposure

6. What were the indications for starting the infant on antibiotic therapy? (the infant may have more than one indication for starting antibiotic therapy)

Select the indication(s) for starting the infant on antibiotic therapy. An infant may have more than one indication for why antibiotic therapy was started.

a. Maternal risk factors **Yes / No / Unknown**

Select "Yes" if the infant was started on antibiotics due to maternal risk factors.

Select "No" if the infant was not started on antibiotics due to maternal risk factors.

Select "Unknown" if after performing due diligence and consulting with other key team members you are unable to determine whether the infant was started on antibiotics due to maternal risk factors.

Note: Maternal risk factors might include maternal fever, GBS status, length of rupture of membranes, chorioamnionitis. Chorioamnionitis is also known as intraamniotic infection.

b. Suspected or proven early onset sepsis or meningitis **Yes / No / Unknown**

Select "Yes" if the indication for starting the infant on antibiotic therapy was suspected or proven early onset sepsis or meningitis.

Select "No" if the indication for starting the infant on antibiotic therapy was not suspected or proven early onset sepsis or meningitis.

Select "Unknown" if after performing due diligence and consulting with other key team members you are unable to determine whether the indication for starting the infant on antibiotic therapy was suspected or proven early onset sepsis or meningitis.

c. Suspected or proven late onset sepsis or meningitis **Yes / No / Unknown**

Select "Yes" if the indication for starting the infant on antibiotic therapy was suspected or proven late onset sepsis or meningitis.

Select "No" if the indication for starting the infant on antibiotic therapy was not suspected or proven late onset sepsis or meningitis.

Select "Unknown" if after performing due diligence and consulting with other key team members you are unable to determine whether the indication for starting the infant on antibiotic therapy was suspected or proven late onset sepsis or meningitis.

d. Suspected or proven ventilator associated pneumonia Yes / No / Unknown

Select "Yes" if the indication for starting the infant on antibiotic therapy was suspected or proven ventilator associated pneumonia.

Select "No" if the indication for starting the infant on antibiotic therapy was not suspected or proven ventilator associated pneumonia.

Select "Unknown" if after performing due diligence and consulting with other key team members you are unable to determine whether the indication for starting the infant on antibiotic therapy was suspected or proven ventilator associated pneumonia.

e. Suspected or proven central venous line infection Yes / No / Unknown

Select "Yes" if the indication for starting the infant on antibiotic therapy was suspected or proven central venous line infection.

Select "No" if the indication for starting the infant on antibiotic therapy was not suspected or proven central venous line infection.

Select "Unknown" if after performing due diligence and consulting with other key team members you are unable to determine whether the indication for starting the infant on antibiotic therapy was suspected or proven central venous line infection.

f. Suspected or proven urinary tract infection Yes / No / Unknown

Select "Yes" if the indication for starting the infant on antibiotic therapy was suspected or proven urinary tract infection.

Select "No" if the indication for starting the infant on antibiotic therapy was not suspected or proven urinary tract infection.

Select "Unknown" if after performing due diligence and consulting with other key team members you are unable to determine whether the indication for starting the infant on antibiotic therapy was suspected or proven urinary tract infection.

g. Suspected or proven necrotizing enterocolitis Yes / No / Unknown

Select "Yes" if the indication for starting the infant on antibiotic therapy was suspected or proven necrotizing enterocolitis.

Select "No" if the indication for starting the infant on antibiotic therapy was not suspected or proven necrotizing enterocolitis.

Select "Unknown" if after performing due diligence and consulting with other key team members you are unable to determine whether the indication for starting the infant on antibiotic therapy was suspected or proven necrotizing enterocolitis.

h. Suspected or proven surgical site infection Yes / No / Unknown

Select "Yes" if the indication for starting the infant on antibiotic therapy was suspected or proven surgical site infection.

Select "No" if the indication for starting the infant on antibiotic therapy was not suspected or proven surgical site infection.

Select "Unknown" if after performing due diligence and consulting with other key team members you are unable to determine whether the indication for starting the infant on antibiotic therapy was suspected or proven surgical site infection.

i. Prophylaxis for urinary tract infection **Yes / No / Unknown**

Select "Yes" if the indication for starting the infant on antibiotic therapy was prophylaxis for urinary tract infection.

Select "No" if the indication for starting the infant on antibiotic therapy was not prophylaxis for urinary tract infection.

Select "Unknown" if after performing due diligence and consulting with other key team members you are unable to determine whether the indication for starting the infant on antibiotic therapy was prophylaxis for urinary tract infection.

j. Prophylaxis for surgery **Yes / No / Unknown**

Select "Yes" if the indication for starting the infant on antibiotic therapy was prophylaxis for surgery.

Select "No" if the indication for starting the infant on antibiotic therapy was not prophylaxis for surgery.

Select "Unknown" if after performing due diligence and consulting with other key team members you are unable to determine whether the indication for starting the infant on antibiotic therapy was prophylaxis for surgery.

k. Prophylaxis for fungal sepsis **Yes / No / Unknown**

Select "Yes" if the indication for starting the infant on antibiotic therapy was prophylaxis for fungal sepsis.

Select "No" if the indication for starting the infant on antibiotic therapy was not prophylaxis for fungal sepsis.

Select "Unknown" if after performing due diligence and consulting with other key team members you are unable to determine whether the indication for starting the infant on antibiotic therapy was prophylaxis for fungal sepsis.

l. Methicillin resistant Staphylococcus aureus (MRSA) colonization Yes / No / Unknown

Select "Yes" if the indication for starting the infant on antibiotic therapy was suspected or proven methicillin resistant Staphylococcus aureus (MRSA) colonization.

Select "No" if the indication for starting the infant on antibiotic therapy was not suspected or proven methicillin resistant Staphylococcus aureus (MRSA) colonization.

Select "Unknown" if after performing due diligence and consulting with other key team members you are unable to determine whether the indication for starting the infant on antibiotic therapy was suspected or proven methicillin resistant Staphylococcus aureus (MRSA) colonization.

m. Other **Yes / No / Unknown**

Other indication: _____

7. Were blood culture(s) obtained prior to initiation of this course of antibiotic therapy? Yes / No / Unknown

Select "Yes" if blood cultures were obtained prior to initiation of this course (the most recent course) of antibiotic therapy.

Select "No" if blood cultures were not obtained prior to initiation of this course (the most recent course) of antibiotic therapy. Go to question 8.

Select "Unknown" if after performing due diligence and consulting with other key team members you are unable to determine whether blood cultures were obtained prior to initiation of this course (the most recent course) of antibiotic therapy. Go to question 8.

7a. Was an organism subsequently identified from the infant's blood culture(s)? Yes / No / Unknown

Select "Yes" if an organism was subsequently identified from blood cultures obtained prior to initiation of this course of antibiotic therapy.

Select "No" if an organism was not subsequently identified from blood cultures obtained prior to initiation of this course of antibiotic therapy. Go to question 8.

Select "Unknown" if after performing due diligence and consulting with other key team members you are unable to determine whether an organism was subsequently identified from blood cultures obtained prior to initiation of this course of antibiotic therapy. Go to question 8.

7b. Indicate the organisms identified:

Select from the below list of selected organisms. A blood culture may grow more than one organism.

- **Known bacterial pathogen (not a resistant organism) Yes / No**

  Select "Yes" if a known bacterial pathogen that is not a resistant organism was subsequently identified on blood culture. The list of known bacterial pathogens is included in Appendix 5.

  Select "No" if a no known bacterial pathogen that is not a resistant organism was subsequently identified on blood culture.

- **Coagulase-negative Staphylococcus (CoNS) Yes / No**

  Select "Yes" if Coagulase-negative Staphylococcus (CoNS) was identified on blood culture.

  Select "No" if Coagulase-negative Staphylococcus (CoNS) was not identified on blood culture.

- **Methicillin-resistant Staphylococcus aureus (MRSA) Yes / No**

  Select "Yes" if Methicillin-resistant Staphylococcus aureus (MRSA) was identified on blood culture.

  Select "No" if Methicillin-resistant Staphylococcus aureus (MRSA) was not identified on blood culture.

- **Vancomycin resistant enterococcus** **Yes / No**

  Select "Yes" if Vancomycin resistant enterococcus was identified on blood culture.

  Select "No" if Vancomycin resistant enterococcus was not identified on blood culture.

- **Gram negative bacilli resistant to 3rd generation cephalosporin Yes / No**

  Select "Yes" if gram negative bacilli resistant to 3rd generation cephalosporin was identified on blood culture.

  Select "No" if gram negative bacilli resistant to 3rd generation cephalosporin was not identified on blood culture.

- **Fungal pathogen** **Yes / No**

  Select "Yes" if a fungal pathogen was identified on blood culture.

  Select "No" if a fungal pathogen was not identified on blood culture.

- **Other** **Yes / No**

  Other organism: _____

8. Were cerebral spinal fluid (CSF) culture(s) obtained prior to initiation of this course of antibiotic therapy? Yes / No / Unknown

Select "Yes" if cerebral spinal fluid (CSF) culture(s) was obtained prior to initiation of this course (the most recent course) of antibiotic therapy. Go to question 8a.

Select "No" if cerebral spinal fluid (CSF) culture(s) was not obtained prior to initiation of this course (the most recent course) of antibiotic therapy. Go to question 9.

Select "Unknown" if after performing due diligence and consulting with other key team members you are unable to determine whether cerebral spinal fluid (CSF) culture(s) was obtained prior to initiation of this course (the most recent course) of antibiotic therapy. Go to question 9.

8a. Was an organism subsequently identified from CSF culture(s)? Yes / No / Unknown

Select "Yes" if an organism was subsequently identified from CSF culture(s). Go to question 8b.

Select "No" if an organism was not subsequently identified from CSF culture(s). Go to question 9.

Select "Unknown" if after performing due diligence and consulting with other key team members you are unable to determine whether an organism was subsequently identified from CSF culture(s). Go to question 9.

8b. Indicate the organisms identified:

Select from the below list of selected organisms. A CSF culture may grow more than one organism.

- **Known bacterial pathogen (not a resistant organism)** **Yes / No**

Select "Yes" if a known bacterial pathogen that is not a resistant organism was subsequently identified on CSF culture. The list of known bacterial pathogens is included in Appendix 5.

Select "No" if no known bacterial pathogen that is not a resistant organism was subsequently identified on CSF culture.

- **Coagulase-negative Staphylococcus (CoNS) Yes / No**

  Select "Yes" if Coagulase-negative Staphylococcus (CoNS) was identified on CSF culture.

  Select "No" if Coagulase-negative Staphylococcus (CoNS) was not identified on CSF culture.

- **Methicillin-resistant Staphylococcus aureus (MRSA) Yes / No**

  Select "Yes" if Methicillin-resistant Staphylococcus aureus (MRSA) was identified on CSF culture.

  Select "No" if Methicillin-resistant Staphylococcus aureus (MRSA) was not identified on CSF culture.

- **Vancomycin resistant enterococcus Yes / No**

  Select "Yes" if Vancomycin resistant enterococcus was identified on CSF culture.

  Select "No" if Vancomycin resistant enterococcus was not identified on CSF culture.

- **Gram negative bacilli resistant to 3rd generation cephalosporin Yes / No**

  Select "Yes" if gram negative bacilli resistant to 3rd generation cephalosporin was identified on CSF culture

  Select "No" if gram negative bacilli resistant to 3rd generation cephalosporin was not identified on CSF culture.

- **Fungal pathogen Yes / No**

  Select "Yes" if a fungal pathogen was identified on CSF culture.

  Select "No" if a fungal pathogen was not identified on CSF culture.

- **Other Yes / No**

  Other organism:

  _____

9. Were urine culture(s) obtained via supra pubic aspiration or bladder catheter prior to initiation of this course of antibiotic therapy? Yes / No / Unknown

Select "Yes" if urine culture(s) were obtained via supra pubic aspiration or bladder catheter prior to initiation of this course (the most recent course) of antibiotic therapy. Go to question 9a.

Select "No" if no urine culture(s) were obtained via supra pubic aspiration or bladder catheter prior to initiation of this course (the most recent course) of antibiotic therapy. Go to question 10.

Select "Unknown" if after performing due diligence and consulting with other key team members you are unable to determine whether urine culture(s) were obtained via supra

pubic aspiration or bladder catheter prior to initiation of this course (the most recent course) of antibiotic therapy. Go to question 10.

9a. Was an organism subsequently identified from urine culture(s)? Yes / No / Unknown

Select "Yes" if an organism was subsequently identified from urine culture(s). Go to question 9b.

Select "No" if no organism was subsequently identified from urine culture(s). Go to question 10.

Select "Unknown" if after performing due diligence and consulting with other key team members you are unable to determine whether an organism was subsequently identified from urine culture(s). Go to question 10.

9b. Indicate the organisms identified:

- **Known bacterial pathogen (not a resistant organism) Yes / No**

  Select "Yes" if a known bacterial pathogen that is not a resistant organism was subsequently identified on urine culture. The list of known bacterial pathogens is included in Appendix 5.

  Select "No" if no known bacterial pathogen that is not a resistant organism was subsequently identified on urine culture.

- **Coagulase-negative Staphylococcus (CoNS) Yes / No**

  Select "Yes" if Coagulase-negative Staphylococcus (CoNS) was identified on urine culture.

  Select "No" if Coagulase-negative Staphylococcus (CoNS) was not identified on urine culture.

- **Methicillin-resistant Staphylococcus aureus (MRSA) Yes / No**

  Select "Yes" if Methicillin-resistant Staphylococcus aureus (MRSA) was identified on urine culture.

  Select "No" if Methicillin-resistant Staphylococcus aureus (MRSA) was not identified on urine culture.

- **Vancomycin resistant enterococcus Yes / No**

  Select "Yes" if Vancomycin resistant enterococcus was identified on urine culture.

  Select "No" if Vancomycin resistant enterococcus was not identified on urine culture.

- **Gram negative bacilli resistant to 3rd generation cephalosporin Yes / No**

  Select "Yes" if gram negative bacilli resistant to 3rd generation cephalosporin was identified on urine culture.

Select "No" if gram negative bacilli resistant to 3rd generation cephalosporin was not identified on urine culture.

- **Fungal pathogen** **Yes / No**

  Select "Yes" if a fungal pathogen was identified on urine culture.

  Select "No" if a fungal pathogen was not identified on urine culture.

- **Other** **Yes / No**

  Other organism: _____

10. Please select the type of systemic antibiotic agent(s) the infant is receiving. Please note all antibiotics that the infant has received or is scheduled to receive on the day of the audit. Antibiotic agents include systemic antibacterial and antifungal agents (refer to Appendix 4).

Please note: An infant may be on more than one agent and may be on antibiotics for different indications. Antivirals, topical and inhaled antibiotics are not eligible agents. Nystatin for oral thrush is not eligible.

Antibacterial agents (*Select from the below list of antibiotic agents).*

Ampicillin
Penicillin
Nafcillin
Oxacillin
Vancomycin
Linezolid
Cefazolin
Cefotaxime
Ceftriaxone
Ceftazidime
Cefepime
Aminoglycoside (including gentamicin, tobramycin, amikacin)
Clindamycin
Metronidazole
Piperacillin/tazobactam (Zosyn)
Ampicillin/sulbactam (Unasyn)
Meropenem
Imipenem
Amoxicillin
Sulfamethoxazole/Trimethoprim (Bactrim)
Other
Other antibacterial agent: _____

Antifungal agents (*Select from the below list of antifungal agents).*

Fluconazole
Amphotericin

Other

Other antifungal agent: _____

11. Is there an order in the paper record or in the electronic medical record detailing when each antibiotic will be discontinued? Yes / No / Unknown

Select "Yes" if there is an order in the paper record or in the electronic medical record detailing when the antibiotics will be discontinued.

Select "No" if there is not an order in the paper record or in the electronic medical record detailing when the antibiotics will be discontinued.

Select "Unknown" if after performing due diligence and consulting with other key team members you are unable to determine whether there is an order in the paper record or in the electronic medical record detailing when the antibiotics will be discontinued.

12. Has the infant received greater than 48 hours of systemic antibiotics? Yes / No / Unknown

Select "Yes" if the infant has received greater than 48 consecutive hours of systemic antibiotics. Go to question 13.

Select "No" if the infant has not received greater than 48 consecutive hours of systemic antibiotics. Go to question 14.

Select "Unknown" if after performing due diligence and consulting with other key team members you are unable to determine whether the infant has received greater than 48 consecutive hours of systemic antibiotics. Go to question 14.

13. If the infant is on > 48 hours of antibiotics, which of the following contributed to your decision to continue antibiotic therapy? Check all that apply.

a. Positive blood culture or culture from other normally sterile fluid (including cerebral spinal fluid, blood, or urine) Yes / No / Unknown

Select "Yes" if a positive blood culture was obtained from any of these normally sterile sites.

Select "No" if a positive blood culture was not obtained from any of these normally sterile sites.

Select "Unknown" if after performing due diligence and consulting with other key team members you are unable to determine whether a positive blood culture was obtained from any of these normally sterile sites.

b. Awaiting culture results Yes / No / Unknown

Select "Yes" if you are awaiting culture results from either blood or other normally sterile fluid (including cerebral spinal fluid, blood or urine).

Select "No" if you are not awaiting culture results from either blood or other normally sterile fluid (including cerebral spinal fluid, blood or urine).

Select "Unknown" if after performing due diligence and consulting with other key team members you are unable to determine whether you are awaiting culture results from either blood or other normally sterile fluid (including cerebral spinal fluid, blood or urine).

c. Laboratory results were concerning for risk of sepsis Yes / No / Unknown

Select "Yes" if laboratory results were concerning for the risk of sepsis.

Select "No" if laboratory results were not concerning for the risk of sepsis.

Select "Unknown" if after performing due diligence and consulting with other key team members you are unable to determine whether laboratory results were concerning for the risk of sepsis.

d. Clinical signs concerning for risk of sepsis Yes / No / Unknown

Select "Yes" if there were clinical signs concerning for risk of sepsis.

Select "No" if there were no clinical signs concerning for risk of sepsis.

Select "Unknown" if after performing due diligence and consulting with other key team members you are unable to determine whether there were clinical signs concerning for risk of sepsis.

e. Clinical signs concerning or diagnostic of necrotizing enterocolitis Yes / No / Unknown

Select "Yes" if there were clinical signs and/or radiologic findings concerning or diagnostic of necrotizing enterocolitis.

Select "No" if there were no clinical signs and/or radiologic findings concerning or diagnostic of necrotizing enterocolitis.

Select "Unknown" if after performing due diligence and consulting with other key team members you are unable to determine whether there were clinical signs and/or radiologic findings concerning or diagnostic of necrotizing enterocolitis.

f. Chest radiograph suggestive of possible pneumonia Yes / No / Unknown

Select "Yes" if the chest radiograph suggestive or diagnostic of possible pneumonia.

Select "No" if there was no chest radiograph suggestive or diagnostic of possible pneumonia.

Select "Unknown" if after performing due diligence and consulting with other key team members you are unable to determine whether there was a chest radiograph suggestive or diagnostic of possible pneumonia.

g. Other site of infection (including wound infection) Yes / No / Unknown

Select "Yes" if there was another site of infection, including wound infection.

Select "No" if there was no other site of infection, including wound infection.

Select "Unknown" if after performing due diligence and consulting with other key team members you are unable to determine whether these was another site of infection, including wound infection

h. Post-operative management Yes / No / Unknown

Select "Yes" if antibiotics were given based upon "routine" post-operative management, without specific concerns for infection.

Select "No" if antibiotics were not given based upon "routine" post-operative management, without specific concerns for infection.

Select "Unknown" if after performing due diligence and consulting with other key team members you are unable to determine whether antibiotics were given based upon "routine" post-operative management, without specific concerns for infection.

i. Central venous line or other device in place **Yes / No / Unknown**

Select "Yes" if the indication for continuing antibiotics was related to a central venous line or other device being in place.

Select "No" if the indication for continuing antibiotics was not related to a central venous line or other device being in place.

Select "Unknown" if after performing due diligence and consulting with other key team members you are unable to determine whether the indication for continuing antibiotics was related to a central venous line or other device being in place.

Note: Other devices include chest tubes, ventricular shunt.

j. Other **Yes / No / Unknown**

Select "Yes" if there were any other indications for continuing antibiotics. Please explain in text box below.

Other: _____

14. Is the need for antibiotic administration the sole reason for continued hospitalization? Yes / No / Unknown

Check "Yes" if the need for antibiotic administration is the sole reason for continued hospitalization.

Check "No" if the need for antibiotic administration is not the sole reason for continued hospitalization.

Check "Unknown" if after performing due diligence and consulting with other key team members you are unable to determine whether the need for antibiotic administration is the sole reason for continued hospitalization.

15. Are the parents aware (by interview at the bedside, from chart notes, or from staff reports) that their infant is on antibiotics? Yes / No / Unknown

Check "Yes" if the parents are aware (based on interview at the bedside, chart notes or from staff reports) that their infant is on antibiotics. Go to question 16.

Check "No" if the parents are not aware (based on interview at the bedside, chart notes or from staff reports) that their infant is on antibiotics. Go to post audit questions.

Check "Unknown" if after performing due diligence and consulting with other key team members you are unable to determine whether the parents are aware (based on interview at the bedside, chart notes or from staff reports) that their infant is on antibiotics. Go to post audit questions.

16. Do the parents know (by interview at the bedside, from chart notes, or from staff reports) when the antibiotics are planned to be discontinued? Yes / No / Unknown

Select "Yes" if the parents know (based on interview at the bedside, chart notes, or from staff reports) when the antibiotics are planned to be discontinued.

Select "No" if the parents do not know (based on interview at the bedside, chart notes, or from staff reports) when the antibiotics are planned to be discontinued.

Select "Unknown" if after performing due diligence and consulting with other key team members you are unable to determine whether the parents know (based on interview at the bedside, chart notes, or from staff reports) when the antibiotics are planned to be discontinued.

Do you have any additional patients to enter? Yes / No

Select "Yes" if there are additional patients in your NICU who are on antibiotics who will be audited.

Select "No" if you have completed auditing all infants on antibiotics in your unit.

Please note, if you attempt to enter more patients than were noted in your answer to unit census, you will receive an error message.

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3. Levin PD, Idrees S, Sprung CL, et al. Antimicrobial use in the ICU: indications and accuracy--an observational trial. Journal of Hospital Medicine: an official publication of the Society of Hospital Medicine. Nov-Dec 2012;7(9):672-678.

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6. Fridkin SK, Baggs J, Fagan R, et al. Vital Signs: Improving Antibiotic Use Among Hospitalized Patients. MMWR. Morbidity and Mortality Weekly Report. 2014;63.

7. Centers for Disease Control and Prevention. Antibiotic resistance threats in the United States, 2013 Atlanta, GA: CDC;2013. Centers for Disease Control and Prevention. Get Smart: Know When Antibiotics Work. http://www.cdc.gov/getsmart/healthcare/. Accessed 12/14/2015.

8. Huttner A, Harbarth S, Carlet J, et al. Antimicrobial resistance: a global view from the 2013 World Healthcare-Associated Infections Forum. Antimicrobial Resistance and Infection Control. Nov 18 2013;2(1):31.

9. Davey P, Brown E, Charani E, et al. Interventions to improve antibiotic prescribing practices for hospital inpatients. The Cochrane Database of Systematic Reviews. 2013;4:CD003543

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11. Ho T, Dukhovny D, Zupancic J, Pursley D, Srinivasan A, Pollock D, Soll R, Buus-Frank M, Edwards E, Morrow K, Ferrelli K, Horbar J. Antibiotic Stewardship in Neonatal Intensive Care Units (NICUs). Submitted to PAS, San Francisco, 2017.

Appendices

Appendix 1: Unit Data Form

Appendix 2: Individual Patient Data Form

Appendix 3: Measures

Appendix 4: Antibiotic Agents

Appendix 5: Bacterial Pathogens

Appendix 1

Vermont Oxford Network
VON Day Quality Audit: Choosing Antibiotics Wisely
Unit Questionnaire

Unit Level Policies and Guidelines
Center number: _____

We are planning to audit our: (choose only one location)
a. NICU b. Neonatal Step-down Unit c. Newborn Nursery (Mother/Baby Unit)

Organizational Commitment and Culture

1. Does your NICU *[or chosen unit]* have a formal written project plan that engages senior leadership in efforts to improve antibiotic use (antibiotic stewardship)?

Yes / No / Unknown

2. Does your NICU *[or chosen unit]* receive any budgeted financial support for antibiotic stewardship activities (e.g. support or salary, training, or IT support)?

Yes / No / Unknown

3. Is there a physician leader responsible for the outcomes of stewardship activities in your NICU *[or chosen unit]*?

Yes / No / Unknown

4. Is there a pharmacist leader responsible for working to improve antibiotic use in your NICU *[or chosen unit]*?

Yes / No / Unknown

5. Does your NICU *[or chosen unit]* have a multidisciplinary team responsible for antibiotic stewardship?

Yes / No / Unknown

If 'No' or 'Unknown' skip to Question 6.

5a. If yes to 5, Which of the following are members of the multidisciplinary team?

	Yes	No	Unknown
Neonatologist(s)	○	○	○
Pharmacist(s)	○	○	○
Infection Prevention and Health Care Epidemiologist(s)	○	○	○
Infectious Disease Specialist(s)	○	○	○
Quality Improvement Specialist(s)	○	○	○
Microbiology Laboratory Technician(s)	○	○	○
Information Technologist(s) (IT)	○	○	○
Nurse(s)	○	○	○
Nurse Practitioner(s) / Physician Assistant(s)	○	○	○
Parent(s) / Consumer Advisor(s)	○	○	○

6. Does your NICU *[or chosen unit]* provide education to clinicians and other relevant staff on improving antibiotic prescribing?

Yes / No / Unknown

Policies, Protocols, and Guidelines

7. Does your NICU *[or chosen unit]* have a policy that requires prescribers to document in the medical record or during order entry the dose, duration, and indication for all antibiotic prescriptions?

Yes / No / Unknown

8. Is there a formal procedure or process prompting the NICU *[or chosen unit]* care team to review the appropriateness of all antibiotics prescribed for infants in the NICU *[or chosen unit]* 48 to 72 hours after the initial order (e.g. "antibiotic time out")?

Yes / No / Unknown

9. Do specified antibiotic agents need to be approved by a physician (such as an infectious disease specialist) or a pharmacist prior to dispensing (i.e. pre- authorization)?

Yes / No / Unknown

10. Does a physician or pharmacist review courses of therapy for specified antibiotic agents (e.g. prospective audit with feedback)?

Yes / No / Unknown

NICU Specific Policies and Guidelines

11. Does your NICU *[or chosen unit]* have specific policies, protocols, or guidelines for the diagnosis and antibiotic treatment (including antibiotic choice, dose, and duration) for the following conditions?

	Yes	No	Unknown
a. Maternal risk factors	○	○	○
b. Suspected or proven early onset sepsis or meningitis	○	○	○
c. Suspected or proven late onset sepsis or meningitis	○	○	○
d. Suspected or proven ventilator associated pneumonia	○	○	○
e. Suspected or proven central venous line infection	○	○	○
f. Suspected or proven urinary tract infection	○	○	○
g. Suspected or proven necrotizing enterocolitis	○	○	○
h. Suspected or proven surgical site infection	○	○	○
i. Prophylaxis for urinary tract infection	○	○	○
j. Prophylaxis for surgery	○	○	○
k. Prophylaxis for fungal sepsis	○	○	○
l. Methicillin resistant *Staphylococcus aureus* (MRSA) colonization?	○	○	○
m. Other			

Other condition:_____

12. Does your NICU *[or chosen unit]* routinely use any of the following electronic systems to prescribe, dispense, or administer medications?

	Yes	No	Unknown
a. Computerized physician order entry or an order management system (CPOE or CPROM)	○	○	○
b. Electronic medication administration record (eMAR)	○	○	○
c. Bar coded medication administration (BCMA)	○	○	○

13. Does your NICU routinely use the Neonatal Early-Onset Sepsis Calculator to evaluate the risk of early-onset infection among infants born at or above 34 weeks gestation?

Yes / No / Unknown

Pharmacy driven interventions to assure appropriate antibiotic treatment

14. Does your NICU *[or chosen unit]* have policies or guidelines for:	Yes	No	Unknown
a. Dose adjustment in cases of organ dysfunction	○	○	○
b. Dose adjustment or customization based on gestational or chronological age	○	○	○
c. Dose optimization (pharmacokinetics/pharmacodynamics) to optimize the treatment of organisms with reduced susceptibility	○	○	○
d. Automatic alerts in situations where therapy might be unnecessarily duplicative	○	○	○
e. Time sensitive automatic stop orders for specified antibiotic prescriptions	○	○	○

Regular monitoring or reporting on antibiotic use and resistance

15. Does your NICU *[or chosen unit]* monitor and report prescriber adherence to specific treatment recommendations?

Yes / No / Unknown

16. Does your NICU *[or chosen unit]* monitor and report adherence of prescribing providers to documentation of the 3 key components for every antibiotic order / prescription (dose, duration, and indication)?

Yes / No / Unknown

Antibiotic use and outcome measures

17. Does your NICU *[or chosen unit]* participate in the National Healthcare Safety Network (NHSN) Healthcare-Associated Infection (HAI) tracking system?

Yes / No / Unknown

18. Does your NICU *[or chosen unit]* participate in the National Healthcare Safety Network (NHSN) Antibiotic Use (AU) and Resistance Module?

Yes / No / Unknown

19. Does your NICU *[or chosen unit]* monitor antibiotic utilization rate (AUR) [either as days of antibiotic therapy / patient OR days of antibiotic therapy / 1000 patient days]?

Yes / No / Unknown

20. Does your NICU *[or chosen unit]* monitor and report antibiotic use for > 48 to 72 hours in infants with negative blood, cerebral spinal fluid, or urine cultures?

Yes / No / Unknown

21. Does your NICU *[or chosen unit]* share NICU *[or chosen unit]*-specific reports on antibiotic use with prescribers?

Yes / No / Unknown

22. Does your NICU *[or chosen unit]* share NICU *[or chosen unit]*-specific reports on antibiotic use with families?

Yes / No / Unknown

23. Is a current antibiogram (cumulative antibiotic susceptibility report) available to prescribers at your NICU *[or chosen unit]*?

Yes / No / Unknown

24. Do prescribers in the NICU *[or chosen unit]* receive direct personalized communication about how they can improve their antibiotic prescribing?

Yes / No / Unknown

Status of NICU *[or chosen unit]* on day of audit

NICU *[or chosen unit]* Census

1. Enter date of audit: ____ / ____ / ____

2. Enter [_____] Census on the day of the audit (will be filled in with either NICU, Step-down Unit or Newborn Nursery, whichever location you chose in the beginning of the audit.)

Patients: _____

Do you have any patients to enter? Yes / No

Go to Patient Data Entry Form

Appendix 2: Individual Patient Data Form

VON Center Number: _____ Patient ID: _____(DO NOT SUBMIT ANY PATIENT IDENTIFIABLE DATA TO VON)

If the infant is currently receiving antibiotics, please answer the following questions:

Infant demographics

2. Enter gestational age at birth in weeks and days: _____weeks _____ days

3. Enter infant's birth weight in grams: _____ grams

4. Enter infant's chronological age (day of life):* Date of birth counts as calendar day 1. _____ days

5. Enter current support infant is receiving (select one only):

☐Assisted ventilation via endotracheal tube or tracheostomy (HFV or CMV) ☐ Continuous Positive Airway Pressure or Noninvasive Ventilation ☐High flow nasal cannula ☐Oxygen only ☐No support

Antibiotic Exposure

6. What were the indications for starting the infant on antibiotic therapy? (the infant may have more than one indication for starting antibiotic therapy)

	Yes	No	Unknown
a. Maternal risk factors	○	○	○
b. Suspected or proven early onset sepsis or meningitis	○	○	○
c. Suspected or proven late onset sepsis or meningitis	○	○	○
d. Suspected or proven ventilator associated pneumonia	○	○	○
e. Suspected or proven central venous line infection	○	○	○
f. Suspected or proven urinary tract infection	○	○	○
g. Suspected or proven necrotizing enterocolitis	○	○	○
h. Suspected or proven surgical site infection	○	○	○
i. Prophylaxis for urinary tract infection	○	○	○
j. Prophylaxis for surgery	○	○	○
k. Prophylaxis for fungal sepsis	○	○	○
l. Methicillin resistant Staphylococcus aureus (MRSA) colonization	○	○	○
m. Other	○	○	○

Other indication: _____

7. Were blood culture(s) obtained prior to initiation of this course of antibiotic therapy? Yes No Unknown

If 'No' or 'Unknown', skip to Question 8.

7a. Was an organism subsequently identified from blood culture(s)? Yes No Unknown

If 'No' or 'Unknown', skip to Question 8.

7b. Indicate the organisms identified:	Yes	No
Known bacterial pathogen (not a resistant organism)	○	○
Coagulase-negative Staphylococcus (CoNS)	○	○
Methicillin-resistant Staphylococcus aureus (MRSA)	○	○
Vancomycin resistant enterococcus	○	○
Gram negative bacilli resistant to 3rd generation cephalosporin	○	○
Fungal pathogen	○	○
Other	○	○

Other organism: _____

8. Were cerebral spinal fluid (CSF) culture(s) obtained prior to initiation of this course of antibiotic therapy? Yes No Unknown

If 'No' or 'Unknown', skip to Question 9.

8a. Was an organism subsequently identified from CSF culture(s)? Yes No Unknown

If 'No' or 'Unknown', skip to Question 9.

8b. Indicate the organisms identified:	Yes	No
Known bacterial pathogen (not a resistant organism)	○	○
Coagulase-negative Staphylococcus (CoNS)	○	○
Methicillin-resistant Staphylococcus aureus (MRSA)	○	○
Vancomycin resistant enterococcus	○	○
Gram negative bacilli resistant to 3rd generation cephalosporin	○	○
Fungal pathogen	○	○
Other	○	○

Other organism: _____

VON Center Number: _____ Patient ID: _____(DO NOT SUBMIT ANY PATIENT IDENTIFIABLE DATA TO VON)

9. Were urine culture(s) obtained prior to initiation of this course of antibiotic therapy? Yes | No | Unknown

If 'No' or 'Unknown', skip to Question 10.

9a. Was an organism subsequently identified from urine culture(s)? Yes | No | Unknown

If 'No' or 'Unknown', skip to Question 10.

9b. Indicate the organisms identified:

	Yes	No
Known bacterial pathogen (not a resistant organism)	○	○
Coagulase-negative Staphylococcus (CoNS)	○	○
Methicillin-resistant Staphylococcus aureus (MRSA)	○	○
Vancomycin resistant enterococcus	○	○
Gram negative bacilli resistant to 3rd generation cephalosporin	○	○
Fungal pathogen	○	○
Other	○	○

Other organism: _____

10. Please select the type of systemic antibiotic agents the infant is receiving. Please note all antibiotics that the infant has received or scheduled to receive on the day of the audit. Antibiotic agents include systemic antibacterial and antifungal agents.

Please note: An infant may be on more than one agent and may be on antibiotics for different indications. Antivirals, topical and inhaled antibiotics are not eligible agents. Nystatin for oral thrush is not eligible.

Ampicillin
Penicillin
Nafcillin
Oxacillin
Vancomycin
Linezolid
Cefazolin
Cefotaxime
Ceftriaxone
Ceftazidime
Cefepime
Aminoglycoside (including gentamicin, tobramycin, amikacin)
Clindamycin
Metronidazole
Piperacillin/tazobactam (Zosyn)
Ampicillin/sulbactam (Unasyn)
Meropenem
Imipenem
Amoxicillin
Sulfamethoxazole/Trimethoprim (Bactrim)
Other antibacterial agent: _____

Antifungal agents
Fluconazole
Amphotericin
Other antifungal agent: _____

11. Is there an order in the paper record or in the electronic medical record detailing when each antibiotic will be discontinued? Yes | No | Unknown

If the infant is < 48 hours of age, skip to Question 14.

12. Has the infant received greater than 48 hours of systemic antibiotics? Yes | No | Unknown

If 'No" or 'Unknown' skip to Question 14.

13. If the infant is on > 48 hours of antibiotics, which of the following contributed to your decision to continue antibiotic therapy?

	Yes	No	Unknown
a. Positive blood culture or culture from other normally sterile fluid (including cerebral spinal fluid, blood, or urine)	○	○	○
b. Awaiting culture results	○	○	○
c. Laboratory results were concerning for risk of sepsis	○	○	○
d. Clinical signs concerning for risk of sepsis	○	○	○
e. Clinical signs concerning or diagnostic of necrotizing enterocolitis	○	○	○
f. Chest radiograph suggested possible pneumonia	○	○	○
g. Other site of infection (including wound infection)	○	○	○
h. Post-operative management	○	○	○
i. Central venous line or other device in place	○	○	○
j. Other :	○	○	○

Other: _____

14. Is the need for antibiotic administration the sole reason for continued hospitalization? Yes | No | Unknown

15. Are the parents aware (by interview at the bedside, from chart notes, or from staff reports) that their infant is on antibiotics? Yes | No | Unknown

If you answer 'No' or 'Unknown' to Question 15, skip Question 16.

16. Do the parents know (by interview at the bedside, from chart notes, or from staff reports) when the antibiotics are planned to be discontinued? Yes | No | Unknown

Appendix 3: Antibiotic Utilization Audit: Key Measures

Key Measures:

1. Existence of antibiotic stewardship program (Yes to 1 to 5)

2. Does your NICU have a policy that requires prescribers to document in the medical record or during order entry the dose, duration, and indication for all antibiotic prescriptions? (Yes to Question 7)

3. Is there a formal procedure or process prompting the NICU care team to review the appropriateness of all antibiotics prescribed for infants in the NICU 48 to 72 hours after the initial order (e.g. "antibiotic time out")? Yes / No / Unknown (Yes to Question 8)

4. Unit Antibiotic Utilization Rate

5. In infants without positive cultures (data from questions 7-9), is the need for antibiotic administration the sole reason for continued hospitalization? (no to questions 7-9 and yes to question 14)

6. Are the parents aware (by interview at the bedside, from chart notes, or from staff reports) that their infant is on antibiotics? Yes to question 15)

Appendix 4: Antimicrobial agents

a. Antibacterial agents

Ampicillin
Penicillin
Nafcillin
Oxacillin
Vancomycin
Linezolid
Cefazolin
Cefotaxime
Ceftriaxone
Ceftazidime
Cefepime
Aminoglycoside (including gentamicin, tobramycin, amikacin)
Clindamycin
Metronidazole
Piperacillin/tazobactam (Zosyn)
Ampicillin/sulbactam (Unasyn)
Meropenem
Imipenem
Amoxicillin
Sulfamethoxazole/Trimethoprim (Bactrim)

b. Antifungal agents

Fluconazole
Amphotericin

Appendix 5: Bacterial Pathogens

1. Achromobacter species [including Achromobacter xylosoxidans (also known as Alcaligenes xylosoxidans) and others]
2. Acinetobacter species
3. Aeromonas species
4. Alcaligenes species [Alcaligenes xylosoxidans and others]
5. Bacteroides species
6. Burkholderia species [Burkholderia capecia and others]
7. Campylobacter species [Campylobacter fetus, C. jejuni and others]
8. Chryseobacterium species
9. Citrobacter species [Citrobacter diversus, C. freundii, C. koseri and others]
10. Clostridium species
11. Enterobacter species [Enterobacter aerogenes, E. cloacae, and others]
12. Enterococcus species [Enterococcus faecalis (also known as Streptococcus faecalis), E. faecium, and other Enterococcus species]
13. Escherichia coli
14. Flavobacterium species
15. Haemophilus species [Haemophilus influenzae and others]
16. Klebsiella species [Klebsiella oxytoca, K. pneumoniae and others]
17. Listeria monocytogenes
18. Moraxella species [Moraxella catarrhalis (also known as Branhamella catarrhalis) and others]
19. Neisseria species [Neisseria meningitidis, N. gonorrhoeae and others]
20. Pasteurella species
21. Prevotella species
22. Proteus species [Proteus mirabilis, P. vulgaris and others]
23. Providencia species [Providencia rettgeri, and others]
24. Pseudomonas species [Pseudomonas aeruginosa and others]
25. Ralstonia species
26. Salmonella species
27. Serratia species [Serratia liquefaciens, S. marcescens and others]
28. Staphylococcus coagulase positive [aureus]
29. Stenotrophomonas maltophilia
30. Streptococcus species [including Streptococcus Group A, Streptococcus Group B, Streptococcus Group D, Streptococcus pneumoniae, Strep milleri and others]

Section 6

iNICQ 2018 and VON Day Quality Audit: Choosing Antibiotics Wisely

FAQs

iNICQ 2018: Choosing Antibiotics Wisely
FAQs

Unit Setting

Query 1. Will the iNICQ 2018 Collaborative be applicable just to the NICU? Or is there benefit for newborn nurseries or others who care for antibiotic-exposed newborns?

The webinars will have clear clinical relevance to all levels of care, particularly for units that are screening for early onset infection, late onset infection, and prescribing and administering antibiotics.

The VON Day Audit, however, will be conducted in a single unit (not multiple units). If your center has a NICU, that will be the site for the VON Day Audit. If your center does not have an NICU per se, it will be appropriate to perform the audit in the unit where antibiotics are actively prescribed and administered.

If you do not have a NICU, you can choose to audit either a Neonatal Stepdown Unit or a Newborn Nursery(Mother/Baby Unit). You can choose only one unit for the audit and you will need to audit the same unit in November.

Query 2. We are a small facility but I would like to change antibiotic practice to better serve our population, even if it is in small numbers. Is this program strictly for neonates that are in hospital post birth only or should we include the population that gets readmitted to the pediatric unit within the first 30 days of life?

Although, the principles of antibiotic stewardship may apply to the neonates in the PICU setting; the VON Day Audit will focus on infants who have been hospitalized continuously since birth.

Query 3. Do the unit-level VON Day Quality Audit questions refer to our entire hospital or just our specific unit?

These questions pertain to the unit that you are auditing, not your entire hospital or center. The unit of interest should be a unit that cares for newborn infants.

IRB Approval

Query 4. Do we need to get IRB approval to participate?

The iNICQ Collaborative, VON Day Quality Audit, and use of the Choosing Antibiotics Wisely Toolkit are designed for the sole purpose of facilitating structured local quality improvement efforts. The aggregated results of the collaborative and improvement stories from participating sites may be presented or published. Because antibiotic therapy and infection monitoring are a prominent part of the Choosing Antibiotics Wisely program, this Toolkit and collaborative activities necessarily address these areas.

It is important for all parties to understand that no specific interventions, bundles, or protocols are being tested or promoted in the Toolkit or QI Collaborative. However, as a result of

involvement in this iNICQ series and local self-assessments regarding the status of current clinical outcomes or antibiotic use or infection metrics, participating teams may choose to alter clinical practices in their NICUs based on the ideas they hear from the faculty and from peer-to-peer learning. Given this we recommend review by your appropriate authority.

Query 5. My center participated in the 2017 Choosing Antibiotics Wisely VON Day Audits. Do I need to resubmit materials to my IRB?

If you previously participated in the Choosing Antibiotics Wisely VON Day Quality Audits, we suggest that you contact your IRB and let them know that you are continuing with the audits for a second year. Your IRB should be able to guide you as what materials you need to submit to them. Each IRB is different so we cannot predict how they will direct you to proceed.

Query 6. Our IRB told us that no approval is necessary and this is "not human subject research." Is that sufficient?

Yes, many IRBs may provide an expedited opinion in this regard. We recommend that you get this opinion in writing for future reference. Should you ever want to publish your local project findings, proof of this detail may be required by the editorial teams of many peer-reviewed journals. It is important to get these determinations in writing, whenever possible, and keep them as an important record for future reference.

Query 7. Does the University of Vermont IRB cover the need to get IRB approval?

No. Local approval is required.

The Committee on Human Research at the University of Vermont has reviewed the protocol for conducting the VON Day Quality Audits and the plans for the iNICQ Collaborative. They have determined that the role of Vermont Oxford Network in these activities is Not Human Subjects Research. However, the University of Vermont's IRB determination pertains solely to the role of Vermont Oxford Network in sponsoring and supporting the VON Day Quality Audits and iNICQ Collaborative.

NOTE:
The approval from the University of Vermont Committees on Human Research <u>does not</u> cover any activities conducted by your local institution or staff participating in the VON Day Quality Audits or iNICQ Collaborative. Prior to participation each site participating in the VON Day Quality Audits and/or the iNICQ Collaborative must obtain any and all necessary human subjects reviews and approvals from their local institutional review boards before participating.

Query 8. What if our organization does not have an IRB? Can we still participate?

VON requires centers to get approval to conduct this project from a local governing authority (typically the IRB). However, in cases where there is NOT an IRB, we have encouraged the center to perform due diligence, and to discuss this project with whatever hospital body or group that exists that has the authority to approve QI work of this nature. Virtually every hospital is doing QI work in some capacity. With investigation, your center should be able to identify the appropriate authority. An IRB is a standard option. But if a Quality Council is the normal operating procedure for your facility, review by this or a similar group will be sufficient.

Query 9. Our center has agreements with others in our network for a multi-site IRB. Will this be sufficient?

As long as the IRB has authority to review work for your center, a multi-site IRB may be used.

Unit Data

Query 10: Regarding Organizational commitment and Culture section questions 1-5, are these questions pertaining to our current practice and culture? The reason I am asking is because we didn't have most of these processes in place, but by participating in this collaboration, we now have a pharmacist and physician leader, are developing a formal written project plan, and have formed multidisciplinary team. Can you please clarify.

This is an interesting question, but these questions should be answered based on current practice, and not planned changes.

Patient Data

Query 11. What is the eligibility criteria for the VON Day Quality Audit?

The VON Day Choosing Wisely audit is intended to audit infants on **systemic** antibiotics in your unit at the time of the audit. Infants are judged to be on antibiotics if they have received antibiotics on the day of the audit or are scheduled to receive antibiotics later that day. You are meant to round on your infants and audit all infants that have been given or are scheduled to be given antibiotics on that calendar day.

Some examples:
If an infant is given it's last dose of antibiotics at 3:00 am on the day of the audit, he/she is eligible. If an infant is given antibiotic eye ointment, they are not eligible.

In repeating the audit (or any portion of the audit) that you might chose as a more frequent metric, in makes sense to audit the unit at a similar time each day, as the flow of patients in the unit may be different at different times of the day (for example, an increase in patient transfers or discharges after rounds).

Query 12. Is there a minimum number of patients needed to participate? And should we gather patients over a number of days to get to that minimum?

No, there is no minimum number of patients. You should audit your unit on ONLY ONE day of your choice within the VON Day time frame. **If you have no eligible patients, you should still complete the unit part of the audit.**

Query 13. Is there a maximum number of patients?

There is a maximum number of 100 patients. It is unlikely that any unit would have >100 patients on antibiotics on one day in your unit; however, should that occur, you will only report on the first 100 patients.

Query 14. Is Question 2 referring to gestational age at the time of the audit or gestational age at birth?

This question is referring to gestational age at birth.

Query 15. Question 6: What were the indications for starting the infant on antibiotic therapy? (The infant may have more than one indication for starting antibiotic therapy). This question specifically refers to the indications at the time of initiating the current course of antibiotic therapy.

Frequently, when antibiotics are started, there may be several possible infectious diagnoses being considered.

For example, a 10-day old, 1200 gram infant who is still on assisted ventilation develops temperature instability and a distended abdomen. At the time of the evaluation, many diagnoses may be considered, including suspected or proven late onset sepsis or meningitis, suspected or proven ventilator associated pneumonia as well as suspected or proven necrotizing enterocolitis. If, in fact, the infant has a central venous line in place, the additional diagnosis of suspected or proven central line infection may also be considered. Therefore, in this case, there are four valid possible diagnoses that would be entertained and therefore checked in responding to the question.

In the same example, if the infant did not have a central venous line in place at the time of the sepsis workup, this would not be a valid answer to that question. In answering the question, you should not consider cultures or other diagnostic tests that come back days later in influencing what you think might be the proven diagnosis or influencing your course of therapy.

Query 16: If an infant was born on January 1, was immediately put on fluconazole and had a blood culture done at the time, and then was started on antibiotics on January 14 – and the birth blood culture was the ONLY blood culture, how would I answer Question 7 – was a blood culture obtained prior to initiation of this course of antibiotic therapy?

Since there was not a blood culture done recently (immediately preceding the current course of antibiotics) the answer would be 'N0'.

Query 17. In questions 7, 8, and 9 concerning cultures that were obtained - what if we do not have the results for any of these cultures?

You should only report the results that you have on the day that you are performing the audit. Therefore if the cultures are still negative you would answer 7b (and 8b and 9b) as 'No' – an organism was not identified. You can call the lab and check and see if they have anything to report, prior to answering the question, but just report on what you know at the time.

Query 18. If a patient had blood and CSF cultures drawn by another hospital before being transferred to your unit, should those be reported?

Yes they should be reported, since those will be used in your decision to continue the course of antibiotics.

Query 19. Some investigators have asked whether or not they should follow up on infants shortly after the day of the audit to complete the audit information that may not be available until days after the audit date.

The audit is intended to be a snapshot of your unit on an individual date. Our use of antibiotics always involves a fair amount of uncertainty in our decision making. This is actually a critical point in antibiotic stewardship. It is important to know how many infants are being treated without proven culture results, particularly in a population where treatment is extended past 48 hours. This represents a potential area for stewardship opportunities. So, the audit is truly meant as a snapshot just of that day. Other data subsequent to the audit should not be included and you should complete the audit with data only reflecting the audit day.

Query 20. If a patient is on multiple agents, do they all need to have an order in the records detailing when they will be discontinued in order to answer Question 11 (Is there an order in the paper record or in the electronic medical record detailing when the antibiotics will be discontinued?) in the affirmative?

Yes, all agents must have an order in either the paper record or the electronic record in order to answer 'Yes' to this question.

Query 21. In Question 12 does that refer to 48 consecutive hours of systemic antibiotics?

The infant should be on 48 consecutive hours of systemic antibiotics to answer 'Yes' to this question.

Query 22. Is Question 13 'check all that apply'?

Yes, if you have more than one reason that contributed to your decision or if the infant is on multiple courses of antibiotics, check all that apply.

Query 23. Are patients on gentamicin eye ointment eligible for the audit?

No, topical eye ointment is not considered a systemic antibiotic, therefore this infant would not be eligible for the audit.

Query 24. I have an infant that is on acyclovir, is this infant eligible for the audit?

No, acyclovir is an anti-viral, and not considered a systemic antibiotic. Therefore this infant is not eligible for the audit.

Query 25. I want to confirm if I should include patients who are on oral nystatin for fungal infection prophylaxis when they have a central line.

Yes, fungal prophylaxis absolutely counts as an exposure. In this case the infant would be eligible. However, if the infant was receiving nystatin topically to the tongue and mouth for thrush the infant would not be eligible. This would not be considered a systemic antibiotic.

Query 26. I have a baby with NEC who is on multiple antibiotics and one is two times a week and another is every 48 hours. Neither were due the day I collected my audit information Do I include them or not since they weren't actually scheduled to be given that day?

This infant should be counted as he/she is technically on antibiotic therapy. The eligibility reads: any infant on any antibiotic therapy at the time of the audit regardless of gestational or chronological age. The infant is on antibiotic therapy, just not receiving the antibiotic on the day that the audit was performed.

Reports

Query 27. When will the report summaries be available?

Usually the report summaries are ready within a week of the close of the audit.

Query 28. ***How will we access our center data once the audit is complete?***

Your reports will be posted in the 'Member's Area' section of the VON website. Detailed instructions on how to access the reports will be sent when the reports are available.

Query 29. How can others at our center access our center data once the audit is complete?

Anyone at your center that has web services access will be able to see these reports. Your local VON Services Administrator or your VON Champion can give grant access to individuals at your center.

Query 30. How do you calculate the unit antibiotic utilization rate (AUR)?

The antibiotic utilization rate (AUR) is calculated by counting ALL babies being cared for in the unit at the time of the audit and evaluating how many of those babies are on antibiotics at the time of the audit. The AUR is a fraction of the total babies cared for (babies on antibiotics/all babies in the unit). If you have a census on the day of the audit of 10 infants and 2 infants are on antibiotics on the day of the audit, you have an AUR of 20% (2/10).

Query 31. What about other measures such as infants on antibiotics for greater than 48 hours?

The other measures utilize different dominators than the antibiotic utilization rate (AUR). For issues regarding parental awareness, the denominator is calculated only in infants ON antibiotics. This means that, from the above example, only the 2 babies on antibiotics would be in the denominator. For example, in reporting whether the "parents aware of antibiotic use", if both parents of the 2 infants on antibiotics were aware of antibiotic treatment, the measure would be reported as 100% (2/2).

For the infants that are on greater > 48 hours of antibiotics, the denominator is the infants on antibiotics AND greater > 48 hours old. This could be a subset of the infants on antibiotics on the day of the audit.