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 does not 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 ‘No’.

**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.