Pharmacist-Managed Pharmacokinetics Service



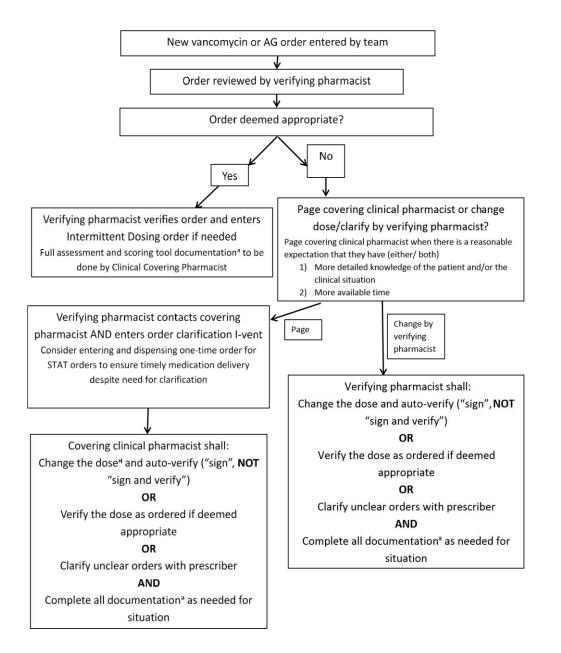
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The recommendations in this guide are meant to serve as treatment guidelines for use at Michigan Medicine facilities. If you are an individual experiencing a medical emergency, call 911 immediately. These guidelines should not replace a provider's professional medical advice based on clinical judgment, or be used in lieu of an Infectious Diseases consultation when necessary. As a result of ongoing research, practice guidelines may from time to time change. The authors of these guidelines have made all attempts to ensure the accuracy based on current information, however, due to ongoing research, users of these guidelines are strongly encouraged to confirm the information contained within them through an independent source.

If obtained from a source other than med.umich.edu/asp, please visit the webpage for the most up-to-date document."

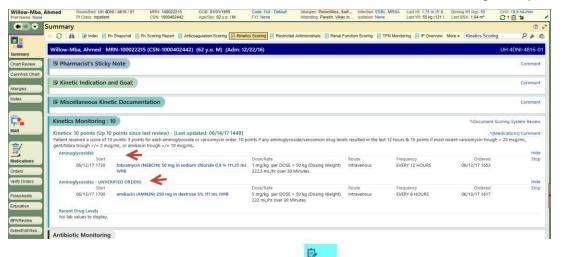
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New Orders Workflow Cont'd-Covering Clinical Pharmacist Responsibility for Verification of Pharmacist-Managed Orders

- When assessing a new therapy (based on a "red dot" or "pencil and paper" icon on the scoring tool)
 - If the dose is appropriate as ordered, check to see if the order is already verified or not.
 If not yet verified, verify the order
 - Indicator that the order is NOT verified is denoted next to the medication name in the scoring tool report



- Box in scoring tool is highlighted light blue
- If you change the order, the new order will auto-verify (sign, do not "sign and verify")

New Orders Workflow Cont'd-Documentation Requirements (slide 3 footnote a)

- In patient list, "PK Review" column, new orders will appear as a "red dot"
 - o Pharmacist must document the following in the sticky note: 1) indication for therapy and 2) goal for therapy. If duration of therapy is known, inclusion of this information is recommended.
 - o DAILY documentation is also required in the "Kinetics Monitoring" field. Then, mark as reviewed—the 'red dot' will turn to a 'green checkmark'.
 - o Note: for vancomycin; documentation in "Restricted Abx" section additionally required
- Ensure that appropriate vancomycin and/or aminoglycoside serum concentrations are ordered (lab order)
 - o If already ordered, assess ordered levels for appropriateness (if changes needed, enter appropriate order)
 - If not already ordered, enter order as appropriate
- Initiate Rx Follow-Up or Day Shift Follow-up iVent, as appropriate
- Documentation of initial PK care plan viewable to multidisciplinary team required:
 - Whenever the pharmacist makes a recommendation for changes in therapy (e.g., dose change on initiation of therapy, dose changes based on serum concentrations, "PRN" dosing)
 - When the pharmacist makes a recommendation to clarify an inaccurate level (e.g., trough drawn at incorrect time)
 - When the pharmacist believes a clarification or other documentation is needed
 - NOTE: For patients on pediatric service lines, ALL levels must be documented in the patient chart
 - NOTE: Communication with providers (in person, via phone or via paging system) is expected when clarification is required

Pharmacist-Managed PK Dosing and Monitoring Assessment of New Serum Concentrations, Dose Adjustments, and Documentation

Complete by end of shift and/or sign out to next shift

Must be completed within 24 hours

Assessment of Serum Concentrations, Dose Adjustments, Documentation, and Follow-Up

- 1. In Clinical Scoring Tool, daily documentation is required in the "Kinetics Monitoring" field
 *Note: New levels will stay on the scoring tool for 12 hours. Critical levels will stay on the scoring tool for 24 hours or until
 a new level that is no longer critical comes back.
- 2. Assess serum concentration and revise PK Care Plan, as appropriate
- a. If dose change is necessary, discontinue currently ordered dose and write order for appropriate new dose 3. Documentation to multidisciplinary team is required using approved PK template for new levels meeting these indications:
 - a. Whenever the pharmacist makes a recommendation for changes in therapy (e.g., dose change on initiation of therapy, dose changes based on serum concentrations, "PRN" dosing)
 - b. When the pharmacist makes a recommendation to clarify an inaccurate level (e.g., trough drawn at incorrect time)
 - i. Note type should be "Medication Management". F2 will bring up "Kinetics Note Templates" option, which will guide you to appropriate template
 - ii. Remember that documentation is also required (DAILY) in the Clinical Scoring Tool, which can either be the copied note or a shortened version.
 - iii. When the pharmacist believes a clarification or other documentation is needed
 - iv. NOTE: For patients on pediatric service lines, ALL levels must be documented in the patient chart
- 4. Ensure that appropriate follow-up vancomycin and/or aminoglycoside serum concentrations are ordered
 - a. If already ordered, assess ordered levels for appropriateness (if changes needed, enter appropriate order) b. If not already ordered, enter order as appropriate
- 5. If previous Rx Follow-Up or Day Shift Follow-Up iVent started and the intervention has been completed (above), close iVent
- 6. Initiate new Rx Follow-Up or Day Shift Follow-Up iVent, as appropriate, for future follow up

^{*}NOTE: Communication with providers (in person, via phone or via paging system) is expected when clarification is required.

Documentation Expectations- Review

- When do you need to write a note in the EMR (medication management note)?
 - Whenever the pharmacist makes a recommendation for changes in therapy (e.g., dose change on initiation of therapy, dose changes based on serum concentrations, "PRN" dosing)
 - When the pharmacist makes a recommendation to clarify an inaccurate level (e.g., level drawn at incorrect time)
 - When the pharmacist believes a clarification or other documentation is needed
 - NOTE: For pediatric patients, ALL levels must be documented in the patient chart

Per UMHHC Policy 07-01-019

Documentation Expectations

- Examples for when to write notes in the EMR:
 - Patient receiving PRN dosing because on renal replacement therapy > write a note every time a dose is entered or level ordered and needs clarification
 - "Dosing by levels" due to poor renal function → write a note every time a dose is entered or level ordered and needs clarification
 - Level comes back and you recommend dose adjustment to team → write a note reflecting recommendation
 - Medical team documents "pharmacist managing vancomycin in progress note"
 if changes are made or clarification is needed, you are responsible for entering medication management note

Documentation Expectations

What about I-vent vs. scoring tool vs. PK sticky note?

I-Vent

Day Shift

Hand-off communication:

- Pending levels
- Any actionable follow-up items that must be addressed next day

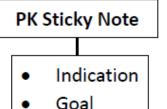
Rx Follow Up

Hand-off communication:

- Pending levels for CE/midnight
- Any actionable follow-up items that must be addressed for CE/midnight

Scoring Tool

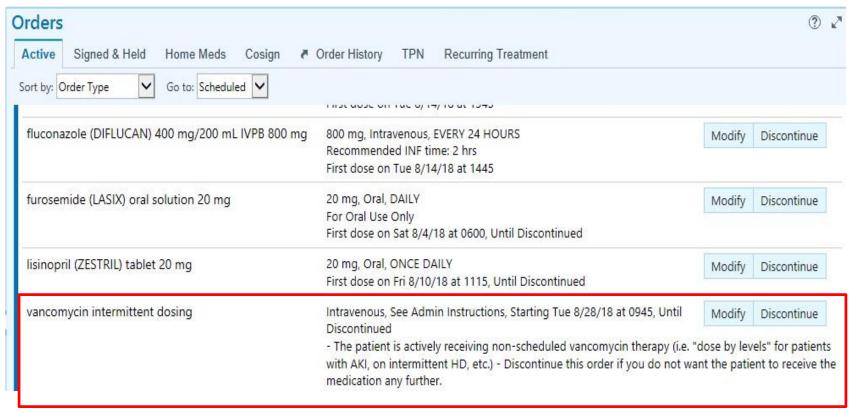
- "No follow-up levels necessary unless XXX"
- "FYI" hand-off communication (does not require specific action)
- Documentation of levels/dose changes
- Daily assessment of dosing, renal function, and clinical status



"Intermittent Dosing" Order

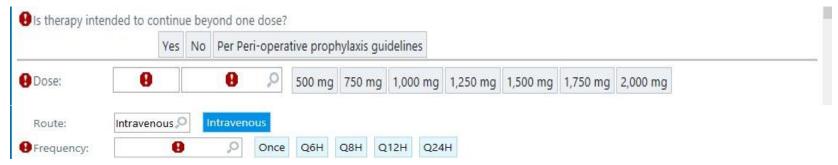
- Replaces "pharmacist to manage" order, which was frequently misunderstood.
- Purpose of placing the order is to indicate active therapy in a patient requiring "PRN dosing" so MiChart knows to fire for review every day
- Only pharmacists can order! So, pharmacists MUST be attuned to whether order needs to be placed.
 - The order instructs physicians to discontinue the order to let pharmacy know that the team does not want to continue therapy.

"Intermittent Dosing" Order (Vancomycin Example)



"Intermittent Dosing" Order Physician Communication

- Vancomycin/Aminoglycoside orders require physicians to answer the following to enhance communication to pharmacy:
- Interpretation of possible order combinations by pharmacist:

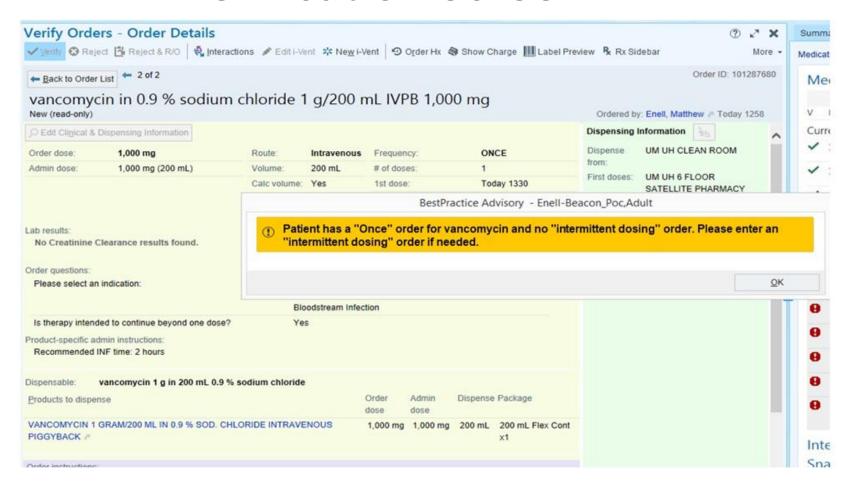


- Yes, scheduled order verify or change as appropriate
- No, scheduled order clarify with prescriber
- Yes, once verify and enter "Intermittent Dosing" order if appropriate for dosing by levels – or change to scheduled dosing if appropriate based on renal function (and write note)
- No, once Verify and dispense single dose
- "Per Peri-operative prophylaxis guidelines" will be defaulted in perioperative order sets

"Intermittent Dosing" Order Pharmacist Order Entry

- BPA in order verification activity (see screenshot next slide)
 will remind pharmacist that "Intermittent Dosing" order is
 needed if all 3 of the following conditions exist:
 - Order question is answered "Yes"
 - Frequency is "Once"
 - There is not an active "Intermittent Dosing" order
- If appropriate for dosing by levels (not appropriate for scheduled dosing), verifying pharmacist should enter order the "Intermittent Dosing" order
- If appropriate dosing unclear, verifying pharmacist may page clinical covering pharmacist per our pharmacist managed order clarification communication guidance (link)

"Intermittent Dosing" Order Verification Screen BPA

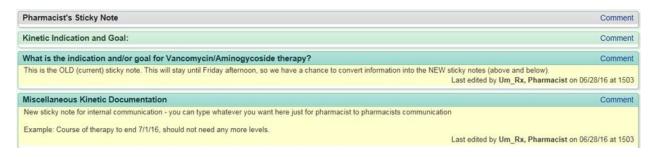


"Intermittent Dosing" Order Other FAQs

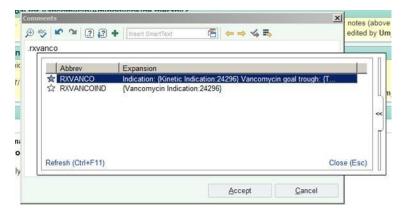
- What if I have a newly admitted or ED patient with missing information about renal function, weight, etc.?
 - Enter (or verify and dispense) one-time dose for first dose (no chart note needed at this point)
 - Enter "intermittent dosing order," and place an iVent stating one-time dose given, waiting for labs to determine ongoing dosing. If the expectation is that this follow-up and determination will be done by a different pharmacist than the one placing the iVent, also page that pharmacist to notify them of follow-up needed.
 - Once labs return:
 - If appropriate for scheduled dosing: pharmacist will schedule doses and d/c the intermittent order, write note and document in scoring tool. OR
 - If appropriate for dosing by levels: pharmacist will determine appropriate follow-up level timing and order level or handoff via iVent and/or scoring tool depending on timing of level needed
- What if a prescriber needs to change a patient from scheduled dosing to dosing by levels due to acute change in renal function?
 - They will need to contact a pharmacist to enter the "Intermittent Dosing" order
- Separate order is needed for each drug: vancomycin, amikacin, tobramycin, gentamicin, streptomycin

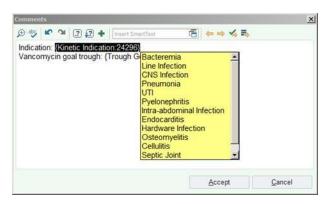
Sticky Notes

- Kinetics Indication and Goal: ONLY include indication and goal here as this information will be pulled into medication management note.
 - Utilize dot phrases (.rxvanco and .rxamino)
- Miscellaneous Kinetics Documentation: pharmacist to pharmacist communication

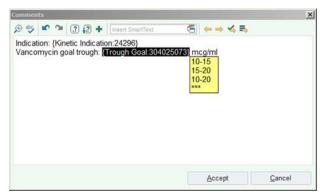


Click comment next to the "Kinetics Indication and Goal" sticky note. Type ".rxvanco" (or ".rxamino" for aminoglycosides)





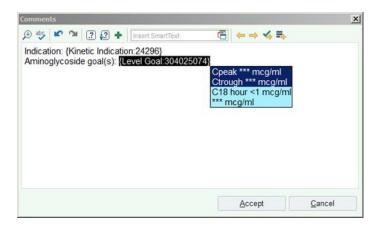
A drop down for vancomycin indication and goal (trough or AUC) are included:



Once you have selected an appropriate indication and goal, the text will populate in the sticky note:



For aminoglycosides (using .rxamino), you can select multiple goal levels for peak/trough, etc.:

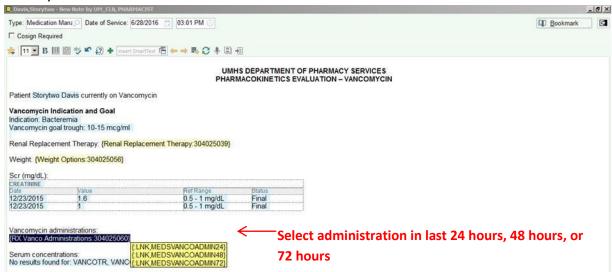


PK Note Templates

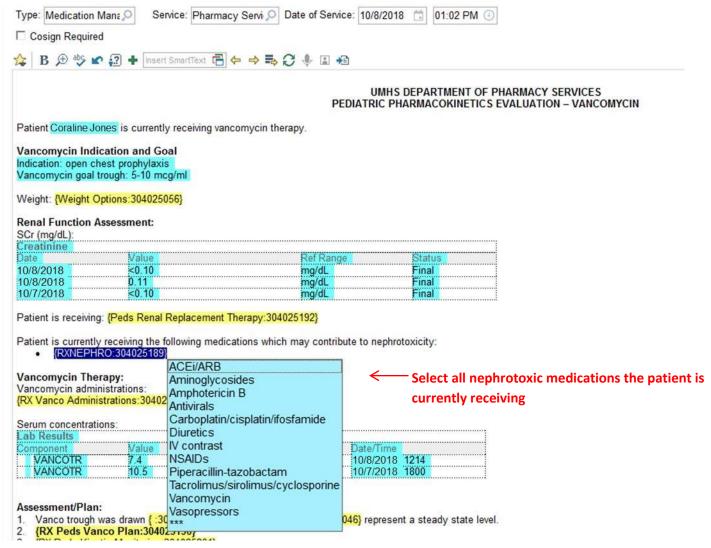
 Once the sticky notes in the scoring tool have been completed, indication and goal will be automatically pulled into the medication management note as seen below.



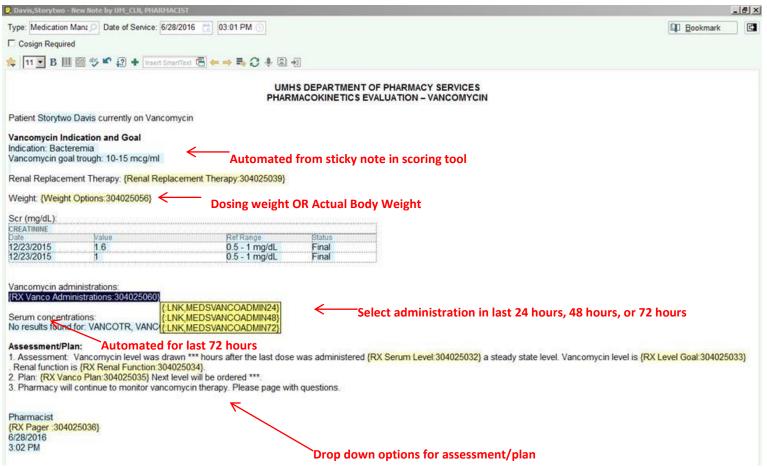
For administration, you can choose if you want to include doses given in the last 24 hours, 48 hours, or 72 hours.



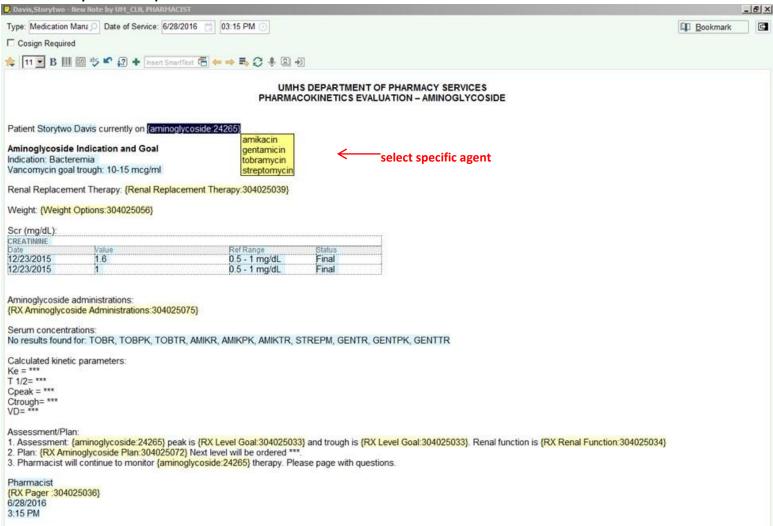
PEDIATRIC ONLY: select the nephrotoxic medications the patient is currently receiving Note: IV contrast and amphotericin count as 7 day exposures.



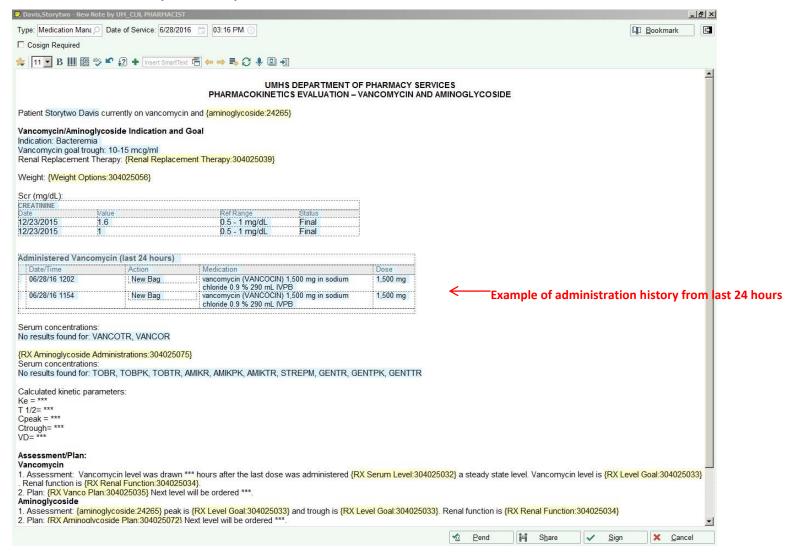
Example of the full "vancomycin medication management note" template.



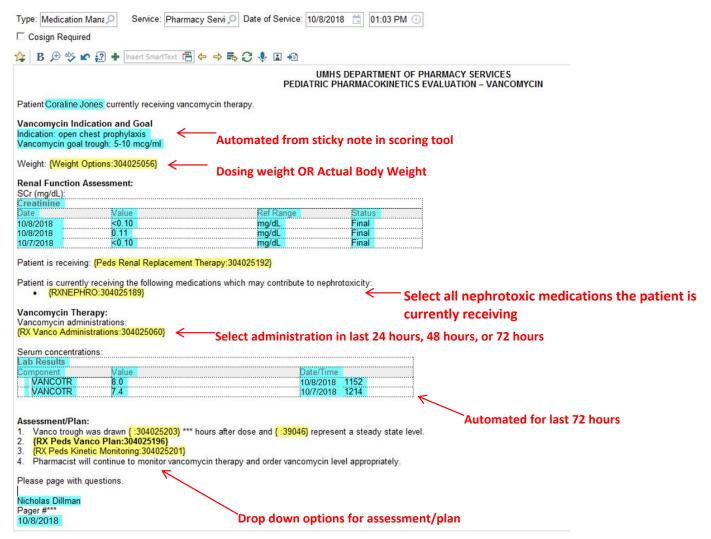
Example of the full "aminoglycoside medication management note" template. Similar to vancomycin template.



Example of the full "vancomycin AND aminoglycoside medication management note" template. Similar to vancomycin template.



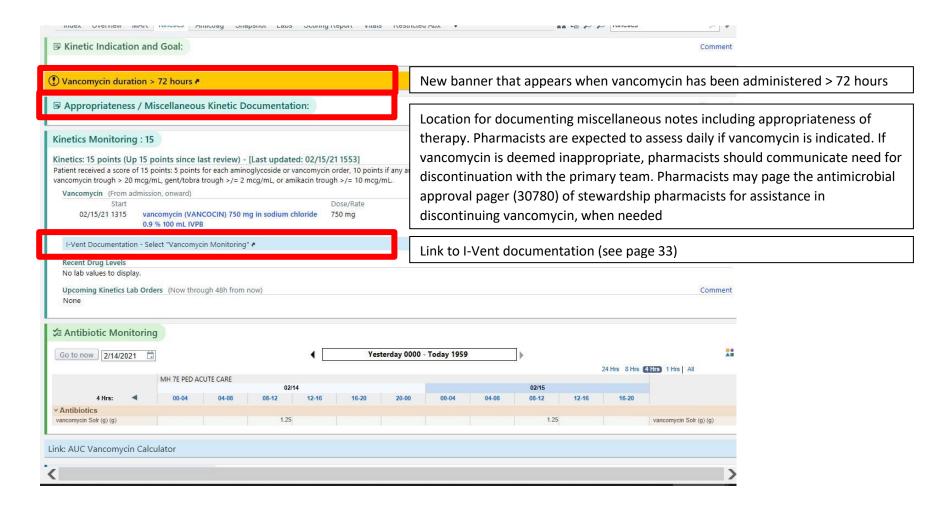
Example of the full "pediatric vancomycin medication management note" template (similar to other pediatric PK templates)



Vancomycin Workflow Updates

- As of 3/3/2012, vancomycin will be removed from tier II workflow
- Avoid obtaining levels in first 48-72 hours, unless significant changes to renal function, septic shock, morbid obesity
- For patients that need therapy beyond 48-72 hours, target AUC of 400-600. Order random level and trough, then use AUC calculator
- Document vancomycin-specific iVent following vancomycin monitoring
- Document goal AUC and personalized trough range in the notes.
 The trough range will be used when transitioning to home therapy

EPIC Kinetics Dashboard Updates



Adult Vancomycin Monitoring Recommendations <u>within</u> 72 hours of Vancomycin Initiation

Monitoring within 72 hours of Vancomycin Initiation

Vancomycin levels should be <u>unnecessary</u> if therapy not anticipated to exceed 72 hours.

Recommend discontinuation of vancomycin 48-72 hours after initiation if there is no indication to continue therapy.

Approximately 90% of patients will have vancomycin discontinued within 48-72 hours and do not require levels.

Do not check vancomycin concentrations within the first 72 hours except in the following situations:

Clinical Situation	Monitoring Recommendation
Documented gram positive infection requiring vancomycin	 Obtain 2 vancomycin levels at steady state and calculate AUC to achieve goal AUC of 400-600
Septic shock Weight > 150 kg	Obtain a random level ~4 hours post-infusion and a trough prior to the next dose for most patients
Significant acute changes in renal function, AKI, or CrCl < 25 ml/min	Obtain a vancomycin level and dose per level Monitor random levels in patients and re-dose when level < 15 mcg/mL

AUC is the <u>preferred</u> method of vancomycin monitoring, with daily goal AUC of 400-600 regardless of MIC Trough-based monitoring should not be routinely used, unless dosing by levels within the first 72 hours.

Adult Vancomycin Monitoring Recommendations <u>after</u> 72 hours of Vancomycin Initiation

Monitoring after 72 hours of Vancomycin Initiation

Recommend discontinuation of vancomycin 48-72 hours after initiation if there is no indication to continue therapy.

Consider ID consult in patients with confirmed MRSA infection who do not improve on vancomycin.

ID consult should be ordered for all patients with MRSA bacteremia.

Use the following table to guide monitoring of vancomycin based on the patient's clinical status:

Clinical Situation	Monitoring Recommendation
Patients with stable renal function (including patients with CKD and receiving CRRT)	 Obtain 2 vancomycin levels after the first dose and calculate AUC to achieve goal AUC of 400-600 Obtain a random level ~4 hours post-infusion and a trough prior to the next dose for most patients to calculate AUC
	• Document individualized trough range that corresponds to AUC of 400-600 for that patient
Patients on conventional dialysis	Check pre-HD level (preferred for floor patients) or 3-hr post-HD level (preferred for ICU patients)
	 Target pre-HD levels of 15-20 mcg/ml, or post-HD level of 10-15 mcg/mL
Patients who have fluctuating fluid	Use clinical judgement to determine monitoring strategy
and/or renal status	• It is reasonable to perform AUC or trough based monitoring. The instability of renal clearance or
	volume of distribution should be taken into account when evaluating levels and subsequent dosing

Frequency of Vancomycin Levels and Monitoring

- · Serum Creatinine should be monitored at least every 48 hours
- Subsequent levels should be obtained:
 - o Every 1-3 days if significant changes to vancomycin dose, renal function or fluid status
 - o Every 3-5 days if on a stable dose with multiple AUCs of 400-600 and stable fluid status and renal function
- Avoid evening and overnight levels if clinically stable

Pediatric Vancomycin Monitoring Recommendations within 48 hours of Vancomycin Initiation

Monitoring within 48 hours of starting vancomycin:

- 1. Vancomycin levels should be unnecessary if therapy not anticipated to exceed 48 hours.
- 2. Do not check vancomycin concentrations within the first 48 hours except in the following situations:

Clinical Situation	Monitoring Recommendation	
Approximately 90% of patients will have vancomycin discontinued within 48-72 hours and most patients do		
not require levels		
Documented gram positive infection	Obtain 2 vancomycin levels at steady state and calculate AUC to achieve goal AUC of 400-600	
Septic shock	Obtain a random level ~2 hours post-infusion and a trough prior to	
Weight >100 kg	the next dose for most patients	
Children with low muscle mass (e.g. muscular dystrophy, cerebral palsy, spinal muscular atrophy)		
Significant acute changes in renal function, CrCl <30 mL/min, therapeutic hypothermia, ECMO, AKI, or neonates <72 hours old whose mothers received peri-partum vancomycin	Obtain a vancomycin level and dose per level Monitor random levels in patients and re-dose when level <15 mcg/mL	

Pediatric Vancomycin Monitoring Recommendations after 48 hours of Vancomycin Initiation

Monitoring after 48 hours of starting vancomycin:

Use the following table to guide monitoring of vancomycin based on the patient's clinical status:

Clinical Situation	Monitoring Recommendation
Patients with stable renal function (including patients with CKD and receiving CRRT)	Obtain 2 vancomycin levels at steady state and calculate AUC to achieve goal AUC of 400-600 Obtain a random level ~2 hours post-infusion and a trough prior to the next dose for most patients to calculate AUC Document individualized trough range that corresponds to AUC of 400-600 for that patient
Patients on conventional dialysis	Check pre-HD level Target pre-HD levels of <15
CHC patients within 72 hours of surgery	Check trough concentration Redose for trough <10
Patients who have fluctuating fluid and/or renal status	Use clinical judgement to determine monitoring strategy It is reasonable to perform AUC or trough-based monitoring. The instability of renal clearance or volume of distribution should be taken into account when evaluating levels and subsequent dosing

- Dose should not exceed 100 mg/kg/day at any point in therapy.
- Consider ID consult in patients with confirmed MRSA infection who do not improve on vancomycin. ID consult should be ordered for all patients with MRSA bacteremia.
- Refer to the following table for recommendations on frequency of ordering vancomycin levels and serum creatinine:

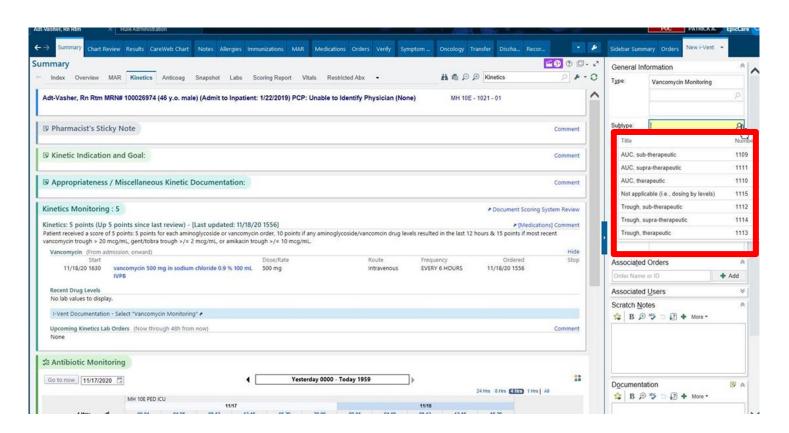
Clinical Situation	Monitoring Recommendation	
Subsequent levels should be drawn every 1-7 days, and serum creatinine should be monitored at least every 48 hours during entire course of vancomycin therapy. Avoid evening and overnight levels if clinically stable.		
Patients with changing fluid status or renal function	Obtain levels every 1-3 days Monitor 2 vancomycin levels to facilitate AUC calculation, when possible In patients receiving one-time doses (i.e., dosing by level), monitor random levels and re-dose when level <15 mcg/mL	
Patients with stable fluid status and renal function requiring long-term therapy	Obtain levels every 5-7 days, after initial level(s) are therapeutic Once a patient is on a stable dose with an AUC between 400 and 600, monitoring of vancomycin troughs may be acceptable in patients with stable fluid status and renal function	

Vancomycin AUC Calculator

- Posted on stewardship website, pharmacy website, and linked from pharmacy EPIC PK tab
- https://www.med.umich.edu/asp/misc/UMich_PK_Calculator.xlsx

Vancomycin I-Vents

- To be completed upon evaluation of level(s) (i.e., after trough and two levels for AUC calculations)
- Select "Vancomycin Monitoring" as Type and the correct response (as seen on image) as subtype



Personalized Trough Range

- Use AUC calculator to determine personalized trough range
- Personalized trough range should be documented in PK notes
- Trough range will be used when transitioning to trough-based monitoring for home therapy