



# Physical and information workflow mapping of vancomycin therapeutic drug management: A single site case study revealing potential gaps in the process

Tsan-Hua Tung<sup>1</sup> · Poching DeLaurentis<sup>2</sup> · Jeffrey A. Sinner<sup>3</sup> · Matthew C. Scanlon<sup>4</sup> · Yuehwern Yih<sup>1,2</sup>

Received: 19 September 2021 / Accepted: 19 October 2021 / Published online: 27 October 2021  
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## Abstract

Vancomycin is one of the most prescribed antibiotics in pediatric intensive care units (PICU) in US hospitals. However, a detailed understanding of workflow and information flow among various stakeholders regarding vancomycin treatment processes in clinical settings is lacking. We conducted direct observations and informant interviews to develop the mapping of key processes and information flow for vancomycin treatment, with an emphasis on therapeutic drug monitoring (TDM) dose adjustment decision-making. A health information technology (HIT) sociotechnical framework was used to identify EHR related safety concerns. A total of 27 vancomycin treatment activities were observed over a 60-h duration including infusion administration, infusion completion, trough concentration blood draw and therapeutic decision making processes. Workflow and information flow mappings revealed (1) deviations between the documented timestamp used for TDM decision making and the actual time the tasks executed and (2) the lack of information flow regarding infusion completion and interruption. Missing features, insufficient usability and lack of integration with workflow and communication in the EHR were deemed safety gaps that may affect the accuracy of therapeutic decisions. Our case study identified gaps in information flow among clinical team members via EHR in TDM processes to provide insights for the improvement of the EHR system for antibiotic treatment purposes. In particular, the potential harm of the missing, uncertain, and inaccurate documented TDM task times warrant further investigations.

**Keywords** Electronic health record · Information flow · Therapeutic drug monitoring · Vancomycin · Workflow mapping

## Introduction

Vancomycin is one of the most prescribed antibiotics in the pediatric and neonatal intensive care units in US hospitals [1]. However, its treatment is frequently reported to be sub-therapeutic, especially for critically ill children and neonates [2, 3]. Therapeutic drug monitoring (TDM) is therefore

recommended to optimize individual treatment effect [3]. Model-based clinical decision support (CDS) tools such as those utilizing Bayesian modeling are also recommended in the newly revised consensus guidelines for vancomycin TDM to enable individualized dosing [4]. Traditionally, vancomycin serum concentrations are essential for an accurate and timely dose recommendation. Erroneous timed serum trough concentrations may lead to miscalculations of doses and thus solutions such as computer provider order entry (CPOE) with guided vancomycin level orders have been implemented to improve the timing of such blood draws [5, 6]. However, system level factors can still introduce potential patient safety hazards in the TDM process. In a recent study regarding safety hazards associated with intravenous (IV) vancomycin, administration and monitoring still account for 39.4% and 37.5%, respectively, of safety issues identified with vancomycin IV administration [7]. Appropriate therapy management (i.e. timing, monitoring), care coordination and information exchange among staff, and documentation are

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This article is part of the Topical Collection on *Implementation Science & Operations Management*

✉ Tsan-Hua Tung  
tungt@purdue.edu; k.thtungt@gmail.com

<sup>1</sup> School of Industrial Engineering, Purdue University, West Lafayette, IN, USA

<sup>2</sup> Regenstrief Center for Healthcare Engineering, Purdue University, West Lafayette, IN, USA

<sup>3</sup> Children's Wisconsin, Milwaukee, WI, USA

<sup>4</sup> Department of Pediatrics, Division of Critical Care, Medical College of Wisconsin, Milwaukee, WI, USA

the major system factors contributing to safety events such as dose omission/delay or improper dose [7]. Moreover, considerations regarding clinical workflows of end-users and existing systems (such as EHR) are called increasingly as it is reported challenging to integrate CDS tools within the current system to meet end-users needs and expectations and to effectively improve vancomycin TDM practice [8–13]. To this end, a thorough understanding of the TDM decision making process, information flow, and routine workflows by key stakeholders is needed.

Modern EHR systems contain critical information, such as infusion administration time, blood sampling time, and lab results that are critical for vancomycin TDM. To our knowledge, detailed workflows regarding how the tasks are executed and documented in the EHR, information flows across stakeholders, and EHR-related safety concerns have not yet been studied in-depth, and any uncaptured safety gaps can have unexpected patient consequences.

This study was conducted as a case study in a single hospital and the aims were to (1) characterize and map the physical and information flows in vancomycin TDM focusing on the therapeutic dose adjustment decision-making process, and (2) systematically identify areas in workflow where gaps in EHR use may impact the accuracy of TDM dose adjustment decisions.

## Methods

Direct observations and follow-up informant interviews regarding IV vancomycin treatment processes were conducted in a children's hospital in the Midwest. The observations were based on protocols regarding clinical workflow mapping [14] and a two-stream model for information flows [15]. Free formed interviews were conducted with stakeholders including physicians, nurse practitioners, pharmacists, nurses, and lab technicians. The observation samples and interview participants were selected based on the availability of the clinicians at the time of the study.

**Observations.** To maximize the diversity and the amount of infusion events observed, direct observations were conducted in a neonatal intensive care unit, two pediatric intensive care units, and an acute care unit. We focused on the process flow and the interactions between stakeholders and the EHR (Epic EHR system) to capture (1) the sequence of the steps in a task, (2) the timestamp of each key step, (3) the corresponding timestamp recorded in the EHR, (4) the timestamps used in dosing decision making, and (5) any unexpected events in the process.

**Informant Interviews.** Free-form interviews were conducted following the direct observations to capture (1) stakeholders' perspectives and experiences for the task, (2)

routines of the task, (3) common and rare events, and (4) obstacles and facilitators of performing the task.

**Analysis.** A descriptive process mapping method was adopted from the PCMedSafety approach for medication use and safety [14, 16]. Various workflow sequences were captured by the observations and through the interviews. EHR-related safety concerns were identified based on Singh and Sittig's sociotechnical model and health information technology (HIT) safety measurement framework [17, 18]. They proposed eight dimensions to evaluate the implementation of a HIT, including hardware and software, clinical content, human-computer interface, people, workflow and communication, internal organizational features, external rules and regulations, and measurement and monitoring.

## Results

In over 60-h observation, 10 intravenous infusion administrations, 7 completed infusions, 4 trough blood draws and 6 dose adjustment decision-making processes were observed. Stakeholder participants in the informant interviews included 1 physician, 5 nurse practitioners, 6 registered nurses, 2 floor pharmacists, 1 pharmacokinetic pharmacist, 1 lab technician, and 1 phlebotomist.

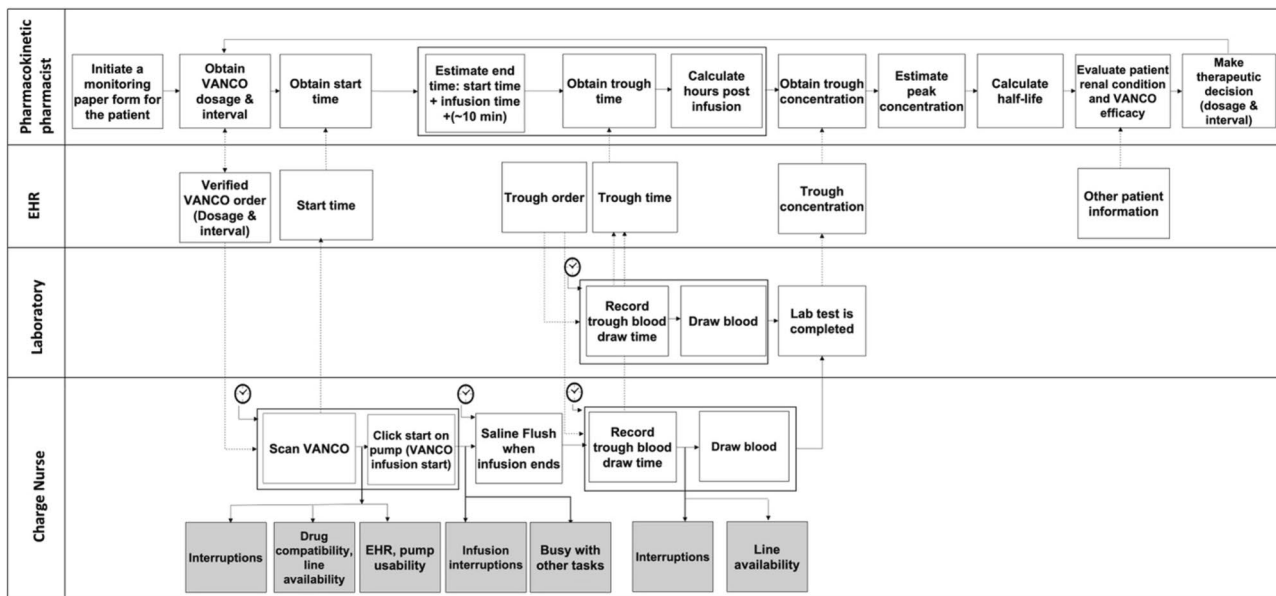
**Individual Domain Expertise Used in Vancomycin TDM Practices.** The timing for the first TDM and TDM frequency varied according to the patient condition. Pharmacists in the pharmacokinetic team established for the Antimicrobial Stewardship program are the stakeholder that perform TDM on patients treated with selected antibiotics such as vancomycin.

*If we know the patient and his health history, we can wait until 48 hours if the patient is still on it. If I don't know the patient, I would prefer to have a (trough) concentration drawn after 1 or 2 doses. (Interview, pharmacist 1)*

*We look at 'who they are', 'healthy or not', 'what's vancomycin for', 'any significant event such as 60 minutes CPR in ER, other drugs to support their lives' to try to predict a 'good' or 'bad' trend, and determine the dose and interval and whether to have a concentration blood draw or not. (Interview, pharmacist 1)*

Pharmacists used a monitoring paper form for TDM therapeutic decisions as outlined in Fig. 1. They copy relevant information from the EHR to the monitoring paper form to perform pharmacokinetic calculation and make dose adjustment decisions.

*We write down important information (from the EHR to the monitoring form). It's easier to monitor (the*



- Each horizontal lane indicates a stakeholder or system involved in the vancomycin TDM process.
- A solid line indicates a physical material flow or a process flow; a dash line indicates an information flow (information extracted from or input into the EHR system).
- A double-sided arrow indicates an interaction between the EHR system and a stakeholder (e.g., a pharmacokinetic pharmacist)
- The Clock symbol indicates a predetermined timing that a task should be performed.
- The shaded boxes indicate scenarios that may cause deviations between the time of task execution and the time used for TDM therapeutic decisions (i.e., timestamps documented in the EHR or time guesstimated by pharmacists).

**Fig. 1** Workflow and information flows for dose adjustment decision making

*patient's condition). We've been using it for a long time. (Interview, pharmacist 1)*

### Uncertainties in Vancomycin Therapeutic Decision.

To thoroughly analyze TDM dose adjustment decision making process, physical workflows and information flows (recording and retrieving) among stakeholders were mapped in Fig. 1. Key information for vancomycin TDM includes vancomycin dosage, infusion start time, completion time, serum trough concentration, trough blood draw time, and other patient conditions such as renal function, microbial result, etc. All information required for therapeutic decision making is available in the EHR except the infusion completion time, despite the fact that infusion completion time and trough blood draw time are two critical timestamps for calculating the half-life of vancomycin.

*There is no completion time recorded in the EHR. It's usually infused for an hour. Ideally the start time plus 1 hour is the completion time, but we usually add 10-15 minutes to reflect the actual completion time based on what we have observed in the past. (Interview, pharmacist 1)*

The pharmacokinetic pharmacists extracted the available information recorded in the EHR and estimated infusion completion time based on their experience when making a dose adjustment decision. However, Fig. 1 revealed

systematic time deviations in several key steps including infusion start, completion, and trough blood draw. That is, the time used for TDM therapeutic decisions (the time documented in the EHR) was not exactly the time that the task was executed at the patient's bedside. Time deviations were observed between the documented infusion administration time in the EHR ('Scan Vanco', the timing when nurses scan the label on vancomycin syringe) and the time that vancomycin was actually given ('Click start on pump', nurses actually start the infusion through the infusion pump) (Fig. 1). We also observed that some nursing activities had no particular preset sequence and they can be carried out in different order (Fig. 2). This may also affect the time deviation.

Process mapping also identified the lack of information flow between the actual infusion completion time and the time used in TDM decision making (Fig. 1). To fully complete an infusion, nurses need to flush the line with 0.9% sodium chloride injection flush solution to ensure that the remaining vancomycin was fully given to the patient. However, there is a varying amount of time between the end-of-infusion alarm on the pump going off and the time of saline flush depending on the nurses' availability (Appendix Fig. 3). Also, any infusion interruptions during the infusion will further delay the completion time and this piece of information was also missing for the decision makers.

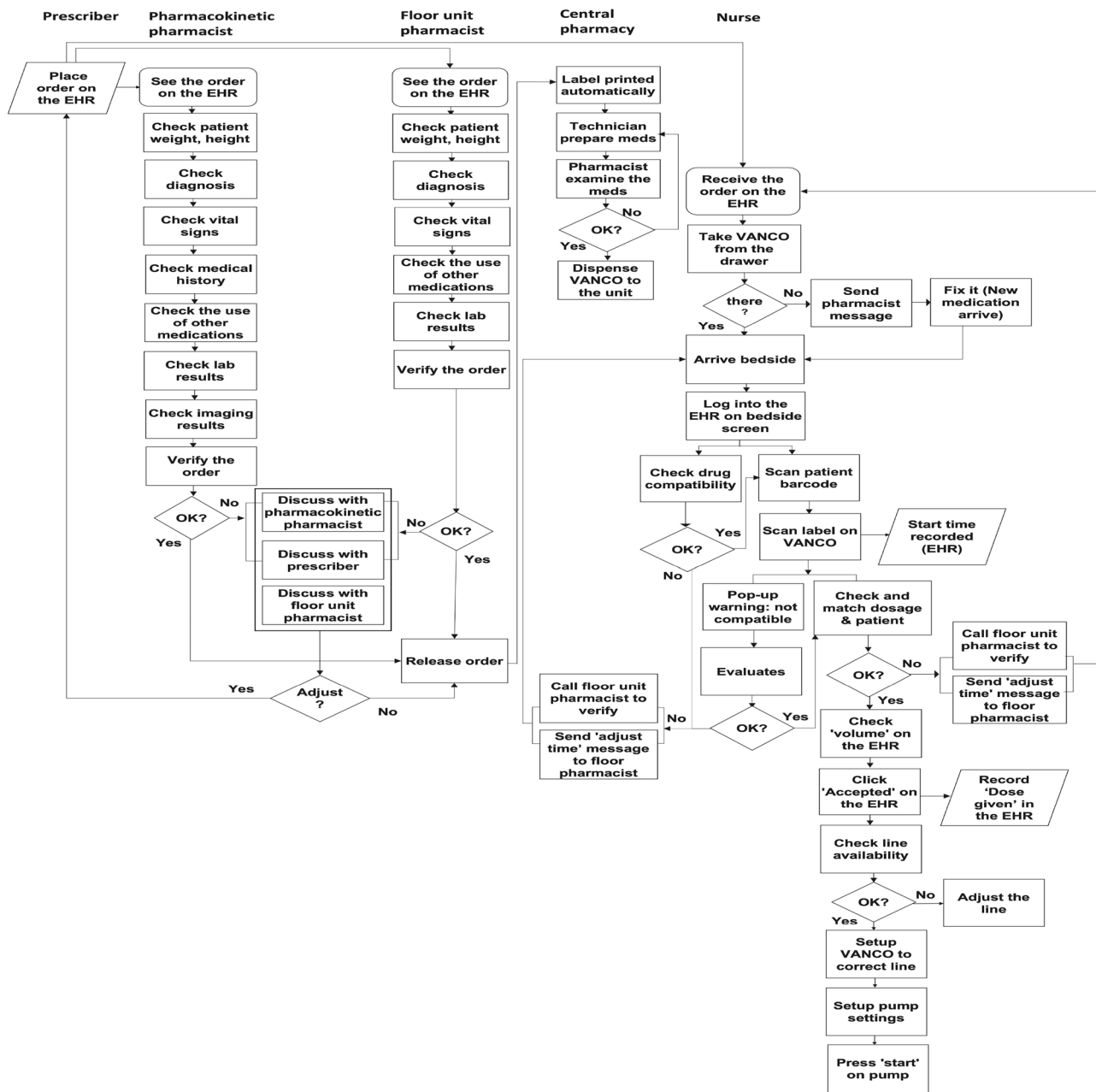


Fig. 2 Administration of vancomycin infusion

**Table 1** Summary of time deviation observed

	Time deviation (in minutes)		
	Actual infusion start time – documented start time in the EHR	Flush time – infusion stop time (when alarm went off)	Actual trough blood draw time – documented blood draw time in the EHR
Maximum	5	9	3
Minimum	2	1	1
Average	3.1	3.5	2
Median	3	2.5	2

*Oh, I don't know if it's (any significant interruption) recorded (in the EHR), at least I don't know where I can find it. Sometimes the nurse told me if there's any significant event during their shift. Sometimes I would ask them if the number (trough concentration) seems abnormal. (Interview, pharmacist 1)*

During the trough concentration blood draw process, the blood draw time is entered through the specimen collection mobile computer by the phlebotomist or in the EHR by the nurse after taking a blood sample (Appendix Fig. 4). Time deviations were also observed between the recorded blood draw time and the actual blood draw time. Small time deviations for each key process (Table 1) were observed during our study which is not surprising due to the limited sample size. However, we learned from stakeholder interviews that a prolonged time deviation could occur.

**Causes of Significant Time Deviation.** Two main comments related to prolonged time deviations between the documented and executed times are technical issues and interruptions.

**Technical issues.** When the user interacts with technology systems, such as the EHR or infusion pump, any event deviating from the norm (typical workflow) will cause delay. The user will need time to troubleshoot, rework, seek for technical support, or find alternate solutions. Those events happen frequently but unpredictably.

*The nurse could not log in to the EHR at the bedside and the blood was already drawn. (Field note, blood draw)*

*Usually it's (patient's weight) already there (pump settings), but if it's not I have to re-enter it. (Interview, nurse 4)*

**Interruptions.** Interruptions, similar to technical issues, happen reliably yet unpredictably and the actions followed are quite different, depending on the situation, patient's condition, clinicians' experience and knowledge. During the infusion administration process, drug incompatibility, infusion line unavailability, and patient's cooperation are the most frequent interruptions mentioned by nurses.

*I'd call the floor pharmacy. If it takes too long (to clarify), I can send a message to the floor pharmacist to adjust (the start) time. (Interview, nurse 1)*

*Sometimes it (the EHR) shows it (vancomycin) is not compatible but it is. (Interview, nurse 2)*

*Sometimes she (the patient) doesn't like it, we need to comfort her. (Interview, nurse 3)*

Infusion completion time can also significantly deviate from what is expected by the decision maker due to unexpected events occurring during the infusion as well as clinical reason to stop.

*Interruptions can occur for many reasons. It could be a pump alarm, patient side disruption, or the catheter just came off. (Interview, physician1)*

**EHR Related Safety Concerns.** Three dimensions of EHR related safety concerns were identified (Table 2) in this case study. The first dimension is related to the clinical content. Key information such as the infusion completion time and the occurrence of interruption during the infusion are missing and not properly documented in the EHR. The second dimension is related to HIT usability. For vancomycin TDM, both the serum concentration and the blood draw time are critical for making dose adjustment decisions that result in ideal therapeutic effects; however, these pieces of

**Table 2** Identified dimensions of the EHR-related safety concerns for vancomycin treatment

Sociotechnical dimension	Safety domain	Summary of safety concern
Clinical content	Safe HIT Using HIT safely	<ul style="list-style-type: none"> <li>• Undeveloped function of documenting infusion end time and flush time</li> <li>• Undeveloped function of documenting infusion interruption</li> <li>• Parallel use of paper and the EHR</li> </ul>
Human- computer interface	Using HIT safely	<ul style="list-style-type: none"> <li>• Usability: serum trough concentration and blood draw time are not shown in the same page</li> <li>• Usability: 'infusion administration time' and 'whether it was actually given' are not shown in the same page</li> </ul>
Workflow and communication	Safe HIT	<ul style="list-style-type: none"> <li>• Undeveloped or unaware function of communicating the occurrence of special event during infusion to another stakeholder (e.g., communication between nurse and pharmacist about any significant interruptions or time delay during infusion)</li> </ul>

information are not displayed on the same page in the EHR. Similar display issues exist for the drug administration time and any deviation from the documentation, for example, if the drug was not given. The third dimension is the integration of workflows and communication. The EHR is unable to communicate or relay critical information effectively regarding blood draw and infusion activities across stakeholders.

## Discussion

This study aimed to (1) characterize and map the physical and information flows in vancomycin TDM focusing on the therapeutic dose adjustment decision-making process and (2) identify EHR related safety concerns that may impact therapeutic decisions in TDM.

**Mapping Processes and Information Flows.** As a domain specific HIT needs to meet certain requirements to be efficient and safe [19, 20], a deeper understanding of current clinical workflow and information flow for precise therapeutic decisions can help developers better design a workflow integrated vancomycin CDS tool. Our process and information flow mapping were used to systematically review the connections between bedside tasks and the corresponding information used for dosing decision making in vancomycin management. We found timing and other information on infusion completion to be lacking, which was critical for pharmacists to make accurate therapeutic decisions. Time deviations between documented timestamps in the EHR (information) and times of task executions (the actual step of the clinical activity) were discovered in both infusion administration and blood draw processes. This discovery means that clinicians need to pay attention to prolonged delays in the TDM process since they may not be well documented. One avenue of improvement is through educational trainings for staff to reinforce the importance of documentation regarding significant events. Another avenue is through interventions such as a paper format infographic displayed in high visibility area or an electronic one implemented in the CDS tools or as a screensaver in the EHR drug administration page [7]. It is also important that a timely and consistent communication method be utilized by all stakeholders so that such critical information can be relayed to all decision makers (such as pharmacokinetic pharmacists) in an efficient manner.

**Important Features to Capture in the EHR.** Research has shown that missing content features can affect the safety of HIT [17, 21]. This study identified two missing features from the EHR that are critical for vancomycin therapeutic decisions: (1) infusion completion time, and (2) major interruptions during an infusion. As an erroneous timed trough concentration may lead to under- or over-estimation of a

dose [7], deviation of key timestamps used in dose calculation may result in an inaccurate therapeutic estimation. The area under the concentration time curve (AUC) was recommended by American Society of Health-System Pharmacists, the Infectious Diseases Society of America, the Pediatric Infectious Diseases Society, and the Society of Infectious Diseases Pharmacists vancomycin consensus guidelines committee in 2020 to replace the trough monitoring in their new consensus guideline for vancomycin TDM [4]. To achieve an accurate AUC calculation, two concentrations are needed: the peak concentration drawn within one to two hours after the infusion completion and the trough within one hour prior to the next dose. Without knowing the exact infusion completion time, the pharmacist may order a peak concentration blood draw at the time that the infusion is still ongoing and thus introduce an error in the dose calculation. Note that the EHR and infusion pump systems were not integrated in the hospital where this case study was conducted. Regardless of whether the information with respect to real time infusion status can be sent from the pump and available in the EHR if they were integrated, this study provides insights on what features should be captured in the integrated system for TDM purposes. In addition to infusion completion time and major interruptions, information such as total infused volume and the planned infusion volume may help clinicians interpret whether the intended dose was properly completed.

**Display Design in The EHR for Decision Making.** The ease of usage and access to information in the EHR/HIT influence the attitude towards the adoption of CDS tools [22, 23]. The current EHR system displays some, but not all, relevant information for TDM purposes on the same page. For example, two critical data points, the vancomycin trough concentration and its sampling time, do not display on the same page in the EHR. This makes the use/retrieval of such information tedious and frustrating, which could, in turn, introduce errors. One such scenario is when the trough concentration is within the target therapeutic window, but the blood sample was not taken at the expected time, leading to an inaccurate dose calculation for the subsequent treatment regimen decision.

The areas identified in this study arose from the disconnect between work-as-imagined and work-as-done [24]. Work-as-imagined is the mental model of how people work that stems from preconceptions, biases and limited information. Designers of an EHR can never know all aspects of clinical work; instead, they design their products based on user input as well as how they *imagine* end users will work. In contrast, work-as-done is how people carry out their daily tasks. The gap between imagined work and work-as-done has been linked to technology-related adverse events involving blood transfusions and barcoding with medication

administration [24]. In this case study of vancomycin TDM, it was identified that the EHR was not designed to optimize the capturing or displaying of some time-sensitive, critical information clinicians need for making dosing decisions. While it is unlikely that work-as-imagined and work-as-done will ever match exactly, there are strategies to narrow the gap between them [25]. Until understanding work-as-done is a priority of designers of technology like EHRs, it is inevitable that the work of prescribing, dispensing, administering and monitoring vancomycin will not be safer simply through technological interventions.

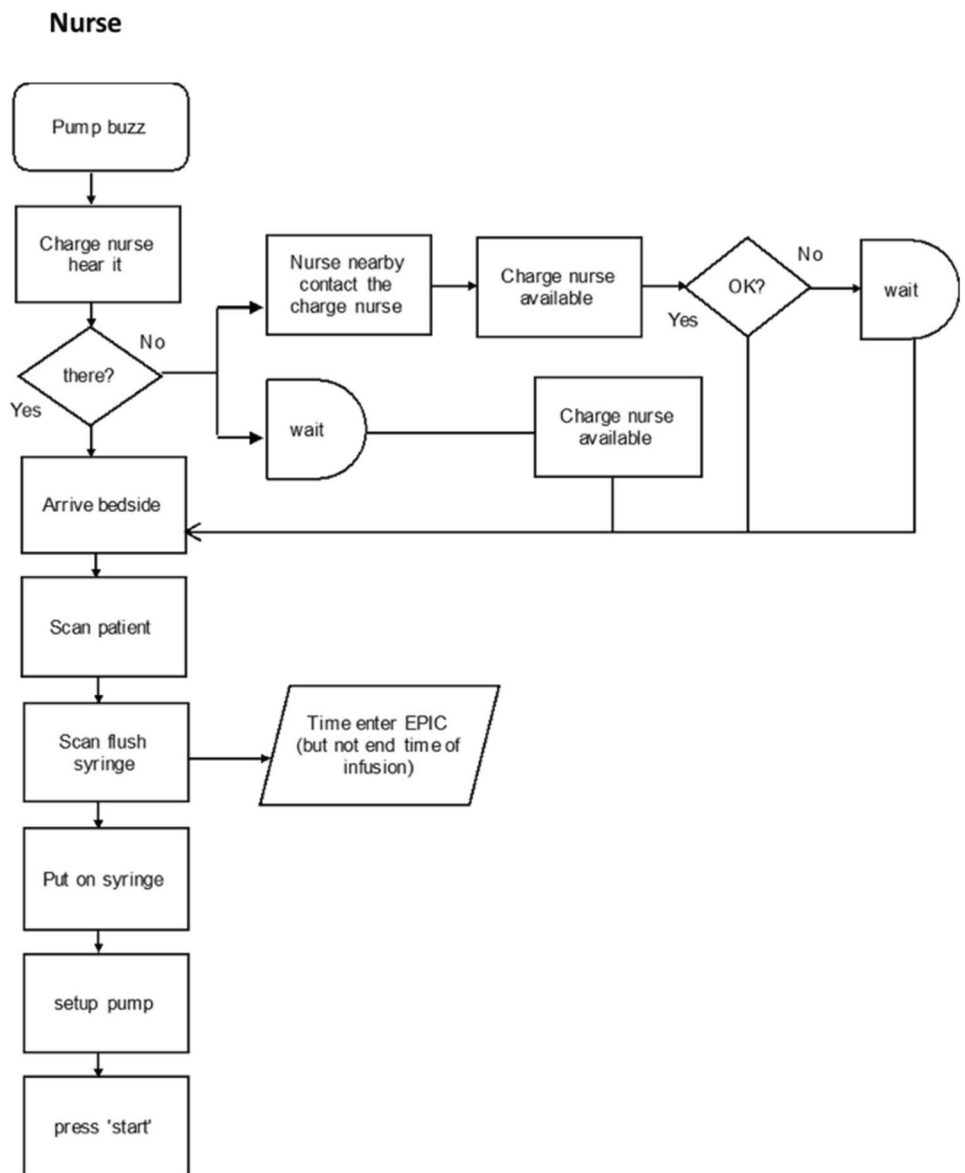
This work has implications on three levels: (1) Patient level: Clinical documentation and information flow could directly impact bedside clinical decisions, which in turn influences the quality of patient treatment and patient safety. (2) Provider level: Unknown or inaccurate information in the clinical systems can increase the mental load of care providers and weaken their trust of the EHR in general. (3) Population health level: Poor quality data may hinder the development of evidence-based practices to optimize treatment effectiveness. It's worth noting that, based on our study, both workflow and information flow designs among frontline care providers during their interactions with IT systems (EHR) and devices (infusion pump) at the operational level can cause data discrepancy. This not only has direct impact on individual patients, but also creates data issues that hinder potential learning for evidence-based practices and optimization of personalized medicine. We also like to highlight the current state of neglect for holistic workflow design (human interactions with IT systems and devices) concerning both clinical environments where frontline care providers deliver care and challenges they encounter at operational level on a daily basis.

**Study Limitations and Future Work.** This case study was conducted in a single hospital. Clinical practices could vary from hospital to hospital and therefore, our findings may not be representative of all practices. Nonetheless, the methodology can be systematically applied to other hospitals and care units with similar effort. In particular, practices vary where decision making may be involved different care providers (physicians, pharmacists, etc.), but infusion processes along with its documentation is commonly performed by nurses regardless. That being said, insights regarding the time deviation between “documented” and “performed” on TDM tasks will still be relevant to hospitals following similar infusion processes regardless of their overall vancomycin TDM practices.

This study formally documented the workflow and information flow of vancomycin TDM at one site and identified gaps in the process where data deviations could impact clinical decisions. A future study with a larger sample size across multiple sites can increase the generalizability of the findings to a broader scope (e.g., the time deviations in the aforementioned key processes of vancomycin TDM). Moreover, a comprehensive simulation study could provide further insights on the level of clinical impact of the missing or inaccurate recorded TDM task times in the future.

## Appendix

**Fig. 3** Process of the completion of an infusion





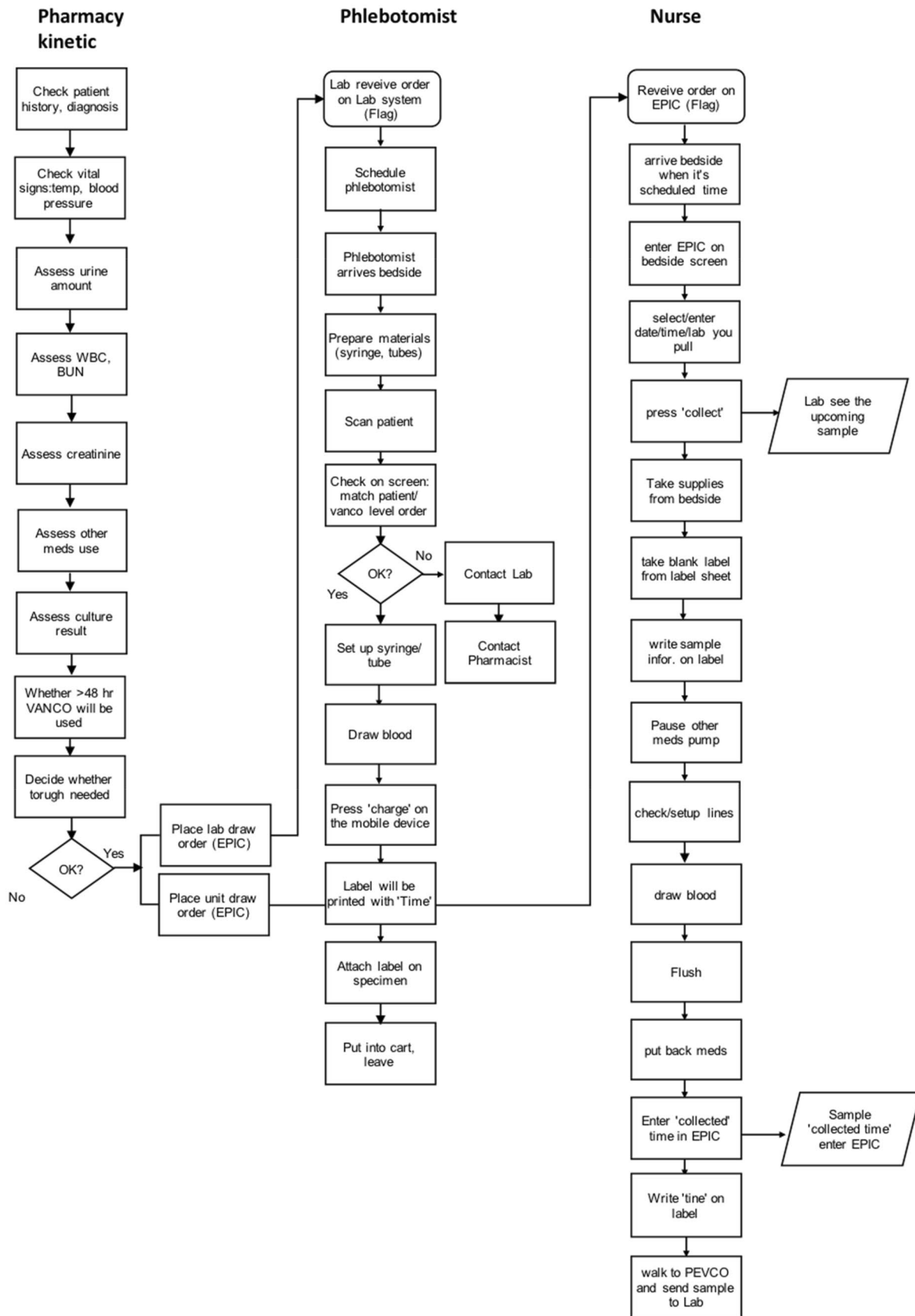


Fig. 4 Process of vancomycin blood sample order and collection. (note: PEVCO is the tube system that ships samples from the floor to the lab)

**Funding** This study was supported in part by College of Engineering and the Regenstrief Center for Healthcare Engineering at Purdue University.

## Declarations

**Ethics Approval** This study did not constitute Human Subjects Research, thus submission of an IRB application was not required.

**Conflicts of Interest** The authors declare that they have no conflicts of interest.

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