An Evaluation of the Process of Chemotherapy Ordering and Delivery from the Perspective of Practitioners, Nurses, and Pharmacists at a Children's Hospital

A Capstone Project

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CERTIFICATE OF APPROVAL

This is to certify that the Master's Capstone Project of

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Has been approved

Capstone Advisor

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ABSTRACT

Introduction: Ordering and delivering chemotherapy is a complex process that requires attention to detail. The number of steps involved and the required degree of coordination of staff members magnify the potential for errors. Computerized practitioner order entry with decision support has the potential to improve the efficiency and safety of the entire chemotherapy system.

Methods: The process of chemotherapy ordering and delivery was evaluated at the Alfred I. duPont Hospital for Children using primarily qualitative methods. Twenty-eight interviews were conducted with staff members with significant involvement in this process. These staff members included pharmacists, hematology/oncology nurses, and hematology/oncology practitioners. These interviews were recorded with a digital recorder and transcribed into 126 single spaced pages. The transcriptions were evaluated by grounded theory and then coded.

Four focus groups were used to finalize ideas for workflow improvement. These focus groups involved (1) pharmacists, (2) practitioners, (3) nurses, and (4) pharmacists, practitioners, nurses, and clinical lab personnel. These focus groups provided a link between the qualitative and quantitative aspects of the study.

The quantitative aspects of the study involved an evaluation of sixteen chemotherapy order sets in order to determine the incidence of significant errors. Other quantitative information was obtained regarding the time involved in getting lab specimens from patients who do not have central venous catheters. Start times and total time from admission to the start of chemotherapy was recorded for pediatric oncology patients at our hospital during September 2010 and January 2011.

Results: The individual interviews revealed four major themes. Each theme had several subthemes or categories. The four themes were: Time, First Do No Harm, Information Exchange, and Responsibility. These themes were used to help elucidate the strengths and weakness of the current chemotherapy process. They were also used as a starting point to develop ideas to improve the system. The focus groups reached consensus on several ideas for workflow improvement: early appointments in clinic, aggressive hydration, home intravenous fluids, home labs, and orders being turned in for review at least one day prior to a planned admission for chemotherapy.

The order set reviews did not reveal any significant errors. The waiting times for pediatric oncology patients were the same or less than other patients, but the amount of time to actually obtain blood from them by venipuncture was greater. The total time from admission to start of chemotherapy was not appreciably different in September 2010 versus January 2011. However, when the orders were turned in at least a day in advance, there was a clinically important improvement in the average start time of the inpatient chemotherapy.

Conclusion: The four themes surrounding the chemotherapy workflow highlight the complexity of the problems involved in the delivery of care. The perceptions of the staff regarding the use of an electronic health record were varied. It was clear that such a system helped to improve some aspects of care, but it made other aspects more difficult. There was consensus about what needs to be done, but actually changing work habits proved more difficult. It is hoped that the momentum gained from this project will translate into major improvements in the chemotherapy process as the division implements the Epic chemotherapy ordering package which is called Beacon.

INTRODUCTION

Background and Significance

General Information:

The use of an electronic medical record (EMR) has been touted as a means for improving the quality of medical care and reducing the risk of errors. [1] While some studies have shown some improvement in quality [2, 3, 4] other studies have shown no improvement [5]. One of the gaps in decision support in the typical EMR is at the level of dispensing. The use of bar code scanning has been considered as a means for reducing such errors. The successful use of such a system requires adequate training, technology that works well and fits the workflow, and good communication with the pharmacy staff regarding the technology. [6] Education about bar code scanning must also include the avoidance of workarounds that can be a threat to patient safety. [7] There has been substantial financial investment in EMRs at the local and national levels [8], and this increases the importance of demonstrating actual, as opposed to theoretical, benefit from such systems.

One of the major features of most EMRs is the electronic entry of orders. It was hoped that computerized practitioner order entry (CPOE) would eliminate many of the problems of written orders. [9] The issues of legibility have been resolved by CPOE, but other problems have surfaced. These problems include incorrect clinical decision support, added work for clinicians, changes in communication among nurses and physicians, and problems with workflow. [10, 11, 12] The use of e-prescribing that

allows both structured and free-text fields improves flexibility, but it may introduce significant discrepancies that “could potentially lead to adverse events and many to severe adverse events, involving hospital admission or death”. [13] This has been found to be particularly common when orders are entered by trainees. [14] Clinical decision support has tremendous potential to reduce medication errors and adverse reactions; but when such systems generate an excessive number of warnings, they tend to be ignored. [15]

High risk medications are especially problematic in relation to CPOE. The administration of chemotherapy using CPOE or some variation of CPOE has been evaluated at several centers. [16, 17] These evaluations have included both adult and pediatric oncology patients. The complexity of the order sets is similar in both groups of patients, but the problems in pediatrics are amplified due to the fact that the chemotherapy doses need to be calculated on a per kilogram or a per meter-squared basis. In some protocols, the basis for the dose calculation changes if the child is over a certain weight or age. One of the other problems with chemotherapy is that many chemotherapy drugs (such as methotrexate) can be given by many routes (e.g. oral, intravenous, and intrathecal) and in a very wide range of doses. This makes the use of an EMR to check doses a difficult task. The University of Rochester School of Medicine used a dose limit set at a patient with a body surface area of 2.2. This “dose limit was exceeded in only 3% of drug administrations”. [18] Intellidose software has been developed in an effort to reduce chemotherapy dosing errors, and it has shown some early success. [19]

There has been national attention regarding major errors in chemotherapy administration. This has led to a number of strategies to reduce and eventually eliminate such errors. Establishing a culture of safety is a key element in this quest. [20] "Workflow integration" and the need to emphasize "safety over convenience" are also very important. [21] Standardization and automation are also emphasized in the discussion of chemotherapy error prevention. [22] The American Society of Clinical Oncology (ASCO) has used an EHR (electronic health record) symposium to evaluate electronic systems as they relate to oncology practice. [23] Further improvements in such systems will need to occur in order to aid in the adherence to safe standards for chemotherapy administration as outlined by ASCO and the Oncology Nursing Society. [24]

The time involved in CPOE (computerized practitioner order entry) has lead to the use of pharmacists or nurses to enter some orders. [25] Acceptance of CPOE by practitioners may improve as the systems become more time efficient. The use of checklists and independent double checking of chemotherapy orders may improve the safety and efficiency of such systems. [26]

Background information specific to this study:

The A. I. duPont Hospital for Children (AIDHC) started using Epic Hyperspace in the outpatient setting in 2000 and has been using inpatient Epic since 2009. In the outpatient arena, chemotherapy orders are entered into an electronic equivalent of the old paper order sheet ("yellow sheet"). These orders are printed on paper, countersigned by a second practitioner, and then entered into the actual EMR ordering system by a clinic nurse. At least one of the practitioners must be an attending pediatric

hematology/oncology physician. These orders are checked against the protocol roadmap by the nurse who enters them and one other nurse. The printed orders (with the countersignatures) are faxed to the pharmacy where two pharmacy staff check them against the roadmap and against what was entered into the actual EMR ordering system. The chemotherapy that is delivered back to the clinic is then checked against the "yellow sheet" orders. This system was developed in response to some chemotherapy ordering errors that nearly reached a patient. The current electronic system does not allow this type of double signature by two pharmacy staff, two nurses, and two practitioners.

The inpatient chemotherapy ordering system utilizes Word documents that have the necessary information and format for inpatient orders. They are completed by one practitioner and then reviewed and signed by another practitioner. Again, at least one of the practitioners must be an attending pediatric hematology/oncology physician. These chemotherapy orders along with any supportive care orders that appear on the written orders are checked by two pharmacy staff members and then entered into the computer by one of the pharmacists. One of the hem/onc attendings enters almost all of his chemotherapy orders, but they are still double checked at each step of the process. The inpatient physician assistant enters most of the supportive care orders. In all cases, the written orders have a copy of the roadmap attached to them, and this is used to check the inpatient orders at each step of the process. The chemotherapy is mixed by the pharmacy and sent to the inpatient unit. It is then checked against the written orders and the roadmap by two nurses. All of the practitioners enter the majority of their own supportive care orders including intravenous (IV) fluid and anti-emetics.

Prior to 2009, the hospital used a different inpatient EMR. At that time, the chemotherapy admission orders were entirely written documents (with double practitioner signatures) that were entered by the unit clerks and then double checked by the nurses and pharmacists. This system produced errors of ordering and errors of transcribing the written orders into computerized orders. Very rarely, errors evaded all of the reviews and reached the patient. The current inpatient system appears to have a lower error rate, but problems still exist. Incorrect doses occur very rarely, but absent anti-emetics or other supportive care medications are still noted on an occasional basis. Guidelines for point of care testing are also sometimes forgotten. Correcting these problems takes time in the form of phone calls and time to enter the new orders or fix the old orders. These issues can also lead to chemotherapy start times that occur later in the day. This is a problem from the perspective of having enough nurses available to cover a patient who is having a number of medications administered as part of a chemotherapy protocol.

Research Questions

(1) What are the technical and human barriers to efficient and error-free entry of inpatient and outpatient chemotherapy and supportive care orders by means of CPOE and/or order entry by pharmacists?

(2) Within the confines of a commercially available EMR, what are the key areas of improvement that will allow safe and efficient order entry, especially from the work environment and human/computer interaction perspectives?

(3) What can be done to improve the flow of information in order to advance the process and how can these improvements be used to provide a launching pad for conversion to a software package that is specifically designed for chemotherapy?

Framework

The conceptual framework of workflow developed by Unertl et al [27] was used for this project. This framework "has two levels: pervasive and specific". The three components of the pervasive level are context, temporal factors, and aggregate factors. The specific level involves the people doing the work, the tools (virtual and physical) used by the workers, the actions performed by the workers, the characteristics of the actions, and the outcomes of the actions.

METHODS

Design

The study was conceived as a primarily qualitative study in order to examine the chemotherapy workflow from the perspectives of the professionals involved in treating pediatric oncology patients with chemotherapy and/or biotherapy. The primary study subjects included the nurses, physicians, physician assistants (PAs), nurse practitioners, and pharmacists involved in the process. All of the staff with significant responsibility

related to the process of delivering chemotherapy were recruited to participate in the study. This was done in the hope that elucidation of their perspectives would allow improvement in the inherent problem of CPOE adding time to the work flow of physicians and nurses.[28] Part of the study centered on questions about improving the use of templated order sets in order to improve the error rate. [29, 30, 31]

The quantitative part of the project examined the average number of errors in the final chemotherapy order set and the start time of the chemotherapy. Research staff (one physician and one clinical nurse specialist) provided an independent check of the orders. Overall, this will be a form of workflow research that will attempt to improve the process of chemotherapy delivery in an effort to make it seamless and error-free.

Qualitative Methods

The qualitative aspect of the study was evaluated by grounded theory. The process of qualitative evaluation was as per Corbin and Strauss as outlined in Leedy and Ormond [32, 33]. The first step of the analysis used open coding. This method allowed the distillation of the information into a group of themes, especially as they relate to problems with the workflow and communication. The second step was axial coding. During this step interrelations were noted. The underlying conditions, environment, the strategies of the individuals, and the outcomes of these strategies were examined. The third step consisted of selective coding in order to form a narrative. The fourth step was the development of a theory.

Quantitative Methods

The quantitative aspect of the study looked at the start time of inpatient chemotherapy during two different months. In addition, sixteen inpatient chemotherapy order sets (paper Word documents and print-outs of the Epic orders) were reviewed by me and by Dyane Bunnell, MSN, RN. They were reviewed primarily to look for errors related to: calculation of the surface area, the doses of chemotherapy, orders related to anti-emetics, and orders related to crucial supportive care medications.

Populations

The population for the study included all the practitioners, nurses, and pharmacists with significant involvement in the chemotherapy process. Three laboratory personnel were also included in one of the focus groups.

Selection of Sample Units

All of the practitioners, nurses, and pharmacists with significant involvement in the chemotherapy process consented to be part of the study.

Consent, Protection, and IRB Approval

Informed consent was obtained from all individuals involved in the process. The Nemours Oncology Institutional Review Board (IRB) approved the study. The study was also reviewed by the Oregon Health and Science University (OHSU) IRB. The OHSU

IRB waived oversight since the entire study was conducted by and with employees of the Nemours Foundation. Please see appendix 4 regarding further information.

Data Collection

There were twenty-eight individual interviews. They were semi-structured interviews in order to allow a more free-flowing exchange of ideas. Nine of the interviews were with practitioners. This group included all of the practitioners with primary responsibility for chemotherapy ordering. Fifteen of the interviews were with nurses. Five of the nurses worked in clinic, and ten of them worked on the inpatient side. This group included all of the nurses with significant responsibility for chemotherapy initiation (inpatient or outpatient). Four of the interviews were with pharmacists, and this group included all of the pharmacists with significant responsibility for mixing chemotherapy. There were one hundred twenty-six single spaced pages of transcription.

There were four focus groups that had semi-structured discussion about the chemotherapy workflow issues. The focus groups consisted of: (1) pharmacists, (2) practitioners, (3) nurses, and (4) nurses, practitioners, pharmacists, and lab staff. The digital recordings of these focus groups are summarized in appendix VII. Data on chemotherapy start times was collected by pharmacy and nursing staff. Information on draw times in the lab was kindly provided by the supervisor of outpatient specimen collection, Sonia Giribaldi.

Data Analysis

Analysis of the individual interviews occurred in several stages. Handwritten notations were made of important issues during the interviews. Key issues were indicated during the transcription of the individual interviews. After all of the individual interviews were transcribed, formal coding was undertaken. The identified categories were grouped into themes. The themes were analyzed as they related to the research questions. The focus group discussions were summarized as noted in appendix VII.

The lab draw information is noted in two graphs as shown in appendix V. The chemotherapy start time data are presented in spreadsheets in appendix VI.

RESULTS

Qualitative Results:

Evaluation of the qualitative data (individual interviews) revealed four themes, and each of these themes had several categories (or sub-themes). Many of these categories were discussed further in the focus groups. However, the primary purpose of the focus groups was not the discovery of new themes. The focus groups were primarily used to reach a consensus on changes in workflow that could lead to improvements in the chemotherapy delivery process. There were no new themes revealed after the eighth interview, but a new category was noted as late as the twenty-sixth interview.

The themes are:

Time: relates to thoughts and perceptions by all three groups of the amount of time that the current workflow consumes and where in the process there could be improvements.

First Do No Harm: relates to the attitude of the staff that the process of delivering chemotherapy to children is an intrinsically dangerous process and needs to be made as safe as possible.

Information Exchange: relates to issues of communication within and among different groups involved in the process of chemotherapy delivery.

Responsibility: relates to the problems surrounding who needs to insure that each step in the chemotherapy process operates smoothly and without errors.

These themes highlight the complexity of the series of steps involved in delivering chemotherapy to children. Each step produces multiple opportunities to make an error that can lead to injury or death. Making the process safe and efficient requires clear and concise communication among all the groups involved. Making the entire process work requires a high level of individual commitment to the patients and their families.

Theme 1: Time

The process of delivering chemotherapy to children is a complex and very time consuming process.

Comments that were related to this theme were subdivided into the following categories:

1. **Initiate the chemotherapy process earlier**
2. **Change of shift**
3. **Workarounds**
4. **Prioritizing**

As noted in the category 1 quotes, initiating the chemotherapy process earlier is one important way to reduce time in the hospital. This is especially important for patients who are being admitted for intravenous hydration and inpatient chemotherapy. Giving chemotherapy in the middle of the night is not ideal from a safety perspective because there are fewer nurses per patient, fewer physicians in the hospital to evaluate the patient or treat and allergic reaction, and fewer pharmacists available to answer questions. Therefore, if the therapy is delayed into the late evening, it may well mean that it won't be given until the next morning due to safety concerns. This translates into an extra 12-24 hours in the hospital.

The majority of patients who are scheduled to be admitted for chemotherapy are seen in the clinic first. The lab results of the patients must be cleared prior to admission and an inpatient bed must be available. Giving the earliest appointments to these patients was discussed by several of the staff members during their interviews, but they also noted that the families don't always show up on time.

Another important time issue that was noted by several individuals is the issue of change of shift. There is a reluctance to start a chemotherapy process around the change of shift. This applies to hanging chemotherapy in the case of the nurses and to mixing chemotherapy in the case of the pharmacists. There is concern that starting such a process at change of shift will lead to one of two things: unpaid overtime or an unsafe

handoff of care to the individual on the next shift. This is an example of a domino effect in a complex process, i.e. the early delays in appointments and labs lead to admissions that occur too close to the afternoon change of shift. This leads to further delays in starting chemotherapy.

When there are multiple issues demanding attention at the same time, prioritizing tasks becomes a significant problem. One crucial area of prioritization that was raised by several individuals from each group is the issue of how lab technicians prioritize the hematology/oncology labs. The lab currently prioritizes the hematology/oncology labs in the middle of the pack: blood gases, stat labs, critical care (the various intensive care units and the emergency department), hematology/oncology, and the other hospital departments/divisions. The need to consistently submit chemotherapy orders for review/entry in a timely way is another issue of prioritization that was raised by several staff members.

Table 1: Representative Quotations for Theme 1: Time
Category 1 (**Initiate the chemotherapy process earlier)**: "I think an important goal is to avoid giving chemo at midnight. I'd like to avoid 10 pm, 8 pm, even 6 pm. I'd like to give the chemo during the day. You have maximal staffing, multiple support, not just the bare bones of an MD and a pharmacist but

multiple pharmacists, educational coordinators, charge nurses, people with expertise in all different areas. If there's a pump problem or a dose problem or the med color is off does that mean it's no good. It's obvious during the day you'll get better service in that regard. Outpatient one of the easiest things to do is to get the patients in early which has been a chronic problem with us; trying to get them in a room at a reasonable hour. Inpatients it sometimes involves when they arrive in clinic and then they're backed-up each day that's probably less of a critical issue."

Category 1 **(Initiate the chemotherapy process earlier)**:

"Well it seems like the process for the majority would start over in the clinic. Maybe making sure that these families that are getting the chemotherapy have the earliest appointments. You get them in earlier; I don't know what happens over there. I think if they are coming to the floor and they are starting in the clinic it would be to get them in earlier, and their hydration and so forth. And those other things you can't control though. Yeah, showing up on time. We know a lot of times they come late and if they want to go downstairs and get lunch first before they come to the floor. Then once they come to the floor if we don't have a bed, they have to wait. Sometimes they have like an hour or so to kill before they can come to the floor. Labs and everything are usually already done, and that's not a problem. I don't think it is. "

Category 2 (**Change of shift):**

"The bigger roadblock that I hit now is nursing change of shift. Two changes of shift

occur: the change of shift at 3 and the change of shift at 7. I'm finding that at the change of shift everything kind of goes on hold."
Category 2 (**Change of shift):** "Not really because a lot of it depends on the patient and the time of day that the orders come. That's huge. If it's getting near the change of shift and trying to find two nurses to physically sit down and verify those orders sometimes it's a roadblock on our side without question."
Category 3 **(Workarounds):** "I think the fact that you still have to have to have the hard chart makes it hard because it wanders."
Category 3 **(Workarounds):** "Um, just writing in specific gravities, that whole process of putting in the point of care testing and pulling up the names and having to pull up multiple screens and get it in there. It's a lot more time consuming than writing on a piece of paper."

Category 3 **(Workarounds):** "I've never retimed them, but the girls on nights have told me it's an issue. If they leave the time, it will pop up as overdue. Instead of retiming the whole thing, they just click it off. You know, bar-code it then when they actually give it. And then put in comments why it was late."
Category 4 **(Prioritizing):** "If I would ask them how do they prioritize? Maybe it would be better if we make it more clear that ours are hem/onc and would that make it better in terms of prioritizing. Sometimes we have four patients and we send them down at the same time I know that they've got all of our four patients and they don't know which one to do first. I'll call them and say can you do this diff first? You know because different people need different things. So I'll do a phone call and ask them how they can make it identifies ours better and clarify the turn around time."
Category 4 **(Prioritizing):** "But the sooner we can get the orders to review them and be prepared and get ready and have the nursing staff and all that. Sometimes we're, you know, short-staffed and getting everything done and prioritized sometimes makes it difficult."
Category 4 **(Prioritizing):** "I think we need to seriously have people dedicated to have the time to do it. It's not just squeeze it into your provider's schedule. I think there needs to be dedicated time for each

discipline, so to speak, to work on this."

Theme 2: First Do No Harm

Comments that were related to this theme were subdivided into the following categories:

1. **Safety**
2. **Double check**
3. **Paper versus electronic health records**
4. **Consistency and standardization**

This theme relates to the concept of error prevention. Safety is paramount in the thinking of all of the staff involved in the chemotherapy process because the medications used to treat cancer in children are highly dangerous with numerous side-effects. Prior near-miss events led to a failure mode and effects analysis (FMEA). This FMEA led to the current chemotherapy process that involves double-checking at every step: writing the orders (practitioners), reviewing the orders (nurses), mixing the chemotherapy (pharmacists), and administering the chemotherapy (nurses). The process appears safe, but some of the practitioners and pharmacists raised concerns that the process has become so complex that it may actually reduce the level of safety.

There was general agreement that the conversion from paper to electronic health records improves safety, especially due to the clarity of the information. In other words, removing the issue of sloppy handwriting from the equation was a significant positive. However, there were still some concerns that relying too much on the computerized

information was risky. There were also concerns about the amount of time that some tasks take in the computer versus on paper.

One of the major advantages of a computerized system is that the chance for human error is reduced. Consistency and standardization of processes was noted to be vital to improving safety and efficiency. The use of an EHR was noted to aid in achieving this goal. However, a more uniform approach by every member of the team was also felt to be crucial. Modification of roadmaps has lead to some errors that required correction. A more stringent process for creating these individualized roadmaps has now been developed. This includes evaluation and signature by two attending oncologists.

Table 2: Representative Quotations for Theme 2: First Do No Harm
Category 1 **(Safety):** "It's better because we are even more nervous and paranoid about the chemo orders, the chemo mistakes, than we were before so independent of any other development in our methodology we're even more nervous and paranoid than we were before."
Category 1 **(Safety):** "It's interesting that you should mention that because one the most substantial advancements in patient safety and outcomes in the last two years was a guy putting together checklists. I think he was at Hopkins. It was a surprisingly simple list. I think there was a PICU type set-up and the 10 things they had to do before they did any procedure. And instituting that simple check list substantially decreased complications

and infections. A lot of it was common sense; one was wash your hands, and just having the checklist really forced people to look at that."
Category 1 **(Safety):** "I think that our order sets become more comprehensive and deliberate and simpler, easier to read. And I actually think that Epic has helped that process."
Category 1 **(Safety):** "My concern is we've added steps into our process and do we make it safer or does that extra work of having you check and that delay is kind of backing everything up so now it's a rush, rush, process."
Category 1 **(Safety):** "I think it's better because I think we're more conscious of safety, and we have worked hard to develop processes and rules that actually get implemented and have made a difference."
Category 2 **(Double check):** "Um in the sense that our safety wise with all the check we have. There are multiple checks nurse-wise, two checks doctor-wise, at least two checks pharmacy-wise. It's being checked, and if there is ever an error, it's being caught well before it even gets to the patient."

Category 2 **(Double check):** "There's little things from the nursing thing that I'm used to always we double check it, but I always put date and initial and time-up when I hang chemo. It's just something; it's a double check; it's physically doing it. To me that's another double check. The process is relatively the same. I'm just more used to having something. I'm a type of, talking about individual things; I'm a checker-offer. I have boxes. I check it. It's done, and we had a chemo checklist per se. You know, you just check the consent. And literally checked it, physically checked it. So you're not saying did I do that, oh I forgot to do that, because it's something up here that you have to remember versus having a checklist that you can literally check off done, done, done and making sure it was done."
Category 2 **(Double check):** "The hard part of it I think is more for the newer nurses because they don't know what orders to look for. We learned what orders are missing by reading all of those orders constantly. The new nurses that don't know the side-effects yet or what orders should be in. I think it's a harder learning process for them."
Category 2 **(Double check):** "Um, and there are double checks in there that should keep you from making a major error. My experience with Epic has not been very positive in that way because most of the drug dosing limits that are in there are not accurate. We are sort of trained to ignore them because so many of them aren't correct for what we do, but ideally a system would actually usually work in that it would check what you are doing in terms of maximum

doses, doses for weight, things like that. That's the main thing I think."
Category 3 **(Paper versus electronic health records):** "I think the fact that you still have to have to have the hard chart makes it hard because it wanders."
Category 3 **(Paper versus electronic health records):** "I think it's clearer. You can read the drug names. You have all of the dosages next to it as far as like how much to give."
Category 3 **(Paper versus electronic health records):** "I consider myself computer savvy but yet I'm old school and I like to see the paper and things like that. As far as inpatient the biggest roadblock some of it is just trying to find the information. Orders are put in differently, and who's putting the orders in, releasing the orders, are they cleared. All the pieces in the EMR seem to be in different places."
Category 3 **(Paper versus electronic health records):** "People need to remember to keep an eye on the technology to make sure it reflects what's on paper and what's real."
Category 3 **(Paper versus electronic health records):** "I think our system is safer now primarily because we haven't abandoned common sense and said we're going to the electronic medical regardless of whether it's safer or not."

Category 3 **(Paper versus electronic health records):** "Um, just writing in specific gravities, that whole process of putting in the point of care testing and pulling up the names and having to pull up multiple screens and get it in there. It's a lot more time consuming than writing on a piece of paper."
Category 4 (**Consistency and standardization):** "I think the whole lab process takes a really, really long time. I think there needs to be consistency with the way the physicians go about the lab process. Some just activate the vincristine, others kind of wait; it's not just the vincristine. A kid who's in DI; they're going to get there chemo no matter what normally unless they're sick; but there are some physicians who don't want it activated until their labs are back. Their chemistry panels can take an hour and a half to two hours to result. It's; I mean that's just from experience, but I don't know. I think on the chemo drugs that aren't count dependent and if the kid looks good, I don't know that the labs are necessarily, that if it has nothing to do, with PEG I understand the coags and things like that. But if it doesn't necessarily, if it's not going to change whether or not we give the drug I don't know that we need to wait for the result."
Category 4 (**Consistency and standardization):** "All those checks and balances weren't in place which I think is an improvement, but I think a big hold-up is the pharmacy. I don't think they have consistency of when to make the chemo and when it's OK to make the chemo. Once the nurse calls or the

communication is there, child's coming; they should make the chemo unless it's not stable. But hardly any; I can only think of VP-16. The doses we give really are stable for 24 hours for the most part. I think that would be an improvement. I mean that should be enough, they're here. They shouldn't have to wait for urine specific gravity and so forth to make it unless there's a stability issue of course."
Category 4 (**Consistency and standardization):** "Well, it means there is no longer the problem of handwriting. It means that things become more standardized. There is less variation in the way the orders are written because we're forced to write it in the fashion that the computer expects it to be written for better or for worse. Ultimately it's for better; there are growing pains that just happens. I think that's the biggest part."
Category 4 (**Consistency and standardization):** "I think that each and every role in the delivery of chemotherapy. I don't want to sound too military about this, but I think there's a process that should be able to be replicated by every single person."

Theme 3: Information Exchange

The movement of information within groups and from group to group is essential to providing chemotherapy to children.

Comments that were related to this theme were subdivided into the following categories:

1. **Communication/coordination**
2. **Order versus chaos**
3. **Transparency and flow**
4. **Chasing**

The physical division of the hem/onc clinic was noted to be a hindrance to communication. Communication between the physician and the nurse was noted to be vital in terms of having a smooth and safe chemotherapy process. This communication was especially important when a change in the orders is needed (due of toxicity or other factors).

The chemotherapy process has many components, and there are too many situations where the standard procedures can fall apart and lead to a chaotic situation. People do not become ill in a convenient orderly manner. Several staff noted that the clinical situation is often "messy" by the very nature of what is occurring.

Computerized orders were noted to be usually clear and consistent. This was not felt to be sufficient to create a safe environment. The interaction of the staff with the computer has lead to confusion and errors. Several people noted that written order sets that have been use for years are organized in a way that mirrors the sequence of events that needs to occur in order for the patient to actually get their chemotherapy. These written order sets tell a story, i.e. they have transparency and flow.

Another significant issue is trying to find lab results, imaging studies, and other information that is needed in order to clear (approve a patient to receive) chemotherapy. These results are a form of non-verbal communication. Chasing these results adds considerable time to the process of safe chemotherapy delivery. It can also lead to a substantial amount of staff and parent frustration.

Table 3: Representative Quotations for Theme 3: Information Exchange
Category 1 **(Communication/coordination):** "The division of the two sides of the clinic is probably the biggest roadblock in communication because people just aren't visible. We see the patients on one side and almost all the providers are on the other side and it's hard to know. When everybody is together you pass each other in the hall constantly and you can throw questions out."
Category 1 **(Communication/coordination):** "The more people you eliminate in a communication process, you know if you just have you and the nurse, whoever the provider and whoever is taking care of, it's going to be better and safer."
Category 1 **(Communication/coordination):** "Communication is always the key to anything I think. I'd make sure everybody's on the same page; everybody's doing it the same way."
Category 1 **(Communication/coordination):**

"I know we need some improvements to make it a little more efficient and timely. I think coordination with pharmacy too, and they've been doing better. What time do you want this chemo? Coordinating with the nurse that has them and so the meds are on time. Things like that; that there needs to be a little better communication."
Category 1 **(Communication/coordination):** "I think communication plays a big part in the chemotherapy process. There have been several times where chemo orders were changed and there was no communication between the physician and the nurse or the pharmacy and the drug needed to get sent back. You have to communicate with the person who's working with you caring for that patient. The nurse is the one who's giving the drug. You know we're in control of administering the medications, but we're not in control of the medical decisions that are being made for the patient. And if a dose is going to be changed or a dose is going to be adjusted, it needs to be communicated to the nurse. You can't just; I mean it's happened several times where a dose got changed and it never got communicated to the nurse. There were two orders in Epic, and the other order didn't get cancelled."
Category 2 **(Order versus chaos):** "I think there's a lot especially with using the computer. Things are easier to read, less confusion about where things are. Everything kind of has its own place and things are in a certain place. Orders are more streamlined because there's just one protocol. We

always have the white sheets and the chemo sheets, but still it seems easier to follow since it's on the computer."
Category 2 **(Order versus chaos):** "We have to be careful how many chemos we activate at one time. So if like you have three kids coming in for chemo and then all three are taking care of different kids and we all activate our chemo at the same time then you're going to put that strain on the pharmacy so it's going to take longer to get your chemo then. We know that."
Category 2 **(Order versus chaos):** "I've been trying to get them to adopt that template. Well, it has it broken down by columns. You know, you put the drug name and dose, the route, and then the rate. And mostly recently they put a section on there for comments so you can put 8.22 micron filters. You can put protect from light."
Category 2 **(Order versus chaos):** "At the last chemo meeting that I went to that ____ was not at the group was kind of talking about oh we don't have to wait for the chemo ticket or they don't want pharmacy to wait for the ticket or for clearing you should just go ahead and make it. And I'm all about, however, three weeks before that ____ had sent an e-mail to the department that at the previous chemo safety meeting it was decided that we had to wait for the ticket. So there's kind of a little bit of confusion."

Category 2 **(Order versus chaos):** "Another thing is the modified roadmaps really need to be two signatures I think. We found another error on one that was modified. It wasn't; the roadmap wasn't in error, but the physician had ordered something in error based on the roadmap because the wording was kind of confusing. But I think it's important that the one's that are modified or even the one's that are kind of made up should have two signatures."
Category 3 **(Transparency and flow):** "So, like I said before like how some of the orders are found under prn orders. You have to go searching for them. I think that they should be listed. So, anyone can read the orders and understand that the pressure is low or the urine output is inadequate or the weight is off and you're not looking under the bolus to find the order, where they are a lot of times. So, anyone that's learning the process can see."
Category 3 **(Transparency and flow):** "Well machines are stupid now so when you put things in a logical way the machine mixes things up in a haphazardly disorganized fashion so it doesn't appear in a linear fashion in an intuitive way. I think that's just a software problem. If you threw a bunch of money at this, I bet you could solve this problem."
Category 3 **(Transparency and flow):** "Computers can go down and the further from paper you get the less comfortable people are with switching to whatever down time issues there are, and at least in the computer

systems we've worked with so far they don't look like the way you think about things The orders are not in in an order that makes sense. You can't just look at the orders and know what to do. You have to pull it out by bits and pieces."
Category 4 **(Chasing):** "And we're chasing them down for results right now for stuff that was just done. So a GFR, audiogram, PFT's, echo whatever needs to be done should be done the week before if we can or the week of rather than the day of."
Category 4 **(Chasing):** "I think a nursing role when we are expecting a patient from the clinic and we're given a time and then orders are handed in then we're being supported to get them checked and make sure that they're being signed and everything correctly. Sometimes if we are busy I'll say that the checking process and that kind of stuff to the pharmacy: Are they cleared? Do they have a ticket? Gets pushed off a little bit."
Category 4 **(Chasing):** "Or the frequency like instead of it saying times three or to start tomorrow instead of today. It's something they know needs to be done, but they won't change it. They know what you really meant, but they won't change it. They'll say we won't do that, you have to give those back to him, and it's just a minor thing that needs to be done. That I find to be a little daunting sometimes, take care of it, just do it, and it will be done, and you won't have to run around with the orders. You guys are downstairs in the OR and you

might be busy."

Theme 4: Responsibility

The key issue in the safe and efficient delivery of chemotherapy is an excellent system that supports the ability of the individual to function effectively. However, individual responsibility is still an important part of the process.

Comments that were related to this theme were subdivided into the following categories:

1. **Personal interest**
2. **Silos**
3. **Fear**
4. **Conflict**

Even with an excellent system in place to guide delivery of the chemotherapy every individual involved in the process must take a personal interest in making the system work smoothly. This means that there should be a willingness to fix any errors that have been made as quickly as possible. Sometimes there is also a need to fix another practitioner's error. The ability and willingness to help make every step of the process safer comes from a realization that each person does not work in a vacuum (or

silo). It also requires a willingness to overcome fear of change (including fear of technology).

It is natural for an element of friction (conflict) to occur in a high stress environment such as pediatric oncology. Honest recognition of these issues should lead to an opportunity to spend less time casting blame on the other person, group, or department. The focus needs to remain on the patient and on improving the quality of care for all the patients.

Table 4: Representative Quotations for Theme 4: Responsibility
Category 1 **(Personal interest):** "There were more checks as far as pharmacy was concerned, and I think part of that was it was a far larger institution and so there wasn't as much personal interest."
Category 1 **(Personal interest):** "Like I said just knowing who is responsible for what, and sometimes like if there is an error on the written orders sometimes people are a little reluctant to come right over to fix them. Depending who's on which physician is responsible to come over and fix them especially with some of our kids, some of them are bone marrow, some of them are regular hem-onc, depending who wrote the orders, the PA wrote the orders. Who's responsible for what portion of."
Category 2 **(Silos):** "To me it really does feel like there's a stumbling block on the pharmacy side of things,

but I say that with a little bit of ignorance in the sense that I don't really know what they do back there. I don't know how busy they are. I don't know what else is going on. So, it's hard for me to completely complain about them when I know that they are responsible for more than just my chemo for the day."
Category 2 **(Silos):** "With the last patient I had, no one had put in the Busulfan lab draws. So, the attending had to sit there, which is very time consuming, and put in all those orders. So, unless it's in an order form the pharmacy will not put them in."
Category 3 **(Fear):** "That's kind of the only issue with order entry right now in the pharmacy. People are afraid; they don't want to take a chemo and they don't want to enter it because they're not comfortable with certain things on the chemo. So it we just kind of got rid of anything that's not medicine related, not drugs, then I feel that would go away."
Category 3 **(Fear):** "It makes it worse or more difficult because there are some. Well sometimes certain doctors don't know how to order. You have to assist them in ordering it, ordering the chemotherapy."
Category 3 **(Fear):** "Everybody had different skill levels. There is a pretty high error potential when people

are learning a new system, and there are always going to be people learning a new system because even if the system has been in place for twenty years you're going to have new people coming in. Computers can go down and the further from paper you get the less comfortable people are with switching to whatever down time issues there are, and at least in the computer systems we've worked with so far they don't look like the way you think about things."
Category 4 **(Conflict):** "One frustration I know on the floor that several of us have experienced is that we find an error or a discrepancy in orders versus what's written and what comes on the EMR and then having and we can't write on it trying to get someone to come fix it. Sometimes we're met with a lot of resistance to doing that it's a lot of work or don't worry about it or the timeliness to get that person over here. Sometimes it's a little thing and sometimes it's a significant thing. And the timeliness of getting that physician to come and sign that off or the PA or whoever it is make the adjustment sometimes impedes the flow. That's one thing."
Category 4 **(Conflict):** "We get resistance if that person who we're asking to make the adjustment didn't write the orders. And I'm not really sure, and from the physician standpoint maybe the physicians should all be onboard but unfortunately it's a bummer, but it has to get done."

Focus Group Information:

The following workflow ideas were reached as a consensus during the focus groups: (1) early appointments in clinic, (2) aggressive hydration in the clinic and on the floor, including boluses if needed, (3) home intravenous (IV) fluids, (4) home labs, and (5) orders should be turned in for review/entry at least one day in advance of a scheduled admission. These ideas were dovetailed into the quantitative part of the study by attempting to put one or more of them in place and observing if there was any change in the start times for the chemotherapy. The last idea was considered to be the most easily achievable because appointment slots get filled fairly quickly and many parents do not want to deal with labs or intravenous fluids at home. The aggressive IV fluids were already being done in many cases.

Triangulation: Limited triangulation of the individual interviews was provided by Dyane Bunnell. She was in general agreement with the outlined themes and categories.

Quantitative Results:

The review of the sixteen chemotherapy order sets did not reveal any important or clinically significant errors. This is an indication that the current process of double-checking the orders at multiple steps may be cumbersome, but it is effective.

One of the issues was early appointments, and having the patients waiting in outpatient specimen collection defeats the purpose of early appointments. As noted in appendix V, the patients are waiting the same amount of time as other patients, but getting blood out of them via venipuncture is taking longer.

Appendix VI shows the data on chemotherapy tracking. In September 2010, the average start time was 1843 hours, and the average elapsed time from admission to starting chemotherapy was 5 hours and 34 minutes. For the September 2010 data and the January 2011 data, we excluded patients who are receiving intrathecal medications because these times are scheduled in the operating room or in the short procedure room. Bone marrow transplant patients were also excluded because they are all admitted several days before starting their pre-transplant chemotherapy. The chemotherapy tracking information in January shows an average start time of 1959 hours and an elapsed time from admission to chemotherapy of 5 hours and 45 minutes. January was a much busier month from the point of view of chemotherapy admissions, and this may explain some of the problems with getting chemotherapy started on day shift. However, when we were able to have the chemotherapy orders turned in at least a day in advance we were able to have an average start time for chemotherapy of 1502 hours.

DISCUSSION

Themes:

Four themes were noted in the data regarding chemotherapy ordering and delivery: Time, First Do No Harm, Information Exchange, and Responsibility. These themes highlight the complexity and intensity of the process of treating pediatric oncology patients as perceived by the staff who are involved in the frontline care of these children. These themes provide insight in the ways the staff members view the possibility of improving the process now and in the future.

Time: Receiving chemotherapy for leukemia or a malignant solid tumor is a time consuming and labor intensive process. However, it is not only the time spent in the hospital or clinic that is important. For the children, the time spent getting treatment is time that is taken away from being with their friends and time taken away from school. For the parents, it is time taken away from their other children, time taken away from their sometimes elderly parents, and time taken away from work. Time taken away from work [34] has a significant financial impact on the family at a time when there are already concerns about how to pay for very expensive cancer treatments. These time issues are known by the staff and should provide further motivation to improve the amount of time the chemotherapy process consumes.

The staff all approved the idea of starting the chemotherapy process earlier, but there where issues about where the problems arise. Currently, the clinic schedule of the inpatient chemotherapy PA has been shifted in a way to allow her involvement in inpatient rounds to be more focused and shorter. This should allow her to see the patients

who are due for admission earlier in the day. This plan evolved because the staff wanted the parents to come in earlier, but none of the staff were anxious to start clinic earlier.

There is a recognition that change of shift is a problem, but there was not much thought given to flexibility of schedules or working some unpaid overtime to help the process move forward. This may take more discussion and perhaps reinstating the concept of having early nurses and late nurses. The outpatient early nurses would start at 8 am and finish at 4:30 pm; the outpatient late nurses would start at 9 am and finish at 5:30 pm. This would also allow some blood product transfusions to run a little later. This can be a problem for staff with child care issues. There is always a give and take with convenience for the patients and their parents versus the convenience and efficiency for the staff. This raises the concept of patient centered care versus staff centered care.

First Do No Harm: Our hospital is highly computerized with an inpatient and outpatient electronic health record. All progress notes are electronically generated, although some are dictated and then placed in the specific encounter after review. This includes operating room notes. In general the system saves time, but there are occasions when paper is faster such as for recording urine specific gravities (which is a key issue for chemotherapy that requires a certain level of hydration). The majority of our medications are bar-coded, and this sometimes creates problems when medications have to be retimed. Many staff members feel that a paper system is more flexible than an electronic system, but there is not much recognition of the yin and yang of flexibility versus safety. More flexibility often (but not always) leads to more errors.

There is a roughly fifty/fifty split on whether the nurses feel they can provide a safe chemotherapy process without some form of paper, especially in the transition period when we go live with Beacon. For a number of the nurses, the paper is still the primary chemotherapy order: "People need to remember to keep an eye on the technology to make sure it reflects what's real". It is fascinating to see this level of attachment to paper in a hospital that has a long track record of EHR use and that is a recent Davies Award winner. The younger nurses are generally more comfortable dealing with the computer than the more senior nurses, but this is not a uniform finding.

Information Exchange: The current process has a number of hand-offs of the patients and the information associated with them. This makes good communication of vital importance, and it was clear that many of the staff wished there was more consistency about how information gets communicated. This raises issues of verbal communication versus electronic communication. In many cases, both kinds of communication were considered to be essential in order to make the process safe. The orders that are placed in Epic led to a number of frustrations: "Well machines are stupid now so when you put things in a logical way the machine mixes things up in a haphazardly disorganized fashion". I don't believe that the machines or their programmers are stupid, but I do believe there isn't enough time spent in communication between the developer of a system and the user. We are currently focusing on the need for massive amounts of communication time between the builders of our customized order sets and the clinical staff. It is hoped that such communication will lead to an

ordering system that will do a more effective job of providing orders that flow in a way that humans can intuitively understand. The work is planned and carried out in a chronological way, and the orders need to appear in this fashion. This perception is common to the vast majority of the clinical staff.

Responsibility: Ultimately, people not machines are responsible for the care of the patients. Unfortunately, many of the staff members are still wearing blinders regarding the concept of us versus them. There was lip service about cooperating about quality improvement, but the perception was usually that some other group or person needs to change their system or their behavior in order to improve the care: "To me it really does feel like there's a stumbling block on the pharmacy side of things". There is a clear need for people to get over their fear of technology in terms of retiming medications or entering orders. There is a low level of tolerance for anything that adds extra time or appears to be unsafe. In some individuals there is a real aura of fear that if they don't understand some electronic task on the first try they will make constant major errors that will impact patient safety. As we develop our new system we are promoting the idea that practice, practice, practice will enable all of the staff to interact with the computer system in a satisfying and safe way.

Quantitative workflow issues:

The data demonstrate that at least one of the suggested workflow changes will improve the start time of the chemotherapy in a clinically significant way if we can motivate the practitioners to get the orders in early.

Possible Future Research:

The A. I. duPont Hospital for Children is currently in the midst of a project to go live with Epic's software product for chemotherapy which is called Beacon. This project involves the development of Beacon order sets for all phases of chemotherapy delivery. It includes inpatient and outpatient chemotherapy. We are starting with a limited number of Children's Oncology Group (COG) protocols. The pursuit of some of the listed goals about early order entry is fertile ground for further quantitative research, and the interaction of the practitioners, nurses, and pharmacists with this new system will also provide multiple opportunities to examine the process of chemotherapy delivery with this new tool in place. This research could include extensive user testing as we go live with Beacon. This type of user testing would be used to make the entire process more efficient and safer.

Limitations:

The interviews were undertaken only by the author, and the level of triangulation was limited by design since this is mainly a one person project. There were no interviews undertaken at another pediatric hospital, and so the findings may not generalizable. The quantitative part of the study was limited to only two months and was undertaken as a pilot study so that baseline information would exist for future research.

CONCLUSION

The questions that were used for the interviews and focus groups sprang from discussions that have occurred at many meetings of the hematology/oncology staff. The themes and categories that arose from these interviews were a mixture of the realities of day to day clinical practice and some of the ideas and emotions that are below the surface in most situations. The ideas for workflow improvement that developed from the interviews and the focus groups have all been discussed in many different forums over the last ten years. It is clear that when one or more of those ideas is followed, the patients are able to receive their chemotherapy during the afternoon on day shift or on early evening shift. This makes the whole process of chemotherapy delivery safer and more efficient given our current pattern of staffing. The question arises as to what can be done to motivate the staff do follow these basic guidelines in order to make the whole process work. There are too many situations where the group or individual does not really view themselves as part of a team or a link in a chain of events that must occur in an orderly fashion if the patient is to receive the safe and efficient care that they all desire. We cannot anticipate the process operating like a smoothly operating machine all of the time because “nothing interferes with the orderly practice of medicine like sick patients”. [35]

However, the electronic tools exist and are being refined as we move in the direction of a software package that is truly designed for giving chemotherapy. The process of developing our new Beacon order sets should make the chemotherapy process smoother and should enhance esprit de corps. It is also important to remember that CPOE for chemotherapy is not a panacea, and "an EMR is not a replacement for critical thinking". [36]

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APPENDICES

Appendix I: Individual Interview Questions

1) How long have you worked at A. I. duPont?

2) How much of that time has been spent as part of the division of pediatric hematology?

3) Do you think the process of ordering and delivering chemotherapy is better or worse than it was five years ago? How is it better or worse?

4) What are the major roadblocks to improving the process?

5) Who are the key players in improving the process? Why are they the key players?

6) How does technology improve the process?

7) How does technology make the process worse or more difficult?

8) What are the communication issues that impact chemotherapy delivery and how can they be improved?

9) How can we improve the start time for the chemotherapy? Why is this important?

10) Do you have any other ideas that would make the chemotherapy process safer and/or more efficient?

Appendix II: Focus Group Questions

1) What do you think are the most common concerns regarding chemotherapy ordering and delivery that have been noted during the individual interviews?
2) What are the staffing issues that would improve the process?
3) What are the patient education issues that would improve the process?
4) What are the scheduling issues that would improve the process?
5) How can a change in the availability of interpretation services improve the process?
6) What are the practitioner issues that could improve the process?
7) What are the nursing issues that could improve the process?
8) What are the pharmacy issues that could improve the process?
9) What can administration do to improve the process?
10) Do you have any other ideas about the chemotherapy delivery issue?

Appendix III: Focus Group Questions (revised 12/13/2010)

1. How can we get our patients to be seen in clinic earlier?
2. How can we get our pre-chemotherapy labs done earlier?
3. What steps can we take to eliminate (or nearly eliminate) paper from the chemotherapy process? Is this desirable? Why or why not?
4. What do you think about practitioners entering their own chemotherapy orders in the inpatient and outpatient settings?
5. How can we review chemotherapy orders early (regular Epic and/or Beacon)?
6. How can we use the chemoticket for our early double-check?
7. Can our late double check be signing and releasing?
8. Many of the ideas for improving the chemo process have been mentioned in the past. Why haven't we been able to implement them before?
9. What do you think about a chemo order entry tip sheet?
10. Do you have any other ideas for improving the process?

Appendix IV: Project Approval Letters from Nemours Office of Human Subjects Protection and OHSU IRB

Nemours Office of Human Subjects Protection
10140 Centurion Parkway North
Jacksonville, FL 32256
Phone: 904-697-4023 Fax: 904-697-4024

MEMORANDUM

DATE:	July 21, 2010
TO:	Gregory Griffin, MD
FROM:	Nemours Oncology IRB
STUDY TITLE:	[177345-2] An Evaluation of the Process of Chemotherapy Ordering and Delivery from the Perspective of Practitioners, Nurses, and Pharmacists at a Children's Hospital
IRB #:	177345
SUBMISSION TYPE:	New Study
ACTION:	APPROVED
APPROVAL DATE:	July 14, 2010
EXPIRATION DATE:	July 13, 2011

Thank you for your submission of Response/Follow-Up materials for this research study. Your initial submission received expedited review and met all DHHS criteria for approval. The approval was contingent on the response to minor stipulations. Your response has received expedited review and is accepted. The above-referenced research study is approved per expedited categories 4 and 5.

The IRB requires that a copy of the participant brochure: "Becoming A Research Volunteer" will be given to every individual enrolled in a research study. The PDF file for this document has been attached to this study as a Board Document.

The IRB has determined that:

- This is "Sub Part D does not apply".
- Informed Consent or Parental Permission is required prior to initiation of any research procedures using only the most current IRB approved form(s) posted as a Board Document in IRBNet. All protocol documents, including Board approved documents are found in the "Study Designer" for each study in IRBNet.
- No children will be enrolled so Assent does not apply.
- The research does not meet the criteria for including a copy of the PPF/ICF and research data in the Nemours' medical record.
- To continue, the research requires IRB review and approval on an annual basis. Otherwise, July 13, 2011 is the last day that research may be conducted. The Principal Investigator is responsible for the timely submission of the continuing review application. Please post this date on your research calendar.

Reviewed/approved documents in this submission:

- Consent Form - Template_Observational_Noninterventional_Research_ICF_02192010.doc (UPDATED: 07/16/2010)
- Other - Project clarification.doc (UPDATED: 07/16/2010)

Activity Details (Approved)The chair screens a fast track application and approves it. No further review is necessary

Author:	Susan Bankowski (CI.Corporate Integrity)	**Activity Date:**	8/20/2010 9:25 AM PDT
For Person:		**Created Date:**	8/20/2010 9:25 AM
Logged For (Study):	An Evaluation of the Process of Chemotherapy Ordering and Delivery from the Perspective of Practitioners, Nurses, and Pharmacists at a Children's Hospital		

Activity Form Property Changes Documents / Tasks / Notifications

Approve

Use this form to **approve** the study as it stands, without further processing.

Short Study Title:	An Evaluation of the Process of Chemotherapy Ordering and Delivery from the Perspective of Practitioners, Nurses, and Pharmacists at a Children's Hospital
IRB Number:	IRB00006657

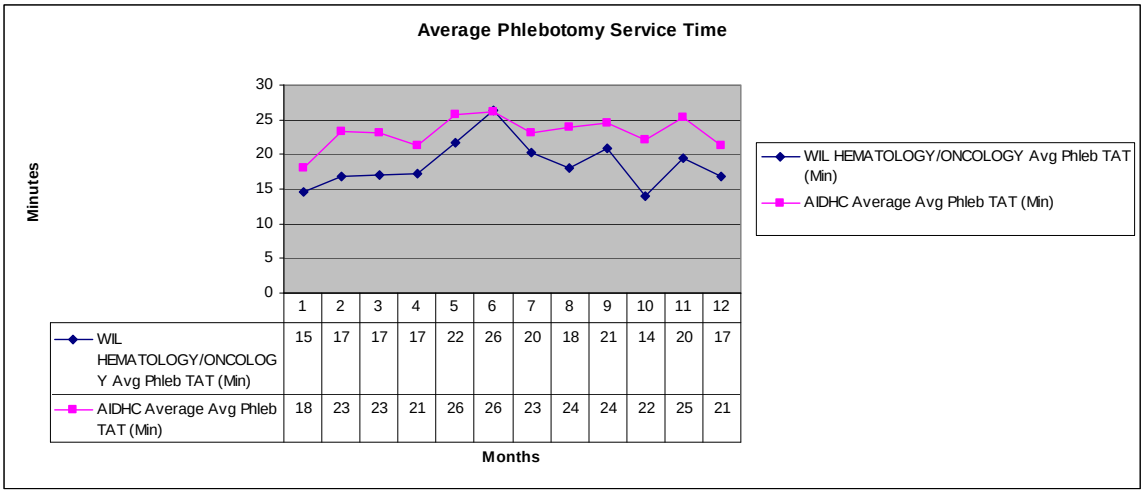
* **Approval effective:** 8/20/2010

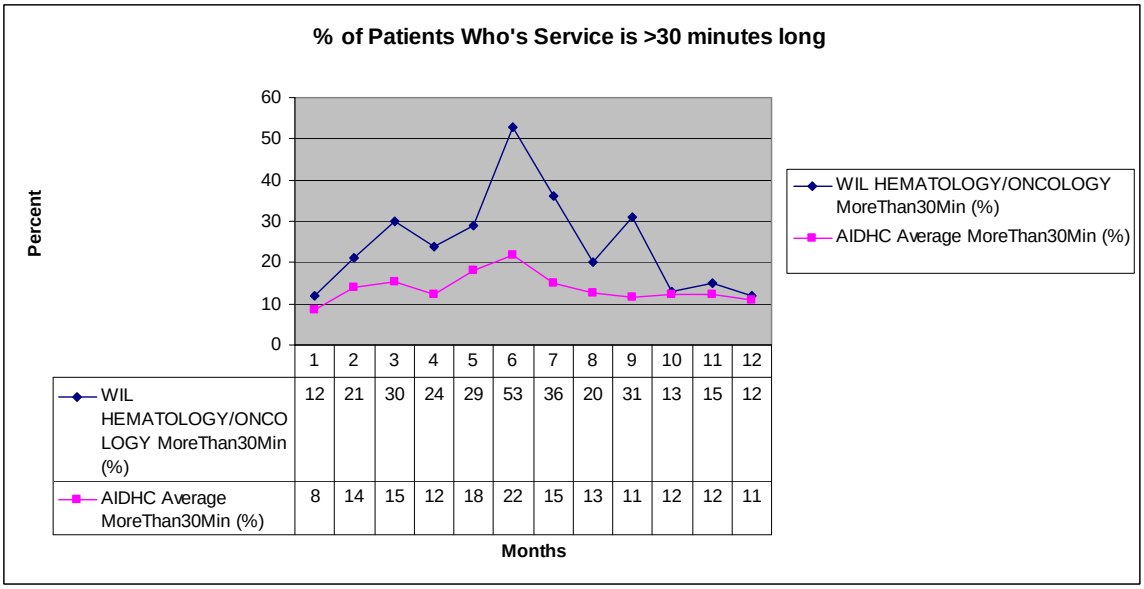
Expiration Date: 8/19/2011

☐ ☐ Disable enforcement of minimum difference of days between Expiration Date and Approval Effective Date.

Memo created by analyst:

Appendix V: Lab draw time issues





Appendix VI: Chemotherapy Tracking

Chemotherapy tracking in September 2010:

Date	Unit	MR#	Patient Admitted	Chemo Begun	Admission to Chemo	
9/1/2010	3CN	30543718	1400	18:15	252 min	
9/1/2010	3CN	30429035	1330	17:45	255 min	
9/2/2010	3CN	30121501	1315	18:51	336 min	
9/3/2010	3CN	10435899	1040	17:57	437 min	
9/3/2010	3A	10254470	850	10:15	25:25:00	next day
9/7/2010	3CN	10242350	N/A	13:42		
9/7/2010	3CN	30443982	N/A	12:00		
9/7/2010	3CN	10242350	N/A	12:00		IT/OR
9/10/2010	3CN	10242350	N/A	21:40		
9/10/2010	3CN	10265155	1700	20:30	210 min	
9/10/2010	3CN	30501104	1415	18:20	245 min	
9/13/2010	3CN	30539408	1415	9:30	19:15	next day
9/14/2010	3A	30430137	N/A	13:39		next day
9/15/2010	3CN	30478364	1246	21:44	538 min	
9/16/2010	3CN	10447070	1335	18:00	265 min	
9/22/2010	3CN	30565055	N/A	16:30		IT/OR
9/22/2010	3CN	30543718	1227	19:50	566 min	
9/22/2010	3CN	30476619	1715	21:15	240 min	
9/24/2010	3A	30565055	N/A	22:16		
9/27/2010	3A	30203898	1347	9:00		bbmt
9/29/2010	3A	30430137	N/A	9:00		IT/OR
9/29/2010	3A	10408984	1420	10:35		BBMT
9/29/2010	3CN	10242350	N/A	9:00		IT/OR
Average Start Time				**18:43**		
Average Time Elapsed (Admit to Chemo)					**334.4 min (5:34)**	

Chemo Tracking January 2011

Date	Unit	MR#	Patient Admitted	Orders Received	Chemo Begun	Admission to Chemo	Comments
1/3/2011	3A	30516024		1/3/2011 1425	1/4/2011 0745		ITs
1/3/2011	3A	30134004		1/3/2011 1537	1/4/2011		ITs
1/3/2011	3A	30134004		1/3/2011 1537	1/5/2011 1703		
1/4/2011		30484486	1/4/2011 1325		1/4/2011 1836	311 min	
1/3/2011	3A	30390582		1/3/2011 1537	1/4/2011 1100		ITs
1/4/2011	3A	30516024		1/4/2011 1753	1/5/2011 1130		
1/4/2011	3CN	30582164		1/4/2011 1255	1/6/2011 0940		ITs
1/4/2011	3CN	30582164		1/4/2011 1255	1/6/2011 1138		
1/4/2011	3CN	30538794		1/4/2011 1300	1/5/2011 0126		
1/5/2011	3CN	10176870	1/5/2011 1345	1/5/2011 1345	1/6/2011 1045		
1/7/2011	3CN	30327203		1/7/2011 1613	1/7/2011 2200		
1/9/2011		30597243		1/9/2011 2100	1/11/2011 0920		ITs
1/10/2011	3CN	30532814		1/10/2011 1145	1/10/2011 1807		
1/10/2011	PICU	30390582		1/10/2011 0:00	1/11/2011 1422		
1/10/2011	3CN	30428416	1/10/2011 1402	1/10/2011 1402	1/10/2011 1450	48 min	
1/12/2011	3CN	30476619	1/12/2011 1308	1/12/2011 1308	1/12/2011 1943	395 min	
1/11/2011		30581088	1/11/2011 1154		1/11/2011 1814	380 min	
1/13/2011	3CN	30531904	1/13/2011 1403	1/13/2011 1403	1/13/2011 2300	537 min	
1/17/2011		10356862		1/17/2011 1230	1/18/2011 1630		
1/17/2011	3CN	10234056		1/17/2011 1240	1/19/2011 2144		
1/18/2011	3A	30469522	1/18/2011 1455	1/18/2011 1455	1/19/2011 0900		BBMT
1/18/2011	3A	30134004		1/18/2011 1520	1/18/2011 2000		
1/18/2011	3A	30484486	1/18/2011 1545	1/18/2011 1455	1/18/2011 2115	330 min	
1/19/2011	3CN	10142557		1/19/2011 1100	1/19/2011 1700		

1/20/2011	3CN	30327203	1/20/2011 1320	1/20/2011 1320	1/21/2011 1400		due on 1/21
1/21/2011	3CN	30582164	1/21/2011 1405	1/21/2011 1405	1/21/2011 2200	475 min	
1/24/2011	3CN	10356862	1/24/2011 1416	1/24/2011 1416	1/25/2011 1927	311 min	
1/25/2011	3CN	10447070	1/25/2011 1315	1/25/2011 1102	1/25/2011 1835	320 min	
1/26/2011	3CN	30531904		1/26/2011 1530	1/27/2011 0920		ITs
1/27/2011	3CN	30531904		1/27/2011 1530	1/27/2011 2056		
1/27/2011	3CN	30134004	1/27/2011 1500	1/27/2011 1500	1/28/2011 1540		due on 1/28
1/31/2011	3CN	30545751		1/31/2011 1430	2/1/2011 1630		
1/31/2011	3CN	30484486		1/31/2011 1830	2/1/2011 1720		

Average Start Time (new admission/same day orders) **19:59**

Average Start Time (patient already admitted/orders submitted prior chemo due date) **15:02**

Average Time Elapsed (Admit to Chemo) **345.22 min (5:45)**

Appendix VII: Focus Groups

Pharmacy:

1) The use of the chemoticket as a means of early second signature was discussed. In the future, this would be an adjunct to the Beacon system for second signature (late). The chemoticket could be used for this purpose by practitioners, nurses, and pharmacists.
2) The possibility of having practitioners review the orders in Epic (rather than on paper) was discussed. In this case, the practitioners would actually review what was live in the system (Epic). It would be an important step in getting rid of transcription.
3) The chemoticket could be used to acknowledge that all parts of the orders are correct or just the chemotherapy. It is currently used to check the labs, and this should probably continue. Urine specific gravity should not be part of the chemoticket. Stable chemotherapy can be mixed once the chemoticket is signed.
4) Smart text could be developed for each group to sign the chemoticket. The schemata could be included in the chemoticket.
5) The current pharmacy sheets that are used to double-check the chemotherapy are not scanned into Epic.
6) What are current Beacon users doing (such as Dallas Children's Hospital)?

7) Do other Children's Oncology Group (COG) institutions have the same level of double checking? It may depend on whether you have been burned before, like Boston.
8) If other hospitals have good ideas, we don't need to reinvent the wheel.
9) Can we streamline the process but maintain or improve safety?
10) How can we get the chemotherapy started earlier? The major ideas were earlier appointments and more aggressive hydration. Other roadblocks were getting the orders on the same day it is to be administered. The orders need to be turned in at least one day in advance.
11) On the outpatient side the .chemogo statement is useful along with verbal communication.

Practitioners:

1) What can we do to get the patients out of clinic and admitted faster? Labs at home and home IV fluid were suggested.
2) Eight o'clock visits for the planned admissions were also discussed.
3) We seem to lack the will to use hyperhydration in the clinic.
4) Hydration at home adds to the complexity and time of doing medical things for the families and might work best with new families. This would require a lot of talking to the parents. They might need to stay at the Ronald McDonald House, and this could increase their time away from home.
5) Somebody has to make this work, and that is part of _____role.

6) Families that don't want to do home labs may still benefit from earlier appointments and higher priority of having their labs run.
7) The lab is very busy at 8 am doing inpatient labs. Ordering everything stat is not realistic or helpful, but having a separate priority for hem/onc may be useful especially for patients who are waiting to be admitted.
8) This is a big patient satisfaction issue. This is true for outpatients getting just vincristine, but we have often heard the comment "this is another wasted day of my life".
9) Can we eliminate paper? Part of this is a nursing issue. Some of them are willing, but some of them are worried. The roadmaps must be up to date. There needs to be some logic to the way the Epic orders print out. Right now it is not chronologic. We probably need to retain the schemata to help the chronology.
10) Who is responsible for the roadmap? The answer is usually the nurse or practitioner who gives the medication. On the inpatient side, it is primarily the inpatient physician assistant (PA).
11) The practitioners should be responsible for entering their own orders. This will require some decision support regarding diluents and other issues. This will save some phone calls to the pharmacy, but the pharmacy will double check anyway.
12) The outpatient order sets will need to be built with multiple days. The .chemogo is not a policy at this time, and there will still need to be a conversation between the nurse and the practitioner.
13) Early review of Beacon orders may be problematic.
14) The orders can be hard to find because they can be in so many places.

15) Use of the chemoticket as part of the double-check process may be possible (including the nurses and the pharmacists).
16) We will need a blank order set in Beacon in order to create order sets on-the-fly.

Nurses:

1) Get patients in clinic earlier. This will require earlier appointments. The inpatient PA needs to have earlier appointments. Issues with the chemotherapy patients are already being addressed with the inpatient PA prior to rounds.
2) Labs could be done at home 1-2 days in advance. Most of the families are pretty good about peripheral venipunctures. Some patients prefer peripheral sticks to accessing their Portacath. If the CBC results are not good, this will save them the driving time of coming to clinic. This may require a discussion with the LabCorp or Quest lab supervisors.
3) Parents are not that happy about home hydration because it keeps the patient and family awake at night.
4) In terms of seeing the entire picture, paper does not help as much because all of the supportive care orders are not listed.
5) The information in the computer is scattered, and you have to open things up.
6) Should the schemata be amplified to include the supportive care medications?
7) Paper roadmaps are staying, but they may not be enough to give a complete picture of the treatment.

8) Practitioner order entry would limit the need for the pharmacy to do this, but West Virginia University Medical Center has pharmacy doing most of the work. There may be resistance from practitioners.
9) All order sets are helpful.
10) Problems with Mesna orders. IV fluid issues with bag versus dose. What about bigger bags.
11) Double check issues will need to be resolved with the hem/onc team and with the Epic team.
12) The team that validates the protocol should make certain that it is built correctly.
13) There are ways to modify doses in Beacon and to propagate those changes if desired. Chemotherapy can be delayed. For inpatients, there will be a release of the whole section of chemotherapy (usually 3-5 days) on day 1.
14) There should be interdisciplinary training primarily so the nurses can help the doctors with order entry issues.
15) How can we motivate people to follow plans to speed up the process? Feel free to remind people. Use the per protocol orders. The inpatient PA is trying to push the process.
16) Pharmacy has staff limitations and with coverage during their dinner hour.
17) Please give feedback to the people who are putting the orders in if there is a problem with doses dropping off, etc.
18) Do not give chemotherapy at the change of shift.
19) Throughput from clinic from clinic to inpatient bed is not as big a concern to hospital administration as emergency department to inpatient bed.

20) We need to reorganize rounds.

Combination Focus Group (Pharmacists, Practitioners, Nurses, and Lab Personnel):

1) Labs at home should avoid the big morning rush.
2) We know when they are due, but we need their labs in order to make a decision regarding chemotherapy that day.
3) The current process involves a lab appointment 1-1.5 hours prior to their practitioner visit. If they have a central line they come to clinic to have the nurse draw the blood; otherwise, they go to OSCA (Outpatient Specimen Collection). The patients are processed by the roomer and then seen by the practitioners.
4) Lab orders are usually standing or per protocol. We need to change the timing of the appointments so the potential admissions are seen earlier. The need to have scheduled lab appointments. The wait time can be up to 90 minutes in OSCA. Patients who are hard to stick can take 40 minutes to have blood drawn.
5) The lab should be called when the labs are needed to make decisions about getting chemotherapy and/or admission.
6) Lab staffing is static.
7) A CBC may rarely take 2-3 hours to have a result.
8) It is very important to have labs in Epic prior to the patient arriving at OSCA. Per protocol orders need to be expanded to the outpatient area and to the infusion room.
9) We need to try to spread out the outpatient chemotherapy appointments.
10) Delays are multifactorial: lab, pharmacy, practitioners, and nurses.

11) Labs at home are possible or labs via peripheral stick can be done at outside labs, but many of the oncology patients are difficult to get blood from peripherally.
12) Staffing does not allow us to have a lab technician in the hem/onc area.
13) We continue to see delays in getting bilirubin levels.
14) An onco/chemotherapy classification for labs is probably not possible. We need better communication with the lab. Would a list of chemo patients on a day-by-day basis be useful?
15) 2:30 pm is the pharmacy change of shift.
16) The inpatient PA needs earlier slots
17) We need feedback on order entry.
18) We need order entry in advance, and we can move the encounter if they don't make counts.