

Acute Dialysis Quality Initiative

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Workgroup 6

The Application of Information Technology in the Study of Acute Renal Failure

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Introduction

The careful application of information technology to the field of acute dialysis may result in both a better understanding of the disease as well as an improvement in patient outcomes. Although the benefit of improving the information technology of acute dialysis may seem self-evident, often these applications increase costs and complexity with little change in understanding or quality of care. To avoid this common trap a targeted assessment of needs and possible solutions is mandatory. The goal of this assessment is to provide balanced perspectives and recommendations which address how information technology should be assessed and applied to acute dialysis therapy to both increase the understanding of the current practice as well as to improve patient care.

To achieve these goal six areas of focus were identified: patient safety, current practice pattern assessment, practice variation, patient assessment, dialysis machine technology, and clinical trials. Given the complexity of dialysis in the acute setting there is great potential for mistakes which could interfere with the potential benefits of therapy. Patient safety assessment represents a key area for information technology to decrease patient complications and increase patient benefits in acute dialysis. To better understand the impact of changes in practice style and patient characteristics, methods for monitoring the current state of practice must be established. As the current state of practice is assessed the level of practice variation will likely provide both a wealth of understanding about possible practice styles but when unmonitored may adversely affect the quality of care. Improving patient assessment methods presents the challenge of balancing the cost of what can be done versus the benefits of what should be done to monitor a patient. Given the reliance of dialysis modalities on dialysis machines, the technology associated with these machines and how people relate to the technology represent an essential area for continuous

improvement. Finally for the field of acute dialysis to evolve and improve over time the information technology used in clinical trial will need to be optimized to yield maximal applicability.

The assessment of the six areas was performed by formulating and answering the six questions.

How should current and future information technological innovations be used to reduce errors in care delivery which could potentially lead to patient harm?

To maximize the positive effects of acute dialysis therapies it is necessary to minimize the potential complications. Medical errors have been repeatedly shown to significantly affect patient morbidity and mortality. In numerous fields information technology has been applied to work flow processes to minimize deviations from planned procedures (1-2). Currently no studies are available which document potential sources of error in the acute dialysis setting. In acute dialysis care delivery errors may occur anywhere within the work flow process. This process is composed of the following stages: patient assessment, order writing, order transcription, order interpretation, nursing care, treatment parameter entry into dialysis machines and fluid pumps, prescription delivery by the equipment, data generation from labs and equipment, patient reassessment and then the treatment adjustments which restart this cycle (see Figure 1). The characteristics of each of these stages may prevent or predispose to potential errors which may lead to patient harm. Examples of potential errors are misinterpretation of physician orders, incorrect calculations, inaccurate charting, illegible writing, overlooked vascular access issues, and inappropriate anticoagulation parameters. These types of error may lead to inappropriate fluid balance, unexpected shift in electrolytes and acid/base states, filter clotting, infection and large discrepancies between prescribed and delivered doses.

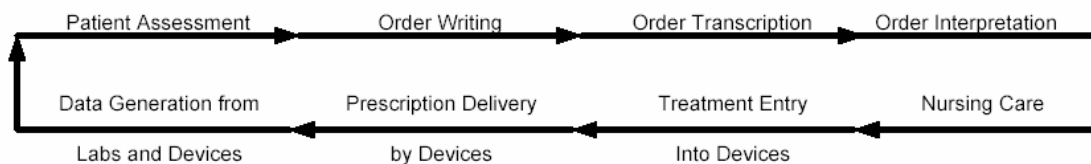


Figure 1: The cycle of patient care and sites for potential errors

Any step in this continuing cycle of assessing and caring for a patient can be a site for potential errors which may lead to patient harm. If an institution monitors each of these steps and develops methods for improvement and reduced errors, then patient safety during acute dialysis will also likely improve.

Current measures for reducing errors focus on both the devices and people involved in the therapy. The device manufacturers are held to well-defined tolerance limitations by national and international regulating bodies. These regulations define both the operating characteristics of the machines as well as how the machine deals with internal errors such as air in the lines or a power failure. Newer pump machines now provide very accurate pump flows, automated fluid balance and system diagnostics.

Despite the well developed intrinsic device safety measures, the interaction between the operator and the machine has much greater room for mistakes. The mistakes can be reduced through careful evaluation of

each step of the work flow process (3). Protocols and training are the main techniques currently utilized to optimize these processes. A Protocol typically consistent of a well defined series of steps which are followed in both the prescribing of and delivering of care. These steps often contain options or branches which accommodate the various potential clinical conditions which might alter care. Currently hospitals use both paper and computer based protocols. Often these protocols are incorporated into the physician orders.

Training occurs upon introduction of new therapies or staff members and then ideally reoccurs at intervals to maintain skill and consistency. Training and protocols should be consistently assessed and then improved to continually optimize the work process. This requires having methods to assess current problems with process and resultant error rates. Based on these assessments, alterations in protocol or training procedures should be defined and thereby result in a continuous quality improvement mechanism. Newer potential methods for decreasing errors include real-time analysis of centralized patient information repositories to detect deviations or conflicts in intended care and computerized physician order entry. Centralized patient information repositories typically consisted of a central server computer system which obtains information from the dialysis pump devices, intravenous drip delivery devices, laboratories, patient monitors, and care providers (Figure 2). Currently some ICU systems have some of these components but very few have all. With all of the

information available to the server in real time, software modules could be developed which would track the interplay of therapeutic interventions and clinical responses. Clinical downturns in patient status could then be quickly identified and therapeutic interventions can be requested. Additionally therapeutic changes which would likely cause a negative clinical impact could then be identified early via patient response simulation.

Computerized entry of physician orders would augment such a system and would likely decrease error on its own (4-5). Upon placing orders for therapy into a computer system the health care provider could be prompted for the needed parameters

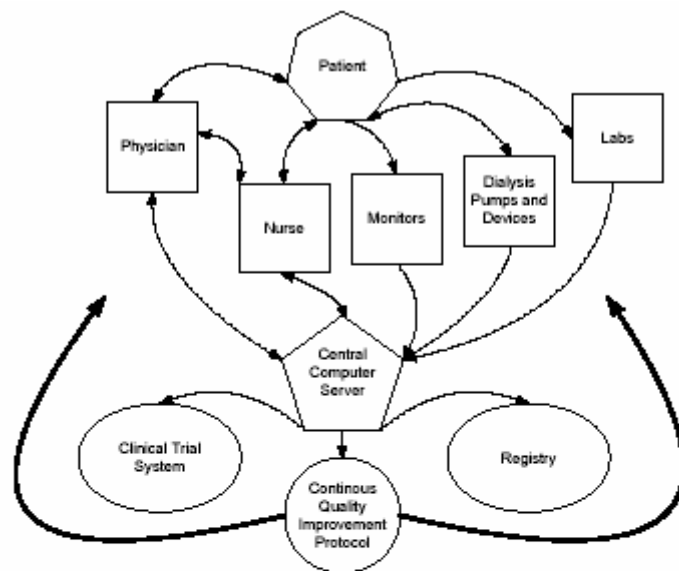


Figure 2: Idealized flow of patient information and assessment using information technology
 Physician, nurses, monitoring systems (blood pressure, telemetry, etc.), labs, and dialysis devices all assess the current status of the patient. When all of this information is combined at a central computer server either through direct download of information from a device or by user documentation, the physician and nurse can quickly interpret the assessments at one time and location. This information can be organized to fit the needs of the specific user. Based upon the current assessment, the physician uses the computer system to enter new orders on the patient. The computer system prompts for completion of pre-define protocols but can incorporate specific variations required by the individual patient. The computer tests the orders for validity and provides decision support by testing the effects of the order via a treatment simulation. Upon completion of the orders the nurse can carry out the orders while documenting completion in the computer. The dialysis devices can then communicated with the computer to verify that the orders match the treatment parameters entered into the device. Likewise the computer can store and monitor alerts generated by the dialysis device. As multiple patients receive treatment, the patient assessment and prescription data in the central computer represents a detailed description of how care is performed by individuals and the institution. This information can then be used to make suggestions that might improve outcomes and the quality of treatment for future patients. This information could also be directly exported to clinical trials or patient registries to increase the understanding of acute renal failure and its treatment on a global scale.

for therapy. These prompts would be consistent and predictable. The entered orders could then be cross checked against existing acceptable treatment parameters and compared with known patient data to determine if potential conflict may occur (6). With more advanced systems it is conceivable that the response to therapy for a given patient may be simulated so that the provider may see the possible effects prior to initiating the therapy. Additionally the computerized version of the orders is legible and can be printed for the paper chart if necessary.

Finally once patient data and/or provider orders are available in a patient database, analysis can be performed to assess correlations among patient characteristics, therapeutic parameters, complications and patient outcomes. By assessing these correlations and subsequently changing the therapeutic protocols, providers can track and maintain continuously improving quality of care and diminishing complications.

How should the current practice of acute dialysis care be monitored?

In order to better assess the effects of new technologies and discoveries in acute renal failure it is necessary to track the current baseline characteristics of practice. With a better understanding of this baseline it will be easier to focus efforts on specific areas for improvement and to see the effects of new discoveries and recommendations. National registries for chronic dialysis (7), cancers (8-9), and many other diseases (10-11) have shown the benefits of tracking diseases and the corresponding therapies. Currently there exists no mechanism on a national or international level to monitor either acute renal failure or its care. In fact most hospitals do not track the current characteristics of therapy beyond the level of a single patient. In order to initiate the formation of a registry for acute renal failure and dialysis, the consensus of the group is to initiate a pilot study to assess the feasibility of creating a multi-center repository of acute renal failure data. This pilot study would aim on a small scale to replicate the workings of a national database. This pilot should generate information on both resource requirements and reporting compliance. To facilitate the study a preliminary minimal dataset of acute renal failure and dialysis parameters should be generated. This dataset should balance the quantity of information needed to understand both the disease and its current treatment with the cost of recording the information. The pilot study would validate and propose modifications to the dataset based upon the study results. Following the completion of the pilot study, national registries should be developed and implemented. Data should be recorded in these registries in such a way that they can be transferred to an international repository to facilitate analysis of the global trends acute dialysis and renal failure.

How should information technology be implemented to reduce unintentional practice variation without limiting innovation and practice preferences?

Wide ranging variation in acute dialysis delivery is both a strength and weakness of the field. Variation in care currently provides a wealth of information and a tremendous base for effective research and innovation. From observational studies this variation can demonstrate the effects of many differing therapies in many different environments. However because of this variation new research findings often

lack cross-applicability and reproducibility across institutions. This diminishes the practicality of broad implementation of specific therapeutic recommendations. In order to balance these strengths and weakness the initial focus for standardizing patient care is to reduce unintentional practice variation without limiting innovation or practice preferences. Unintentional practice variation often limits an institution's ability to assess and improve therapy over time because of uncontrollable inconsistency.

The most common method used to control variation is a policies and procedures manual. This manual should clearly explain the intended methods and conditions under which therapy is initiated and delivered. Because in acute renal failure the indications and methods for therapy have not been adequately determined, policies will need to remain flexible. These procedures can be summarized in prescription or protocol sheets which can be integrated into the prescribing doctor's orders.

For these policies and procedures to be consistently followed training should be a reoccurring part of maintaining an acute dialysis program. Most programs rely on industry, conferences, or peer educating to train their staff. Currently no formal certification process exists to quantify competency. Each institution must therefore set up its own mechanisms for assessing competency and the need for updated training. Computer technology can improve this area by creating simulated therapy sessions which both train and assesses the skills of the nurses (12). Given the controlled nature of computer simulation, specific responses should be expected based upon the current procedures and policies of the institution. Deviations from expected responses can then be quantified and then reduced via online information and education. An external body providing such a system to certify nurses could be of value.

Despite training the complexity of dialysis therapy can still lead to unintentional practice variation. Information technology may further improve this process by providing computerized flow charts and computerized order entry. Variation in charting format, content, and calculations may have a dramatic effect on interpretation of the current therapeutic and clinical status of a patient. Computerized charting forces all individuals to record and present therapy in an identical and accurate manner. These computerized charts can be customized to meet the specific needs of an institution. Currently there are no computerized solutions which automate the specific tasks involved in monitoring a patient on continuous dialytic therapies. Some ICU clinical information systems have been adapted to make a first attempt at this issue but still lack all of the specific components which would be present in a robust complete system. Computerized protocols (13) and order entry should be combined with computerized charting to improve the consistency of the therapy. With computerized order entry, orders may be validated against the institutions standardized protocols as they are entered. Once the order is in a computer system nurses can consistently document and verify that each part of the order was carried out as prescribed.

Once both physician orders and patient parameters are recorded within a computer, reports should be generated to determine levels of consistency, protocol compliance and outcomes. These reports should not be used to enforce consistency, which may be very distinct from quality, but rather to identify problem areas in which protocols and workflow process may need to be improved. Consistently adhering to a bad

protocol is clearly worse than delivering variable but well thought out therapy. Using this information dialysis programs should assess, improve and reassess the quality of their care delivery.

Although the field of care for acute renal failure may be too young to expect large scale standardization, increased knowledge and methods dissemination across institutions and nations may facilitate some natural reduction in the extremes of practice variation. This group felt that developing an internet repository of examples of therapeutic decisions and problem solving could provide some consistency in terminology and approach to problems. Additionally the group felt that industry should use the internet to distribute updateable standardized methods for utilizing machines.

How should information technology be applied to improve the assessment of the current state of a patient and then influence further decisions about care?

Current static mechanisms for tracking a patient's response to therapy limit the complexity of analysis which may be performed to make decisions regarding further care. If information is acquired in an analyzable format during therapy then real time analysis can be performed which may provide greater insight into patient assessment and therapeutic decisions. Currently there are thousands of biologic sensors and methods for networking and obtaining patient information. Almost any type of analysis could be performed in real time. The current limiting factor in this regard is not the technology but instead determining which analyses would provide meaningful information at an acceptable cost increase (14). Both the content and frequency of useful analyses needs to be determined (15). For example a potassium value every 5 minutes will have doubtful impact on outcome but clearly at least daily potassium is crucial in an acute setting. Additionally, performing more analyses results in more information presented to the provider. If the new information does not aid decision making it may detract by distracting from more relevant values. Thus one of the first steps in developing real time analysis systems will be to determine which analyses and measurement frequencies result in meaningful improvements in the assessment of patient state and direction.

As more information becomes available, information technology will be challenged to display the information in such a way that inferences can quickly, easily and reliably be made from the data. This display should make it easy for the provider to detect the signal carrying the information about a patient's status from the large quantity of excess noise presented by less useful data (16-17). This group's opinion was that the display technology should be easy to read, easy to navigate, and be customizable for a specific user's needs or role. Particularly helpful would be the artful display of multiple patient variables at one time in relation to each other. This could be accomplished either by displaying covariant variables simultaneously in a graph such as fluid balance and central venous pressure or by displaying indexes of patient status. These indexes would represent validated summaries of multiple variables which relate to a validated surrogate outcome marker such as a severity index.

Taken to an extreme this information analysis could lead to open-loop and closed loop control systems for acute dialysis. Both control systems involve software determining the next intervention based upon the current patient parameters. In an open-loop system a person is required to enact the recommended intervention. In a closed-loop system the software can initiate the intervention without human interaction. Currently open loop systems have been shown to help wean patients from ventilators (18) and closed-loop systems have been used to control blood pressure by controlling pressor infusion pumps (19). These closed loop techniques have even been developed to control blood volume during hemofiltration (20). It is currently unclear what the targets could be for an open or closed loop system. Possibilities considered included: fluid balance, blood pressure, anticoagulation, thermal balance, and blood volume. The group's consensus recommendation was that these and other potential targets should be assessed first in open loop systems then if proven valuable they should then be tried in a closed-loop system. It was acknowledged that it is possible that some targets may only achieve beneficial status in a closed loop system as the turn around time in an open loop system may be too long to be beneficial. In order to facilitate easy integration of information from multiple sources the group also advocates device manufactures creating a standard data interface and organization.

How should information technology be applied to acute dialysis pump systems to improve the quality of acute dialysis care delivery?

The current acute dialysis pumps systems provide both hardware and software to manage the delivery of therapy to a patient. The software component of these systems represents a key point for information technology to improve the quality of dialysis care delivery. Both the user interface and the analysis of the data available to the machine can have an impact on both the current understanding of the patient as well as influence future management decisions. There are currently no published studies which show the effects of the user interfaces on resultant care delivery. The group highly recommends studies to determine the effects of specific user interfaces on error reduction and consistency of care delivery.

There was little consensus within the group regarding the quantity of analysis performed by the machine versus the quantity performed by external software. Complicated analysis performed within the machine would require the machine to gather data from outside the machine. With the current level of standardization of device interfaces, collecting data consistently would be very difficult. By using only the information generated within the machine the analysis would be very limited. The group did reach consensus that machines should be responsible for requesting user intervention when immediate reaction is needed secondary to an acute important change in the dialysis circuit. Additionally the group recommends assessing how pump systems can be used to accommodate open and closed loop control systems to regulate fluid balance.

How should information technology be applied in the design of future clinical trials to enhance the applicability of trial outcomes?

Clinical trials clearly represent key steps in the development of the acute dialysis field. These trials will need to answer key questions in such a way that the results are as broadly applicable as possible. These trials should also be organized in such a way to facilitate meta-analysis to direct further inquiries.

Information technology will be the back bone of these trials and will have an impact on the utility of the outcomes. Currently from an informational technology point of view clinical trials in acute renal failure suffer from lacking consistent dataset and endpoint definitions. As a result the group recommends that a robust but minimized dataset should be defined and then used at a minimum in all clinical trials. This dataset should allow the determination of severity illness, renal failure and recovery, and new endpoints with definitions which will likely change through time. In this manner clinical trial occurring over time can be compared and potentially pooled in meta-analysis. Additionally given the wide range of potential practice variation in dialysis delivery, the group highly recommends that trial incorporate protocol tracking and verification into the dataset for analysis. This will help in analyzing the degree of standardization within the trial and give more strength to the conclusions regarding the trials outcomes. Methods to increase the ease of data collection by both device and clinical information systems is also encouraged.

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