Treatment Optimization for Patient Safety (TOPS)

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Executive Summary

Treatment Optimization for Patient Safety (TOPS)

TOPS is a (patented) patient treatment management system that uses techniques such as continuous process improvement and lean manufacturing to monitor and manage the treatment delivery process in an inpatient setting. Standardized treatment regimens (i.e., order sets, etc. describing all aspects of treatment delivery) are used as templates by health-care workers to develop patient specific treatment plans. TOPS is then used to monitor plan versus actual and identify deviations. Where appropriate, deviations from the plan or adverse outcomes to the treatment can generate alerts to the healthcare worker that needs to respond to the situation (and only that healthcare worker). TOPS also contains an alert management system (patent pending) that can identify points of system failure in the treatment delivery system. These might be caused by understaffing for the current patient load, poor design of an alert resulted in alert fatigue, a resource shortage such as insufficient oxygen or any other reason that causes system failure.

Hospital benefits

Just as similar techniques have improved performance in other industries, TOPS will improve treatment quality and patient outcomes. This will result in fewer readmissions allowing the hospital to serve a larger community. These methods also result in higher efficiency and a more effective staff. This means current staffing levels can address the needs of a larger patient load at a lower cost. Given the chronic shortage of healthcare staff (particularly nurses), these benefits also have a very beneficial effect on treatment outcomes.

Next Steps

As originally conceived, TOPS contains a high-level overview of not just the treatment delivery system but also the interfaces to most of the supporting operations needed to run the hospital. (See figure 1.) TOPS was awarded a US patent in 2010 when many hospitals were still in the early stages of implementing EMR systems. While the interfaces are still valid, many of the supporting operations have been implemented in EMR systems such as those from Epic or

Cerner yet the core function of managing the treatment delivery process has still not been addressed. Now however, it appears quite possible that an inexpensive version of TOPS could be

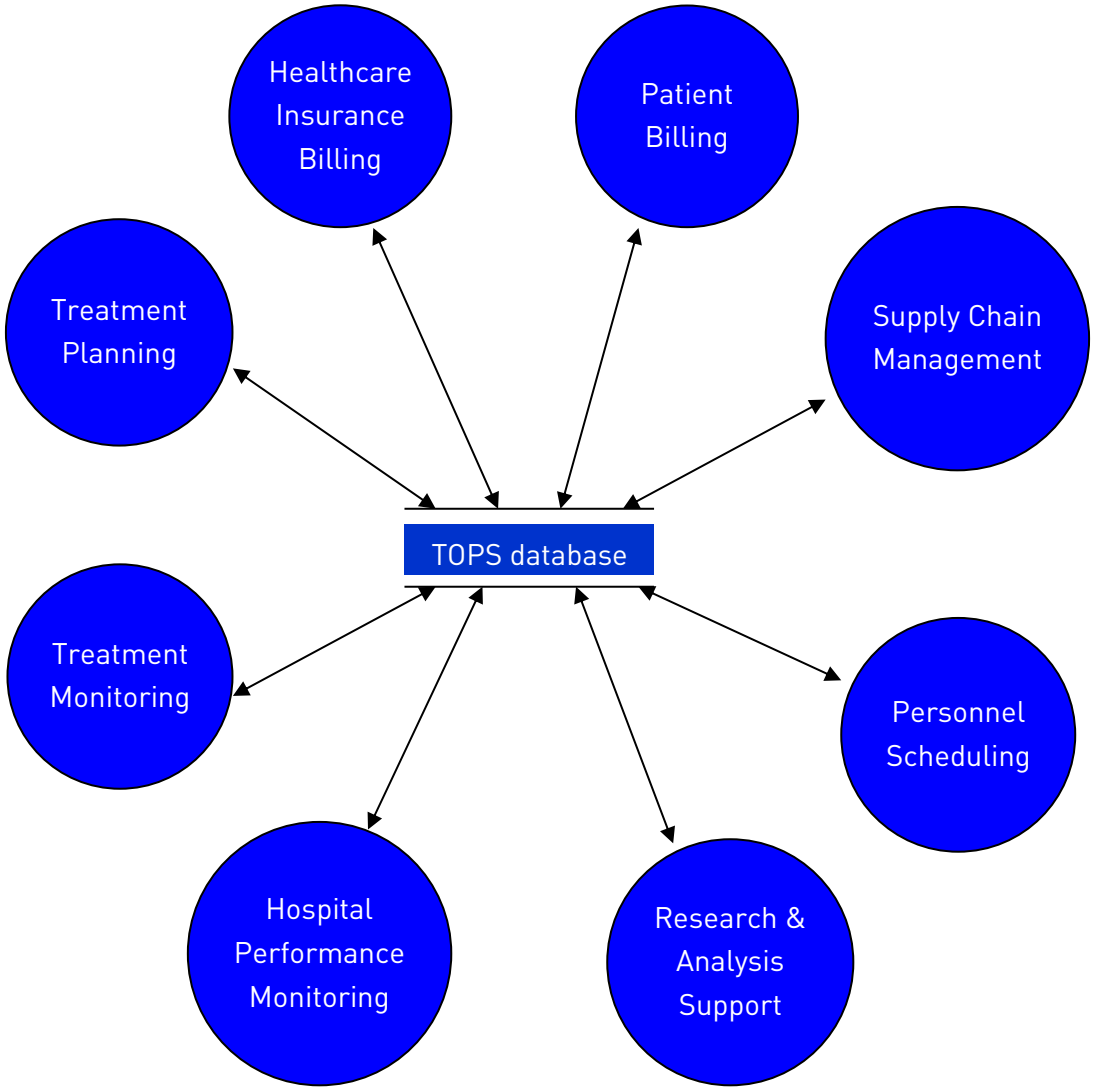

Figure 1. – Early view of TOPS (circa 2005)

built on top of an existing EMR system. Ashbec LLC is now looking for a partner hospital that would be willing to fund a feasibility study to determine if such a system could be built inexpensively using that hospital's EMR implementation as its base.

Treatment Optimization for Patient Safety (TOPS)

What is TOPS?

Treatment Optimization for Patient Safety (TOPS) system is designed to allow hospitals to define, control and continuously improve the treatment delivery process.[1] The use of TOPS will allow hospitals to virtually eliminate preventable medical error thereby dramatically improving quality and lowering the cost of health care. Recent estimates of the number of Americans that die annually from preventable medical error published in the Journal of Patient Safety and the British Medical Journal range from roughly 250,000 to more than 400,000. Prior to the onset of the current pandemic, preventable medical error was the third leading cause of death in the United States. The Institute for Healthcare Improvement has estimated that 15 million patients admitted to hospitals annually are inadvertently harmed to a sufficient degree that they require additional treatment.

In the course of managing the treatment delivery process, TOPS will also capture information that will be used to streamline hospital operations including purchasing, inventory control, personnel scheduling and billing. The use of this information by TOPS or an existing EMR system and the impact of this information on hospital operations will be discussed in more detail.

How does it work?

The approach underlying TOPS is driven by treatment regimens and the treatment plans created from them. A treatment regimen may include a variety of "treatment events" such as:

- Medications delivered in specific doses in specific intervals,
- Physical therapy activities to manipulate a patient manually,
- Surgical procedures,
- Recurring events that capture information such as dietary requirements,
- A wide variety of tests and images used to determine the patient's condition and reaction to treatment.

In general, treatment events include all tasks performed in the hospital for the patient's welfare and safety. A treatment regimen is then a collection of the treatment events that is designed to treat a patient with a specific diagnosis. It is intended to include everything the hospital must do to treat the patient.

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[1] TOPS is covered by US Patent No. 7,765,114 issued July 27, 2010. Additional patents may still be pending.

An attending physician can use TOPS to access the database of treatment regimens. The physician can create a patient specific treatment plan by using a selected treatment regimen as a template for the plan. If the patient has been diagnosed with multiple conditions, the physician(s) will have the ability to combine multiple treatment regimens to create a single treatment plan. TOPS will automatically review the resulting treatment plan for possible allergic reactions, undesirable drug interactions or other predictable problems. Ultimately however, it will be the attending physician's responsibility to ensure the quality of the overall treatment plan.

When the physician applies one or more treatment regimens to create this plan, the treatment events in the resulting treatment plan will now have a specific time at which they should occur. That time may be relative to the start of the treatment plan or at some specific interval following an earlier treatment event but each event will have a time component that can be monitored. For example, a specific test may be required at a certain time interval after a specific medication is administered or a particular surgical procedure is performed.

For treatment events other than tests or other activities whose sole function is information gathering, specific success criteria and known indicators that the treatment is not working will be defined. The definition of the treatment event must include these criteria and a method for detecting treatment outcomes. The method may involve the results of lab tests (in a subsequent treatment event), the use of automated monitoring equipment or simply an observation by a health care worker. For example, a criterion might be "the patient should be experiencing less pain within one hour of taking this medication." The verification method might simply be a healthcare worker asking the patient to rate their pain level and recording the results in TOPS. TOPS will monitor the treatment schedule to determine that all events are executed on time and are producing desirable outcomes. Uncompleted events or events that produced undesirable outcomes will generate an escalating series of alerts until the problem is corrected.

What makes TOPS unique and indispensable?

There are a number of techniques used in a variety of industries to continually improve business performance. Some of these include continuous process improvement (CPI), business process reengineering (BPR), Lean Manufacturing and Six Sigma to name just a few. However, all of these techniques require that the business activity to be improved must have a defined process with specific steps. This process definition must be standardized and used every time the business activity is performed. The process must be repeatable. In other words, the process definition must be clearly understood by anyone executing the business activity so that different

people performing the same activity will execute the same steps. If the process has these characteristics, it becomes predictable and it can be managed.

In the past, the treatment delivery process has never had these characteristics. By providing a framework and technology for dynamically creating treatment plans from standardized treatment regimens, TOPS can apply business transformation and quality control techniques never before possible in a hospital setting.

The treatment regimen forms the basis of a treatment plan that will be followed for a specific patient. The plan constitutes a process definition for the process of delivering treatment to the patient. Using this process definition as a standardized, repeatable and predictable process, TOPS monitors and controls the execution of the process and applies continuous process improvement methods to continually improve the delivery of treatment in hospital. Only by using this technique can continuous process improvement methods be used to virtually eliminate preventable medical error.

Similarly, only this technique allows treatment results to be compared across patients. Without this level of process control for the delivery of the treatment, there is no assurance that the results of the treatment are comparable since there is no assurance that error in the treatment delivery was avoided in the treatment instances being compared. To determine treatment efficacy, TOPS can eliminate the "noise" generated in an uncontrolled treatment process. In general, TOPS will produce an unprecedented level of treatment quality and patient safety.

Using TOPS

TOPS is intended for use by all health care workers contributing to the treatment of the patient. Information in TOPS will be shared by physicians, nurses, nurses' aides, pharmacists, lab technicians and dietitians among others. This shared information will allow these healthcare workers to work more effectively as a team and ensure that the patient's treatment plan will be executed as designed.

When a treatment regimen is to be applied to a specific patient, the result is a customized treatment plan. The treatment plan will be compared to all information known about the patient (e.g., existing medications, allergies, etc.) to identify any unsuitable aspects of the treatment plan. This includes functions such as those provided by traditional CPOE[i] systems that support prescribing medications. It is also intended to include issues such as ambulatory limitations, allergies to food or other items that might be encountered in a hospital environment (e.g., latex), etc.

Once the treatment plan is finalized and committed by the attending physician, TOPS will monitor the execution of the treatment plan to ensure that the plan is followed. Either deviations from the plan or unexpected/undesirable outcomes will cause TOPS to issue alerts to the appropriate healthcare worker(s). To the extent possible, TOPS will accept information from automated monitoring equipment to monitor the overall execution of the treatment plan. For example, TOPS would have access to the output of automated equipment monitoring blood pressure, heart rate, temperature, etc. Similarly, where possible TOPS will monitor automated devices such as infusion pumps that participate in the treatment delivery to ensure they are properly programmed and functioning correctly. Where that is not possible, TOPS will require the appropriate healthcare worker to verify execution of the plan with desirable outcomes. To help ensure that the proper treatment is delivered to the correct patient, TOPS can be implemented with the ability to geographically locate both patients and health care workers. (Typically, this would be through the use of RFID[ii] tags embedded in wristbands or ID badges.)

At any point in time, any healthcare worker responsible for execution of a particular treatment plan can indicate a problem with the plan. TOPS will issue the appropriate alerts to healthcare workers that will determine the required response. In the event that a problem is identified in the underlying treatment regimen, TOPS will facilitate the identification of all affected treatment plans.

Where appropriate, RFID technology can also be used to track controlled substances and other consumable supplies. Combined with knowledge of the supplies called for by the treatment plans, this will allow TOPS or the hospital EMR system to monitor supply usage, inventory levels and automatically reorder supplies only when they are needed. TOPS will also have sufficient information in the treatment plans to facilitate short-range personnel planning or other resource requirements such as the need for medical imaging equipment. The information captured during execution of the treatment plans will also be sufficient to drive billing activities. In general, the treatment monitoring capability of TOPS will capture sufficient information to drive the equivalent of a hospital Enterprise Resource Planning (ERP)[iii] system embedded within TOPS or the hospital EMR system.

Another use of the RFID capability would be identifying the location of the nearest available piece of equipment of the given type. For example, if a nurse needs to start a patient on a medication that is to be delivered by an infusion pump, TOPS could help the nurse locate the nearest available infusion pump.

TOPS will also provide value long after the patient has been discharged. The information captured regarding the efficacy of treatment regimens will allow hospitals to demonstrate to insurance providers that the billed costs are justifiable. In addition, Ashbec's hospital partners

will have the ability to consolidate outcomes from all of the hospitals in their system throughout the world. The resulting database could be used to identify best practices as well as problems specific to a small percentage of the population that would not be discovered during the typical clinical trials. For example, a new treatment might be determined to have an undesirable side effect in people with a rare genetic trait. Another example might be identifying the treatment as being less effective among diabetic patients. This knowledge will allow hospitals to demonstrate to insurance providers that they are using the most effective treatment for a given patient.

This will also allow the hospital to refine treatment regimens to hone in on the most effective treatments for a given patient. In addition, preventable medical errors will be discovered and treatment regimens are modified to prevent the errors from recurring. As a result of the combination of these factors, healthcare delivery will be continually improved.

Managing the treatment delivery process

TOPS is currently envisioned to include an alert management subsystem (patent pending) that will provide the computer system with self-correcting features and hospital administration with the ability to fine tune the treatment delivery process. The subsystem will monitor alerts issued by TOPS. If a design error results in alerts being issued to healthcare workers not directly involved in correcting the issue involved, the subsystem can suspend the issuance of those alerts (assuming such a suspension would not endanger the patient) until the error can be corrected. Similarly, if an alert overload is detected as a result of understaffing situation, the subsystem will provide the system administrator with detailed information allowing the fine-tuning of staffing plans.

For example, consider the following hypothetical situation. Assume that a decision has been made to assign seven patients to each nurse in a particular unit. For most of the nurses, this might be a strenuous but feasible workload. However, one particular nurse can't handle more than five patients. How will this manifest itself? As the day progresses, the nurse will fall farther behind in as a result of alerts will be issued for treatment events that were scheduled but not completed. When the number of alerts for this nurse in a given time period reaches a threshold, the alert management subsystem will detect and alert overload (in other words, a system failure). The nursing supervisor could receive an alert describing the problem. The supervisor could then reduce the load on that particular nurse preventing the nurse's seven patients from becoming readmissions as a result of preventable medical error.[iv]

As a result of the subsystem's ability to pinpoint failure points in the treatment delivery process, hospital staff will have an unprecedented ability to fine tune how and where resources are applied. This will impact not only staffing but physical resources as well.

Product Interfaces

Perhaps the most effective way to describe TOPS is to describe how the system would be used by people in a variety of roles including organizations external to the hospital such as insurance providers and the legal system. Here we will discuss how each of these roles would be impacted by TOPS and the benefits that would be derived.

Attending physicians

As a physician initially examines a patient, observations and test results are captured for or retrieved from the patient's history. When the physician settles on a diagnosis, the system can be used to identify alternative treatment regimens for the given diagnosis. In the simple case of diagnosing a single condition, the physician can accept a standard treatment program, customize an existing treatment regimen or create an entirely new treatment regimen. If the physician chooses to customize or create a treatment regimen, that regimen can be saved for future use by that physician. Hospital administration will have the ability to allow access to these new treatment regimens by all physicians at the hospital.

The system will assist in merging treatments for compound diagnoses but the DOCTOR ALWAYS HAS ULTIMATE RESPONSIBILITY for ensuring that the treatment plan will be safe and effective. In the more complex case of treating one patient with multiple conditions, the physician will select a treatment regimen for each diagnostic code. The system will then create a preliminary treatment regimen for the specific patient by combining these treatment regimens. To the extent possible, the system will check for interactions between the combined treatment events and flag any questionable interactions. It will be the physician's responsibility to review the resulting treatment regimen and customize it as necessary to ensure the proper treatment regimen is ordered for this patient. Again, the physician will have the ability to save any customized treatment regimens so they never have to perform the same customization twice.

While in the hospital, a patient will have a single treatment plan. In the event that a specialist is treating only one aspect of a patient's condition while the patient is also being treated for other problems, all of the physicians will be able to see treatments ordered by their colleagues. As new treatments are added to the treatment plan by any physician, TOPS will perform its standard checks to ensure that any new treatments can be incorporated without conflicting with the existing treatment plan. This will facilitate coordination of a team of physicians.

There are a number of advantages from a doctor's perspective for this approach.

- TOPS will help the doctor quickly prepare detailed treatment plans for their patients.
- TOPS will ensure that either the doctor's orders will be executed or the doctor will be alerted in the event of a problem.
- The doctor will always have immediate access to the best available treatment practices in the form of the treatment regimens in the TOPS database.
- The system will provide complete documentation of the doctor's actions and alternatives considered. This will eliminate the vast majority of malpractice litigation[v]. As TOPS builds a historical database across multiple hospitals and physicians demonstrating reduced costs associated with malpractice, insurance costs for the physicians using TOPS will decrease.

Nurses and Nurse's aides

Nurses and nurse's aides will be in constant contact with TOPS via tablet PCs, notebook PCs, PDAs or other electronic devices. Patients can be assigned to specific nursing teams with each treatment event in the patient's treatment plan assigned to a specific healthcare worker. The nursing teams will be able to view all treatment events for which they are responsible across all of their patients in a time sequenced list. Selecting an event from the list would bring up the treatment plan for that specific patient so that all pending treatment events for that patient are immediately visible. Any treatment event can be selected and expanded to show all relevant documentation regarding the execution of the task. Visual and audible reminders will be used as appropriate to ensure that all treatment events are executed in a timely fashion. Where appropriate, completion of the treatment event can be entered on the same device. Overdue tasks will result in a series of escalating alerts over time. Should the nursing staff anticipate or identify a problem with the treatment plan, they will have the ability to raise an electronic "red flag" that will notify the team of healthcare workers assigned to this patient that there is an issue that must be resolved.

Because of the detailed nature of the treatment plan that is being monitored by TOPS, the amount of documentation (either electronically or in paper form) that must be created by the nursing staff will be significantly reduced. This will also greatly reduce the time required to bring incoming nursing staff up to speed when the shift change occurs. Both of these factors will increase the time the nursing staff has available for the patients.

One feature of TOPS that has received a strong positive response from those in the nursing profession is the ability to geographically locate both doctors and patients within the hospital. Many nurses have complained of going to a patient's bedside to deliver a medication or perform a procedure only to discover the patient was in the shower or another part of the hospital. As

noted earlier, TOPS can use GPS and/or RFID technology to track people as well as things (e.g., portable medical equipment) giving nurses the ability to locate either with much less effort.

Nursing supervisor

TOPS will facilitate the assignment of patients to nursing teams including reassignment as needed during breaks or shift changes. By reviewing the list of treatment events for all patients assigned to a particular nurse (in effect, the nurse's work schedule), the nursing supervisor can quickly identify workload imbalances. In addition, the escalating alerts from TOPS will immediately notify the nursing supervisor of missed assignments, task overloading or any other problem that could affect patient safety.

Pharmacist

TOPS will provide the pharmacy staff with full CPOE capabilities or interface to the hospitals CPOE capability embedded in their EMR system. Medications could be tracked at any point in time. TOPS will provide real-time data on patient's condition and medication history to the pharmacy as well as to other healthcare workers assigned to the patient.

Patient

TOPS will help make patients and potentially their families active participants in the patient's treatment planning and delivery. TOPS will provide patient history and treatment plan information on a secure basis to patients and other responsible parties designated by the patient. (Hospital administration would have the ability to indicate that information about certain treatment events or outcomes would not be automatically displayed until a healthcare worker has conveyed the information personally to the appropriate parties.) Access to this information will help make the patient an active participant in their own treatment and help avoid misconceptions and mistaken assumptions on the part of their healthcare team by taking advantage of information that only the patient or those closest to them might have.

Research/Quality Control

TOPS will quickly become the primary source of medical research data. Because TOPS will be the only system with the necessary process control to ensure that treatment plans are properly executed, the resulting outcomes will be free from the noise introduced by preventable medical error. As a result, the clarity associated with treatment efficacy from treatments administered by TOPS will be unassailable. As discussed below, this will give hospitals very strong positions when negotiating with insurance providers over the appropriateness of specific treatments. In addition, as the number of patients treated in hospitals using TOPS continues to increase, the sheer size of the database will allow researchers to identify adverse effects on small populations that would not be identifiable in the typical clinical trial. As a result, the appropriate

use of new medicines and medical equipment can be determined at a faster pace than ever before possible.

Accounting

TOPS will affect the hospital accounting operations in a number of ways.

Billing/Accounts Receivable

As mentioned above, the data on treatment efficacy and the standardization made possible by TOPS will greatly strengthen the position of hospitals with respect to insurance providers. Currently, both hospitals and insurance providers employ legions of analysts to review treatment records and determine payment amounts. As TOPS becomes more prevalent across the country, this expensive overhead will become unnecessary. Eventually, the entire billing process could be automated by providing the information needed to EMR systems resulting in reduced overhead, much faster recognition of revenue by the hospitals and lower costs for the insurance providers.

Purchasing/Receiving

TOPS will have complete information regarding all inventories and supplies used in treatment delivery. Hospital administration will have the ability to define reorder points at which EMR systems could automatically place orders with preapproved vendors. When these supplies are received and entered into inventory, EMR systems should have the ability to automatically schedule payment to the vendor. This will give hospital administration the ability to reduce inventory holding costs while maintaining sufficient inventory to meet emergency needs.

Legal

Legal wrangling over malpractice is a reality that can't be ignored. The cost of malpractice insurance for both doctors and hospitals has dramatically increased and now represents a substantial cost. One of the immediate impacts of the availability of TOPS would be the simplification or elimination of many of the malpractice suits that might arise over treatments monitored by the system. A good malpractice defense attorney advises doctors that the best defense against malpractice suits is to religiously document every step in the treatment process. TOPS will provide a complete audit trail of the treatment options considered and the actual treatment. Faced with such detailed documentation, many potential malpractice suits would never go to court. Those that do could be easily defended.

The overall impact should be a dramatic reduction of the costs associated with liability protection. Attorneys will naturally advise their clients that such a system is to their benefit because of the protection it provides to clients and the support it provides to the attorneys defending them. Malpractice insurance providers will see their costs reduced. Eventually

hospitals that have implemented TOPS will be able to establish liability insurance discounts from their insurance providers.

Insurance providers

Initially, TOPS will provide a substantial windfall for insurance providers or health systems that include an insurance provider. By virtually eliminating preventable medical error, TOPS will greatly reduce the cost of providing health care to the population covered by hospitals implementing TOPS. All insurance providers for that clientele will initially benefit because insurance rates will initially assume previous payout levels. As mentioned above, administrative overhead related to hospital billing will also be greatly reduced. Over time, economic pressures will force insurance providers to reduce healthcare insurance rates but it is expected that this will take years. As TOPS usage spreads across more hospitals, the insurance providers will at least be able to avoid rate increases thereby improving their increasingly tenuous political and regulatory positions.

Hospital benefits

Highest treatment quality

Because of the continuous process improvement characteristics of TOPS, hospital partners will quickly become the best hospitals in the nation. The hospital partners will become the focal point for treatment regimen improvements from across the country as well as the earliest recipient of the knowledge gained by analyzing the rich database of treatment outcomes. Hospital partners that choose to share results with other hospitals using TOPS will improve even faster. Teaching hospitals that use TOPS will become highly desirable locations for physician training.

Rich research database

This database will provide information on treatment outcomes that will allow

- Identification of treatments customized for small populations with unusual characteristics,
- Adverse effects of new medications that were too unusual to be picked up during standard clinical trials,
- Beneficial effects of medications not initially anticipated, and
- Early identification of problems with the use of new medical equipment,
- Strong evidence-based proof of treatment efficacy for use with insurance providers.

Patient safety

Obviously the most important benefit to the hospital is an increased ability to provide high-quality medical care to their community. This will quickly translate into a major marketing advantage in their local markets. Because reduced readmissions will result in increased treatment capacity, hospitals will have the ability to provide more care when resources are scarce as in the current pandemic.

Reduced malpractice insurance costs

Just as described above regarding physician malpractice insurance costs, hospitals too are subject to continually increasing costs for malpractice insurance. As with physicians, all hospital staff will be assisted in the delivery of patient treatments to ensure that all sources of preventable medical error are eliminated. The documentation record created in the process will drive down malpractice costs.

Reduced non-reimbursable treatment costs

Every hospital has a certain percentage of uninsured patients that simply cannot pay for medical care. They treat these patients nonetheless. Studies have indicated that these patients are in fact at higher risk for death or injury from preventable medical error. This implies that the cost of treating these patients (borne by the hospital) will be higher than that of the average patient in the absence of a system such as TOPS. By eliminating preventable medical error, reducing readmissions and increasing the efficiency of the staff, TOPS will reduce this unreimbursed expense while allowing the hospital to provide high-quality medical care.

Increased capacity at the highest levels of treatment quality

In general, hospitals that adopt TOPS will be regarded as the best hospitals in their communities. This will result in an increased demand for hospital services. Fortunately, TOPS not only improves quality, it results in more efficient use of hospital staff and resources resulting in an increased capacity and an increased ability to provide quality healthcare for a larger population. Better management of the treatment delivery process will also attract better healthcare workers seeking greater job satisfaction thereby reducing recording costs. This will help address the chronic worker shortage.

Summary

The Treatment Optimization for Patient Safety (TOPS) system will produce higher quality medical treatment at reduced costs with more efficient use of labor. The patented characteristics of TOPS that result in continually improving the quality of treatment delivery will make the approach vastly superior to any competing health information system.

[i] **CPOE -- Computerized Physician Order Entry**. CPOE systems are currently in use in the more technologically advanced hospitals. All CPOE systems accept medication orders from physicians and verify that new medications will not have an undesirable interaction with any of the other known medications for this particular patient. Some CPOE systems may also check each new medication against known patient allergies.

[ii] **RFID -- Radio Frequency Identification**. RFID tags are most commonly encountered in retail shopping situations to deter shoplifters. RFID tags can either actively transmit a signal or transmit only when in the presence of an RFID reader. In the simplest situations, the signal contains sufficient information to identify the "tagged" item. Geographic location can be determined by triangulating on the tag based on which readers (each with a known geographic location) are within range of the tag.

[iii] **ERP -- Enterprise Resource Planning**. ERP systems have primarily been used in manufacturing industries. Introduced in the 1990s, ERP systems are intended to integrate information from and about all of the major business functions in an enterprise. This would include inbound and outbound logistics, inventory, accounts payable, accounts receivable, manufacturing operations and human resources. For example, an ERP system with knowledge of inventory levels, parts consumed in the manufacturing process and planned production would have the ability to reorder needed parts just in time for them to be used in the manufacturing process. The enterprise would thereby reduce their inventory holding costs and suppliers could be immediately paid when the parts arrived. Overall, ERP systems dramatically improve enterprise efficiency.

[iv] **Alert Overload --** in a situation such as this, one might think that the nurse would do a good job with five patients and only two would be in jeopardy. Unfortunately, information overload doesn't work that way. When a worker reaches overload, the mental buffers flush. They will forget what has been done for which patient and won't be able to keep up with the treatment plan for any of the patients. As a result, all of the nurse's patients would be at risk.

[v] **Malpractice defense** -- a top malpractice defense attorney describes the advice he gives his clients as follows. If the three most important factors in selling real estate are location, location and location, the three most important factors in malpractice defense are document, document and document. Malpractice suits are often based not on what a physician did but a perceived failure to consider an alternative course of action. TOPS will document alternative treatment regimens considered, customization of the treatment regimen(s) to the specific patient to create a treatment plan and the execution of the treatment plan. In the same way that the outcomes captured by TOPS can be used to demonstrate to an insurance company that the appropriate treatment has been selected and is being invoiced for payment, the TOPS database can be used to support the physician's development of the patient's treatment plan and its subsequent execution. Presented with this level of documentation, most malpractice suits will be dropped.