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(54) **TREATMENT MANAGEMENT SYSTEM**

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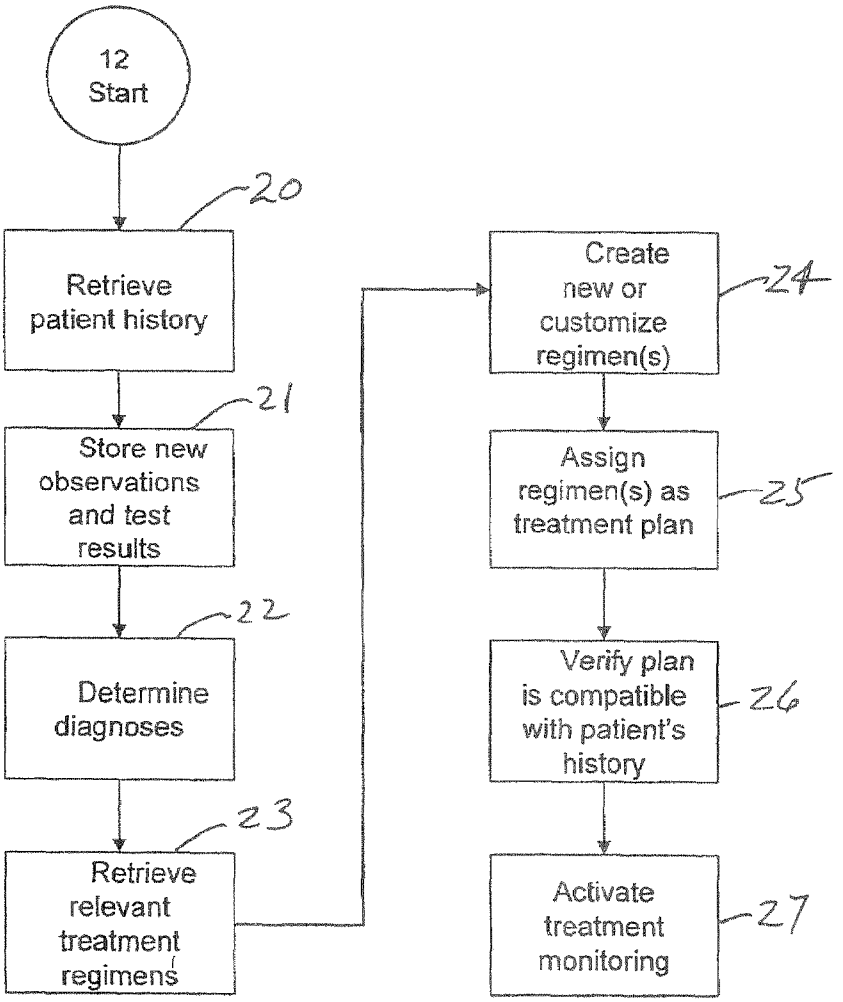
(57) **ABSTRACT**

A system and a method for managing patient treatment stores in the database a patient history for each patient including data related to observations, test results, diagnoses, treatment regimen(s) and a treatment plan associated with the patient. The treatment plan is administered to the patient and medical device operating data related to the tasks of the associated treatment regimen is stored in the database. A reminder is issued if a task associated with the treatment regimen is not completed on time and the effectiveness of the treatment regimen is evaluated based upon the data stored in the database so that only effective treatment regimens are retained in the system. The system performs treatment planning, treatment monitoring, hospital monitoring healthcare insurance billing, patient billing, research and analysis support, supply chain management and personnel scheduling.



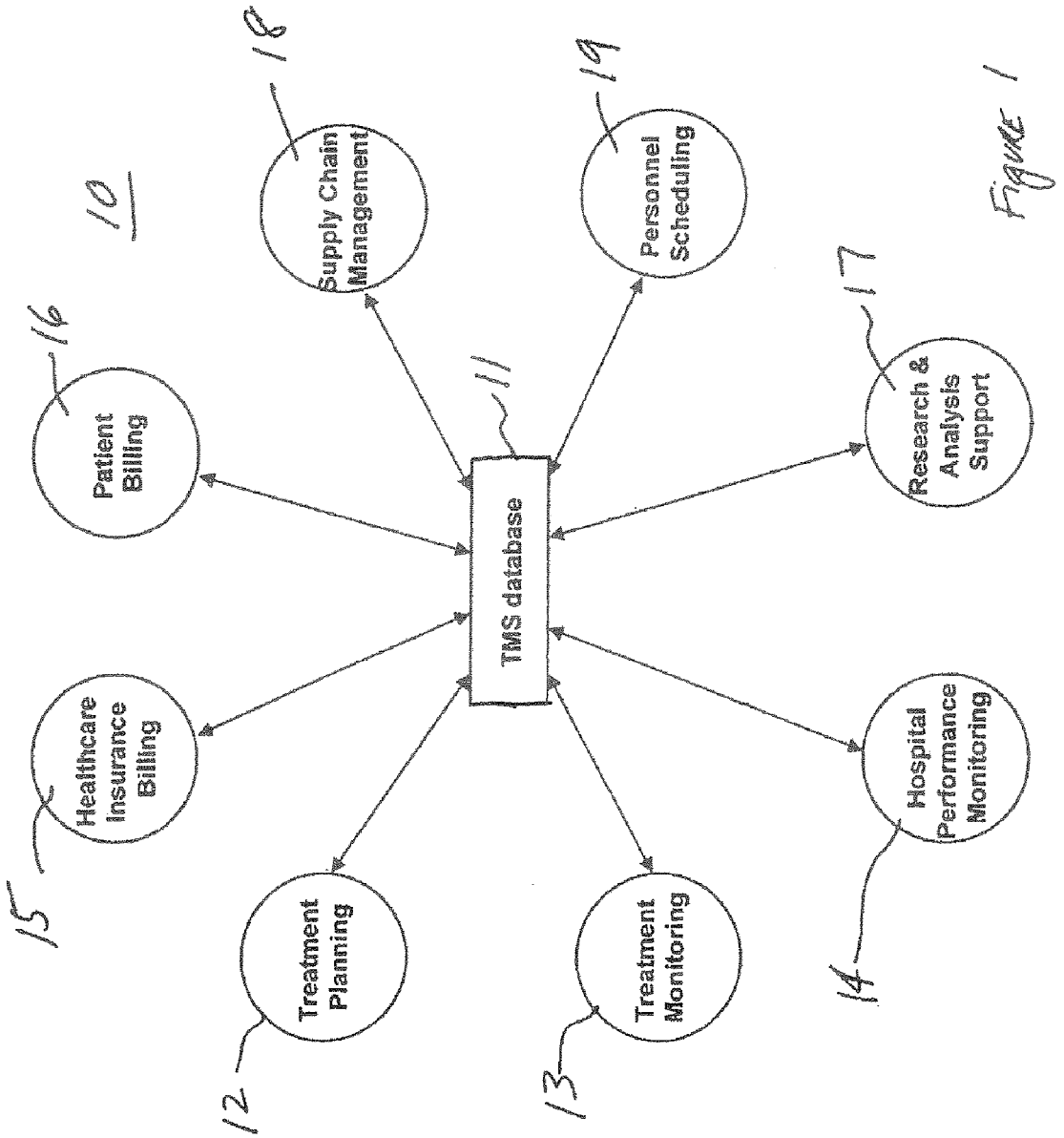

10
TMS database
11
Treatment Planning
12
Treatment Monitoring
13
Hospital Performance Monitoring
14
Healthcare Insurance Billing
15
Patient Billing
16
Research & Analysis Support
17
Supply Chain Management
18
Personnel Scheduling
19

Figure 1

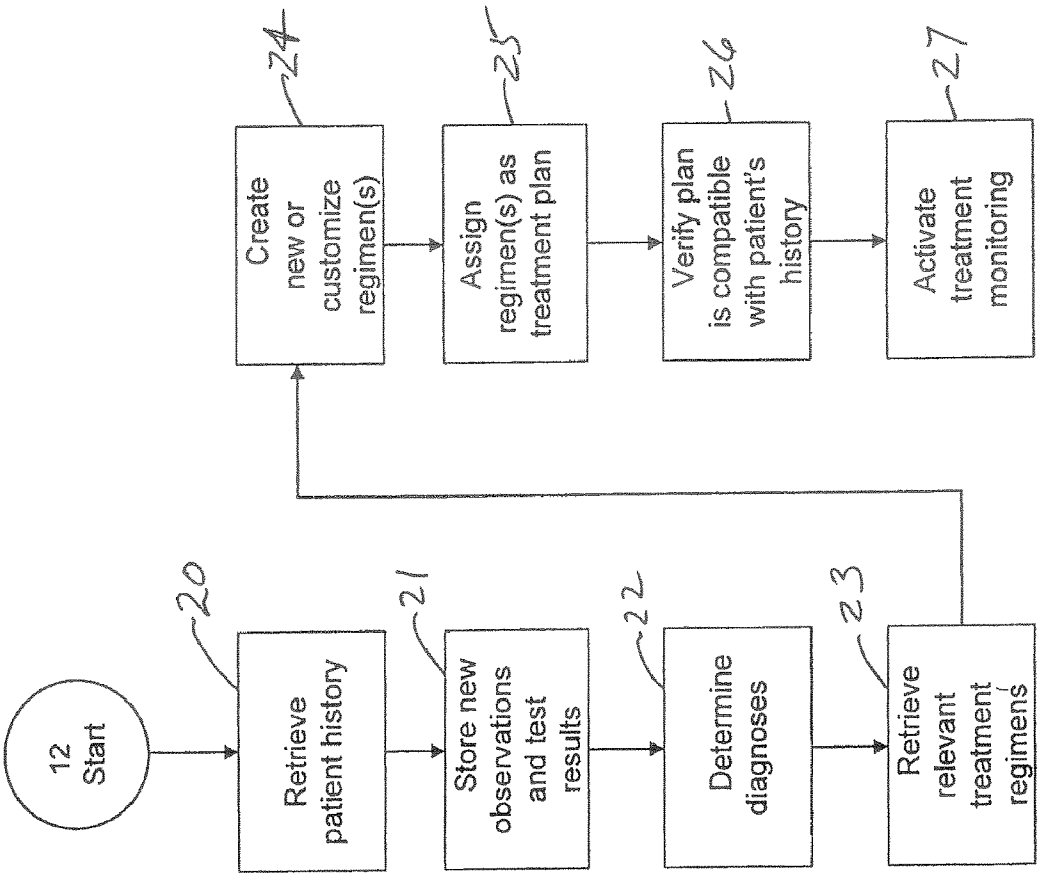

12
Start
20
Retrieve patient history
21
Store new observations and test results
22
Determine diagnoses
23
Retrieve relevant treatment regimens
24
Create new or customize regimen(s)
25
Assign regimen(s) as treatment plan
26
Verify plan is compatible with patient's history
27
Activate treatment monitoring

Figure 2

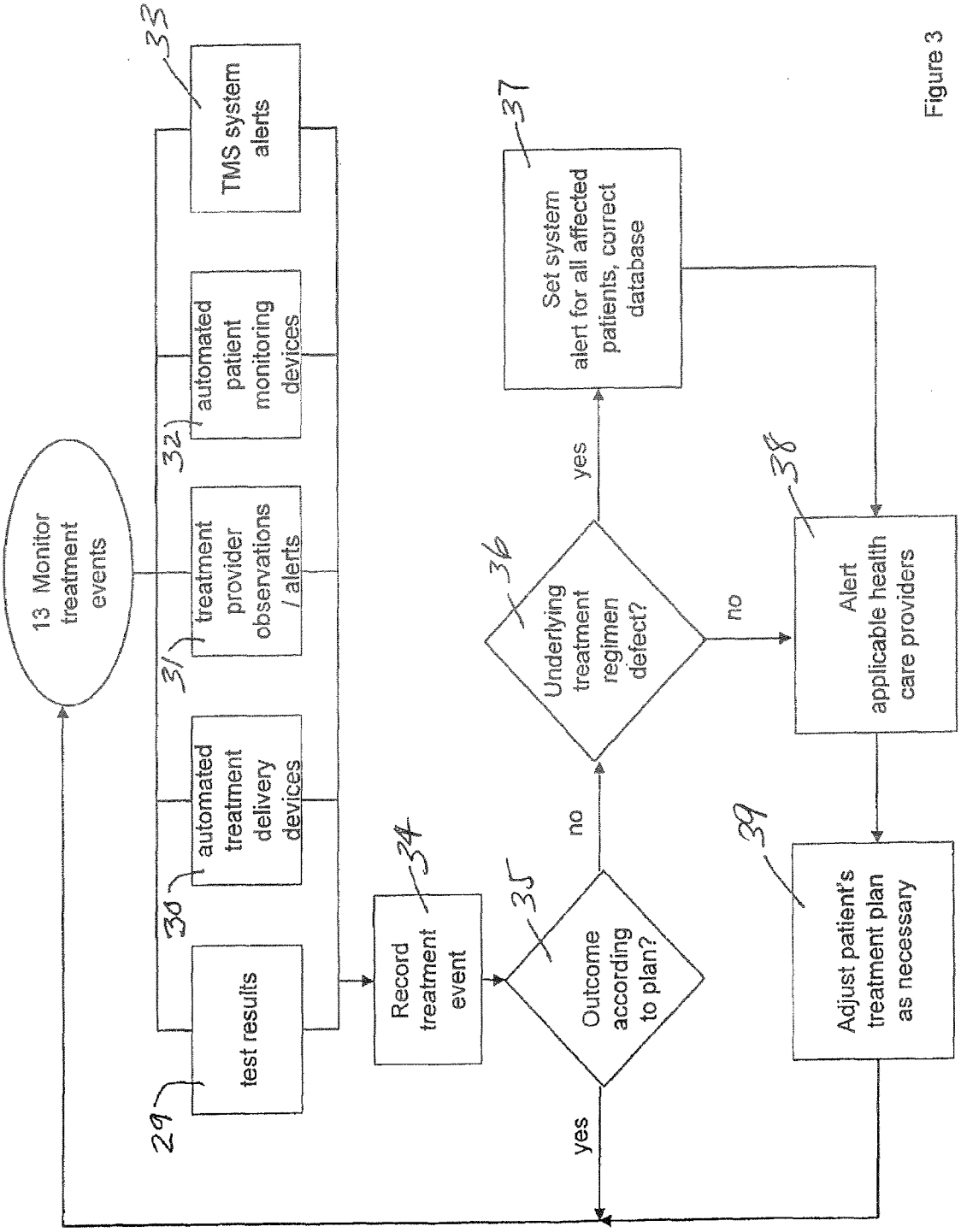

13 Monitor treatment events
test results
automated treatment delivery devices
treatment provider observations / alerts
automated patient monitoring devices
TMS system alerts
29
30
31
32
33
Record treatment event
34
Outcome according to plan?
35
no
yes
Underlying treatment regimen defect?
36
yes
no
Set system alert for all affected patients, correct database
37
Alert applicable health care providers
38
Adjust patient's treatment plan as necessary
39

Figure 3

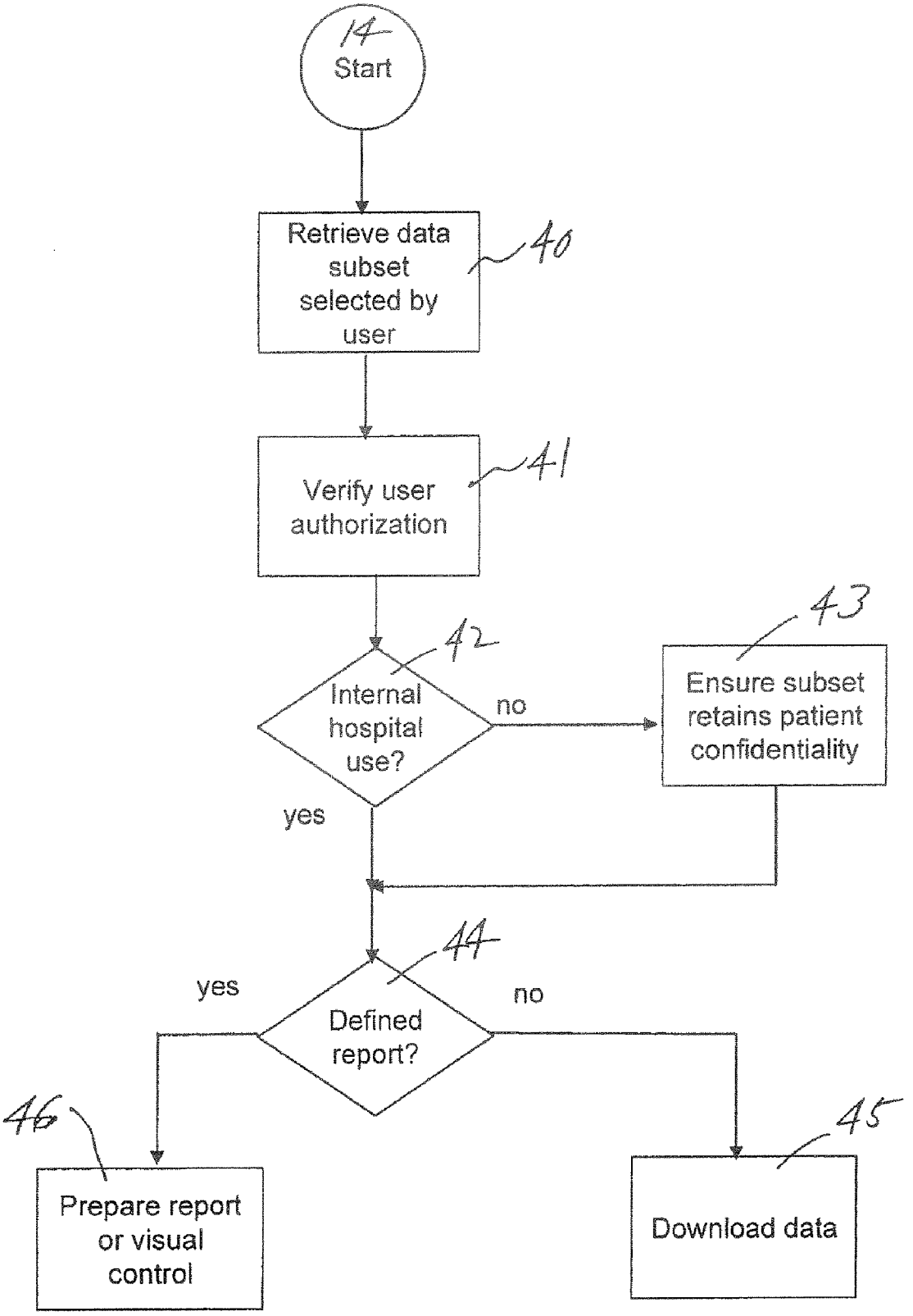

14
Start
Retrieve data subset selected by user
40
Verify user authorization
41
Internal hospital use?
42
no
Ensure subset retains patient confidentiality
43
yes
Defined report?
44
yes
no
Prepare report or visual control
46
Download data
45

Figure 4

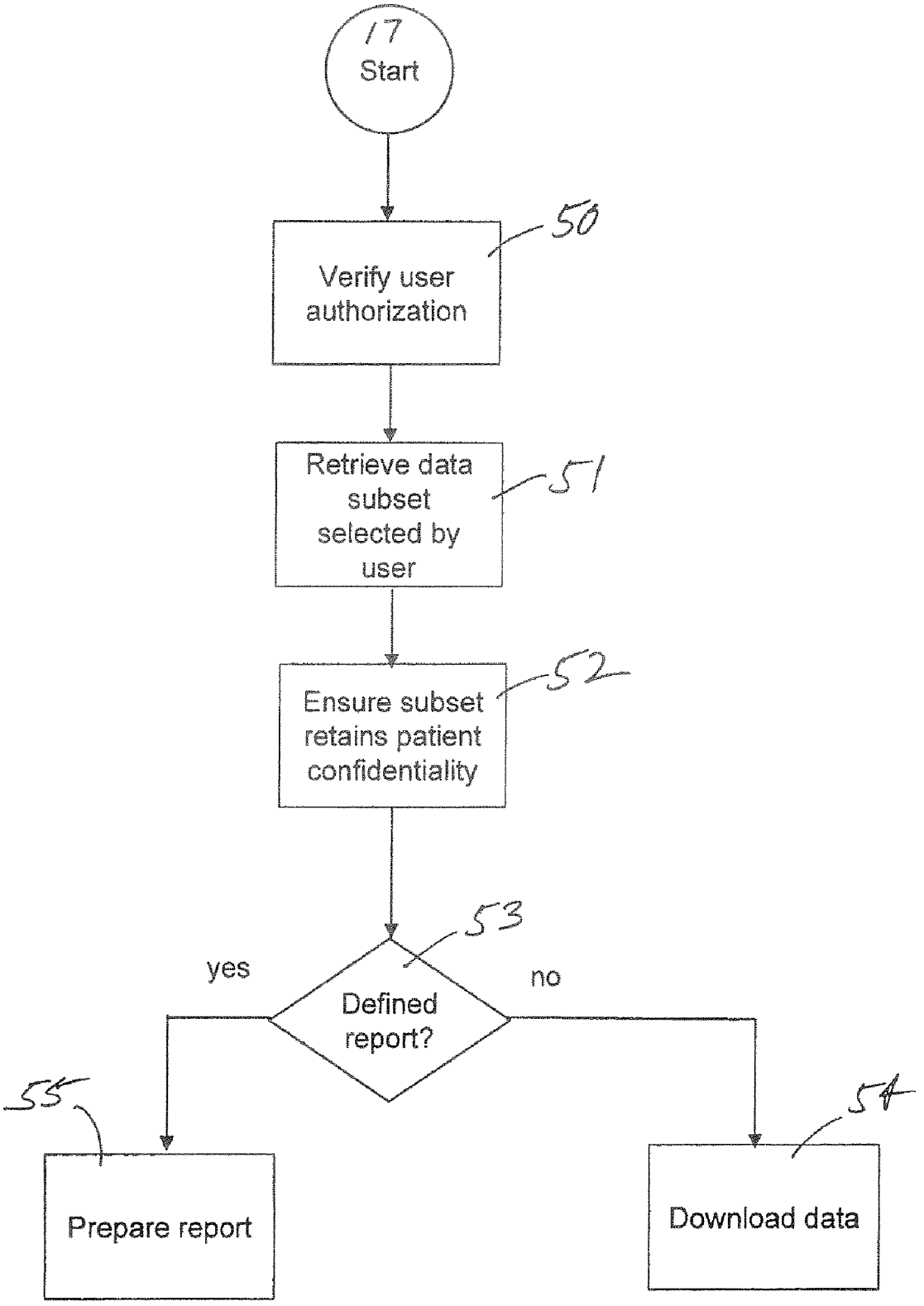

17
Start
50
Verify user authorization
51
Retrieve data subset selected by user
52
Ensure subset retains patient confidentiality
53
Defined report?
yes
no
55
Prepare report
54
Download data

Figure 5

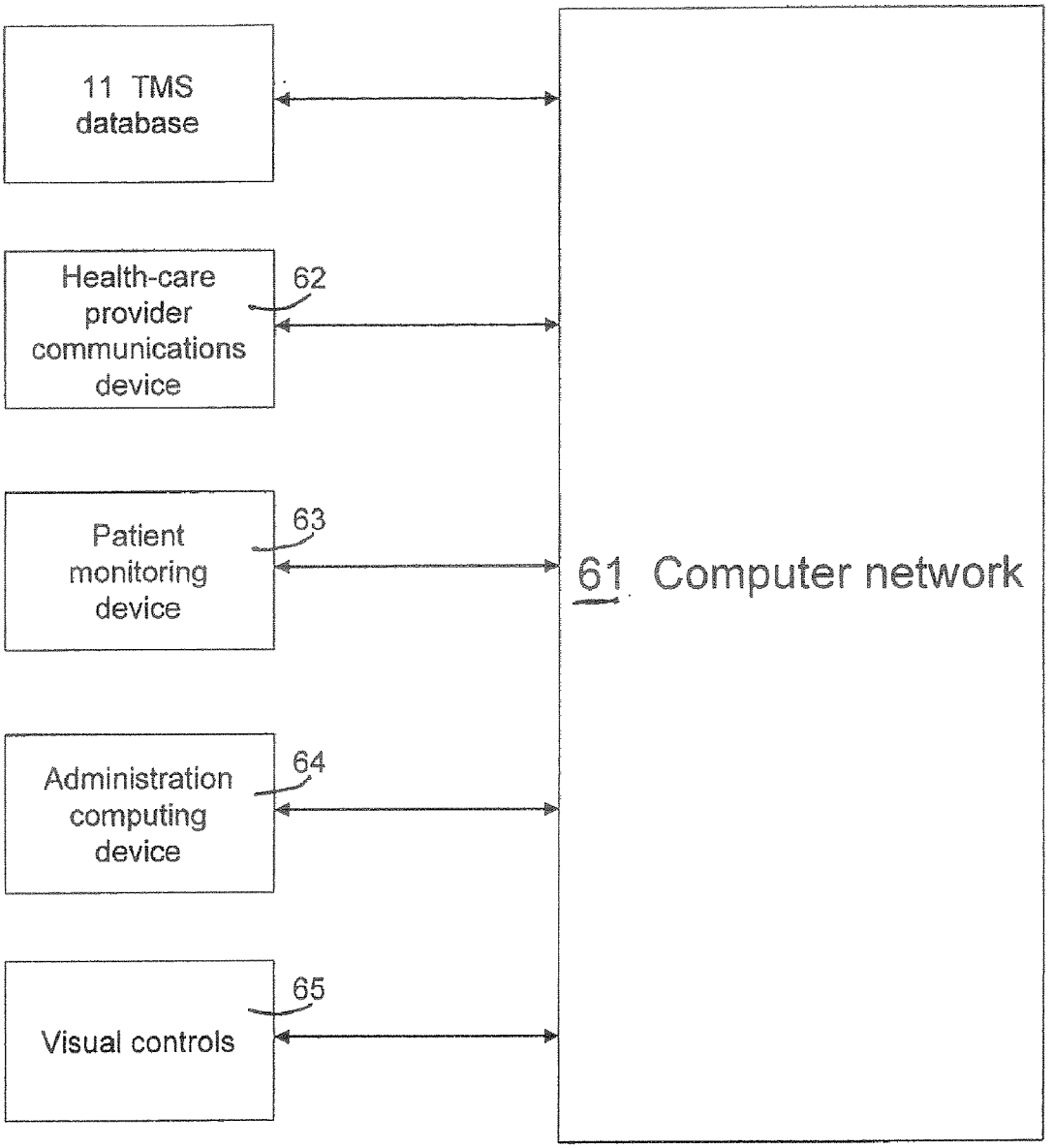

11 TMS database
Health-care provider communications device
62
Patient monitoring device
63
61 Computer network
Administration computing device
64
Visual controls
65

Figure 6

TREATMENT MANAGEMENT SYSTEM

CROSS-REFERENCE TO RELATED APPLICATION

[0001] The application is a continuation of U.S. Ser. No. 11/356,384 filed Feb. 16, 2006, which in turn claims the benefit of U.S. provisional patent application Ser. No. 60/692,627 filed Jun. 21, 2005.

BACKGROUND OF THE INVENTION

[0002] The present invention relates generally to an apparatus and a method for managing the treatment of hospital patients.

[0003] The U.S. Pat. No. 4,839,806 discloses a computerized dispensing of medication that provides automated direction and guidance for nurses and allows for data entry regarding whether or not medication was dispensed (See Abstract).

[0004] The U.S. Pat. No. 4,857,716 discloses a patient identification and verification system and method that include an overdue drug alert system (Col. 16, lines 28-50) in conjunction with a patient data entry and recording system. The system also includes checks for drug incompatibility (Col. 14, lines 40-43).

[0005] The U.S. Pat. No. 4,916,441 discloses a portable handheld terminal **22** having a display screen **40** and a bar code reader **42** that is contemplated for use as the point of care data input and retrieval device in a patient care system and in communication with a network file server **24** via a local area network. Scheduled actions, defined by a customized hospital parameter table, may be displayed on the display screen along with a warning light and/or an audible beep. (Col. 11, lines 60-67). A "scratch-pad" capability (Col. 12, lines 12-30) is also provided for the terminal, but is recited to be stored in the terminal only.

[0006] The U.S. Pat. No. 5,416,695 discloses a method and apparatus for alerting patients and medical personnel of emergency medical situations. An exemplary embodiment of the apparatus is recited for use with an ambulatory patient **300** and provides body function data from sensors **320** via a telemetry device **310** to a host computer **12**. The host computer provides alerts if any of the body function data exceeds limits set by a physician or other caregiver.

[0007] The U.S. Pat. No. 5,822,544 discloses a patient care and communication system featuring audio, visual, and data communication (See Abstract).

[0008] The U.S. Pat. No. 5,912,818 discloses a system for tracking and dispensing medical items that includes a plurality of hook registers **10** that are adapted to contain medical devices, medications, or the like. The hook registers are in communication with a computer **84** via a local area network **82**, which is also in communication with an administrator's workstation **86**, an electronic lock drawer **96**, a hospital information system **90**, an admission-discharge-transfer system **88**, and a medical dispenser **100**. The system discusses the use of alarms (Col. 22, lines 28-35).

[0009] The U.S. Pat. No. 6,039,251 discloses a method and system for secure control of a medical device such as a pump **26** at a patient's home **11** from a medical care facility **12**.

[0010] The U.S. Pat. No. 6,070,761 discloses a vial loading method and apparatus for intelligent admixture and delivery of intravenous drugs that includes communication with nursing stations, data entry terminals, and patient databases by a hospital network (See FIG. **17**).

[0011] The U.S. Pat. No. 6,397,190 discloses a veterinary medication monitoring system and apparatus that utilizes a PDA and alarm functions for a veterinary treatment system, where the PDA receives data at the veterinarian's office and the PDA provides alarms to the handler/owner of the animal to provide care. Actions taken are also stored in the PDA.

[0012] The U.S. Pat. No. 6,790,198 discloses a patient medication IV delivery pump with wireless communication to a hospital information management system.

[0013] The U.S. Patent Application No. 2001/0050610 discloses a hospital informatics system that includes a plurality of interconnected modules (chart **200**, clinical data entry **400**, nursing functions **500**, clinical guide **600**, MD functions **700**, kardex and pharmacy **800**, admitting **900**, order entry **1000**, and administration **1100**—See FIG. **1** and cover page).

[0014] The U.S. Patent Application No. 2002/0169636 discloses a system and method for managing patient care that includes a plurality of functional modules **16**, **18**, **20**, and **22** in communication with a control unit **14** that controls of a patient care device **12** that is in turn in communication with a pharmacy system **34**. The functional modules are recited to be a variety of pumps, monitors, or input/output devices (see Paragraph **26**). Various databases (See FIG. **3**) are utilized to provide operational protocols or characteristics for the modules **16**, **18**, **20**, and **22**.

[0015] The U.S. Patent Application No. 2003/0009244, 2004/0073329, and 2004/0143459 each disclose a patient care management system **30** and method for collecting data and managing patient care that includes a connection with a pharmacy information system **20** and a hospital information system **40** via a hospital network **5** as well as connections with a bedside CPU **80** and at least one infusion pump **92**.

[0016] The U.S. Patent Application No. 2003/0141981 discloses a system and method for operating medical devices, such as an infusion pump **120**, wherein a caregiver **116** utilizes a digital assistant **118** to control the infusion pump. The operation of the infusion pump is also modified by operating parameters entered by a treating physician (FIG. **5**B) and confirmed by patient IDs such as on a wristband **112***a* and by a computer at a pharmacy **104**. Alarms and errors are generated upon conflicts.

[0017] The U.S. Patent Application Nos. 2003/0135388 and 2004/0104271 disclose a medication delivery system for electronically controlling a medication delivery device **30** that includes a handheld computing device **22** that reads data from a patient tag **24** and medical container **28** before allowing the device to deliver medication through a catheter **37**. The system contemplates preventing the activation of the delivery device if allergies, etc. are present (See FIG. **39**).

[0018] The U.S. Patent Application No. 2004/0172299 discloses a system and method for facilitating clinical care that allows users to document numerous types of clinical interventions including patient assessment **12**, problem identification **143**, recommendations **16**, outcome/follow-up 18, and status **20** (Paragraph **28** and FIG. **2**).

[0019] The U.S. Patent Application No. 2004/0193325 discloses a method and apparatus to prevent medication error in a networked infusion system having an infusion device **20** and a computing device **26** connected by a network **30** that may be wired or wireless. An alerting device **28** is provided to notify medical personnel when the medication or the dose is not clinically acceptable.

SUMMARY OF THE INVENTION

[0020] The present invention concerns a patient treatment management system comprising: at least one network; at least one hospital information database in communication said at least one network; at least one treatment database in communication with said at least one network; and at least one handheld device in communication with said at least one network, said handheld device operable to transmit patient information to said hospital information database and said treatment database and receive patient care instructions from said treatment database.

[0021] The patient treatment management system according to the present invention comprises: at least one network; a treatment management system database in communication said at least one network; and at least one module in communication with said management system database through said at least one network, said at least one module being one of a treatment planning module; a treatment monitoring module; a hospital performance monitoring module; a healthcare insurance billing module; a patient billing module; a research and analysis module; a supply chain management module; and a personnel scheduling module.

[0022] A patient treatment management system for a hospital according to the present invention comprises: at least one database for storing data related to a patient including observations, test results, diagnosis and treatment regimen; at least one healthcare provider terminal for use by healthcare providers to exchange said data with said database; at least one monitoring device for sending medical device operating data related to the patient during the treatment regimen to said database; and a computer connected to said at least one database, said at least one healthcare provider terminal and said at least one monitoring device and generating an evaluation of the treatment regimen based upon said data. The system also can include at least one visual control connected to said computer for communicating to the healthcare providers information related to a potential problem associated with the treatment regimen. The system further can include at least one administration terminal connected to said computer for use by administrators to select and monitor performance measures of the treatment regimen. The system includes a software program operated by said computer and having at least one of a treatment planning module, a treatment monitoring module, a hospital monitoring module, a healthcare insurance billing module, a patient billing module, a research and analysis support module, a supply chain management module and a personnel scheduling module.

[0023] A method for managing patient treatment according to the present invention comprises the steps of: providing a database; storing in the database standard treatment regimens indexed by diagnosis and applicable to a wide variety of patients; storing in the database data related to patients including observations, test results, diagnoses and treatment regimens; storing in the database a patient specific treatment plan based on set treatment regimens (possibly customized); storing in the database medical device operating data related to the treatment regimens; storing in the database the results of executing the treatment plan to date including any adverse outcomes; and evaluating effectiveness of the treatment regimens based upon the data stored in the database. The method includes determining a diagnosis for a patient based upon the stored observations and test results data, identifying all of the stored treatment regimens associated with the diagnosis, either customizing one of the identified treatment regimens or creating a new treatment regimen, and storing in the database the customized treatment regimen or the new treatment regiment. The selected treatment regimen(s) will be combined if necessary and assigned as a treatment plan for a specific patient. The plan will be compared with the patient's known history to determine if there are identifiable incompatibilities. The method includes monitoring the administration of the treatment plan and issuing a reminder if a task associated with the treatment regimen is not completed on time. The method further includes monitoring the administration of the treatment plan, issuing an alert if a success indicator associated with the treatment regimen is not achieved and identifying other patients undergoing the same treatment regimen. The method also can include monitoring the selected performance measures associated with the treatment regimens.

[0024] The method can include generating visual controls to enable healthcare providers to anticipate and/or react to problems associated with administration of the treatment plans. The method also can include evaluating the treatment regimens and storing in the database only those treatment regimens that are effective. The system further can include using the data in the database to perform at least one of treatment planning, treatment monitoring, hospital monitoring, healthcare insurance billing, patient billing, research and analysis support, supply chain management and personnel scheduling.

DESCRIPTION OF THE DRAWINGS

[0025] The above, as well as other advantages of the present invention, will become readily apparent to those skilled in the art from the following detailed description of a preferred embodiment when considered in the light of the accompanying drawings in which:

[0026] FIG. **1** is a block diagram of the treatment management system in accordance with the present invention;

[0027] FIG. **2** is flow diagram of the operation of the treatment planning module shown in FIG. **1**;

[0028] FIG. **3** is flow diagram of the operation of the treatment monitoring module shown in FIG. **1**;

[0029] FIG. **4** is flow diagram of the operation of the hospital performance monitoring module shown in FIG. **1**;

[0030] FIG. **5** is flow diagram of the operation of the research and analysis support module shown in FIG. **1**; and

[0031] FIG. **6** is a block diagram showing the connections between the components of the treatment management system in accordance with the present invention.

DESCRIPTION OF THE PREFERRED EMBODIMENT

[0032] U.S. provisional patent application Ser. No. 60/692,627 filed Jun. 21, 2005 is hereby incorporated herein by reference.

1.0 System Overview

[0033] A medical treatment management system (TMS) **10** in accordance with the present invention is shown in FIG. **1**. A TMS database **11** is at the center of a plurality of modules that communicate information required by the system **10**. The overall purpose of the TMS is to improve quality and lower the cost of inpatient hospital care. The TMS is designed to impact patient care immediately and capture information that can be used to analyze past events and improve future performance.

[0034] The modules that communicate with the TMS database **11** are:
Treatment Planning module **12**
Treatment Monitoring module **13**
Hospital Performance Monitoring module **14**
Healthcare Insurance Billing module **15**
Patient Billing nodule **16**
Research & Analysis Support module **17**
Supply Chain Management module **18**
Personnel Scheduling module **19**

2.0 Treatment Planning

[0035] 2.1 The Treatment Planning module **12** draws on treatment regimens indexed by diagnosis in the TMS database **11**. A treatment regimen may include a variety of "treatment events" such as:

[0036] medications delivered in specific doses in specific intervals,

[0037] physical therapy activities to manipulate a patient manually,

[0038] surgical procedures,

[0039] recurring events that capture information such as dietary requirements,

[0040] a wide variety of tests and images used to determine the patient's condition and reaction to treatment.

[0041] The treatment regimen is a collection of these events that occur in sequence and possibly at specific time intervals. It is intended to include everything the hospital must do to treat a patient. Treatment sequence may be dependent on other treatments. 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 treatments other than tests or other activities whose sole function is information gathering, specific success criteria will be defined as well as known indicators that the treatment is not working. These criteria could be measurable results or more subjective in nature (i.e., "the patient should be experiencing less pain within one hour of taking this medication.").

[0042] When the treatment regimen is to be applied to a specific patient, the regimen will be compared to all information known about the patient (e.g., existing medications, allergies, etc.) to identify any unsuitable aspects of the treatment regimen for this particular patient. This includes functions such as those provided by traditional CPOE 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.

[0043] As a physician initially examines a patient, observations and test results are captured in the patients history. As shown in FIG. **2**, the treatment planning module **12** begins with a step **20** of retrieving the patient history from the TMS database **1**. In a step **21**, new observations and test results are stored in the patient history in the database. When the physician settles on a diagnosis in a step **22**, the system can be used to identify alternative treatment regimens for the given diagnosis wherein all treatment regimens relevant to the diagnosis are retrieved from the database in a step **22**. The physician can create a new treatment regimen or customize an existing treatment regiment in a step **24**. The physician then assigns one or more treatment regimens as the treatment plan for the patient in a step **25**. The system compares the treatment plan with the information in the patient history in a step **26** to verify that the plan is compatible with the history. 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 in a step **24**. 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. After the plan verification, treatment monitoring is activated in a step **27**.

[0044] 2.2 Physician has Ultimate Responsibility and Control

[0045] 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.

3.0 Treatment Monitoring

[0046] 3.1 Monitors the Execution of the Physician-Approved Treatment Plan

[0047] The Treatment Monitoring module **13** of the system **10** will monitor the patient's treatment for events as shown in FIG. **3**. Such events include test results in a step **29**, automated treatment delivery services in a step **30**, treatment provider observations/alerts in a step **31**, automated patient monitoring devices in a step **32**, and TMS system alerts in a step **33**. All of the events generated in the steps **29** through **33** are recorded in the database in a step **34**. At a decision point **35**, each event is checked as it occurs to determine whether the outcome is according to the treatment plan. If the outcome is according to plan, the method branches at "yes" and returns to the monitoring for the next event to occur or that has occurred. If the outcome is not according to plan, the method branches at "no" to a decision point **36**. The decision point **36** determines whether there is an underlying regiment defect causing the outcome. If there is a defect, the method branches at "yes" to a step **37** wherein a system alert is set for all affected patients and the treatment regimen is corrected in the database. If there is no defect, the method branches at "no" to a step **38** wherein an alert is issued to the applicable healthcare providers. Next, the method executes a step **39** wherein the patient's treatment plan is adjusted as necessary and returns to the monitoring for the next event to occur or that has occurred.

[0048] The steps **36** through **39**, for example, may deal with a task required by the treatment regimen that was not delivered in a timely fashion. The system will remind the healthcare provider responsible for completion of the task in the step **38**. The system will continue to monitor the delivery of the treatment regimen and if the task is still not completed, an escalation process will begin. In the case of a treatment that is inconsistent with the treatment regimen, e.g. an incorrect medication dosage from an infusion pump, the responsible health care provider will be immediately notified with an

alert. Escalation of notices for treatments inconsistent with the treatment regimen will be very rapid.

[0049] Success/failure indicators for specific treatments will have a default behavior as follows. If a specified success indicator does not occur, a low priority alert will be delivered to the attending nurse and will be delivered to the attending physician during the physician's next review of the patient record. The treatment regimen can require a higher priority alert for specific success/failure indications. For example, the occurrence of the indicator might trigger immediate paging of the physician and a high priority alert for the attending nurse or other hospital staff. These alerts can be customized during the creation of the treatment regimen database and further customized when the regimen is applied to a specific patient.

[0050] 3.2 Monitors the Patient for Unexpected Responses to the Treatment

[0051] As described above, each treatment regimen will include the definition of indications that the treatment is working as expected. For example, the patient's temperature may be expected to lower by a certain amount in a certain timeframe. The average clotting time for a patient receiving a blood thinner might be expected to follow a predictable progression, etc. The patient's condition might be provided by patient monitoring equipment, test results or healthcare provider observations. In the event that the patient is not responding to the treatment as expected, the appropriate health care providers will be notified as specified in the treatment regimen. Information sources that will provide success/failure indicators could include staff interviews of the patient, continuous monitoring equipment linked to the hospital wireless area network (see below), lab results entered for the patient, or radiologist interpretation of imaging results.

[0052] There will of course be indicators of treatment success, failure or complications that are not anticipated in the treatment regimen. Any person that is responsible for delivering any portion of the treatment can raise an alert based on their judgment and observation of the patient's condition. The default system action will be to issue a high priority alert to the attending nurse, nursing supervisor, doctor on call and the patient's primary physician. However, the priority levels of the alerts in the default action can be customized by the hospital administration. The hospital administration can also add specific administrators that should be alerted in the event that problems are identified in a standard treatment regimen. The action taken in a specific case can also be customized by the person raising the alert. Regardless of any customization, at a minimum an alert will be delivered to the individuals mentioned above at some level of priority. The intent is not only to provide immediate assistance to the patient question but to quickly identify problems with standard treatment regimens before the problems can proliferate to additional patients.

[0053] When a problem is identified in a standard treatment regime the attending physician will have the ability to identify all of his or her additional patients that are being treated with that treatment regimen or a customized regimen based on the standard treatment regimen in a step **37**. Hospital administration will have the same ability across the entire hospital. This will ensure that the standard treatment regimens will quickly improve and that the improvements will immediately be propagated to all affected patients. In effect, this will be a key mechanism used to facilitate the hospital's transformation to a learning organization.

[0054] 3.3 Inputs from Healthcare Professionals Linked to Wireless Area Networks

[0055] Doctors, nurses and other health-care providers will access the system through portable devices that allow two-way communication with the system. At a minimum, this communication will be through one or more wireless area networks within the hospital. It may also include appropriately secure access through the Internet. Examples of the type of devices that might be suitable would include:

[0056] Laptops (possibly using speech recognition)

[0057] Tablet PC's

[0058] PDA's (potentially with bar-code readers)

[0059] Small, portable PC's that project keyboards and monitor displays onto any flat surface

[0060] All portable or shared input devices should have the capability of using biometrics to identify the user of the device quickly and easily. One such example might be a fingerprint reader incorporated into the device. Non-portable devices used for input that do not have equivalent functionality should be connected to a security system that identifies the (one) individual given access to the secure area containing the device. The security system must be capable of detecting both the entry and exit of the authorized user and any other potential users. If any potential unauthorized users have entered the secure area, the device connection will be treated as not secure regardless of the presence of an authorized user.

[0061] 3.4 Inputs from Automated Devices

[0062] Health care providers will be responsible for creating the link between an automated device and the patient. For example, when a nurse connects the patient's IV to an infusion pump that is connected to the wireless area network, he or she will identify the patient attached to the device for the system. This may be done by bar-code scanning of a patient bracelet, reading an RFID tag on the patient or some similar technology. If the device is turned off, the link will be broken. Examples of such automated devices might be:

[0063] imaging systems

[0064] infusion pumps or other treatment delivery systems

[0065] a wide variety of patient monitoring devices

4.0 Hospital Performance Monitoring

[0066] 4.1 Performance Measures for Hospital Administration

[0067] The Hospital Performance Monitoring module **14** of the system **10** will include the ability to analyze the records of patient visits to capture a picture of the hospitals performance that can be used by hospital administration to continually improve treatment quality and reduce costs. Performance in this context can be viewed from a number of perspectives with a number of different measures. Different measures might reflect treatment quality, financial performance, legal liability costs or the performance of specific medical teams or staffers. It will be the hospital administration's responsibility to decide which measures will be used in for what purposes they will be employed. (See sections "4.2 Performance measures for public consumption" and "4.4 Visual controls".) As shown in FIG. **4**, a first step **40** is to retrieve a data subset selected by the user. A next step **41** is to verify user authorization. At a decision point **42**, a check is made and the method branches at "no" is the data is not for internal hospital use. A step **43** is performed to ensure that the subset retains patient confidentiality and the method joins a "yes" branch from the decision point **42**. At a decision point **44**, if a report is not

defined, the method branches at "no" and enters a step **45** wherein the data subset is downloaded from the database **11**. A defined report causes a branch at "yes" and the method enters a step **46** wherein a report is prepared or a visual control (See Section 4.4) is generated.

[0068] 4.2 Performance Measures for Public Consumption

[0069] The system will capture performance measures similar to existing measures reported in public documents such as the Leapfrog Survey. Such measures could be used to provide credible data that can be used in the hospital's marketing efforts. Thus, the collected data is organized in a step **40** and reports of the various measures are generated in a step **46**. These measures might be provided in the for of brochures that are updated quarterly or even in automated displays in public areas that provide real-time information wherein information is published. Hospital administration should have great flexibility in determining what measures to use and how to use them.

[0070] 4.3 Example

[0071] An enormous amount of information is captured by the system. Hospital administration can use this information to provide measures of performance from a number of perspectives. The list below provides some examples but it barely scratches the surface of what is possible.

[0072] mortality rates

[0073] average cost per patient stay

[0074] average cost per patient-year for a given population

[0075] number of patients cared for annually per bed

[0076] average annual liability costs per bed

[0077] any of the above broken out by medical specialty, practitioner, diagnosis, medication, surgical procedure, etc.

[0078] vacancy rates

[0079] 4.4 Visual Controls

[0080] Many visual controls already exist in a hospital setting. For example, if the ER waiting room is overflowing, is an obvious indicator that the system is not handling the load. The information captured by the TMS system will give hospital administration the ability to create additional visual controls in the step **46**. These controls will appear in areas easily accessible by the staff and may or may not be visible to the patients. The intent of these controls is to allow the staff to anticipate problems before they occur. For example, the anticipated queue size for medical imaging equipment based on treatment orders across the hospital might be displayed for relevant staff members. For areas where just-in-time inventory control is not appropriate, inventory levels of critical supplies might be displayed in real-time. Many of these controls will have to be based on hospital size, medical specialty involved or other implementation specific details. The system will provide the flexibility to customize visual controls for specific implementations.

5.0 Healthcare Insurance Billing/Patient Billing

[0081] The treatment management system **10** according to the present invention will have the ability to provide automatic, timely and accurate invoices to responsible parties through the Healthcare Insurance Billing module **15** and the Patient Billing module **16**. The diagnosis code used to index the treatment regimen data either will be identical to or mapped to the DRG codes used for insurance billing. The system will have knowledge of all supplies, services and facilities used in treating the patient and can therefore bill accordingly. The system will have the capability to Support electronic billing or produce printed bills as needed by the responsible party or parties.

6.0 Research & Analysis Support

[0082] 6.1 Efficacy of Treatment Regimens

[0083] For certain types of doctor and hospital services, the consumption of the services is closely correlated to the locally available supply. The use of these supply sensitive services accounts for a major portion of the variation in per capita healthcare cost between geographic regions. Studies have shown that healthcare costs in more expensive regions can be three times that of lower-cost regions. The Dartmouth Atlas Project provides a wealth of information on variations in treatment regimens and costs in different regions of the United States. For more information see "http://www.dartmouthatlas.org". There was no statistically significant variation in quality measures such as mortality rates between regions. In other words, the increased expenditures did not result in any readily apparent improvement in medical quality.

[0084] There are also instances where treatment regimens vary because medical science has not advanced sufficiently to show that a particular treatment regimen has a clear advantage. In such cases, doctors must use their own opinions. While this will always be the case, this system **10** captures both the treatment regimens and the associated outcomes with the Research & Analysis Support module **17**. This will allow medical researchers to assess aggregate data and compare different treatment regimens for similar diagnoses. Combined with the self learning nature of the system, more effective treatment regimens should emerge much more quickly and be stored in the system. Again, both cost and quality would be impacted. Analysis and publication of the data captured by the treatment monitoring systems should lead to a substantial increase in treatment standardization.

[0085] As shown in FIG. **5**, the method starts with a step **50** of verifying user authorization. Next, a data subset selected by the use is retrieved from the database **11** in a step **51**. A step **52** ensures that the subset retains patient confidentiality. In a decision point **53**, if a report is not defined, the method branches at "no" to a step **54** wherein the data is downloaded. If a report is defined, the method branches at "yes" to a step **55** to prepare the report.

[0086] 6.2 Impact on Health Care Cost for Specific Patient Populations

[0087] The treatment management system **10** will capture sufficient information to estimate the impact of the system itself on the quality and cost of any patient population for which there is a sufficient sample size. This might be based on demographics such as identifying the impact on geriatric patients or children. Health-care insurance providers may wish to compare the cost of healthcare for their customers that use hospitals that have implemented the treatment management system versus those that use hospitals that have not implemented it. Differences in cost and quality across geographic regions could be analyzed. The potential combinations are too numerous to list here.

[0088] 6.3 Expansion of Hospital Performance Measurement

[0089] The cost and quality of health care delivered can be compared across hospitals or groups of hospitals within the same hospital system. A given hospital system might compare the performance of hospitals in different metropolitan

areas, geographic regions, etc. If the data were made publicly available, comparisons across hospital systems would be possible.

[0090] 6.4 Analytical Support Related to Liability

[0091] Given the litigious nature of our society, hospitals and physicians will be involved in malpractice litigation no matter how high the quality of the care they provide. Malpractice attorneys tell their clients that the best way to avoid legal difficulties is "document, document, and document!" The system provides very detailed documentation of each patient's treatment. Reporting facilities will be provided for litigation support.

[0092] The system **10** will also capture liability expenses related to diagnoses. This information can be used by the hospital administration to document lower liability expenses for their providers of liability insurance. This documentation can be used to justify lower insurance premiums for the hospital.

[0093] 6.5 Combinations of the Above

[0094] The system **10** will provide a very flexible analysis capability. The key limitation on this capability will be to ensure that any subset of the data to be analyzed is of sufficient size to ensure patient confidentiality. This analysis capability can be used to help standardize on the most effective treatment regimens, quickly identify unexpected side effects of new medications and in general, dramatically improving the quality of health care provided to the public.

7.0 Supply Chain Management

[0095] 7.1 Implementation of Lean Manufacturing Concepts

[0096] By capturing information about the current usage of medications and other supplies through the Supply Chain Management module **18**, the system **10** will allow much tighter inventory control. The system will use concepts similar to those in lean manufacturing systems to improve quality and eliminate waste. Consumable supplies will be replenished as they are used (in much the same way that kanban systems work in automobile manufacturing). Just-in-time practices will allow hospital inventories to be minimized such that inventories will not substantially exceed levels needed for emergency services.

[0097] For this process to work in any facility (manufacturing, medical or otherwise), the facility manager must have the ability to control production to the extent that an even level of output can be produced. For large hospitals most of the activities will approximate this even level of output simply because of the law of large numbers. Unfortunately, for smaller hospitals and for low-volume specialties within larger hospitals, this even level of output would not be dependable. As a result, the system will provide the ability to use a more traditional inventory management approach when JIT methods are not appropriate.

[0098] 7.2 Inventory-Related Security Issues Such as Management of Controlled Substances

[0099] By increasing the number of inventory turns, the time required to identify a discrepancy in the inventory levels of any controlled substances would be greatly reduced. Should anyone attempt to steal any of these managed supplies, hospital administration would be quickly alerted to the possibility of theft.

[0100] It addition, the use of individual identification at the dose level would allow the source of any defective medications to be quickly identified. This could be implemented through any appropriate technology such as bar-code labels or RFID tags. For example, the system **10** would be able to identify the location of all medications from a defective lot. Any recalled medications could be quickly located and returned to the manufacturer. The same capability could be applied to other supplies of a sensitive nature.

[0101] 7.3 Improved Support of Purchasing and Accounts Payable Functions

[0102] Purchasing at the tactical level will be largely automated. Once appropriate agreements are in place with the suppliers, the system will place orders based on the actual consumption of supplies. (As noted above, more traditional inventory control methods such as calculated economic reorder points can be used where substantial volume fluctuations make JIT inappropriate) Suppliers could be automatically paid on receipt of delivery without waiting for an invoice.

8.0 Personal Scheduling

[0103] 8.1 Immediate Detection of Personnel Overload/Imbalance

[0104] Because each treatment event in a treatment regimen is assigned to a particular role (e.g., nurse, radiologist, etc.), the system has complete knowledge of the short-term requirements for skilled staff. Based on hospital administration supplied parameters, personnel overloads or imbalances in general can be quickly identified using the Personnel Scheduling module **19**. Work cells based on medical specialty can be identified and allocated based on expected demand. This technique will facilitate rapid movement of patients through the hospital when appropriate and provide an allocation unit that can be used to react quickly to demand fluctuations.

[0105] 8.2 Improved Productivity

[0106] Using automated medical records and the best available input devices, the time required to complete their responsibilities by hospital staff in general will be reduced. For example, in some hospitals nurses ending their shift must have a significant overlap with the incoming nurse to brief them on the patients that will be under their care. While the function will still be required, the system should dramatically reduce the time required for the briefing.

[0107] Physicians entering a treatment regimen that they have used before can do it much more efficiently. Physician productivity will continue to improve as they use the system. The use of work cells based around medical specialties will streamline the treatment of patients after their initial diagnosis. (It may be very appropriate to measure both treatment quality and quantity produced by the medical teams functioning within work cells.)

9.0 TMS Database

[0108] 9.1 Stored Data Such as:

[0109] The TMS database **11** underneath the system will contain a variety of stored information. Some of the major categories that will be captured are as follows:

[0110] treatment regimens by diagnosis

[0111] treatment plan by patient

[0112] patient history

[0113] patient billing information

[0114] healthcare insurance provider information

[0115] hospital employee information

[0116] hospital facility information

[0117] vendor information

[0118] 9.2 Event Driven Control Structure

[0119] In addition to the more common stored information, the system will also capture information about events. This information will be used to drive the control structure operating the treatment process. In general, two types of events will be tracked:

[0120] Planned events such as removing a cast or administering the next dose of medication

[0121] Ad hoc events such as an adverse reaction to the treatment plan.

[0122] System actions will be triggered by the occurrence of an event. For most events, an input from a healthcare provider or an automated device will indicate that an event has occurred. The system action triggered by the event may be as simple as recording the event in the patient's history. Depending on the nature of the event, the system might react by notifying a healthcare provider that the patient has had an adverse reaction to the treatment regimen. Planned events have a time based component. When the event is planned, a future time based event is recorded. If the planned event takes place before the associated time based event, the time based event will be deleted. If not, the time based event will serve to notify the system that the planned event did not occur on schedule and the appropriate action should be taken. These planned events will be stored as part of the treatment management system database.

10.0 Implementation Issues

[0123] 10.1 Architecture

[0124] As discussed above, the system **10** will be based on an event driven architecture. It must also be kept in mind that the patient will be mobile. Input devices providing information about the patient or the treatment regimen may be connected to multiple PCs throughout the network. For example, the patient may be taken from their room to use facilities in another part of the hospital. Such facilities might include everything from showers to medical imaging equipment. Monitoring equipment connected to them may move from being wirelessly connected to a PC in a nursing station to being wirelessly connected to a PC in radiology. A radiologist may use that same PC to transfer images to the patient's history. Using technologies such as wireless networks and RFID, the capabilities of the system should move with the patient throughout the hospital. While not required for every implementation, access by remote physicians could be provided via the Internet.

[0125] 10.2 Security

[0126] The system must have very high standards for security and confidentiality. In particular, it must be compliant with HIPPA. This implies that all wireless area connections must be encrypted. Similarly, VPN technology and other emerging technologies should be used to ensure that any Internet access is secure. All devices providing access to the system must have the ability to identify the user of the device biometrically. All inputs to the system must include validation of the user. This validation must be both quick and accurate. Fingerprint readers would be an example of a technology that would be suitable for this purpose. In addition, patient specific information stored in the database must be encrypted.

[0127] 10.3 Expandability

[0128] While initial implementations of the system will be focused on specific hospitals, the architecture and design should facilitate access to patient records across entire hospital systems. This would be expanded to provide access from remote physicians' offices for those physicians associated with the hospital system. Access to a particular patient's information across hospital systems anywhere in the world would be provided in a full implementation

[0129] 10.4 Components of the System

[0130] FIG. **6** is a block diagram showing the connections between the components of the treatment management system **10**. A network **60** includes the TMS database **11** connected for data exchange with at least one computer **61**. The computer **61** runs software that performs all of the data storage and retrieval associated with the database **11** as described above. A healthcare provider terminal **62** represents multiple input/output devices of various types utilized by doctors, nurses, lab technicians, etc. to exchange data with the computer **61**. A monitoring device **63** represents various medical devices used in the treatment regimen that exchange data with the computer **61**. An administration terminal **64** represents one or more input/output devices of various types utilized by hospital administrators, managers, etc. to exchange data with the computer **61**. A visual controls block **65** represents the devices described in Section 4.4 above that exchange data with the computer **61**.

[0131] In accordance with the provisions of the patent statutes, the present invention has been described in what is considered to represent its preferred embodiment. However, it should be noted that the invention can be practiced otherwise than as specifically illustrated and described without departing from its spirit or scope.

What is claimed is:

1. A patient treatment management system for a hospital comprising:

at least one database for storing data related to a patient including observations, test results, diagnosis, at least one treatment regimen and a treatment plan;

at least one healthcare provider terminal for use by healthcare providers to exchange said data with said database;

at least one monitoring device for sending medical device operating data related to the patient during the administration of the treatment plan to said database; and

a computer connected to said at least one database, said at least one healthcare provider terminal and said at least one monitoring device and generating an evaluation of the treatment regimen based upon said data.

2. The system according to claim **1** including at least one visual control connected to said computer for communicating to the healthcare providers information related to a potential problem associated with the treatment regimen.

3. The system according to claim **1** including at least one administration terminal connected to said computer for use by administrators to select and monitor performance measures of the treatment regimen.

4. The system according to claim **1** including a software program operated by said computer and having at least one of a treatment planning module, a treatment monitoring module, a hospital monitoring module, a healthcare insurance billing module, a patient billing module, a research and analysis support module, a supply chain management module and a personnel scheduling module.

5. A method for managing patient treatment comprising the steps of:

a. providing a database;

b. storing in the database data related to patients including observations, test results, diagnoses and treatment regimens;

c. storing in the database medical device operating data related to the treatment regimens; and

d. evaluating effectiveness of the treatment regimens based upon the data stored in the database.

6. The method according to claim **5** including determining a diagnosis for a patient based upon the stored observations and test results data, identifying all of the stored treatment regimens associated with the diagnosis, either customizing one of the identified treatment regimens or creating a new treatment regimen, and storing in the database the customized treatment regimen or the new treatment regiment.

7. The method according to claim **5** including monitoring the administration of the treatment regimen and issuing a reminder if a task associated with the treatment regimen is not completed on time.

8. The method according to claim **5** including monitoring the administration of the treatment regimen and issuing an alert if a success indicator associated with the treatment regimen is not achieved.

9. The method according to claim **8** including identifying other patients undergoing the same treatment regimen.

10. The method according to claim **5** including monitoring the selected performance measures associated with the treatment regimens.

11. The method according to claim **10** including generating visual controls to enable healthcare providers to anticipate problems associated with administration of the treatment regimens.

12. The method according to claim **5** including evaluating the treatment regimens and storing in the database only those treatment regimens that are effective.

13. The system according to claim **5** including using the data in the database to perform at least one of treatment planning, treatment monitoring, hospital monitoring, healthcare insurance billing, patient billing, research and analysis support, supply chain management and personnel scheduling.

14. A method for managing patient treatment comprising the steps of:

a. providing a database;

b. storing in the database a patient history for each patient including data related to observations, test results, diagnoses and treatment regimens associated with the patient;

c. administering to each patient at least one of the treatment regimens based upon the diagnosis;

d. storing in the patient histories in the database medical device operating data related to the administration of the treatment regimens;

e. issuing a reminder if a task associated with one of the treatment regimens is not completed on time; and

f. evaluating effectiveness of the treatment regimens based upon the data stored in the database.

15. The method according to claim **14** including monitoring the administration of each of the treatment regimens and issuing an alert if a success indicator associated with any one of the treatment regimens is not achieved.

16. The method according to claim **15** including identifying other patients undergoing the same treatment regimen.

17. The method according to claim **14** including either customizing one of the stored treatment regimens or creating a new treatment regimen and storing in the database the customized treatment regimen or the new treatment regiment.

18. The method according to claim **14** including monitoring selected performance measures associated with the treatment regimens.

19. The method according to claim **14** including generating visual controls to enable healthcare providers to anticipate problems associated with administration of the treatment regimens.

20. The system according to claim **14** using the data in the database to perform at least one of treatment planning, treatment monitoring, hospital monitoring, healthcare insurance billing, patient billing, research and analysis support, supply chain management and personnel scheduling.

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