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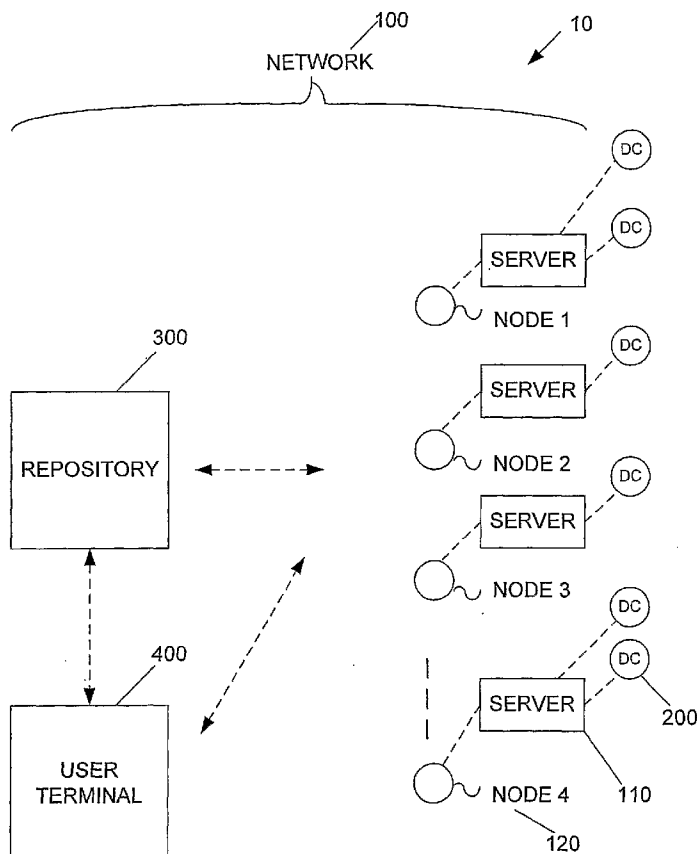
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(54) Title: CLINICAL DATA DATABASE SYSTEM AND METHOD FOR A CRITICAL CARE AND/OR HOSPITAL ENVIRONMENT



(57) Abstract: A system for capturing and maintaining a categorized flow of data in a clinical environment includes a distributed computer network, a plurality of data clusters dispersed over the network, a repository adapted to store data representative of the identity of patients, means for querying the repository to identify one of the data clusters associated with a particular patient and in response to such identification of the data cluster, allowing said particular patient or a user to query clinical data associated with the patient from said identified data cluster.

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**Clinical Data Database System and Method for a Critical Care
and/or Hospital Environment**

CROSS-REFERENCE TO RELATED APPLICATIONS

[0001] This application claims priority of U.S. Provisional Patent Application Serial No. 60/535,390, filed on January 9, 2004.

FILED OF THE INVENTION

[0002] This invention is in the field of medical information systems, and more particularly related to optimized methods and systems for capturing and maintaining a categorized flow of data in a clinical environment

BACKGROUND OF THE DISCLOSURE

[0003] Clinical data is defined as data related to a patient. It includes data such as ADT, vital signs, analog waves, summaries, and the like. Clinical data is categorized by the patient; each patient has its own data. Clinical data is collected from various sources, such as medical devices, and hospital systems or may be manually entered by clinical staff. This can result in a huge amount of data flow that needs to be captured online. The clinical data, once captured, should be available for browsing, manipulating and query. In order to achieve high-performance for such issues (browsing/queries/manipulating), the data store (that is, the physical file itself where the data is kept) should have as small a size as possible (one that fits the machine hardware) and yet maintain all the patient data in the same store (to avoid the need for cross-file queries). Having multiple storages (for example, separate stores for each patient) can pose a maintenance problem. In addition, for the method of capturing and maintaining clinical data to be scalable, it should be possible to add additional hardware to handle parts of the clinical data flow. This invention provides a load balancing system and method for capturing clinical data, while keeping the number of physical data stores, and their size, low as possible.

SUMMARY OF THE INVENTION

[0004] The system and method of the invention establishes a data base architecture that is particularly suited for entry, storage, management and access for clinical data in a critical care

and/or more general hospital environment. The system and method of the invention is preferably operative over a geographically distributed network including multiple servers, data stores and user access terminals, but could alternatively be operative over a local area network. In one form, communication between network nodes can be effected over the internet.

[0005] In accordance with the invention, the database architecture includes a plurality of data stores referred to as Data Clusters. Each Data Cluster may store medical record data for predetermined number of patients. By way of example, the data stored for a patient at a Data Cluster may include heart rate data, body temperature data, diagnosis code data, demographic data as well as other data typically used in critical care and/or more general hospital environments. The amount of the data stored for various patients in a Data Cluster may vary from patient to patient. There may be clinical data that is representative of frequent data points over a short time period, or less-frequent data points over a long time period. Preferably, the Data Clusters are each associated with a particular server in the network. Each such server may be associated with zero, one or more Data Clusters.

[0006] A Repository is employed to maintain, in effect, a table of information which includes meta-data for each Data Cluster. The meta-data for a Data Cluster is representative of the identity of each patient for whom medical data records are stored on the Data Cluster, and of the type (and in some cases, the range) of data values stored at the Data Cluster.

[0007] The database architecture is accordingly structured so that a user of the system and method of the invention, may desire, for example, to obtain temperature and heart rate data for a particular patient over a certain time period. To obtain this information, the user may, at a user terminal, communicate his desire to the Repository. The Repository, in response, scans the meta-data, and identifies the user, the identity of the Data Cluster in which the desired information is stored, as well as ranges for the data values, if applicable. The user can then query over the network, the particular Data Cluster. In response to such queries, the queried Data Cluster returns the requested data to the user at his terminal. The user terminal may be for example a desktop computer hardwired to the network, or may be a wireless handheld computer, or some other conventional device.

[0008] With the above described architecture, standard procedures and protocols for medical data are applied to the data and communication of the same so that requisite privacy, security and integrity are maintained. A principal advantage of the system and method of the invention, is the establishment of a distributed database that permits easy, fast and efficient queries for clinical data in a critical care and/or more general hospital environment, particularly when compared with clinical data systems of the prior art.

DESCRIPTION OF THE DRAWINGS

[0009] Figure 1 shows, in block diagram form, a clinical data system in accordance with the invention.

DESCRIPTION OF THE PREFERRED EMBODIMENT

[0010] A clinical data system 10 of the present invention is shown in Figure 1. The system and method of the invention establishes a data base architecture that is particularly suited for entry, storage, management and access for clinical data in a critical care and/or more general hospital environment. The system and method of the invention is preferably operative over a geographically distributed network 100 including multiple servers 110, data stores 300 and user access terminals 400, but could alternatively be operative over a local area network. In one form, communication between network nodes 120 can be effected over the internet.

[0011] A Data Cluster 200 is a categorized storage location, that holds information for certain sets of categories (that is, patients). A master index establishes a patient-cluster relationship. The system/method directs clinical data flow for each patient to his/her respective Data Cluster. The content of the Data Cluster is described in an external file - referred to as the Repository 300. The Repository 300 includes meta-data that describes the content of all the Data Clusters. This Data Cluster-Repository approach allows a reduction in storage requirements and is easier to maintain, compared to prior art approaches. The Data Cluster size can be selected, based on various parameters such as: maximum number of patients, registration date, and the like. Each Data Cluster 200 is classified by a status, "Active" or "Non-Active". Once a Data Cluster 200 reaches its pre-defined limit, it changes status from Active (wherein it may accept new patients) to Non-Active (wherein it may not accept new patients), and a new Data Cluster is created with

the status Active. Several Data Clusters can be present on a single server in a multi-server environment, wherein one of the Data Clusters on that single server is Active. By establishing predetermined fixed sizes to the Data Clusters, the storage loading on the various servers in the multi-server environment can be balanced between the Active Data Clusters on the various servers. This architecture allows system administrator to configure a solution that best fits the hardware capabilities.

[0012] In a preferred form of the invention, the various components have the following form:

Repository:

Description:

[0013] The Repository 300 is a single hospital-wide database that enables users of the system to locate and understand the clinical data in the patient-centric Data Clusters.

[0014] The repository mainly includes Meta-Data, principally in the form of data representative of patient identifications and characteristics of the clinical data.

[0015] Clinical data collected from different sources (medical devices / hospital systems / medical communications devices) and different locations (hospital units) all are associated with the same repository. With this approach, the disparate patient data are available (i.e., accessible) and understandable (i.e., in an expected, and usually standard, form) regardless of the Data Cluster they are in, while keeping the "size" of the Data Clusters size relatively small (preferably, the Data Clusters may only contain pointers to the Meta-Data in the Repository, and not the Meta-Data itself).

Repository Content:

[0016] Cluster Index - A list of all Data Clusters in the system and the physical locations of the respective Clusters.

[0017] Patient Master Index - Data representative of the particular Data Clusters on which the data for the respective patients are resident. The Patient Master Index data supports the EMPI (Enterprise master patient index) standard.

[0018] User and Permissions Table - Data associated with the system users (consistent with the HIPPA requirements).

[0019] Meta-Data - Data defining all the clinical data resources and their characteristics. For example: the 'Heart Rate' resource has the 'Normal Values Range' characteristic (can accept value between 50-180) and the identification number - 576.

Data Cluster:

Description:

[0020] The Data Cluster 200 is a data store where the patient clinical data is saved.

[0021] Each Data Cluster 200 can support a customized number of patients, consistent with the hardware.

[0022] Data in the Data Cluster, that is collected from various sources, supports the HL7 standards.

[0023] All of the data for a single patient resides in a single cluster (a single patient's data can not be present in more than a single Data Cluster).

Content:

- Patient identifier
- Admissions list
- Demographic data (e.g.: patient name, address)
- Diagnosis (e.g.: problem list, ICD 9 / 10)
- Vital signs data (e.g.: temperature, blood pressure, heart rate, etc)
- Analog wave data (e.g.: ECG)
- Running orders

- Care plans
- Any other clinical data

Workflow example:

[0024] Steps for locating patient clinical data:

A user wants to check if the Body Temperature value of patient 'John Doe' at 11:15 PM was out of the normal range.

- 1) User issues Query to the Repository's 'Patient Master Index' to identify the Data Cluster upon which 'John Doe' data resides.
- 2) User issues Query to the Repository's 'Cluster Index' to identify the physical location of the identified Data Cluster.
- 3) User issues Query to the Repository's Vital Signs Meta-data to determine the 'HR' identification and 'Normal Values Range'.
- 4) User locates the identified Data Cluster as described in the Repository's 'Cluster Index'.
- 5) User issues Query to the located Data Cluster, requesting the Vital Signs patient data, using the Repository's patient identifier and the 'HR' identification.
- 6) User receives the requested patient data value, as sent by the Data Cluster, and Compares the retrieved value with the 'Normal Values Range' meta-data that was retrieved from the Repository.

Medical standards and regulations:

[0025] Data residing both in the Repository and in the Data Clusters meet with the following standards and regulations.

- EMPI Standard (Enterprise master patient index)
- HL7 - Health care messaging protocol

- HIPPA - Permissions regulations for disclosure of clinical data
- ICD 9 / 10 - A diagnosis coding convention
- CPT - Clinical Path Ways standards

[0026] In other forms of the invention, different configurations are used.

[0027] Those of skill in the art will recognize that the invention may be embodied in other specific forms without departing from the spirit or essential characteristics thereof. The presently described embodiments are therefore to be considered in all respects as illustrative and not restrictive, the scope of the invention being indicated by the appended claims rather than by the foregoing description, and all variations of the invention which are encompassed within the meaning and range of equivalency of the claims are therefore intended to be embraced therein.

What is claimed is:

1. A clinical data system, comprising:
 - A. a distributed computer network including a plurality of nodes, one or more of said nodes including at least one server,
 - B. a plurality of data clusters dispersed over said network, each of said data clusters being associated with one of said servers, and said data clusters each being adapted to store clinical data associated with one or more patients,
 - C. a repository adapted to store data representative of the identity of patients having clinical data associated with particular ones of said data clusters, and
 - D. means for querying said repository to identify one of said data clusters associated with a particular patient having clinical data associated therewith and residing on said identified data cluster, and in response to such identification of said data cluster, for querying said identified data cluster to request clinical data associated with said patient and residing thereon.
2. A system according to claim 1, wherein each of said data clusters stores medical record data for a predetermined number of patients.
3. A system according to claim 2, wherein said medical record data includes heart rate data, body temperature data, diagnosis code data, or demographic data of patients.
4. A system according to claim 1, wherein each of said servers is associated with zero, one or more said data clusters.
5. A system according to claim 1, wherein said means for querying is a user terminal.
6. A system according to claim 1, wherein each of said data clusters is classified by an active or a non-active status.
7. A system according to claim 6, wherein each of said data clusters is characterized by a predetermined capacity limit for an amount of data storable therein.

8. A system according to claim 7, wherein each of said data clusters changes status from active to non-active when an amount of data stored in said data cluster reaches said predetermined limit.
9. A system according to claim 7, wherein said active status for a data cluster indicates that the amount of data stored in said data cluster is below said capacity limit for said data cluster.
10. A system according to claim 7, wherein said inactive status for a data cluster indicates that the amount of data stored in said data cluster is at said capacity limit for said data cluster.
11. A system according to claim 1, wherein said repository is a single hospital-wide database.
12. A system according to claim 1, wherein said repository includes a cluster index, which is a list of all said data clusters in said system and physical locations of said data clusters.
13. A system according to claim 1, wherein said repository includes a patient master index data representative of said data clusters on which said clinical data associated with respective patients resides.
14. A system according to claim 1, wherein said data cluster is adapted to store at least one patient data for a patient being representative of one or more of a patient identifier, an admission data, demographic data, diagnosis data, vital sign data, analog wave data, running orders, care plans, or other clinical data.
15. A method for capturing and maintaining a categorized flow of data in a clinical environment, comprising the steps of:
 - A. a user issuing a query to a repository, wherein said repository stores identification information of patients and an index of a plurality of data clusters storing clinical data of said patients;
 - B. said repository, in response, identifying an identity of a particular patient and identifying a data cluster having the clinical data associated with said particular patient;

- C. the user issuing a query to said identified data cluster to request the clinical data associated with the particular patient; and
 - D. the user receiving the requested clinical data from said identified data cluster.
16. A method according to claim 15, wherein said user issues said queries from a user terminal.
17. A method according to claim 15, wherein said repository and said plurality of data clusters form a data network.

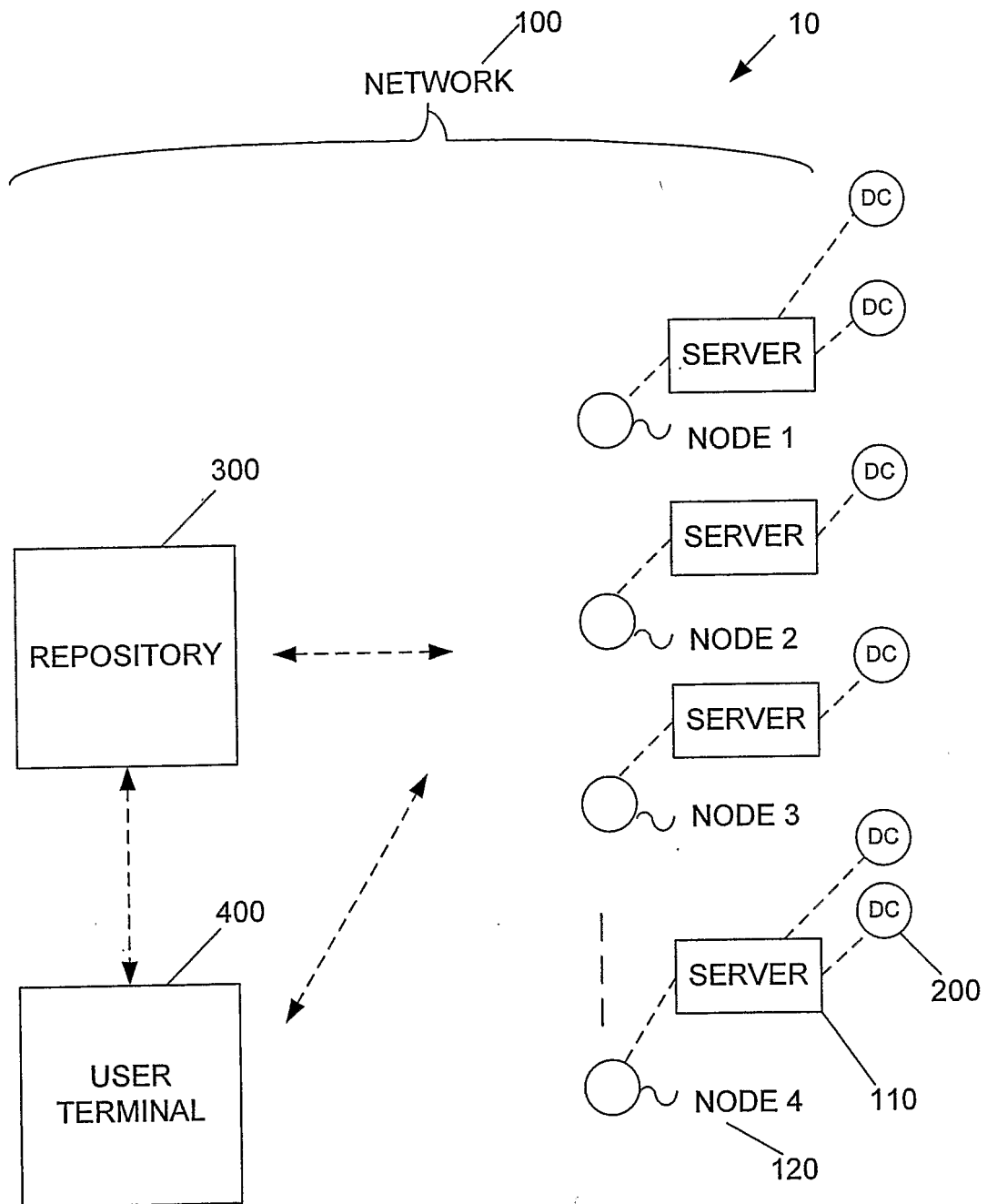


FIG. 1

专利名称(译)	用于重症监护和/或医院环境的临床数据数据库系统和方法		
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摘要(译)

用于在临床环境中捕获和维护分类的数据流的系统包括分布式计算机网络，分散在网络上的多个数据集群，适于存储代表患者身份的数据的储存库，用于查询储存库的装置。识别与特定患者相关联的数据集群之一并响应于数据集群的这种识别，允许所述特定患者或用户从所述识别的数据集群查询与患者相关联的临床数据。