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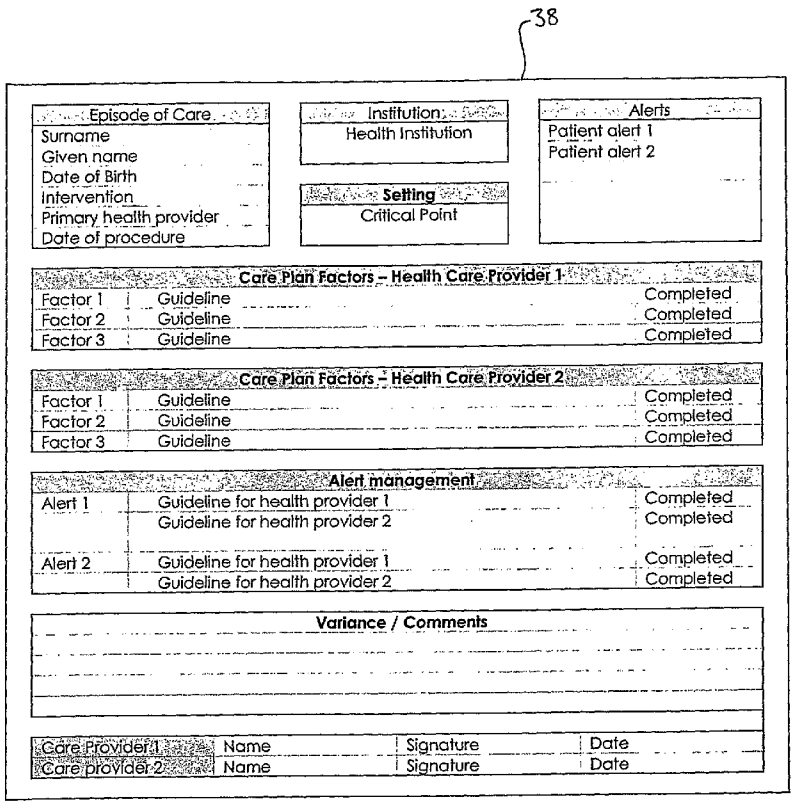

Fig 13

(57) **Abstract:** The present invention relates to a clinical pathway system which provides the capacity for automatic generation of comprehensive care plans that are unique, and specific to every patient in every setting during an episode of care, from Pre Admission to Discharge. As such, it ensures that treatment recommendations in respect to usual requirements and those specific patient attributes termed alerts are communicated in every setting.

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A pathway system

The present invention relates to a pathway system and, in particular, to a clinical pathway system for generating critical point guidelines that uniquely reflect individual requirements of procedural interventions, patients, health care providers, and institutions.

BACKGROUND OF THE INVENTION

Many patients receive health care that entails procedural intervention. This may occur in a wide variety of circumstances. Examples include complex surgical procedures requiring admission to hospital, procedural treatment administered in Day Care facilities, and ambulatory or Outpatient procedural treatment administered in medical or dental facilities.

In order to improve the delivery of health care, efforts have been made to standardize treatment protocols. This process aims to improve treatment efficiency by minimizing variations from a predefined standard treatment program. Such approaches form the basis of clinical pathways.

Clinical pathways represent an existing management program in the form of a management workflow that is created to define the usual care provided to patients undergoing procedural intervention. In current practice, such pathways typically comprise a daily guide to the specific treatment that is normally provided, in a specified context. Current clinical pathways known to the Applicant are typically specific to the procedure, the surgeon, and the institution. They are created as fixed documents, and this single document is used for all patients undergoing a particular treatment by a particular doctor.

As such, existing Clinical Pathway systems cannot uniquely account for all care plan factors, including factors relating to particular patient alerts, and have several other limitations, including:

- the difficulty in modifying a paper based document to address real time changes in the clinical condition of a patient;
- the need for separate pathways, resulting from the difficulty in accounting for specific preferences of individual health care providers in the management of certain aspects of care using a single pathway;

- the fact that predefined generic pathways do not reflect all of the treatment modifications that may be required for any given patient. In particular, lack of specificity in regard to the co-morbid conditions of the patient means that predicted generic management recommendations do not address many highly significant aspects of care; and

- the fact that different institutions often differ in management practice, based on factors such as established protocols, or resource constraints.

Pathways that are not reflective of the specific needs of a particular patient, health care provider and institution have little utility in clinical practice. As a result, such pathways although well established in principle, are not in common use.

Existing pathways therefore do not allow for the routine creation of customized care plans that are specific for each episode of care. To achieve this, it is necessary to incorporate information relevant to patient alerts. Specifically, this requires:

1) *The identification of relevant alerts.*
Approaches to the collection of data relevant to patient alerts vary between different institutions. Most often, data is collected by different staff in different contexts. For example, anaesthetic, allied health and nursing notes typically focus on different patient characteristics and alerts. As a result, relevant documentation is found in different areas of the medical record.

Some institutions utilize checklists to collect this information. These may be in the form of Patient Registration Forms, Anaesthetic or Preadmission documentation. These documents are generic in design, and do not specifically take into account all the conditions that may be relevant to a particular intervention.

2) *Defining the consequence of each alert on the care that would normally be given.*
The recognition of an alert does not automatically generate a guideline for the management of this condition. Guidelines that define the implication of an alert on patient management are not incorporated in the patient record. Most do no exist as explicit documents. Those that do are found external to the patient record. These may be stored within reference folders, as well as charts or remote electronic resources. As a result, the management of any alert relies on:

- education of individual staff; or
- individual staff deriving this information from an external resource.

3) *Modification of treatment recommendations to account for the preference of individual health care providers or institutions*

4) *Communication of this information to health workers at each step in the patients management.*

Patient care often involves the modification of usual treatment to account for circumstances that are specific to a particular episode of care. These variations usually reflect the presence of patient alerts, or individual preferences of health care providers. At present, information regarding variations in treatment is conveyed from one setting to another in a linear fashion. That is, information must be recorded at each point of care, and conveyed to health care workers who are involved at the next step in treatment. Failure to do so at any point may mean that his information is lost to staff responsible for later patient care.

The applicant is aware of several systems which attempt to improve pathways by:

- Converting paper based documents to interactive electronic records;
- Facilitating real time user input, such as ad hoc treatment orders;
- Responding to the input of external factors, such as test results;
- Allowing the integration of multiple simultaneous pathways; and
- Assisting with the collection and analysis of outcome data.

Despite the application of such systems, particularly over the past 10 - 15 years, very few health care settings have made a transition to electronic clinical pathways. This reflects several disadvantages that are intrinsic to such approaches.

A lack of supporting electronic infrastructure is a major impediment to the adoption of complex electronic pathways. For example, most hospitals do not have interactive electronic screens at the bedside that can be used to display and modify treatment guidelines through constant real time data manipulation. Developing appropriate linkages for integration of test

results and patient management guidelines has proven difficult. In addition, there is no consensus regarding appropriate electronic formats for data management. The high cost of implementation, including staff training for complex programs has been a major disincentive.

In summary, where clinical pathways are in use, they most often comprise predefined documents. These do not allow the generation of treatment guidelines that uniquely recognise the specific characteristics of individual patients (patient alerts) or the preference of individual health care providers. Patient alerts may require treatment to be modified at various points in the continuum of care. At present, these modifications cannot be incorporated into a single integrated guideline. In addition, there is no current mechanism by which the specific treatment consequences of these factors can be explicitly defined for each of the settings in which care will be delivered.

It is therefore an object of the present invention to overcome at least some of the aforementioned problems or to provide the public with a useful and practical alternative that can be effectively implemented in all healthcare environments.

SUMMARY OF THE INVENTION

In one form of the invention there is proposed a pathway system for generating management guidelines for service providers within each setting of a service episode, said pathway system characterised by:

a procedures database adapted to store predefined templates relating to each procedure within each service setting;

an alerts database adapted to store predefined templates relating to service recipient alerts that require each procedure to be modified;

a means of modifying said procedural templates to account for one or more service plan factors that require said procedure to be modified;

a means of modifying said alert templates to account for said one or more service plan factors; and

a means of integrating said procedural and alert templates to provide a final management guideline for each setting that is accessible by each service provider.

Preferably said one or more service plan factors includes a procedural preference of an institution in which said service episode is being carried out.

In preference said one or more service plan factors includes a procedural preference of the service provider.

In preference said pathway system further includes a conflict resolution database adapted to store rules which define the required procedure for when two or more service recipient alert templates are required for a particular setting.

In preference said one or more service plan factor preferences can be modified at any time during the service episode.

In a further form of the invention there is proposed a clinical pathway system for generating management guidelines for healthcare providers within each setting of an episode of care, said clinical pathway system characterised by:

a procedures database adapted to store predefined templates relating to each procedure within each service setting;

an alerts database adapted to store predefined templates relating to patient alerts that require said procedure to be modified;

a means of modifying said procedural templates to account for one or more care plan factors that require said procedure to be modified;

a means of modifying said alert templates to account for said one or more care plan factors; and

a means of integrating said procedural and alert templates to provide final management guidelines for each setting that are accessible by each healthcare provider.

Preferably said one or more care plan factors includes a procedural preference of a healthcare institution in which said service episode is being carried out.

In preference said service settings include preadmission, admission, theatre, recovery, ward and discharge.

In preference said one or more care plan factors includes a procedural preference of the healthcare provider.

Preferably said clinical pathway system further includes a conflict resolution database adapted to store rules which define the required procedure for when two or more patient alert templates are required in a particular setting.

Preferably said one or more care plan factor preferences can be modified at any time during the episode of care.

In a still further form of the invention there is proposed a pathway system characterised by:

a service recipient;

a plurality of service settings required to complete a service episode;

a service provider for each setting;

a means of storing information relating to a usual procedure for each service setting;

a means of storing information relating to specific requirements of the service recipient for each service setting; and

a means of accessing a matrix of information derived from the above means of storing to form a single explicit management plan for use by each service provider in each setting.

Preferably said pathway system further includes a means of storing information relating to service plan factors that require modification to the usual procedure.

In preference said pathway system further includes a means of modifying said specific service recipient requirements and said service plan factor information at any time during the service episode.

In a yet further form of the invention there is proposed a clinical pathway system characterised by:

a treating institution;

a patient undergoing an episode of care in a plurality of different settings;

a treating practitioner for each setting;

a means of storing information relating to a usual procedure for each setting;

a means of storing information relating to specific preferences of the treating practitioner;

a means of storing information relating to specific preferences of the treating institution;

a means of storing information relating to specific alerts of the patient to be treated;

a means of accessing a matrix of information derived from the above storage means to form a single explicit management plan for use by treating practitioners within each setting.

Preferably said clinical pathway system further includes a means of modifying said specific preferences at any time during the service episode.

In a still further form of the invention there is provided a method for generating a single, explicit clinical pathway guideline for a healthcare setting in an episode of care, said method characterised by the steps of:

a) creating a basic template which describes how care is normally provided for a particular procedure in a particular healthcare setting;

b) incorporating at least one care plan factor guideline into said basic template;

c) incorporating at least one alert guideline into said basic template;

d) modifying said care plan factor guidelines and alert guidelines to account for requirements of a healthcare institution, thereby creating an institution template;

e) modifying said care plan factor guidelines and alert guidelines to account for requirements of a healthcare provider, thereby creating a provider template; and

f) integrating said modified care plan factor and alert guidelines to thereby create a final guideline for care within said particular healthcare setting.

Preferably said steps (d) and (e) are interchangeable.

In preference said method includes the further step of resolving any conflicts between multiple alert guidelines in accordance with predefined rules.

In preference said guideline is presented in either electronic or paper based format.

BRIEF DESCRIPTION OF THE DRAWINGS

The accompanying drawings, which are incorporated in and constitute a part of this specification, illustrate an implementation of the invention and, together with the description, serve to explain the advantages and principles of the invention. In the drawings:

Figure 1 illustrates the principle by which a Final Guideline is created;

Figure 2 illustrates how guidelines for Care Plan Factors and Alerts may be modified to account for specific requirements of a particular Institution;

Figure 3 illustrates how guidelines for Care Plan Factors and Alerts may be modified to account for a particular health care provider;

Figure 4 illustrates how the usual management of an alert is modified to arrive at a final guideline to be presented in the pathway;

Figure 5 illustrates a further principle of the pathway system relating to patient alerts and conflict resolution;

Figure 6 illustrates the methodology whereby Care Plan Guidelines and Alert Guidelines may be modified and integrated in every setting;

Figure 7 illustrates a still further principle of the pathway system relating to recognition of specific factors and entering of newly recognised factors;

Figure 8 illustrates a yet further principle of the pathway system relating to individual provider preferences taking precedence over default usual management guidelines;

Figure 9 illustrates the database interaction required to generate a single guideline in the pathway system of the present invention;

Figures 10-11 illustrate examples of user interfaces in which care plan factors and alerts can be tailored to suit specific requirements;

Figure 12 illustrates a flow chart for management guideline generation and the way in which such guidelines may be altered during the episode of care;

Figure 13 illustrates a format for presenting final guidelines in a particular Setting, in accordance with a first embodiment;

Figure 14 illustrates a format for presenting final guidelines in a particular Setting, in accordance with a second embodiment; and

Figure 15 illustrates an electronic format for presenting final guidelines, in accordance with a third embodiment.

DESCRIPTION OF THE PREFERRED EMBODIMENTS

The following detailed description of the invention refers to the accompanying drawings. Although the description includes exemplary embodiments, other embodiments are possible, and changes may be made to the embodiments described without departing from the spirit and scope of the invention. Wherever possible, the same reference numbers will be used throughout the drawings and the following description to refer to the same and like parts.

It is to be understood at the outset that although the following description refers specifically to a clinical pathway system, this is not intended to limit the scope of the invention to use in healthcare. The pathway system described could be used across a range of other applications.

The following terms are used throughout this specification.

Procedural Interventions

Procedural interventions are defined as health care that involves the delivery of specified treatment or treatments, the general nature of which can be predicted and predefined as a series of treatment stages.

Episode of Care

An Episode of Care is defined as all of the activity relevant to the management of a specific patient in relation to a specific hospital admission, or outpatient treatment. This includes activity associated with pre-admission assessment and post-discharge care.

Critical Point or Setting

A treatment Setting is a predefined point in the episode of care that is potentially associated with a change in physical location (for example outpatient clinics, operating theatres, hospital wards, etc), or change in health care provider staff. Each Setting is considered synonymous with a Critical Point in the delivery of care.

Care Plan Factor

A Care Plan Factor is a predefined individual element of treatment which is required in the delivery of care. These comprise, but are not limited to:

- the institution;
- the providers delivering care;
- the procedures to be performed;
- the specific attributes of the patient that influence the delivery of care.

Care Plan Factors are defined in the context of a specific setting, and specific procedure.

Care Plan Guidelines

A Care Plan Guideline is a predefined guideline that is presented at a designated treatment Setting to define the management of a particular Care Plan Factor in this Setting.

Alerts

Alerts are an important type of care plan factor, being a critical predefined set of documented existing medical conditions, medical treatments or patient determined items that can apply to any patient. They are characteristics of a patient which, if not recognised, increase the potential for inadvertent harm to the patient, or others involved in their care. Alerts have an impact on how patient care should be provided.

Alert Guideline

An Alert Guideline is a predefined guideline that is presented at a designated treatment Setting to define the management of a particular Alert in this Setting.

It is to be understood that the above definitions are merely a guide for interpreting these terms and are not intended to narrow the invention. The definitions may well be interpreted more broadly, for example, where the present invention is applied in other environments.

When considered broadly, the present invention relates to a pathway system for generating a service plan or guideline in a service episode environment involving a number of predefined critical points (or settings) within the service episode, and a number of plan factors which are predefined individual elements of service relevant to the creation of the guideline. The system identifies factors that are of relevance to the creation of the plan, and generates a guide as to the service that should be provided to a particular service recipient in the context of a specific setting. The plan provides information about the usual service that is expected, and also the service that must be provided based on the plan factors, which may include information or alerts specific to a particular service recipient. The guidelines are constructed by assembling information from a matrix of stored data repositories.

In a preferred embodiment of the invention, the pathway system is in the form of a clinical pathway system for a healthcare environment such as a hospital, in which the system is used to generate care plans or guidelines that are uniquely customised for every individual patient. Again, this is achieved by identifying the factors that are of relevance to the creation of the care plan, such as the specific attributes of the patient (alerts), the procedure to be performed,

the provider delivering the care, and the institution, and generating a guide to the care that should be provided for a particular patient in the context of a particular setting, such as admission, theatre, recovery, discharge, etc. The resulting guidelines will therefore contain information regarding the management that is expected for all care plan factors, including patient alerts, as these relate to all settings for all procedures.

The present invention therefore provides a mechanism to customize the content of clinical pathways by accurately defining the treatment that is expected, based on the intended procedure, the specific preferences of the nominated health care providers, the requirements of the health care institution, and the co-morbid conditions of the patient undergoing treatment. As a result, patients undergoing procedural care commence with a management plan that uniquely reflects their own treatment requirements.

In providing procedural treatment, information must be recognised and communicated to every health worker involved in a patient's care. This often requires transfer of information from one physical location to another. Four sets of data are relevant. These comprise:

1) Knowledge of the usual requirements for a particular treatment;

2) Understanding of the specific preferences of the treating practitioners (eg doctors, nurses, allied health workers);

3) Specific requirements and characteristics of the treating institution; and

4) Information regarding the management consequence of the specific alerts of the patient to be treated.

The system and method of the present invention improves the ability of health care providers to deliver safe, effective, efficient procedural care. It does so by providing the capacity to automatically integrate different sets of information to provide a unique management plan for every individual episode of care. This is achieved using appropriate computer software, herein referred to as a "program", and appropriate hardware for storing relevant information. Although not specifically described, it is to be understood that such a program would be installed across a network of computers in a health care institution so that the information is made accessible to designated, or all staff.

It will become apparent to those skilled in the art that the present invention provides for a matrix of information derived from the abovementioned four sources to be integrated into a single explicit management plan that is uniquely created prior to each individual episode of care. The output of the program comprises a guide to the care that should be provided by every health care worker. This information is presented as a series of work flows, one for each critical point of interaction. Where a variation from usual care is needed, the guidelines communicate not only the factor to be addressed, but also the specific treatment modification that is needed at each critical point.

Figure 1 illustrates the principle by which a Final Guideline 10 is created. General aspects of care for each specific procedure (termed Care Plan Factors) are defined within a Basic Template 12. The influences of Alerts on the delivery of care for each procedure are defined within an Alerts Database 14. Guidelines for the management of both Care Plan Factors and Alerts may be modified to suit the requirements of individual institutions and health providers. After such modification, Care Plan Guidelines and Alert Guidelines are integrated to create a Final Guideline. This guideline will now be specific for each individual patient episode of care.

Guidelines are created at the commencement of any episode of care – either prior to treatment (for example, in a Pre-Admission Clinic), or at the time the treatment episode begins. Guidelines are based on the treatment that is intended. The content of the guideline reflects:

1. The usual treatment requirements based on the intended treatment. This is hereafter referred to as a *Basic Template.* Basic Templates are written and stored within a specified database in the program;

2. Institutional requirements – Variations in treatment that reflect individual institutional practices. Templates so modified are hereafter referred to as *Institutional Templates*;

3. Provider preferences – Variations in treatment that are specific to a given health care provider. Templates so modified are hereafter referred to as a *Provider Templates* and;

4. Patient alerts – Characteristics of the patient which require modification of usual treatment. These are hereafter referred to as *Final Guidelines.*

That is, Final Guidelines are specific for the intended procedure, particular patient, specified healthcare providers and treating institution. For example, a Final Guideline may be specific for Patient A, having Operation B, under the care of Surgeon C and Anaesthetist D, at Institution E.

Final Guidelines are intended to be automatically generated through a simple user interface. This requires selection of the following information from predefined lists:

1. Intended procedural intervention;
2. Treating institution (whose management variations are accounted for);
3. Identified patient alerts (whose management variations are accounted for);
4. Specified Health Care Provider (whose management variations are accounted for)

Within the program, a single unique pathway is generated through a series of steps. The process begins with selection of a Basic Template. This is a description of the usual treatment requirements based on the intended procedure. Any number of Basic Templates can be created and stored within the nominated program database. The Basic Template for a procedure is then modified. The sequence of modification does not influence the outcome of the final guideline.

Stage 1 **Basic template**

Each Basic Template is specified for a particular procedure. Procedures may include ambulatory interactions, treatment in a day care facility, or inpatient treatment within a health care facility. Each Basic Template defines the usual treatment that is provided at each setting accounted for by the program. These settings are based on critical transitions in care.

Usual treatment – This is specified by defined activity related to a series of Care Plan Factors. Care Plan Factors may include, but are not limited to: patient treatments or interactions, staff documentation, education, communication and investigations.

Settings – The settings utilised in the program include, but are not limited to, the following critical transitions in care – Pre-Admission Clinic, Patient Admission, Theatre, Recovery, Intensive Care, Return to Ward, and Discharge.

Stage 2 **Creation of Final Guidelines through modification of a Basic Template**

Three types of modification are required to create a final guideline. The sequence of modification does not alter the content of the final guideline.

- Modification for treating institution - The Basic Template is modified to suit the specific requirements of the treating health care facility. Modifications are based on institutional constraints or established management preferences. Management Guidelines for every Care Plan Factor may be modified at every Setting, to account for any institutional variation. The Institutional Template is the result of these modifications.

Figure 2 illustrates a template 16 which has been so modified. In this illustration, the guideline for management of Care Plan Factor 1 is modified in Setting 2 to suit the specific requirements of Institution 3. Similarly, the guideline for the management of Alert 1 is modified in Setting 3. It should be noted that, in practice, the program would most commonly be established within one institution, for the sole purpose of defining the care provided to patients of that institution. In that case, creation of a Final Guideline would commence with Institutional Templates that incorporate variations based on the specific requirements of that institution.

- Modification for treating health provider/s - The Basic Template may be modified to account for the preference of individual health care providers in the specific institution. Guidelines for every Care Plan Factor may also be modified at each Setting to account for the personal preferences of every health care provider accounted for within the program. This is illustrated in Figure 3 which shows a template 18 that has been modified to meet the specific requirements of a particular health care provider, in this case being health care provider 3. These modifications result in the creation of a Provider Template. This template defines the usual care for a particular procedure provided within one institution, recognising the individual requirements of specified providers.

- Incorporation of Patient Alerts – In order to create a Final Guideline, the usual care must be modified to account for the relevant characteristics of each individual patient. Patient characteristics that influence the delivery of care are known as Alerts. As detailed in the following paragraphs, the management of patient Alerts is defined within the context of a particular procedure. For each Alert, Alert Guidelines are defined that specify the management that should be undertaken at each Setting. Alert Guidelines may themselves

modified to account for the personal preference of each provider, as also shown in Figure 3. When more than one alert is specified, the program automatically scans Alert Guidelines in each setting and resolves potential conflicts in management guidelines.

We turn now to the way in which the system allows patient alerts to be managed.

The creation of a guideline requires that patients are evaluated for the presence of Alerts. Alerts are patient characteristics that may require modification to the usual guidelines for care. Recognition of patient Alerts, and automatic modification of treatment guidelines to account for these, is a core functionality of the program.

Any number of Alerts can be accounted for using the following method:

1) An Alert is specified within the program;

2) The usual management of this Alert is defined for each procedure and setting covered by the pathway; and

3) Variations in the management of this Alert are also specified, as they apply for each institution and individual provider accounted for within the program.

A chart 20 reflecting this concept is illustrated in Figure 4.

As a result, the program is able to automatically specify how, for example, alert A is managed in setting B for a patient undergoing procedure C within institution D, recognising the particular treatment preference of health provider E.

Conflicting management recommendations are possible when multiple alerts are selected. This may arise for example, when a particular drug is recommended in the management of one factor, but the same drug is contra-indicated in the presence of a second factor (for example a drug allergy). In this circumstance, conflicts are automatically resolved according to predefined rules that are stored within the program's database, as illustrate in the chart 22 of Figure 5.

The different steps and principles of the pathway system of the present invention are schematically illustrated in the chart 24 of Figure 6. The table demonstrates the activity required to specify the guidelines that will be presented for one Care Plan Factor and one Alert in the one Setting. This automated process of modification and integration is the basis by which Final Guidelines are created. In order to generate a Final Guideline, this activity is automatically

undertaken for every Care Plan Factor and Alert, in every Setting. After conflict resolution, the resulting Final Guideline is therefore a single workflow that is presented to each setting. The workflow specifies the activity that is intended for each health care provider in this setting.

An illustrative example of an application of the present invention is as follows.

A patient is to be admitted to undergo removal of a kidney, by Doctor A and Anaesthetist B. They are seen in the Pre Admission Clinic by the Pre Admission Nurse.

The device to generate the care plan will have been installed in the institution where care is to be delivered. The content of care plans is therefore already tailored to the usual requirements of this institution.

Among the information presented in this setting will be a Care Plan Factor termed "Discharge Expectations". The system ensures that the instruction presented to the Pre Admission staff in respect of "Education" are customised to reflect the specific requirements of Doctor A.

The same patient may also have a specific comorbidity that must also be managed, such as Sleep Apnoea. This would be identified as an alert, and accounted for in the care plan. The system of the present invention will ensure that instruction presented to the Pre Admission Staff in respect of Sleep Apnoea are customised to reflect the specific requirements of Doctor A.

Final Guidelines are generated at the onset of treatment and may be adjusted at any time in the subsequent episode of care by redefining any of the defining criterion. These include:

- Intended procedure – (eg if the treatment that is deemed necessary differs from that which was specified prior to admission);
- Patient Alerts – (eg if new patient characteristics are identified during the course of treatment);
- Health Care Provider – (eg if care is transferred to another provider); and
- Institution - (eg if the patient is transferred from one facility to another)

The resulting guidelines may be presented as paper based documents, or electronic screen based workflows, as will be described in more detail further below. For each episode of care,

guidelines are generated by specifying the procedure, providers, patient alerts (and institution). The program integrates this information to automatically create a unique management guideline. This is specific to each episode of care. The output comprises a final guideline (work flows) for the care that should be provided at each critical point in the management of the patient.

Specific factors may be recognised that require the usual management of a patient to be modified during the episode of care. Examples include patient Alerts, or particular preferences of health care providers.

Once a factor is entered, the resulting change in care is automatically incorporated into the management guidelines. This defines the activity that will be required to address the factor at each critical point. In this way, the treatment consequences that are relevant to each specific factor are automatically defined for staff involved in later patient care. This ensures that relevant information will be presented to staff at each critical point. The program avoids reliance on staff to pass information from one setting to the next. In addition, it automatically specifies the treatment consequence of each specific factor, that is, management recommendations are incorporated within the patient record at every critical point.

The chart 26 shown in Figure 7 relates to changes to the specific parameters that define a guideline and, in particular, they way in which these can be recognised at any stage either before or during an episode of care. The program allows newly recognised factors to be entered, and guidelines amended to account for alteration in the care that is expected. This ensures that treatment guidelines for staff involved in current and later care are automatically updated.

Figure 8 illustrates a further flow chart 28 reflecting the way in which the specific preferences of individual health care providers are automatically accounted for when management guidelines are generated. The program ensures that these specific requirements override the default usual guidelines for care. This creates a management document that reflects the requirements of staff involved in the particular episode of care for which the guideline has been created. Specific factors in this context may include Care Plan Factors, or Alert Guidelines.

In order for the program to be able to process several sets of data as described above, several databases are required, and their interaction to generate a single guideline is shown in the chart 30 of Figure 9. The databases comprise:

- Procedure Database – This database stores Basic Templates. These define the usual management of every Care Plan Factor at every Setting specified within the program. The number of settings may vary for each Procedure. Care Plan Guidelines define the activity required of each health care provider at each setting.

- Alerts database – This database defines the management of patient Alerts. The management of patient Alerts is specific for every procedure. Within the framework of each procedure, Alert Guidelines are specified for each setting. These define the activity required of every health care provider in each Setting.

- Institutional Preference Definitions Database – This database defines the influence of specific institutional factors on each Care Plan Guideline and Alert Guideline. These are able to be specified for every Care Plan Guideline and every Alert Guideline in every Setting for every Procedure. Items in this database are assigned a higher priority than Care Plan Guidelines defined in the Procedural Database, or Alert Guidelines defined in the Alerts database.

- Provider Preference Definitions Database – This database defines variations in management guidelines that reflect the preference of individual providers who are specified within the Program. These are able to be specified for every Care Plan Guideline and every Alert Guideline in every Setting for every Procedure. Items in this database are assigned a higher priority than Care Plan Guidelines defined in the Procedural Database, or Alert Guidelines defined in the Alerts database. When concurrent fields are specified, Guidelines from the Provider Preference database are presented. Health care providers work within an institution, and for this reason, there is no conflict or interaction between Provider Preference and Institutional Preference Databases.

- Conflict Resolution Database – This database stores rules related to potential interaction of Alert Guidelines. Conflicting guidelines may be generated as a result of certain combinations of patient Alerts being selected. In each setting, Alert Guidelines are screened for potential conflict. Where this occurs, the conflict is resolved with reference to rules stored in the Conflict Resolution Database. The stored non-conflicting guidelines are assigned a higher priority and this data is presented.

The usual process by which care is delivered may be defined with respect to published guidelines (where these exist), or current established practice. Similarly, the management of patient alerts may be defined with respect to available guidelines or current practice.

Variations based on personal or institutional preference are established by direct communication. All of the above data is entered into databases that are established within a software program. The present invention relates to the process of integrating these sets of data. Information regarding the number of and nature of patient alerts, or treating health care workers may be entered manually, or imported from other electronic data sets.

The program may include a simple user interface such as that which is shown in the interface 32 of Figure 10. In the embodiment shown, the entry of Care Plan Factors and Guidelines is facilitated by the user interface by allowing every Individual Care Plan Factor to be exactly tailored to suit the specific requirements of the treating institution, intended procedural intervention, treatment setting and nominated provider. Figure 11 shows that the entry of Alert Guidelines is also facilitated by a similar user interface 34.

Integrated guidelines are therefore created by specifying relevant information derived from these data sets. This information is relevant to the episode of care for which the guidelines are created. A further example could be as follows:

- The procedural intervention that is intended is Inguinal Hernia Repair
- The specific providers whose individual preferences are accounted for within the program are: Surgeon A and Anaesthetist B
- The specific alerts that are relevant to the patient being treated are: Diabetes and Aspirin
- The critical points for which treatment guidelines are required are: Preadmission Clinic, Admission, Theatre, Recovery, Return to Ward, and Discharge
- The treating institution is usually set as default for each institution.

Guidelines are automatically generated within the program by integrating management guidelines that have been established for each of these parameters. During this integration, specific preferences and requirements override general recommendations for care. The result is a

document that is unique to each episode of care. The document consists of management guidelines that are presented as work lists for each critical point.

As mentioned previously, management guidelines may be altered during the episode of care. This is achieved by entering newly recognised information that is relevant to any of the data sets defined above. Once entered, the program incorporates this information to create a new set of integrated guidelines for the current setting and all subsequent critical points. A flow chart 36 of this process is shown in Figure 12.

Guidelines can be presented in either an electronic (e.g. screen based), or hard copy (e.g. paper based) format. In each setting, the following information is displayed:

- Identifying patient demographics
- All Alerts identified in relation to the patient
- Guideline for management for health provider involved in the delivery of care

In preference, the guidelines are presented in a format that is intuitive, and which clearly and comprehensively define the intended treatment.

The presentation of printed guidelines 38 in a format according to a first embodiment is illustrated in Figure 13. This output is directly suited to environments lacking access to an interactive information technology resource.

A further embodiment is shown in Figure 14 where the guidelines 40 are presented as work flows that are specified for each provider.

A still further embodiment is shown in Figure 15 in which the interface 42 is electronic, and information can be viewed through selection of differing screens.

It is to be understood however that any suitable format which allows the abovementioned information to be accessed, is appropriate.

The present invention is intended for use as an application to support healthcare institutions, however, is not intended to be limited to this use. The capacity to define and integrate management guidelines is most relevant to institutional care. Use of the system is intended to support the delivery of procedural care in healthcare institutions, particularly hospital

and say procedure settings. This may include procedural intervention in the context of medical, surgical, radiological and dental treatment.

The particular attributes of the present invention include, but are not limited to, the following:

- The capacity to generate treatment guidelines that uniquely and specifically define the care that should be provided in the context of each individual episode of care;
- The capacity to present these guidelines as work flows that specify the management of each Care Plan Factor in every Setting;
- The capacity to modify these management guidelines at each Setting to suit the context of a particular procedural intervention, particular health care provider and particular institutional requirement;
- The capacity to define the management implication of any patient Alert at each Setting during an episode of care;
- The capacity to automatically screen for, and resolve, potential conflicts in treatment that may arise when the management guidelines for multiple Alerts are presented;
- The capacity to define and modify management information in a manner that automatically presents appropriate guidelines for care to every subsequent setting;
- The capacity to present integrated guidelines for Care Plan Factors and patient Alerts as a series of workflows – providing relevant management information to all health care providers at each critical point in the continuum of care;
- The capacity to generate these automatically through a simple user interface; and
- The capacity to achieve these outcomes in an environment that lack complex interactive information technology.

Therefore, the present invention has been developed to meet a specific need. That is, to bridge the gulf between generic documents, which have not been widely utilized as they lack the specificity required to define the exact treatment that is intended for any particular episode of care, and interactive electronic programs, which have not been adopted because of the significant

associated costs, requirement for hardware and software integration through a complex information technology infrastructure, and operational complexity for staff. The invention provides the first explicit repository of information regarding the usual treatment guidelines for all procedures, all alerts and all providers. Those skilled in the art will recognise the value of this capacity in replacing the plethora of disparate information sources currently used. The capacity also ensures that changes in practice (through acquisition of new knowledge) can be simply and effectively incorporated into practice.

The invention allows electronically assembled information to be presented in either electronic or paper based format. If an electronic medium is established, specific patient attributes may be altered at any setting. This allows the guidelines for care at that setting to be modified in the light of new information that may be recognised. In addition, modification of alert information in one context will mean that care plans in all subsequent settings are also modified appropriately.

Further advantages and improvements may very well be made to the present invention without deviating from its scope. Although the invention has been shown and described in what is conceived to be the most practical and preferred embodiment, it is recognized that departures may be made therefrom within the scope and spirit of the invention, which is not to be limited to the details disclosed herein but is to be accorded the full scope of the claims so as to embrace any and all equivalent devices and apparatus.

In any claims that follow and in the summary of the invention, except where the context requires otherwise due to express language or necessary implication, the word "comprising" is used in the sense of "including", i.e. the features specified may be associated with further features in various embodiments of the invention.

CLAIMS

1) A pathway system for generating management guidelines for service providers within each setting of a service episode, said pathway system characterised by:
a procedures database adapted to store predefined templates relating to each procedure within each service setting;
an alerts database adapted to store predefined templates relating to service recipient alerts that require each procedure to be modified;
a means of modifying said procedural templates to account for one or more service plan factors that require said procedure to be modified;
a means of modifying said alert templates to account for said one or more service plan factors; and
a means of integrating said procedural and alert templates to provide a final management guideline for each setting that is accessible by each service provider.

2) A pathway system as characterised in claim 1 wherein said one or more service plan factors includes a procedural preference of an institution in which said service episode is being carried out.

3) A pathway system as characterised in claim 1 or claim 2 wherein said one or more service plan factors includes a procedural preference of the service provider.

4) A pathway system as characterised in any one of the above claims wherein said pathway system further includes a conflict resolution database adapted to store rules which define the required procedure for when two or more service recipient alert templates are required for a particular setting.

5) A pathway system as characterised in claims 1-4 wherein said one or more service plan factor preferences can be modified at any time during the service episode.

6) A management guideline generated by the pathway system of any one of claims 1-5.

7) A clinical pathway system for generating management guidelines for healthcare providers within each setting of an episode of care, said clinical pathway system characterised by:
a procedures database adapted to store predefined templates relating to each procedure

within each service setting;

an alerts database adapted to store predefined templates relating to patient alerts that require said procedure to be modified;

a means of modifying said procedural templates to account for one or more care plan factors that require said procedure to be modified;

a means of modifying said alert templates to account for said one or more care plan factors; and

a means of integrating said procedural and alert templates to provide final management guidelines for each setting that are accessible by each healthcare provider.

8) A clinical pathway system as characterised in claim 7 wherein said one or more care plan factors includes a procedural preference of a healthcare institution in which said service episode is being carried out.

9) A clinical pathway system as characterised in claim 8 wherein said service settings include preadmission, admission, theatre, recovery, ward and discharge.

10) A clinical pathway system as characterised in any one of claims 7-9 wherein said one or more care plan factors includes a procedural preference of the healthcare provider.

11) A clinical pathway system as characterised in any one of claims 7-10 wherein said clinical pathway system further includes a conflict resolution database adapted to store rules which define the required procedure for when two or more patient alert templates are required in a particular setting.

12) A clinical pathway system as characterised in any one of claims 7-11 wherein said one or more care plan factor preferences can be modified at any time during the episode of care.

13) A clinical pathway system generated by the clinical pathway system of claims 5-10.

14) A pathway system characterised by:

a service recipient;

a plurality of service settings required to complete a service episode;

a service provider for each setting;

a means of storing information relating to a usual procedure for each service setting;

a means of storing information relating to specific requirements of the service recipient for each service setting; and

a means of accessing a matrix of information derived from the above means of storing to form a single explicit management plan for use by each service provider in each setting.

15) A pathway system as characterised in claim 14 wherein said pathway system further includes a means of storing information relating to service plan factors that require modification to the usual procedure.

16) A pathway system as characterised in claim 15 wherein said pathway system further includes a means of modifying said specific service recipient requirements and said service plan factor information at any time during the service episode.

17) A management plan formed by the pathway system of claims 14-16

18) A clinical pathway system characterised by:
a treating institution;
a patient undergoing an episode of care in a plurality of different settings;
a treating practitioner for each setting;
a means of storing information relating to a usual procedure for each setting;
a means of storing information relating to specific preferences of the treating practitioner;
a means of storing information relating to specific preferences of the treating institution;
a means of storing information relating to specific alerts of the patient to be treated;
a means of accessing a matrix of information derived from the above storage means to form a single explicit management plan for use by treating practitioners within each setting.

19) A pathway system as characterised in claim 18 wherein said clinical pathway system further includes a means of modifying said specific preferences at any time during the service episode.

20) A clinical pathway system formed by the clinical pathway system of claim 18 or claim 19.

21) A method for generating a single, explicit clinical pathway guideline for a healthcare setting in an episode of care, said method characterised by the steps of:
a) creating a basic template which describes how care is normally provided for a particular procedure in a particular healthcare setting;
b) incorporating at least one care plan factor guideline into said basic template;

c) incorporating at least one alert guideline into said basic template;

d) modifying said care plan factor guidelines and alert guidelines to account for requirements of a healthcare institution, thereby creating an institution template;

e) modifying said care plan factor guidelines and alert guidelines to account for requirements of a healthcare provider, thereby creating a provider template; and

f) integrating said modified care plan factor and alert guidelines to thereby create a final guideline for care within said particular healthcare setting.

22) A method for generating clinical pathway guidelines as characterised in claim 21 wherein said steps (d) and (e) are interchangeable.

23) A method for generating clinical pathway guidelines as characterised in claim 21 or claim 22 wherein said method includes the further step of resolving any conflicts between multiple alert guidelines in accordance with predefined rules.

24) A guideline for care generated by the method of claims 21-23.

25) A pathway guideline generated by the systems and method of any one of claims 1-24 wherein said guideline is presented in either electronic or paper based format.

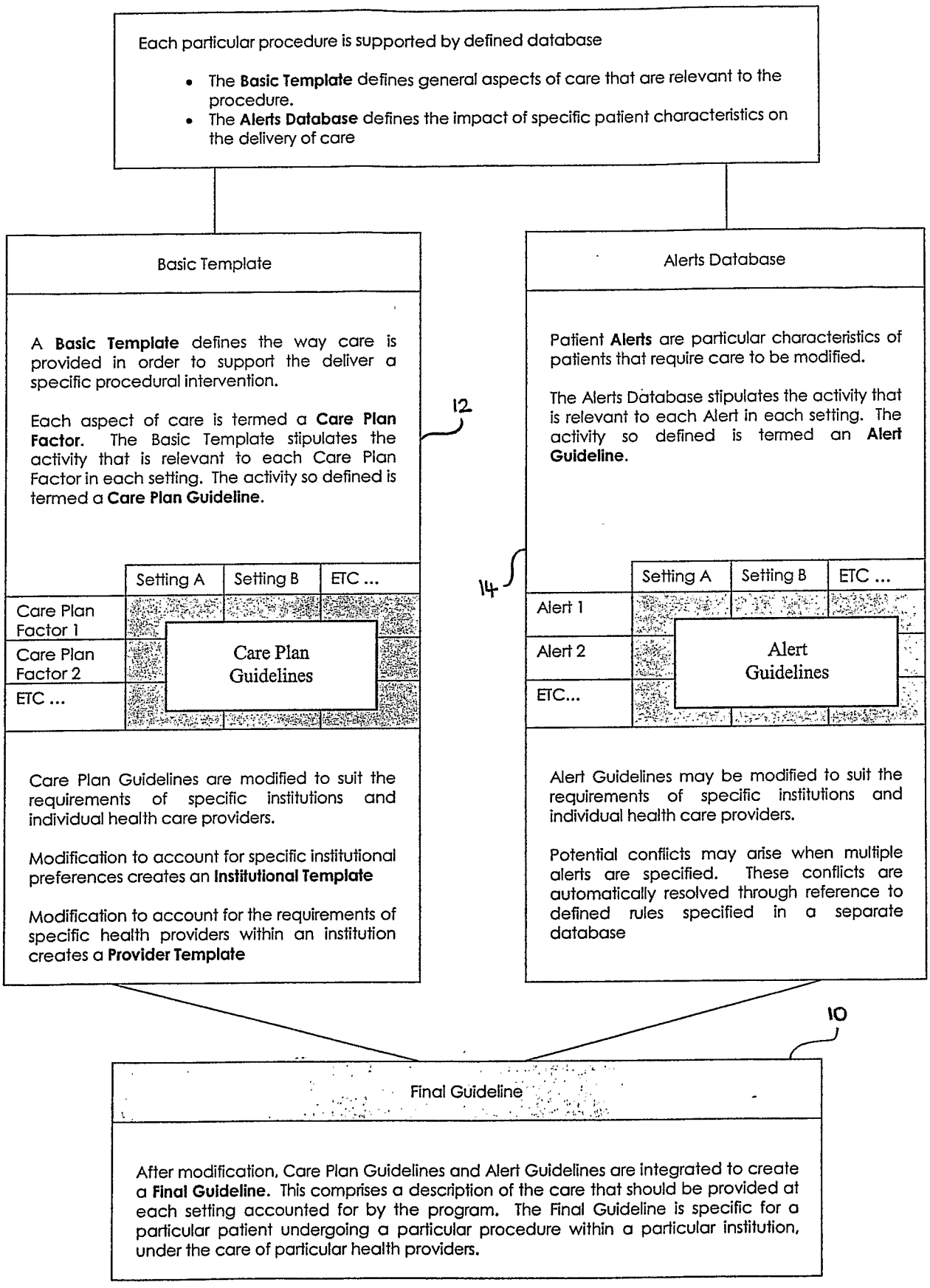

Each particular procedure is supported by defined database
The Basic Template defines general aspects of care that are relevant to the procedure.
The Alerts Database defines the impact of specific patient characteristics on the delivery of care
Basic Template
A Basic Template defines the way care is provided in order to support the deliver a specific procedural intervention.
Each aspect of care is termed a Care Plan Factor. The Basic Template stipulates the activity that is relevant to each Care Plan Factor in each setting. The activity so defined is termed a Care Plan Guideline.
12
Setting A
Setting B
ETC ...
Care Plan Factor 1
Care Plan Factor 2
ETC ...
Care Plan Guidelines
Care Plan Guidelines are modified to suit the requirements of specific institutions and individual health care providers.
Modification to account for specific institutional preferences creates an Institutional Template
Modification to account for the requirements of specific health providers within an institution creates a Provider Template
Alerts Database
Patient Alerts are particular characteristics of patients that require care to be modified.
The Alerts Database stipulates the activity that is relevant to each Alert in each setting. The activity so defined is termed an Alert Guideline.
14
Setting A
Setting B
ETC ...
Alert 1
Alert 2
ETC...
Alert Guidelines
Alert Guidelines may be modified to suit the requirements of specific institutions and individual health care providers.
Potential conflicts may arise when multiple alerts are specified. These conflicts are automatically resolved through reference to defined rules specified in a separate database
10
Final Guideline
After modification, Care Plan Guidelines and Alert Guidelines are integrated to create a Final Guideline. This comprises a description of the care that should be provided at each setting accounted for by the program. The Final Guideline is specific for a particular patient undergoing a particular procedure within a particular institution, under the care of particular health providers.

Fig 1

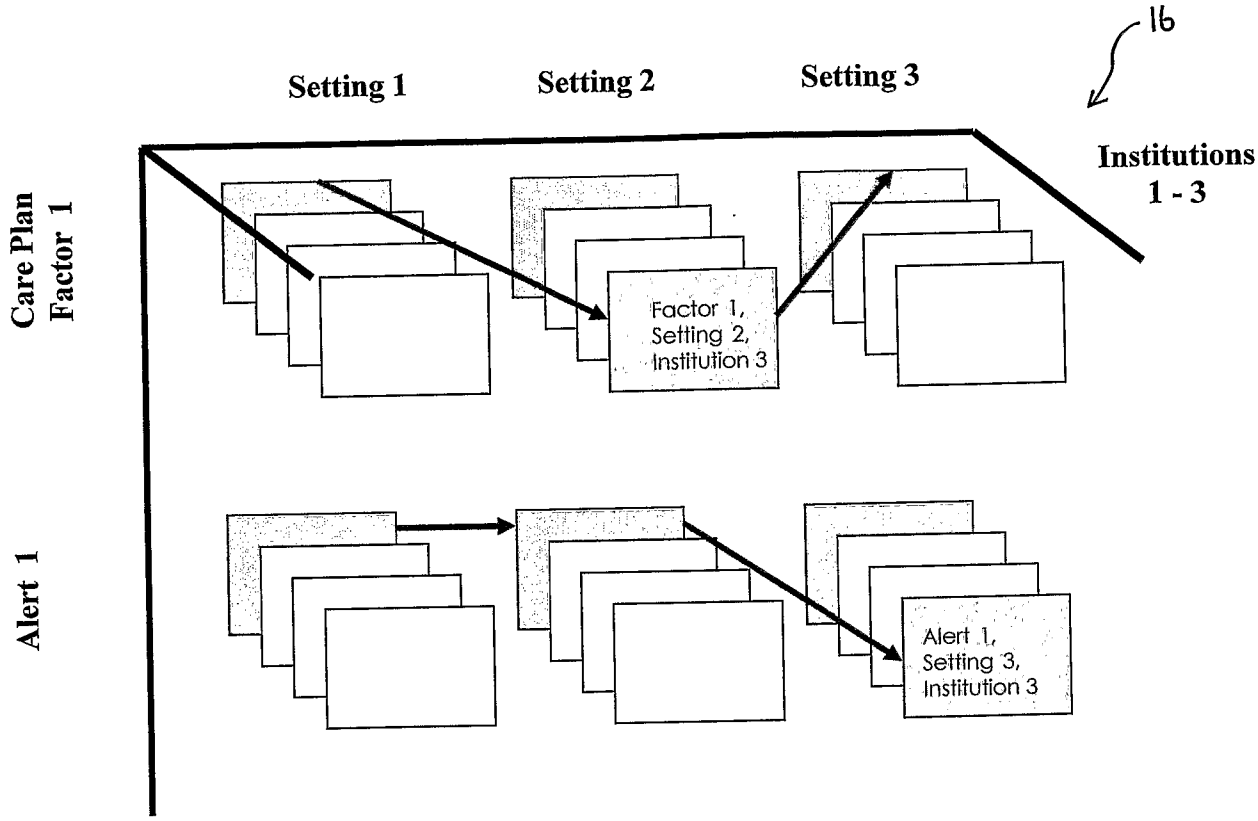

16
Setting 1
Setting 2
Setting 3
Institutions
1 - 3
Care Plan
Factor 1
Factor 1,
Setting 2,
Institution 3
Alert 1
Alert 1,
Setting 3,
Institution 3

Fig 2

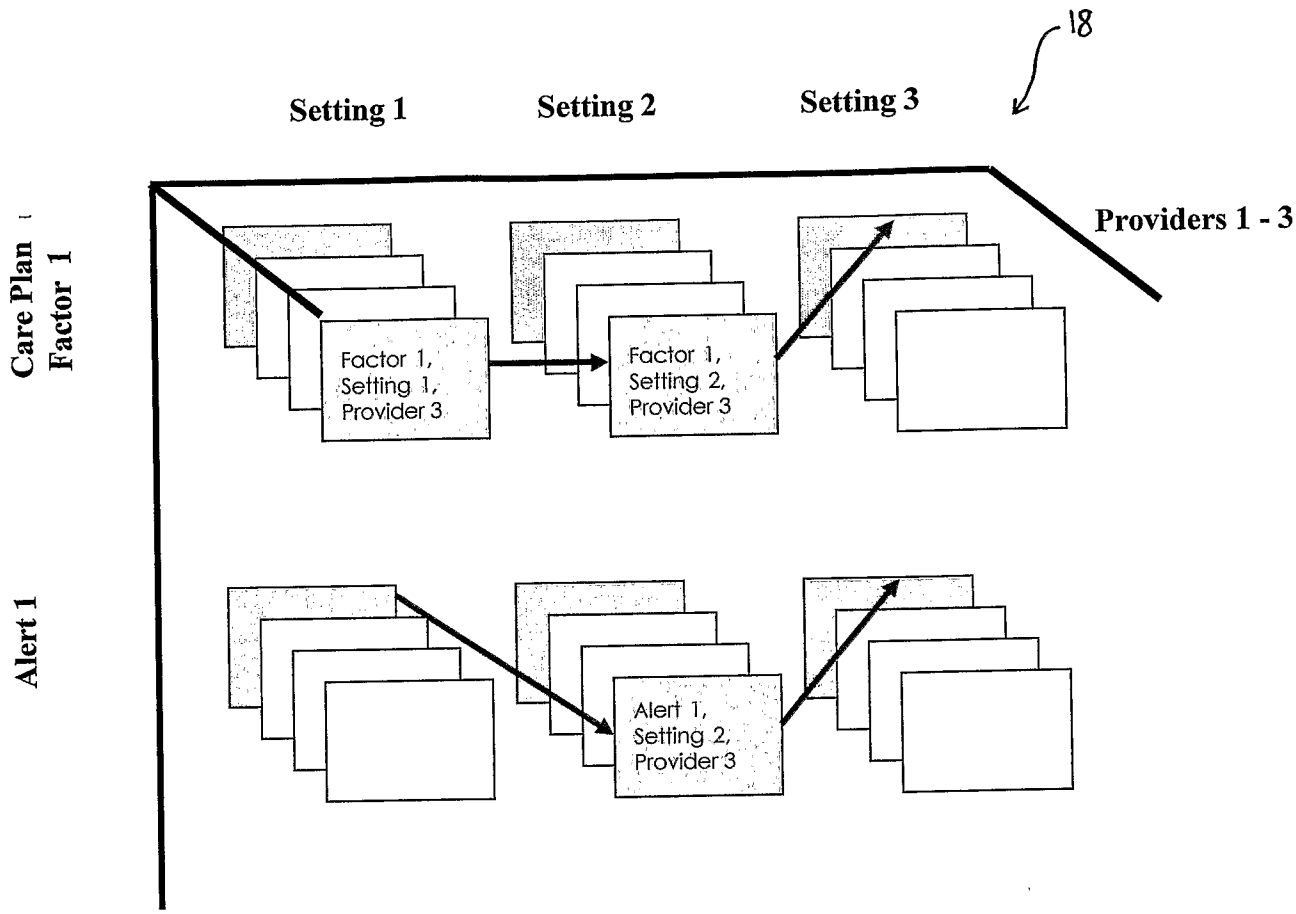

18
Setting 1
Setting 2
Setting 3
Providers 1 - 3
Care Plan Factor 1
Factor 1, Setting 1, Provider 3
Factor 1, Setting 2, Provider 3
Alert 1
Alert 1, Setting 2, Provider 3

Fig 3

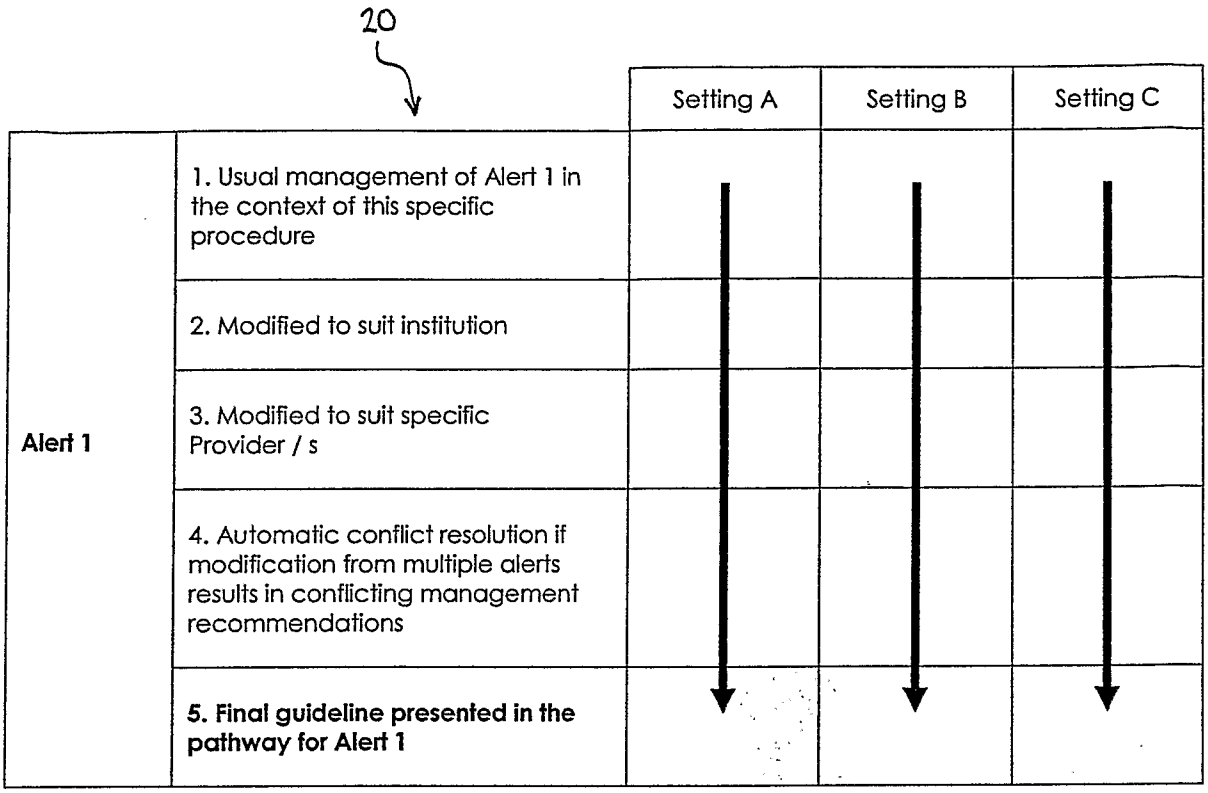

20
Setting A
Setting B
Setting C
Alert 1
1. Usual management of Alert 1 in the context of this specific procedure
2. Modified to suit institution
3. Modified to suit specific Provider / s
4. Automatic conflict resolution if modification from multiple alerts results in conflicting management recommendations
5. Final guideline presented in the pathway for Alert 1

Fig 4

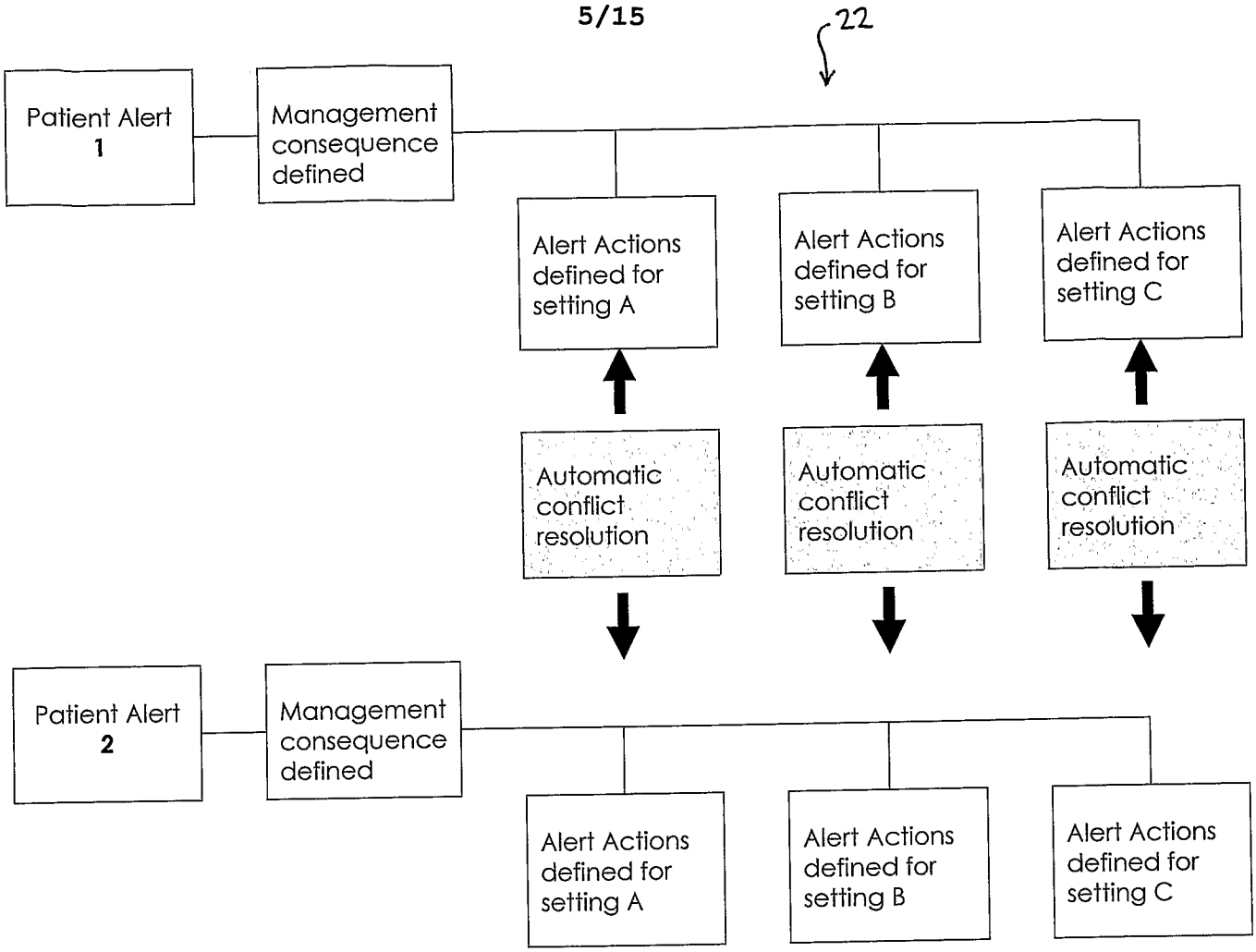
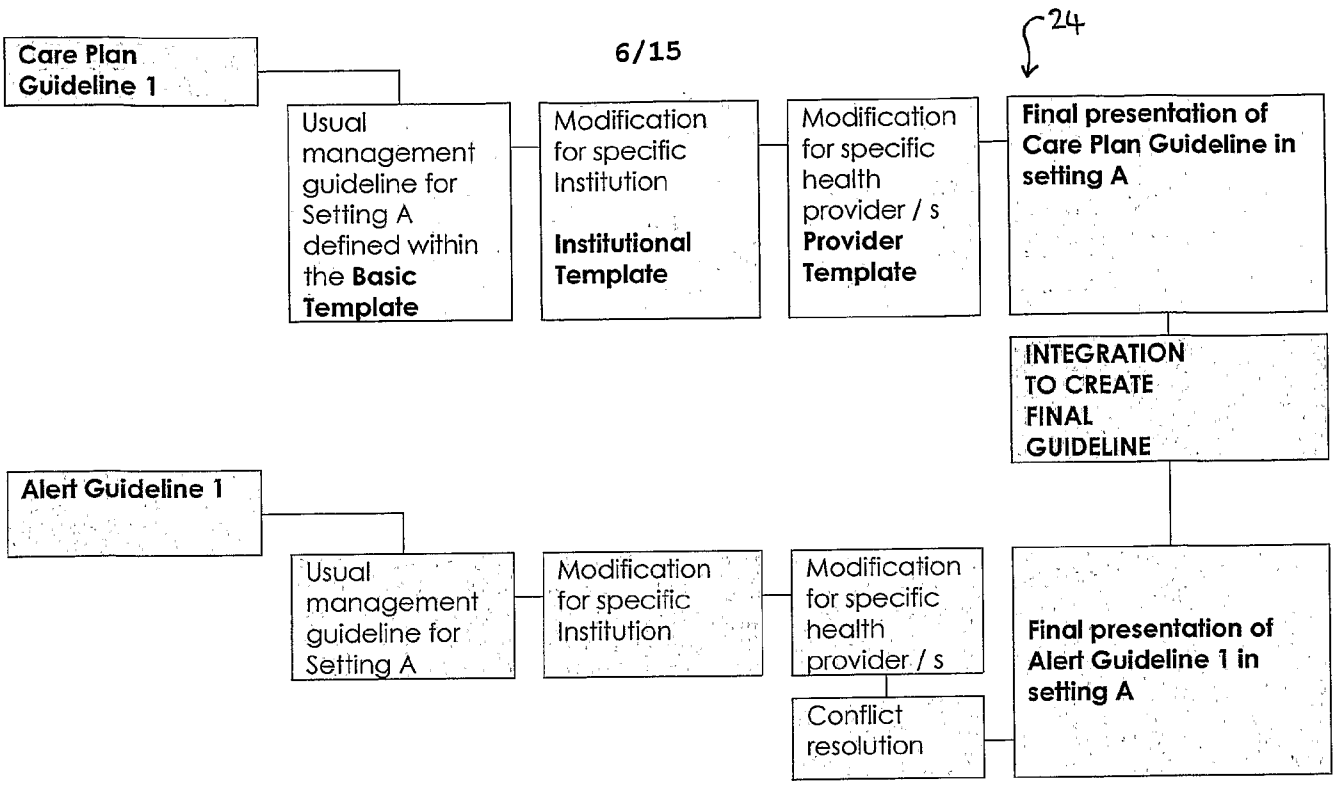

22
Patient Alert 1
Management consequence defined
Alert Actions defined for setting A
Alert Actions defined for setting B
Alert Actions defined for setting C
Automatic conflict resolution
Automatic conflict resolution
Automatic conflict resolution
Patient Alert 2
Management consequence defined
Alert Actions defined for setting A
Alert Actions defined for setting B
Alert Actions defined for setting C

Fig 5



ITEMS

Basic templates consist of a series of **Care Plan Guidelines**. Each Guideline describes how a particular Care Plan Factor is managed in each setting defined within the program

Alert guidelines may be added to a template. This allows care to be modified to suit the characteristics of each individual patient

BASIC TEMPLATES

The basic template describes how care is normally provided for a specific procedure. Every individual procedure is defined by a unique basic template.

Care Plan Factors and Alert Guidelines are specifically defined for every **Basic Template.**

MODIFICATION FOR INSTITUTION

The usual activity specified by both Care Plan Factors and Alert Guidelines is modified to suit the specific requirements of each individual institution.

This modification creates an **Institutional Template**

MODIFICATION FOR PROVIDER PREFERENCE

The usual activity specified by both Care Plan Factors and Alert Guidelines is modified to suit the specific requirements of each individual health care provider within the institution.

This modification creates a **Provider Template**

INTEGRATION CONFLICT RESOLUTION AND PRESENTATION

Conflicts that potentially arise from multiple alerts are automatically resolved.

The resulting guidelines are integrated and presented for each setting. This creates the **Final Guideline**

Fig 6

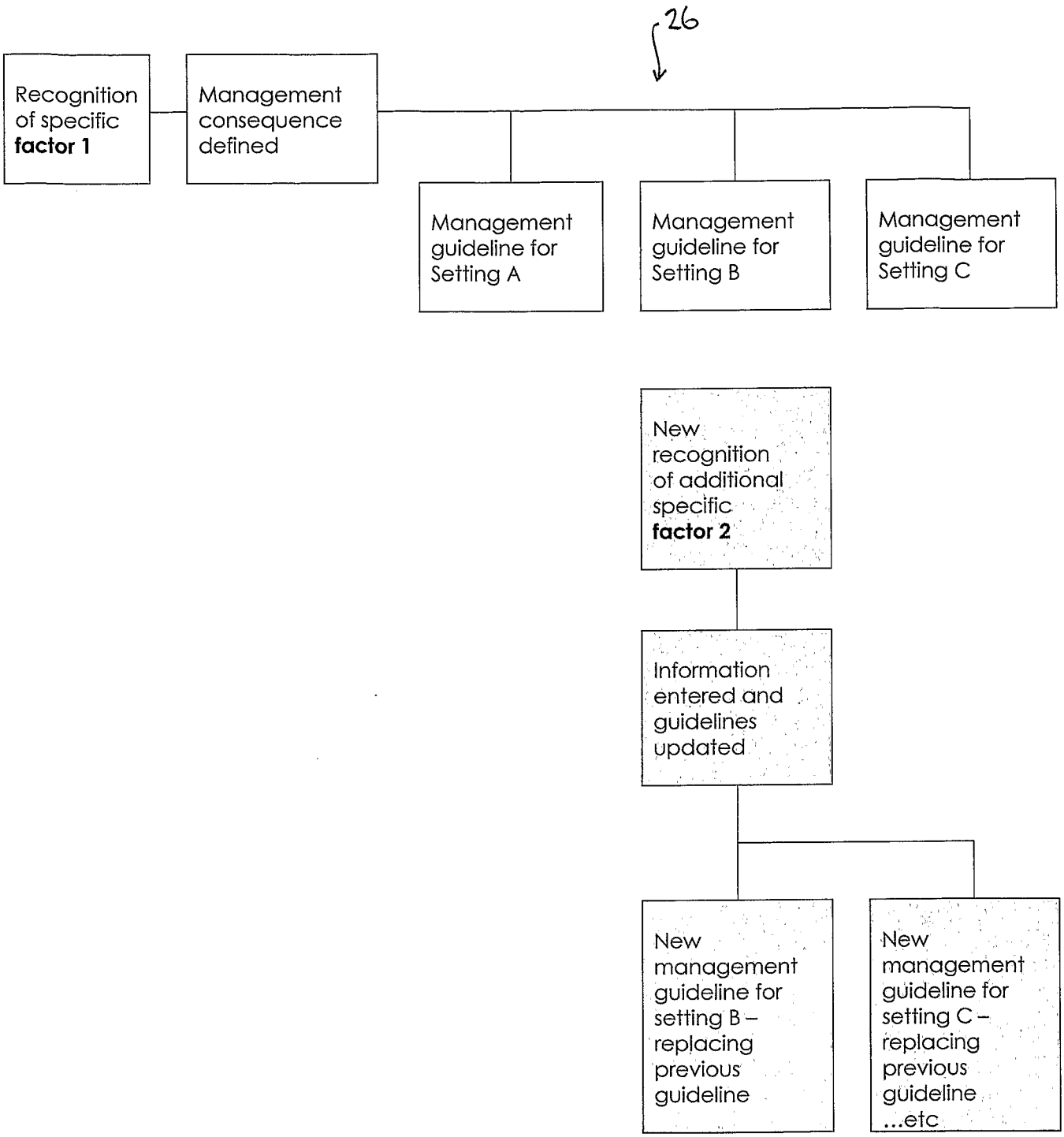

26
Recognition of specific **factor 1**
Management consequence defined
Management guideline for Setting A
Management guideline for Setting B
Management guideline for Setting C
New recognition of additional specific **factor 2**
Information entered and guidelines updated
New management guideline for setting B – replacing previous guideline
New management guideline for setting C – replacing previous guideline ...etc

Fig 7

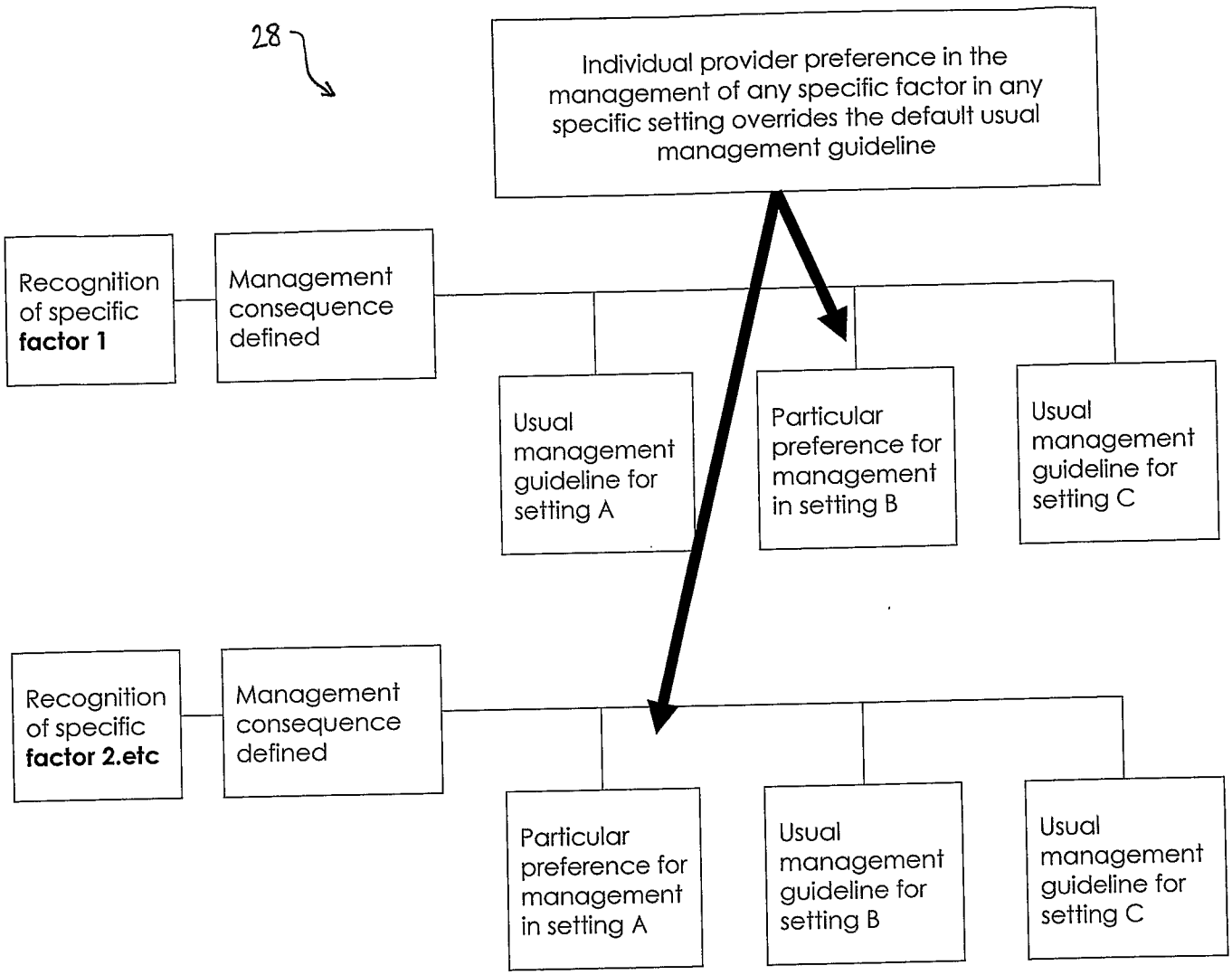

28
Individual provider preference in the management of any specific factor in any specific setting overrides the default usual management guideline
Recognition of specific **factor 1**
Management consequence defined
Usual management guideline for setting A
Particular preference for management in setting B
Usual management guideline for setting C
Recognition of specific **factor 2.etc**
Management consequence defined
Particular preference for management in setting A
Usual management guideline for setting B
Usual management guideline for setting C

Fig 8

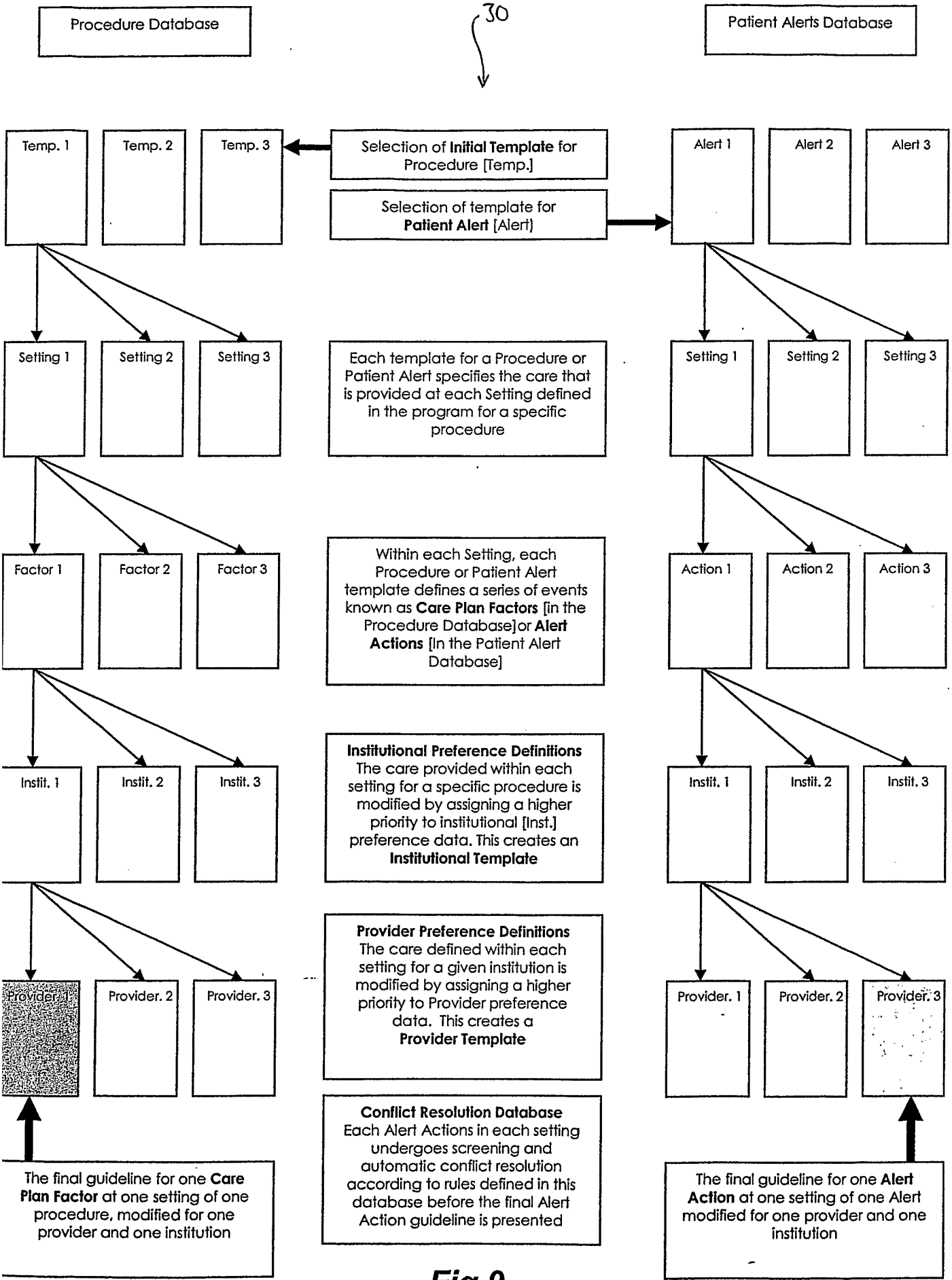

Procedure Database
30
Patient Alerts Database
Temp. 1
Temp. 2
Temp. 3
Selection of Initial Template for Procedure [Temp.]
Selection of template for Patient Alert [Alert]
Alert 1
Alert 2
Alert 3
Setting 1
Setting 2
Setting 3
Each template for a Procedure or Patient Alert specifies the care that is provided at each Setting defined in the program for a specific procedure
Setting 1
Setting 2
Setting 3
Factor 1
Factor 2
Factor 3
Within each Setting, each Procedure or Patient Alert template defines a series of events known as Care Plan Factors [in the Procedure Database]or Alert Actions [In the Patient Alert Database]
Action 1
Action 2
Action 3
Instit. 1
Instit. 2
Instit. 3
Institutional Preference Definitions
The care provided within each setting for a specific procedure is modified by assigning a higher priority to institutional [Inst.] preference data. This creates an Institutional Template
Instit. 1
Instit. 2
Instit. 3
Provider. 1
Provider. 2
Provider. 3
Provider Preference Definitions
The care defined within each setting for a given institution is modified by assigning a higher priority to Provider preference data. This creates a Provider Template
Provider. 1
Provider. 2
Provider. 3
Conflict Resolution Database
Each Alert Actions in each setting undergoes screening and automatic conflict resolution according to rules defined in this database before the final Alert Action guideline is presented
The final guideline for one Care Plan Factor at one setting of one procedure, modified for one provider and one institution
The final guideline for one Alert Action at one setting of one Alert modified for one provider and one institution

Fig 9

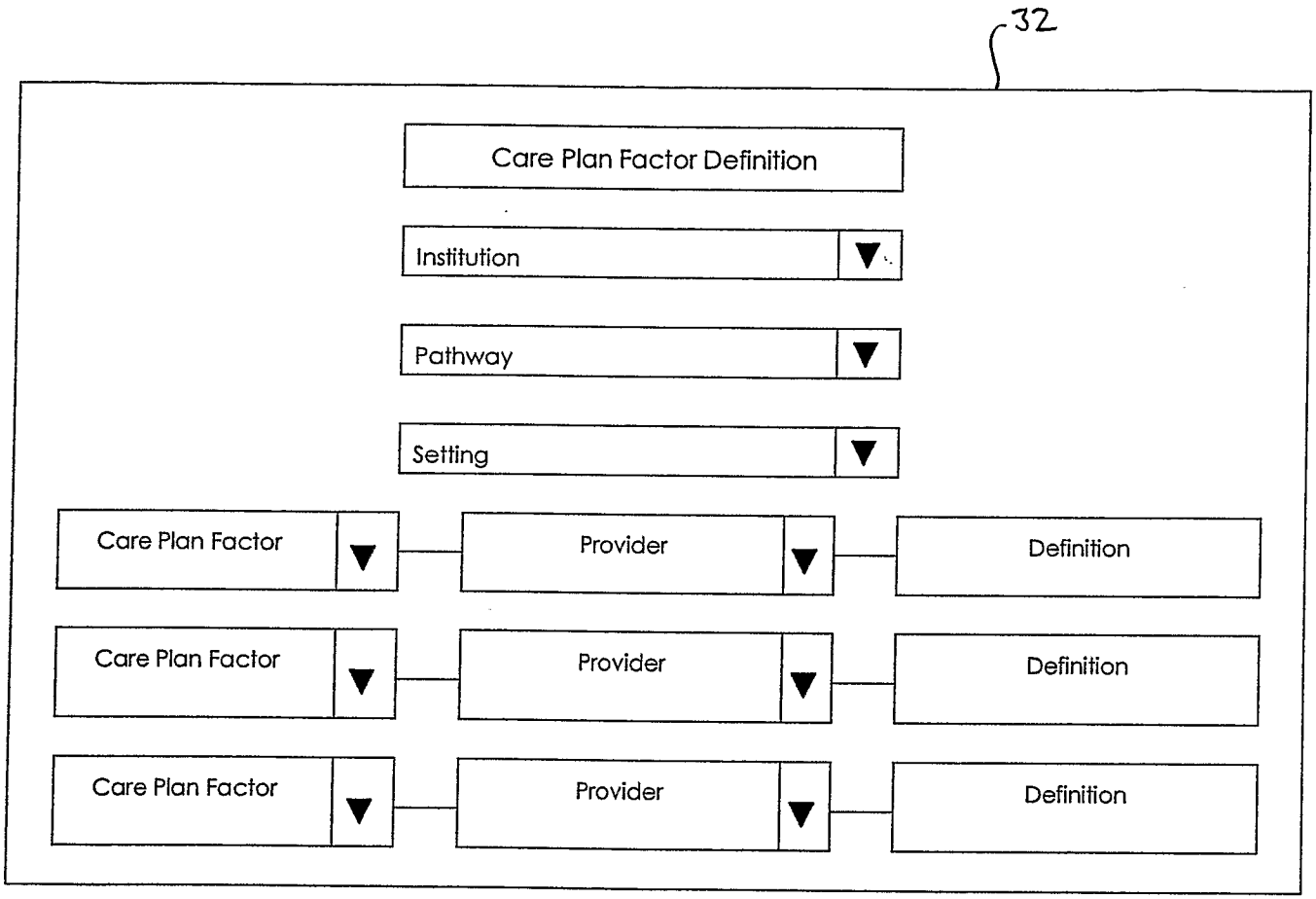

32
Care Plan Factor Definition
Institution
Pathway
Setting
Care Plan Factor
Provider
Definition
Care Plan Factor
Provider
Definition
Care Plan Factor
Provider
Definition

Fig 10

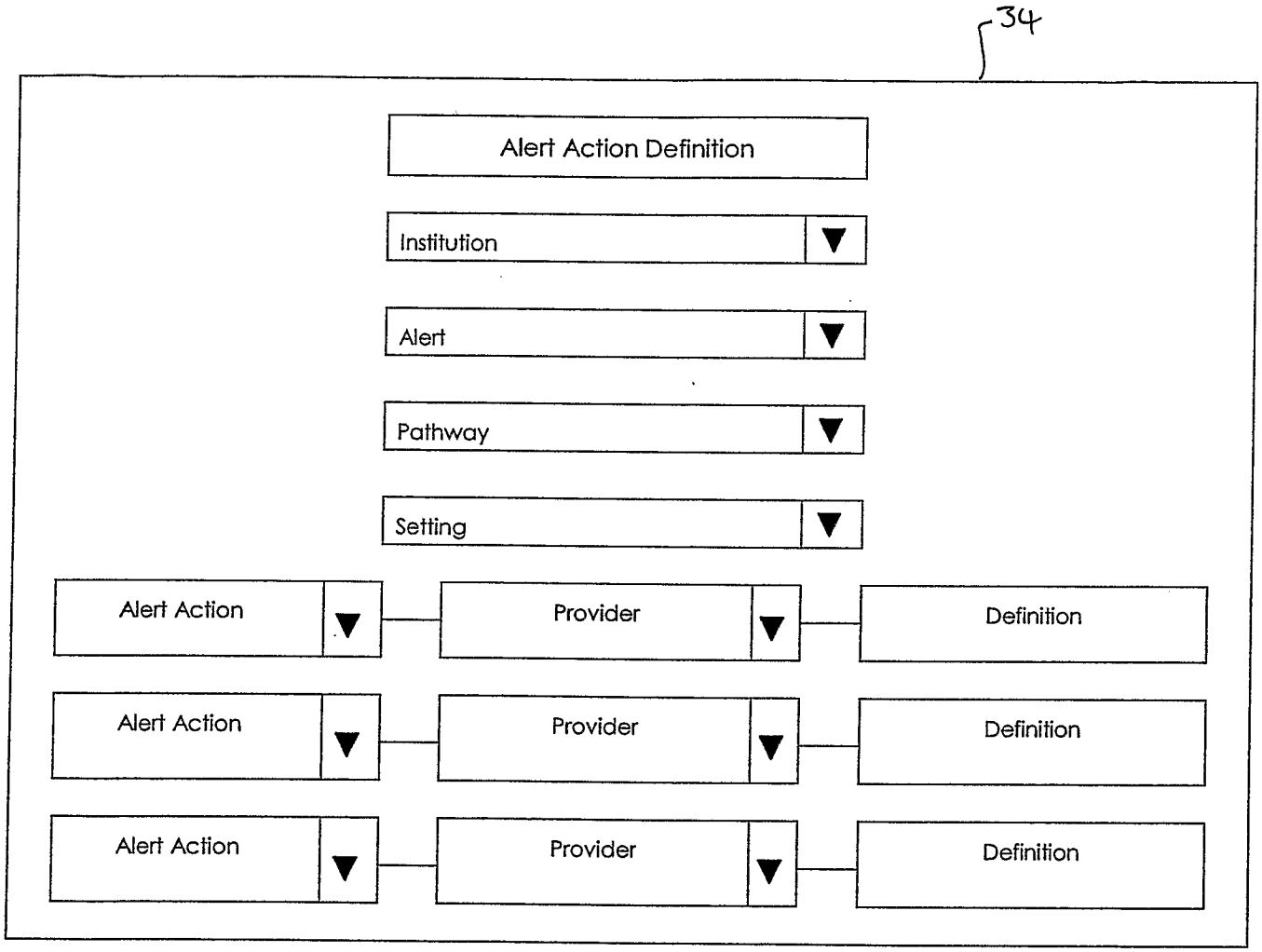

34
Alert Action Definition
Institution
Alert
Pathway
Setting
Alert Action
Provider
Definition
Alert Action
Provider
Definition
Alert Action
Provider
Definition

Fig 11

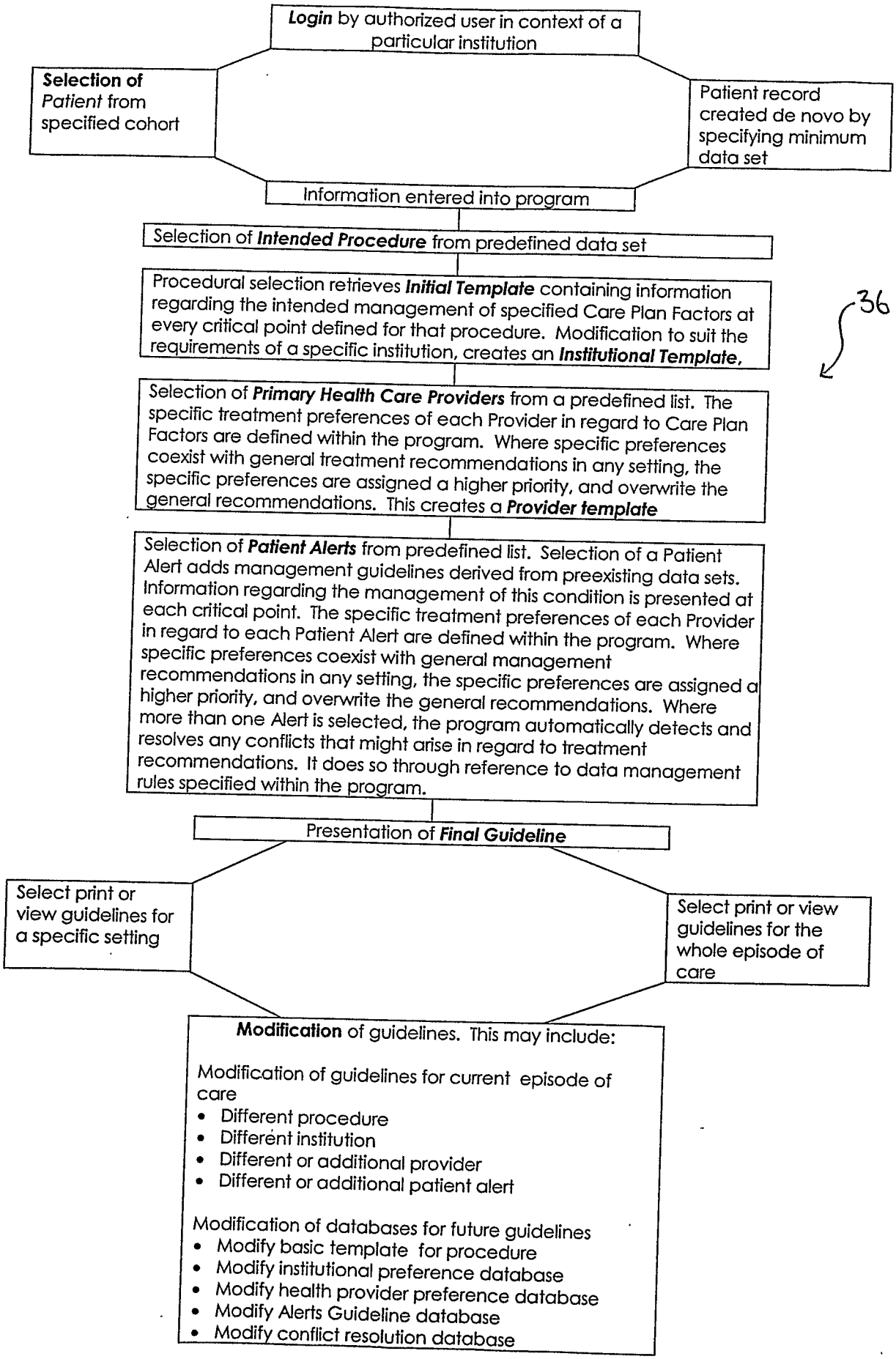

Login by authorized user in context of a particular institution
Selection of *Patient* from specified cohort
Patient record created de novo by specifying minimum data set
Information entered into program
Selection of ***Intended Procedure*** from predefined data set
Procedural selection retrieves ***Initial Template*** containing information regarding the intended management of specified Care Plan Factors at every critical point defined for that procedure. Modification to suit the requirements of a specific institution, creates an ***Institutional Template.***
36
Selection of ***Primary Health Care Providers*** from a predefined list. The specific treatment preferences of each Provider in regard to Care Plan Factors are defined within the program. Where specific preferences coexist with general treatment recommendations in any setting, the specific preferences are assigned a higher priority, and overwrite the general recommendations. This creates a ***Provider template***
Selection of ***Patient Alerts*** from predefined list. Selection of a Patient Alert adds management guidelines derived from preexisting data sets. Information regarding the management of this condition is presented at each critical point. The specific treatment preferences of each Provider in regard to each Patient Alert are defined within the program. Where specific preferences coexist with general management recommendations in any setting, the specific preferences are assigned a higher priority, and overwrite the general recommendations. Where more than one Alert is selected, the program automatically detects and resolves any conflicts that might arise in regard to treatment recommendations. It does so through reference to data management rules specified within the program.
Presentation of ***Final Guideline***
Select print or view guidelines for a specific setting
Select print or view guidelines for the whole episode of care
Modification of guidelines. This may include:
Modification of guidelines for current episode of care
• Different procedure
• Different institution
• Different or additional provider
• Different or additional patient alert
Modification of databases for future guidelines
• Modify basic template for procedure
• Modify institutional preference database
• Modify health provider preference database
• Modify Alerts Guideline database
• Modify conflict resolution database

Fig 12

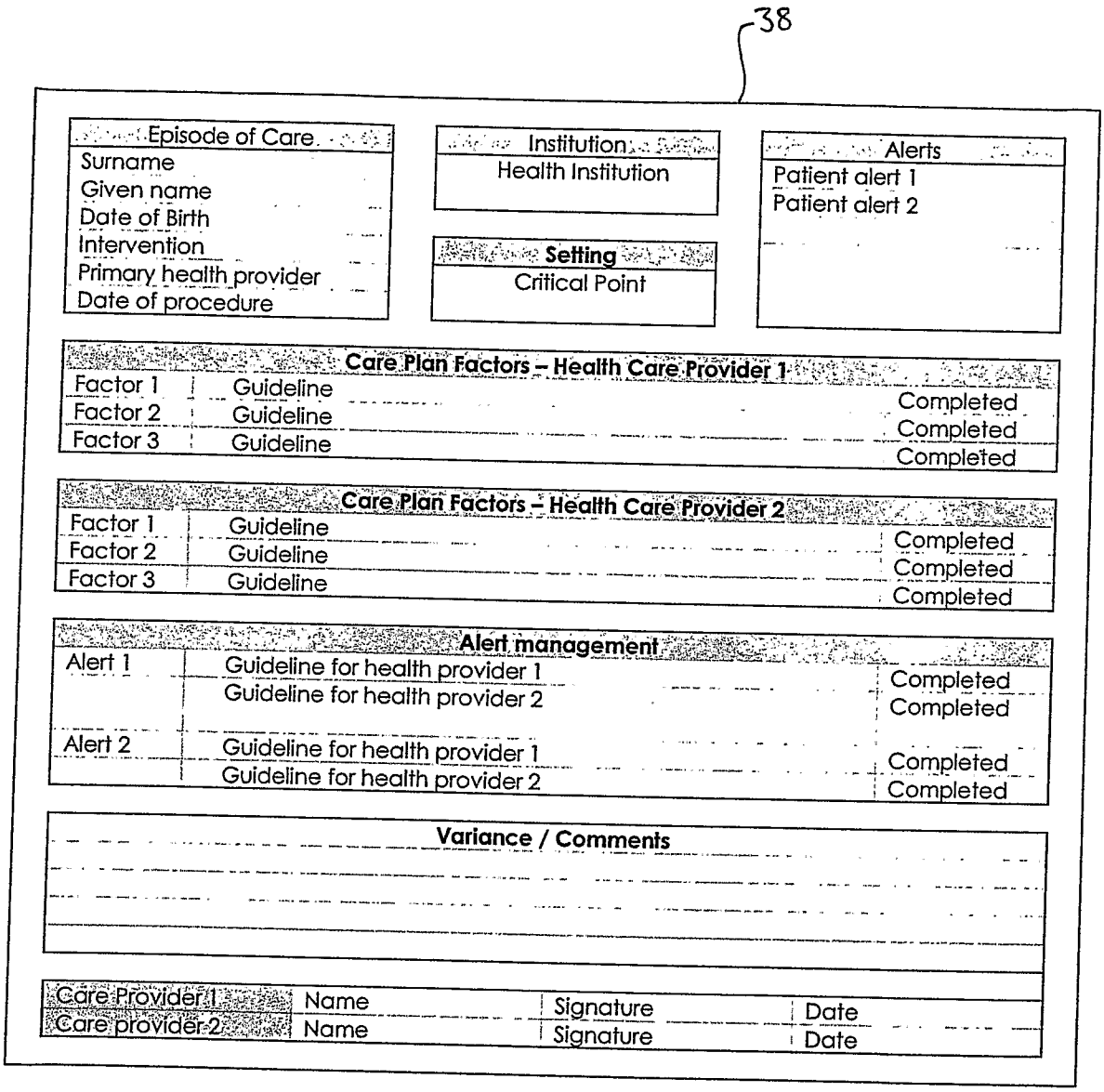

38
Episode of Care
Surname
Given name
Date of Birth
Intervention
Primary health provider
Date of procedure
Institution
Health Institution
Setting
Critical Point
Alerts
Patient alert 1
Patient alert 2
Care Plan Factors – Health Care Provider 1
Factor 1 Guideline Completed
Factor 2 Guideline Completed
Factor 3 Guideline Completed
Care Plan Factors – Health Care Provider 2
Factor 1 Guideline Completed
Factor 2 Guideline Completed
Factor 3 Guideline Completed
Alert management
Alert 1 Guideline for health provider 1 Completed
Guideline for health provider 2 Completed
Alert 2 Guideline for health provider 1 Completed
Guideline for health provider 2 Completed
Variance / Comments
Care Provider 1 Name Signature Date
Care provider 2 Name Signature Date

Fig 13

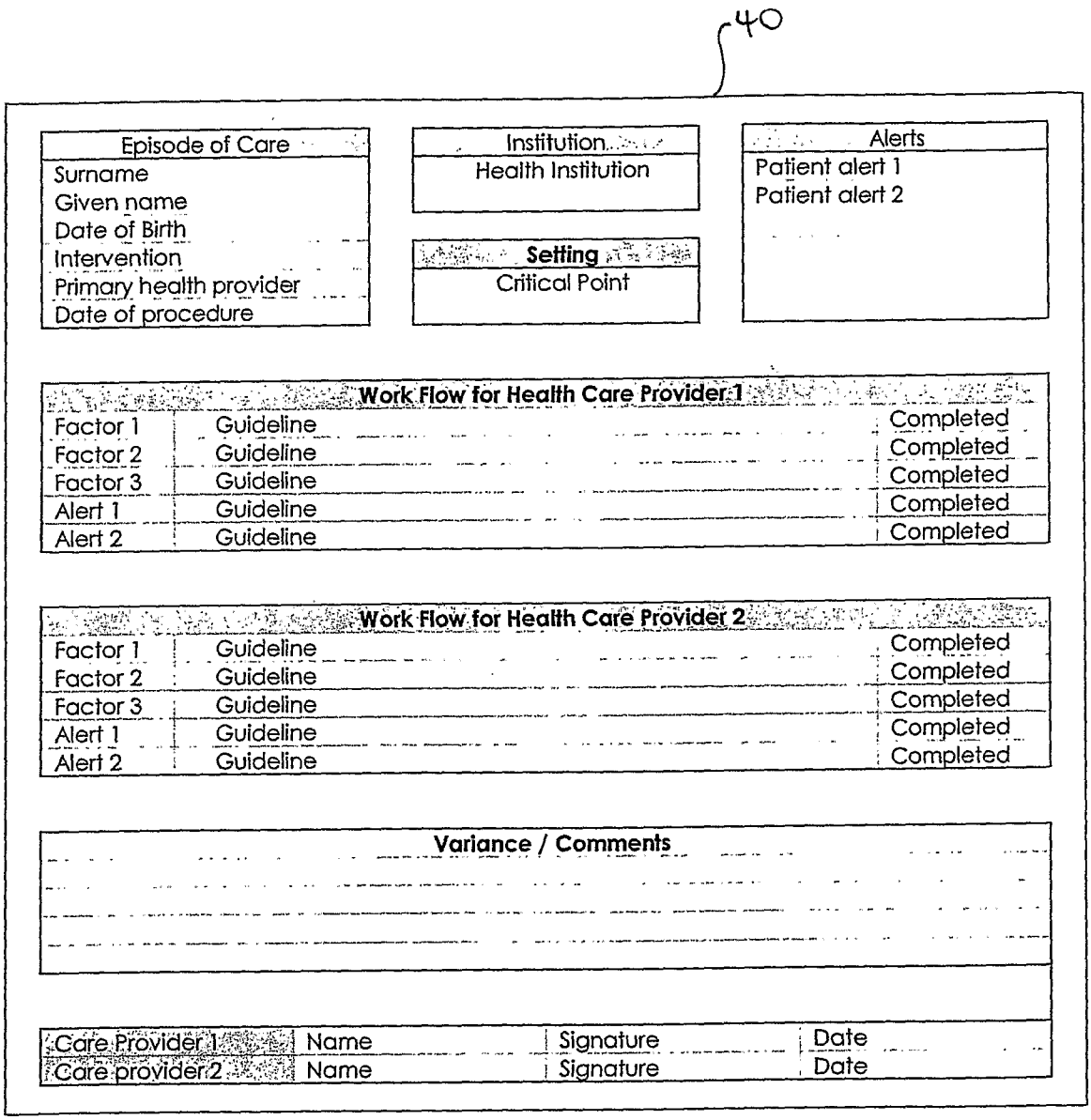

40
Episode of Care
Surname
Given name
Date of Birth
Intervention
Primary health provider
Date of procedure
Institution
Health Institution
Setting
Critical Point
Alerts
Patient alert 1
Patient alert 2
Work Flow for Health Care Provider 1
Factor 1 Guideline Completed
Factor 2 Guideline Completed
Factor 3 Guideline Completed
Alert 1 Guideline Completed
Alert 2 Guideline Completed
Work Flow for Health Care Provider 2
Factor 1 Guideline Completed
Factor 2 Guideline Completed
Factor 3 Guideline Completed
Alert 1 Guideline Completed
Alert 2 Guideline Completed
Variance / Comments
Care Provider 1 Name Signature Date
Care provider 2 Name Signature Date

Fig 14

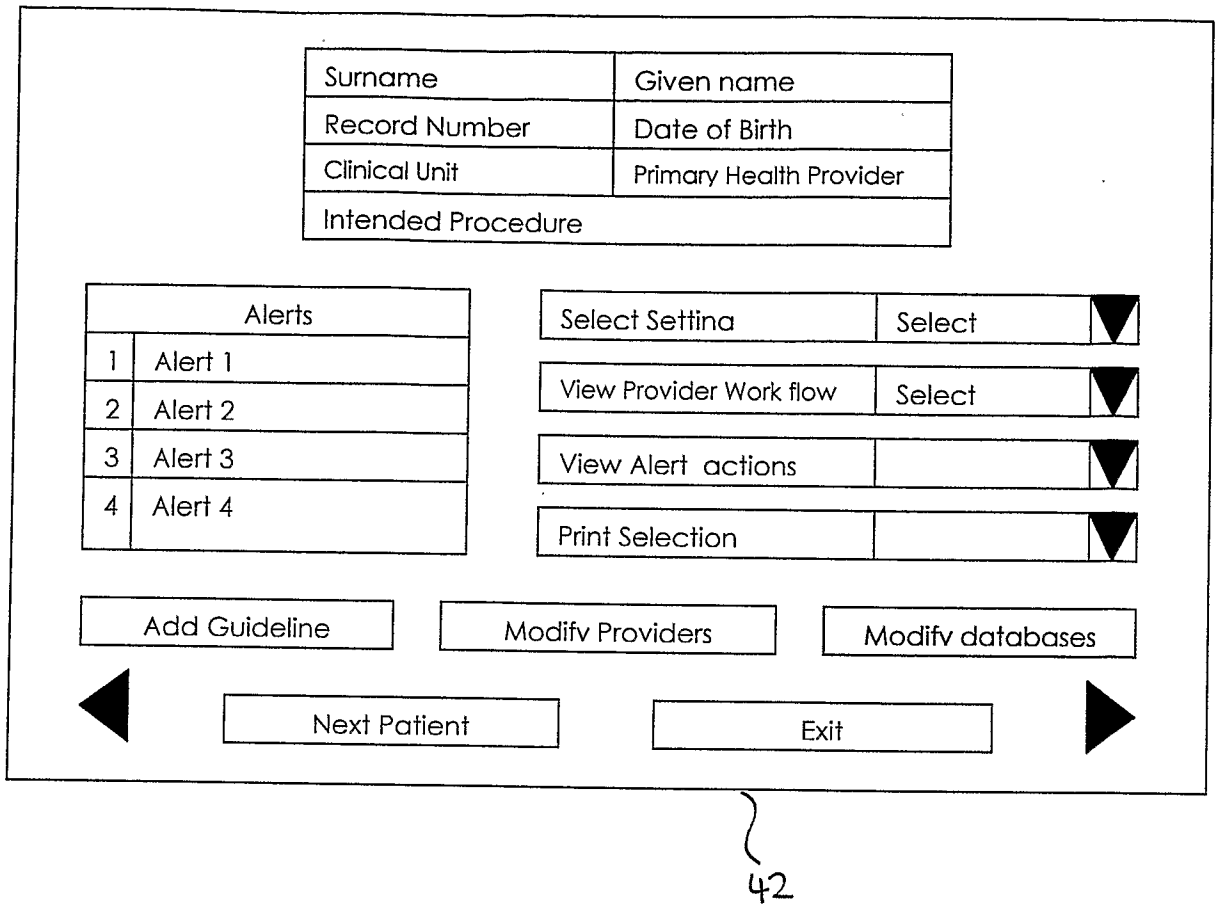

Surname
Given name
Record Number
Date of Birth
Clinical Unit
Primary Health Provider
Intended Procedure
Alerts
1 Alert 1
2 Alert 2
3 Alert 3
4 Alert 4
Select Settina
Select
View Provider Work flow
Select
View Alert actions
Print Selection
Add Guideline
Modifv Providers
Modifv databases
Next Patient
Exit
42

Fig 15

INTERNATIONAL SEARCH REPORT

International application No.
PCT/AU2008/000983

A. CLASSIFICATION OF SUBJECT MATTER

Int. Cl.

G06F 17/50 (2006.01) ***G06F 17/30*** (2006.01)

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)
EPODOC, WPI, G06 and Key words (Health, medical, clinic, guideline, protocol, checklist, template computer, system, treatment)

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US 2003/0014279 A1 (LINDA et al) 16 January 2003 See Abstract, Figs 2-5, Page 1 Paras 0008 – 0009, Para 0033, Para 0036, Paras 0037- 0038 and Paras 0042 and 0043.	1-3, 5-10, 12-22, 24-25
X	WO 1998/050871 A1 (CLINICOMP INTERNATIONAL, INC) 12 November 1998 See Abstract, Page 2 Para 1-2, Para 5, Page 6 Para 2.	1-3, 5-10, 12-22, 24-25
A	WO 2002/041231 A2 (THE JOHN HOPKINS UNIVERSITY) 23 May 2002 See Abstract lines 1- 4 , Para 0006 lines 1-5, Para 0008 – 0009, Para 0020	

☐ Further documents are listed in the continuation of Box C ☒ See patent family annex

* Special categories of cited documents:

"A" document defining the general state of the art which is not considered to be of particular relevance

"E" earlier application or patent but published on or after the international filing date

"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)

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"P" document published prior to the international filing date but later than the priority date claimed

"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone

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Date of the actual completion of the international search	Date of mailing of the international search report
15 September 2008	18 SEP 2008
Name and mailing address of the ISA/AU AUSTRALIAN PATENT OFFICE PO BOX 200, WODEN ACT 2606, AUSTRALIA E-mail address: pct@ipaustralia.gov.au Facsimile No. +61 2 6283 7999	Authorized officer **XAVIER SIMON** AUSTRALIAN PATENT OFFICE (ISO 9001 Quality Certified Service) Telephone No : +61 2 6283 2623

INTERNATIONAL SEARCH REPORT

Information on patent family members

International application No.
PCT/AU2008/000983

This Annex lists the known "A" publication level patent family members relating to the patent documents cited in the above-mentioned international search report. The Australian Patent Office is in no way liable for these particulars which are merely given for the purpose of information.

Patent Document Cited in Search Report		Patent Family Member					
US	2003014279						
WO	9850871	AU	57456/00	AU	61100/98	AU	65071/96
		AU	90146/98	CA	2213997	EP	0812441
		US	5946659	US	6401072	US	6434531
		US	6665647	WO	0101321	WO	9627163
		WO	9906936				
WO	0241231	AU	32419/02	US	2004039602		

Due to data integration issues this family listing may not include 10 digit Australian applications filed since May 2001.

END OF ANNEX