

(19) World Intellectual Property Organization
International Bureau



(43) International Publication Date
24 December 2003 (24.12.2003)

PCT

(10) International Publication Number
WO 03/107250 A2

(51) International Patent Classification⁷: **G06F 19/00**, 17/60

(21) International Application Number: PCT/US03/15447

(22) International Filing Date: 16 May 2003 (16.05.2003)

(25) Filing Language: English

(26) Publication Language: English

(30) Priority Data:
60/381,191 16 May 2002 (16.05.2002) US

(71) Applicant and

(72) Inventor: **Morre, Gordon, T.** [US/US]; 9 Rutland, Street, Cambridge, MA 02138 (US).

(74) Agent: **SMITH, James, M.**; HAMILTON, BROOK, SMITH & REYNOLDS, P.C., 530 Virginia Road, P.O. Box 9133, Concord, MA 01742-9133 (US).

(81) Designated States (*national*): AE, AG, AL, AM, AT, AU, AZ, BA, BB, BG, BR, BY, BZ, CA, CH, CN, CO, CR, CU, CZ, DE, DK, DM, DZ, EC, EE, ES, FI, GB, GD, GE, GH, GM, HR, HU, ID, IL, IN, IS, JP, KE, KG, KP, KR, KZ, LC, LK, LR, LS, LT, LU, LV, MA, MD, MG, MK, MN, MW, MX, MZ, NI, NO, NZ, OM, PH, PL, PT, RO, RU, SC, SD, SE, SG, SK, SL, TJ, TM, TN, TR, TT, TZ, UA, UG, US, UZ, VC, VN, YU, ZA, ZM, ZW.

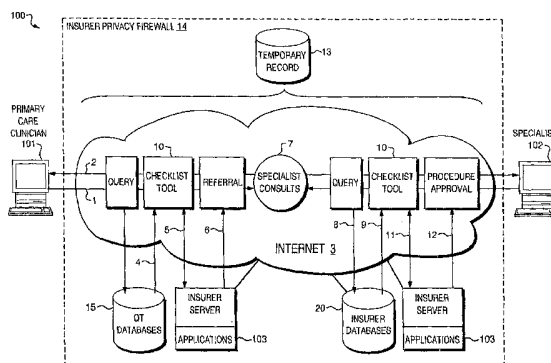
(84) Designated States (*regional*): ARIPO patent (GH, GM, KE, LS, MW, MZ, SD, SL, SZ, TZ, UG, ZM, ZW), Eurasian patent (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM), European patent (AT, BE, BG, CH, CY, CZ, DE, DK, EE, ES, FI, FR, GB, GR, HU, IE, IT, LU, MC, NL, PT, RO, SE, SI, SK, TR), OAPI patent (BF, BJ, CF, CG, CI, CM, GA, GN, GQ, GW, ML, MR, NE, SN, TD, TG).

Published:

— without international search report and to be republished upon receipt of that report

For two-letter codes and other abbreviations, refer to the "Guidance Notes on Codes and Abbreviations" appearing at the beginning of each regular issue of the PCT Gazette.

(54) Title: CHECKLIST-BASED FLOW AND TRACKING SYSTEM FOR PATIENT CARE BY MEDICAL PROVIDERS



(57) **Abstract:** Interactive methods and systems for directing, integrating, documenting, and tracking steps taken by medical providers during the process of care for a patient's given condition. Doctors' actions are directed by a prescriptive protocol - a checklist of discrete steps designed for efficient or optimal care of an individual patient's specific condition. The step-by-step checklist is abstracted from decision tree guidelines for the optimal work up and treatment for the condition using probability-based methodology. The care protocols can be derived from widely available and non-proprietary guidelines and decision trees based on public medical research literature. In one embodiment, the invention can be employed by a primary care clinician at the point of referral into the specialist sector, and at the specialist level when proposing a risky or expensive or otherwise problematic medical or surgical diagnostic or treatment intervention. At these two critical transaction points in care, the checklist functions like a lock, based on a hidden clinical decision algorithm (an explanation of which can be displayed upon request). The system asks the clinician for data and then generates the patient's optimal checklist, displaying it as a point and click form keyed to the stage of care being undertaken by each doctor. As the clinician enters data into the checklist, a decision engine determines whether the checklist data satisfies pre-determined criteria for authorization of the proposed action. The system can also document each transaction taken in the process of care to create an electronic record that can be made accessible to all clinicians involved in the process of care.

CHECKLIST-BASED FLOW AND TRACKING SYSTEM FOR PATIENT CARE
BY MEDICAL PROVIDERS

RELATED APPLICATION(S)

This application claims the benefit of U.S. Provisional Application No.
5 60/381,191, filed May 16, 2002, the entire teachings of which are incorporated
herein by reference.

BACKGROUND OF THE INVENTION

Medical care costs and quality are a serious problem facing America as well
as other developed countries. Globally, costs are rising rapidly. About 80-90% of
10 health care costs is for clinical services. It is widely documented, in reports such as
Crossing the Quality Chasm (IOM, 2001), that these services, in virtually all
countries, are inefficient, frequently unsafe, often not appropriate, and regularly not
delivering services that have been shown to improve health. Estimates by experts
suggest that upwards of 30% of the cost of clinical care is wasted on unnecessary
15 and inefficient care.

This poor care is deeply imbedded in American health care delivery and
financing methods. Many have said that our health care is a village industry and
that industrial types of solutions might help better manage the transactions that
constitute medical care.

20 There is a significant opportunity for improvement through rationalizing the
process flow typical of medical care (we will call this the medical "supply chain") –
with the patient usually moving from least to most technically complex care. These
transactions for every patient with an episode of illness, and ultimately a single
diagnosis, are currently unmanaged and poorly integrated and coordinated. The
25 looseness of this process results in errors, omissions, missing information,
duplication, re-work, inefficiency, sub-optimal quality, poor service, and high cost.

Many attempts have been made in the past to improve pieces or parts of the

medical supply chain. These have ranged from utilization management - in which clinicians are asked to justify the appropriateness of their actions and to receive approval from the insurer – to putting large financial incentives in the hands of primary care doctors to manage care (so-called gate-keeping). While each of these
5 appears to have some effect on reducing costs, concerns about quality, withholding of care, and double agent behavior of doctors have largely blocked these approaches. Utilization management, pre-authorization, and gate-keeping for pay have been waning and, as they have done so, medical costs have resumed an upward trajectory of 8-10% per year after five years of stability in the 1990's.

10 The use of expert guidelines is one approach that has been proposed to improve decision-making in health care. Expert guidelines are widely available commercially and publicly, and many sources exist for updating and publishing them to doctors in paper or electronic form. It has been claimed that new inventions in branching electronic decision support systems can guide and monitor the decisions
15 that doctors make. Examples of such systems are discussed in, for instance, U.S. Patent No. 5,953,704, to McElroy, *et al.*, U.S. Patent No. 6,049,794, to Jacobs, *et al.*, U.S. Patent No. 6,353,817, to Jacobs, *et al.*, and U.S. Patent No. 5,517,405, to McAndrew, *et al.*

 Studies have shown, however, that such guidelines are rarely utilized by
20 doctors and therefore have not had much impact on improving care. *See, e.g.*, Effective Health Care: NHS Centre for Reviews and Dissemination. 5:1. February, 1999. ISSN:0965-0288; Davis D, Thomson MA, Oxman AD *et al.* Translating Guidelines into Practice. CMAJ. 1997; 157:408-16; Wensing M, Van der Weijden TRG. Implementing Guidelines And Innovations In General Practice. Br J Gen Pract
25 1998;48:991-7. In short, these guidelines have not been easily incorporated into the daily work of doctors so that they are feasible to use at the point of care and in the process of care. Most such systems provide so much information and are so complicated that doctors do not use them.

 Other approaches to manage care have depended on electronic medical
30 records (EMR), suggesting that these will provide the basis for documenting and structuring medical care. Electronic reminders and electronic prescription writing

are good examples of an EMR approach to support good practice. However, electronic medical records have been resisted by most doctors and are in place in only four percent of medical practices in the US. These installations are largely in hospitals, and occasionally very large group practices. Therefore, few practices
5 where decision tools are needed for support and integration of care actually employ a comprehensive EMR. Because of the high operating cost in time and money, many feel that comprehensive EMRs will be long in coming to office practice.

One of the primary problems with existing decision support tools is that they fail to adequately recognize and respond to how doctors actually do their work.
10 Doctors are time constrained and practical. Any electronic support system should be easy to use in the workflow at the point of care and, so far, none of the present designs are. Moreover, an electronic support tool must deal with the true nature of the medical supply chain i.e.– that the process of care constitutes a series of linked handoffs, not independent acts taken separately by different doctors. Serious medical
15 problems are managed as a series of integrated transitions and transactions, usually starting with a referral by a general practitioner or primary care clinician into the specialist and hospital sector. This train of events proceeds for an individual patient's episode of care for a condition, by a referral to a specialist based on the referring doctor's best diagnosis, then to increasingly specialized doctors for further
20 opinions and study, and then often ends with a specialist delivering a complex diagnostic and treatment regimen, even surgery, to attempt to treat the problem. Each step is an input to the progression of care for what is usually a single problem and its ultimate resolution that "closes the case" on the episode. This constitutes the "supply chain" in medical care. Each step of the process is an input to the next. If
25 done well, each step and handoff is appropriate and efficient, adds value, and contributes to the overall result. Done poorly, and the care suffers.

The time pressures of doctors and the disintegration of the work of doctors from one another makes designing a practical support system difficult. Typical guideline decision support tools are complicated and require considerable time to
30 use. They often function more like textbooks than as a simple process support tool. Moreover, there is no system that supports, coordinates, and tracks the supply chain

and links together care decisions, documentation, monitoring and feedback as the patient's care progresses.

SUMMARY OF THE INVENTION

The present invention relates to a system and method that enables health care
5 providers, and primary care physicians in particular, to efficiently and effectively
manage their patient's care into and throughout the specialist and hospital supply
chain. In one aspect, the invention employs a simple checklist method of
representing complex, expert based decision trees. This system simultaneously
serves as an electronic checklist support system, a Web-based temporary electronic
10 medical episode record, and a tracking tool that assists primary care physicians (and
other doctors) to track patient progress. The invention is able to control process
flow, facilitate communication and coordination between doctors, document medical
care, and assure that all doctor "suppliers" using the system are operating to
worldwide best standards of care. The system reduces the workload of doctors,
15 minimizes the threat of malpractice, educates and improves the doctors who use it,
and creates a mechanism for patients and doctors to share in the decisions about
care.

According to one aspect, the invention comprises a condition-specific
checklist accessed interactively via a computer network, such as the Internet. This
20 checklist can be derived from publicly available guidelines or decision trees. While
other currently utilized decision support systems present the actual decision engine
and logic as flexible guidelines (i.e. a type of branching logic educational textbook
for clinicians), the present system differs from the known decision support tools in
that it first re-frames guidelines into a prescriptive format (variously called clinical
25 care pathways, protocols, or criterion-referenced standards) based upon the patient's
initial data and condition. This protocol, which is designed to be adhered to like a
blueprint for medical care, is then translated into a checklist of data points, with the
decision logic completely hidden from the user behind this simple checklist
representation. The underlying logic and even advice and references can be made

available if desired, but the interface with the doctors is normally kept uncomplicated.

In one embodiment, this simple checklist is further refined into a type of PERT, or flow chart, reflecting data points on an optimal cost-effective pathway for care. Two data inputs can be used to optimize the path in real time. First, the system tailors the generic checklist to the specific condition of each patient by applying probability theory (Sox, Probability Theory in the Use of Diagnostic Tests. Annals of Internal Medicine, 104:60-66, 1986.) The optimal protocol for each patient depends on the cost, risks, and added value of every test or maneuver performed in the work up. With the proper patient data about the prior likelihood of the suspect condition (entered by the Primary Care Clinician), Bayes' theorem can be applied automatically to calculate the value of any and every test or maneuver (i.e. an item of medical history or a physical examination finding) using the test or maneuver's sensitivity and specificity, – the two universal descriptive characteristics of test performance. The system can assist the primary care doctor to estimate the patient's prior probability of the illness. The system can then use this information to calculate the value of variations in the protocol, yielding a unique, patient-specific checklist that represents the optimally effective pathway or sequence for the patient.

A second input is that, as each successive data point is entered into the checklist, an underlying logic can be applied to calculate and change the conditional probabilities, and thus dynamically modify the checklist in real-time to optimize the number, sequence, and type of responses (tests and maneuvers) needed.

While assisting through all the transactions represented on the checklist, the invention generally acts most powerfully at, and tightly integrates, the transactions at two critical transition points of care that dominate the performance of the supply chain. These are the handoff of the patient from the primary doctor to the specialist and the point at which a specialist undertakes complex, expensive, and risky testing or treatment, especially surgery. Underlying these two steps are clusters of data points, linked to decision algorithms, that function like a lock on a gate. The checklist data are the key to opening the gate. Once the gate (referral to the specialist, ordering an expensive new drug, or approval for the test, procedure or

surgery) is “unlocked” by the proper data, the patient’s care is automatically approved and appropriate payment can be authorized.

The system creates an especially “tamper-proof” lock at the specialist level. Since the care pathway always starts with the primary care clinician’s data, the
5 present system can use these prior data to create a two-key (like a safety deposit box) lock at the specialist level. Data elements entered by the primary care clinician are automatically re-entered on the checklist and become part of the lock and key at the time the specialist proposes care that must be approved. By having data that must be agreed by at least two different doctors, the quality and reliability are enhanced
10 and the likelihood is lowered significantly that data could be manipulated by a specialist to win approval for proposed care.

The present invention can function in an interactive electronic environment. Both software and the temporary medical record structure can be made available as an Application Service Provider capable of operating as a standalone or dropped into
15 an insurer’s IS environment and behind its privacy firewall. Doctors can gain access to the tools and the patient record via the Web, preferably using a security device. Data are input by the patient’s doctors selecting from point and click representations. Both input to and display of the record can be on any interface device that accesses the web (computer, handheld device, wap phone, voice recognition system, etc.).

20 The present system can also document steps of medical care as a standalone temporary episode record, which participating doctors can access and use anywhere and at anytime. While providing all the functionality of an EMR (one record, used by all clinicians to integrate care, document their specific actions, and communicate the results and status) to support their care for the specific episode, the “mini”-record
25 of the present system does not require that the doctors use, pay for, or implement an EMR.

Like a PERT chart assists a builder, the final checklist guides the actions of the doctor and also can alert them if the actions are not followed. As the primary care doctor and then each subsequent specialist points-and-clicks his or her way
30 through the checklist, hidden inference engines and decision rules logic can test whether or not the sequence and the data at each step meet the built in decision

criteria. If they do, the collected data are incorporated and passed on to the next stage in the supply chain. At each stage in the supply chain additional clinical data points are requested and added to the patient's unique episode record. If the checklist data do not satisfy the decision criteria, the system can warn the doctor responsible for care at that point and, on request, provide documentation of the gap, supply literature or expert advice about the problem.

Since data are recorded as a temporary episode record, this electronic record can transmit, monitor, record, and provide instant access to all process information. It assures faultless and timely communication between all those involved in an individual patient's care.

In one aspect, the present system tracks and ties together the progress of care and provides primary care doctors with information that enables them to monitor and manage the patient's care. The temporary episode record integrates all transactions entered through the system. Algorithms can automatically extract tracking data that describes both logistic (where, what, and when) and quality performance (appropriate, comprehensive, safe) of the patient's care. These can be published back to the primary care doctor as part of a progress report on all patients undergoing active care by specialists. These measures are preferably displayed in an easy-to-read screen. Armed with continuously updated information presented in a simple scorecard, primary care doctors (and patients) are enabled to coordinate and optimize the process sequence of care of individual patients. With this report, which can highlight and warn the primary care doctor when there are problems with one of his or her patients (delays or decisions that are off the expert pathway), primary care doctors will be enabled to manage their patient's care electronically and easily. At the same time, if the specialist "data key" fails to unlock the approval gate, the system can notify the primary care doctor and, if the specialist chooses to appeal the algorithmic decision, the primary care doctor will be the first to adjudge the need.

When the episode is completed (specialist's care is finished and the patient is returned to primary care), the temporary episode record can be copied, either electronically or in paper form, and can be amalgamated with the patient's overall medical record. The temporary episode record can also be stripped of its patient

identifiers, put in a system-wide data base, and expunged from the active system data base. This system-wide database can aggregate data across all patients, doctors, and insurers using the system. It supports analysis of medical care by condition, insurer, doctor, and other parameters, and it can create epidemiological information that can be used to understand care, compare it to that delivered by others, and support management to improve operational and clinical processes. In one aspect, data from this system-wide database can be used to help estimate the prior probability that a particular patient has a suspect condition, thus further optimizing the specific checklist or treatment protocol for the patient's care.

10 The present invention takes a unique approach to improving the flow of patients into, and throughout, the health care supply chain. The methods and systems of the invention need not rely on branching, interactive guidelines, but instead can utilize simple checklists that are derived from, and are simple representations of, underlying guideline logic. Also, unlike other lists (such as the lists promulgated by Physician Standard Review Organizations (PSRO) in the 15 1960's and 70's), the checklists of the present invention can be brought interactively to the point of care via modern electronic communication media, and they can simultaneously serve as a trackable, patient-specific medical record of the episode of care. Also, the checklists of the present invention are generally research evidence based, modifiable and customized based on individual patient data, continuously 20 updated with new information and research, and accessible at the point of care in real time. In this way, the present invention provides a very simple tool for primary care clinicians to assure that their performance, and that of every subsequent doctor providing care in an episode of illness, achieves expert standards of quality.

25 BRIEF DESCRIPTION OF THE DRAWINGS

The foregoing and other objects, features and advantages of the invention will be apparent from the following more particular description of preferred embodiments of the invention, as illustrated in the accompanying drawings in which like reference characters refer to the same parts throughout the different views. The drawings are not necessarily to scale, emphasis instead being placed upon illustrating 30

the principles of the invention.

Fig. 1 is a schematic diagram of the hardware and general interactive environment in which the invention operates;

Fig. 2 is a high level flow diagram of the system;

5 Fig. 3 is a pictorial representation of the system;

Fig. 4 depicts the referring primary care clinician screen;

Figs. 5 and 6 depict the criterion-referenced checklist gating a typical referral;

10 Fig. 7 shows the primary care clinician screen of approval or other actions needed;

Fig. 8 depicts the primary care clinician's screen of participating specialists eligible for referral;

Fig. 9 depicts the computer generated referral note;

Fig. 10 is a low-level flow diagram of the specialist system;

15 Fig. 11 depicts the specialist's screen for selecting a procedure;

Fig. 12 displays the specialist's criterion referenced checklist gating approval of the procedure;

Fig. 13 displays the specialist's screen of approval or other actions needed;

Fig. 14 displays a typical clinical guideline;

20 Fig. 15 displays the derivation and representation of critical, required action points;

Fig. 16 is a schematic showing the creation of a checklist;

Fig. 17 is a flow diagram showing the process of using the Bayes' theorem formula to construct sets of preferred checklist sequences;

25 Fig. 18 is a flow diagram depicting the use of the primary care clinician's use of the checklist-based flow and tracking system;

Fig. 19 displays the use of the checklist over multiple visits and assembly into a temporary episode record;

30 Fig. 20 depicts a flow diagram showing feedback loops to primary care clinician to provide data for monitoring and managing the supply chain;

Fig. 21 is a high-level block flow diagram showing the feedback and

monitoring mechanism;

Fig. 22 depicts the primary care specialist tracking summary screen; and

Fig. 23 depicts the patient tracking detail screen.

DETAILED DESCRIPTION OF THE INVENTION

5 A description of preferred embodiments of the invention follows.

The present invention provides an evidence-based checklist of criteria for referral or procedures to primary care and specialist clinicians to assure that standards in these processes are met. By entering prompted patient information, the clinicians call up a customized optimal checklist that reminds, guides, and approves
10 the clinician's actions.

A general block diagram of one embodiment of the system is provided in Fig. 1. A primary care clinician interfaces with the system 100 via a user interface, which can comprise a desktop, handheld device, a WAP phone, or all other devices that access the Internet. The user is connected, through any communication path
15 through the Web 3, to at least one database maintained behind an insurer's privacy firewall 14. The at least one database can include one or more system databases 15 (such as a guideline/checklist database, a prior probability database, a procedure threshold approval database, and a temporary episode record database), and one or more insurer databases 20 (such as a consultant database, a primary care doctor
20 database, an eligibility database, a laboratory, an X-ray vendor, and a claims payable database).

Via guided questions keyed to the type of referral 2 being proposed, the clinician enters data 1, which are operated upon by a decision engine 5 (located in server 103) utilizing probability-theory (e.g. Bayesian) logic, to generate a specific
25 and unique check list 10 of actions that are the required inputs to an appropriate referral. Further queries for items of data may be directed to the primary clinician based on logic imbedded in hidden, condition-specific decision trees. Once criteria for referral have been satisfied, the gate for the referral is opened and a referral note 6 is generated from the data entered and from information in the insurer's database.

The specialist clinician interfaces with system 100 via any user interface 102 and receives the information from the primary clinician, accessing it from a confidential and secure temporary, electronic recording 13 of prior transactions in the clinical episode. Upon completion of the consultation 7 with the patient, the specialist can enter data, in structured or free form, for electronic transmission back to the referring primary clinician. Alternatively, the specialist clinician may propose to order further tests or plan a procedure 8. These proposed actions generate guided questions 9 from the database, to which the clinician responds. From these data, a Bayesian decision engine generates a specific and unique check list of actions 10 that represent the required inputs 11 for the requested next step, which is determined by the insurer's server using pre-determined decision criteria. Once criteria have been satisfied, the gate for the proposed action is opened and approval authorization 12 is delivered. All these transactions and sequencing are monitored, recorded in the temporary recording, and published back to the primary clinician in a standardized format that allows the primary clinician to track the care of individual patients.

Fig. 2 depicts a high-level flow diagram of the authorizing process. The referring primary care clinician selects the referral specialty 16 (and optionally, but not necessarily, a particular specialist physician) and enters descriptive patient information 17. Inference engine 18 operates on this data using Bayes' formula to produce a patient-specific interactive checklist of actions and data required for authorization of the specialist referral. Easily-understandable medical representations of the checklist items are then presented to the primary care physician, in sequence or in list form, and the referring physician enters requested data for each checklist item. As each item of data is entered into the checklist, the inference engine 18 uses decision logic to determine whether or not the data satisfies the pre-determined criteria for authorization of the referral. The inference engine 18 can also use the data entered into the checklist to update the remaining checklist items, modifying the number and sequence of remaining checklist items to further optimize the list to the patient's particular medical condition. The inference engine can also provide feedback and advice to the primary clinician regarding the patient's

care. At step 19, the inference engine 18 notifies the primary care physician whether or not the criteria for referral have been satisfied. At this stage, the primary physician may choose to discontinue the referral and terminate the session. If the requested referral is authorized, however, the physician can then activate an automated referral process. It should be noted that in some embodiments, the primary physician may be permitted to override a refusal in certain circumstances, and proceed with the proposed referral.

If the physician proceeds with the referral, the patient's identifying information is entered 20 and eligible specialist consultants are pulled from the insurer's data base 20 and published to the referring primary clinician. If the particular specialist for referral has not already been identified, the referring physician then selects a specialist from the list. The system can automatically generate the referral note, which is reviewed and optionally modified by the primary care physician, and then automatically transmitted to the specialist at step 21.

The specialist then sees the patient and either completes the consultation or requests further tests or a procedure. If the specialist determines that a costly or potentially risky course of treatment or testing is needed, the specialist logs onto the system 100 and selects the proposed treatment or test from a list of possible medical actions. Patient information from the primary clinician and the specialist automatically populates the action checklist 22, and a new checklist 23 of remaining required information for authorization of the proposed action is generated by an inference engine. Once all required criteria on the check list have been satisfactorily entered 24, automatic authorization 25, or the action steps, is given to the specialist and the proposed action is carried out. 26.

Fig. 3 is a pictorial representation of the system. Sequential steps are shown with 27 and 28 representing the inference engine operating on the check list to determine if minimal criteria have been met so that the referral 27 and the request for further tests or procedure 28 are appropriate and authorized according to expert, evidence-based criteria. The criteria can be determined by an insurance provider, for instance, or physicians' group leaders.

Figures 4-9 show screen shots of the primary care clinician screens. Screens are point and click, making them easy to use with personal digital assistants that can be used in the examination or consulting room. Fig. 4 depicts the personal identification of the referring primary care clinician, drawn from and updated into the insurer's database. Figs. 5 and 6 show the checklist items for referral, using a gynecologic referral as an example. Fig. 7 shows the feedback screen, once the inference engine has determined if criteria have been met or not. Figure 8 shows specialty-specific specialists, which can be automatically pulled from the insurer's database using a simple algorithm of location, for instance, or other desired criteria. The list of specialists can also include an indicia 29 which indicates whether or not the specialist also uses the system, or meets other desired performance criteria. Figure 9 is an example of the patient's referral letter, which can be automatically and algorithmically generated from the information input by the primary care clinician and pulled from the insurer's data base.

In one aspect, specialists can also enter process suggestions into the system that can be automatically reported back to the primary care physician at the time of a referral. For instance, the specialist might indicate that he or she would like to have the patient prepared for their visit in a certain way, like showing up 15 minutes early, or filling out certain forms, etc., prior to the visit. In some embodiments, the specialist can modify the clinical decision pathway, and thus the checklist, to account for the unique preferences of the specialist, so long as the basic logic of the guideline was maintained. For example, a specialist might prefer an alternative type of test or workup where the medical literature did not support one alternative or the other. In this case, the algorithmically-generated checklist could be modified to some degree to account for these types of individual preferences, so long as they were reasonably consistent with the medical literature and the views of other experts in the field.

Figure 10 represents a low-level flow diagram of the specialist interaction with the system. After completing the consultation on the referred patient, the specialist logs on the system through an Internet connection from any of multiple user interfaces 102. Using a PIN number, the specialist enters the patient

identification number, activating the temporary episode record **35**. The specialist then may return the patient to the referring primary care clinician with a notification that the consult is complete **30** and/or a consultation note (which may be entered into the system as free text and/or pre-structured options) or decide to request further
5 tests or procedures **31**. In the latter case, the specialist identifies the planned test or procedure **32** from a list, and the system utilizes prior patient data to generate a unique action checklist **33** from a procedure approval database. This unique list is presented to the specialist on the GUI as a checklist of actions **34**, similar to the previously-described checklist that is presented to the referring physician for
10 authorization for a referral. Prior data **36** residing in the database are automatically drawn from the temporary episode record of the patient to populate the checklist **34**. Interacting with the checklist, the specialist enters remaining requested data **35**. Data are checked against a decision algorithm operating in an insurer's or other entity's server **37**. Once action criteria have been satisfied, approval **38** is posted to
15 the specialist user interface, and can be automatically transmitted to the claims payable database **39**.

Figures 11-13 are screen shots of specialist user interactions with the system. Figure 11 shows a partial list of procedures that a gynecological specialist would choose from when requesting approval for a planned procedure. Figure 12 shows an
20 example of one point-and-click representation of the action step checklist of information required to assess whether criteria have been met. Figure 13 demonstrates the feedback to the specialist regarding whether the procedure has met criteria for approval.

Figures 14-17 depict the method by which checklists are constructed from
25 publicly available expert, evidence-based guidelines. Figure 14 depicts a representative clinical guideline arranged as a branching decision tree. This example, for sinus infection, is typical of hundreds of such guidelines available on public web sites such as www.guideline.gov without charge. Guidelines are sequential steps in the work up and care of a designated clinical condition. Actions are followed by an
30 outcome or decision step **40** consisting of a branching alternative that depends on the

result of the action. Such guidelines have been developed and deployed for many years, but research shows that they are generally not used much by doctors.

Figures 15 and 16 show the first step in transforming the guideline into a checklist. Action points, where an intervention (an item of medical history, a physical examination maneuver, or a test or procedure) of some type is performed and data collected, are identified 41. These data points mark the progressive movement of the clinical care along the decision tree. The figure displays these critical, required action points for the demonstration guideline. For this simple guideline, the action points could be displayed sequentially (Fig 16) as a checklist of required items on a decision path 42. However, a checklist that merely builds off usual guidelines is not an adequate set of actions to represent optimal decision making. Optimal decision making is the minimum set of actions or steps needed to get to a pre-determined point of major transition in the process of care (to refer, to do further testing, to perform a surgical procedure, or to determine that the patient does not have the suspect condition). This set varies both by the probability or odds that a patient has the condition at each step of the decision tree and the optimal sequencing will vary depending on results from prior steps. The minimum, or optimal, path depends on data manipulations that includes knowledge of the prior probability of the condition for which the doctor is proposing any specific maneuver or action and the change in probability resulting from additional data inputs resulting from the specific action step. The basic formula used to calculate these "post-treatment probabilities" is called Bayes' Theorem.

Figure 17 shows how Bayes' theorem is used in creating an optimal checklist for the specific patient under care. For each and every condition, a decision tree is selected from public sources and modified by expert input 43. For each condition, a set of presenting symptoms and physical examination findings is defined. Based on combinations of these findings (present or absent) and a patient's personal history of risks of the condition and the frequency of the condition in the population that represents the group to which the patient belongs, an initial probability level of the condition is established. In the embodiment illustrated here, three levels of prior probability of the condition--low, medium, or high--are defined 44. Given the three

states of prior probability, each step in the decision tree is subjected to Bayes' theorem calculation based on the pretest probability and the sensitivity and false-positive rate (i.e. specificity) of the condition **45**. Based on each of the three starting probabilities, an optimal (least risk, least cost, best increased probability) sequence of steps can be constructed to reach an agreed level of probability of the condition **49**. Each sequence will differ in its elements and sequencing based on the level of initial prior probability. Thus, three decision trees are created, and each is subject to an extracting process in which the action steps are identified **42** and published as a checklist. These checklists, for all conditions and for all defined prior probability states for the condition, are stored in a checklist database **48**. For each of three "gates" or points of major transitions in care (decision to refer to a specialist, decision by a specialist to perform high risk/ high cost tests, and decision to perform a procedural intervention) an analysis of the risks and benefits of the intervention is conducted, based on literature, and a prior probability approval threshold for the condition is identified at which the risks and the benefits of the procedure exactly balance **49**, assuming the patient is neutral about these. These risks and benefits can also be modified by individual patients, using utility theory approaches, and could be used to raise or lower the probability threshold for the action to take place. These probability thresholds are defined as the level needed for approval of the step (opening the gate) and are stored in an approval threshold database **50**. The system compares the cumulative probability from the checklist results to the threshold approval probability to determine if the threshold has been met **51**.

Figure 18 is a flow diagram depicting a primary care clinician's use of the checklist-based flow and tracking system. From any user interface, a primary care clinician accesses the system **52** via the Internet. Responding to questions based on the selected referral specialist, the clinician enters patient data that defines the suspected condition at the beginning of the work up **53**. Drawing from a database **54** of initial probabilities, the system estimates the initial probability, or pre-test odds **55** of the condition. This calculation classifies the condition as low, medium or high probability and leads the system to draw **56** the appropriate checklist **49** from the checklist database **48**. In one aspect, the prior probability of the patient's diagnosis

can be estimated by a decision algorithm that assigns the patient to a prior probability level (e.g. low, medium, or high) based upon inputs such as patient data, medical history, information from the medical literature, and frequency of the condition, particularly within groups of people of whom the patient is a member. In a preferred embodiment, the prior probability algorithm estimates the patient's prior probability based on, at least in part, an analysis of the accumulated experience of many patients as represented in a system-wide database of all patients using the system. In this way, the accuracy of the prior probability estimates will be improved as more and more insurers, doctors, and patients utilize the system, thus creating a larger historical record of many different patient experiences and medical conditions.

Once the system produces **56** the appropriate checklist **49** from the checklist database **48**, the clinician then enters responses to the checklist based on patient data **57**. In general, if the patient's initial probability of having the condition is high, the checklist will be short; if low, the checklist will be longer, in order for the cumulative posterior probability (the probability as calculated following the incorporation of additional new data) to equal or exceed the approval threshold. As each checklist item is entered, the system calculates the posterior probability of the suspect condition according to algorithms **58** and compares **59** the result to the threshold probability in the approval threshold database **50** required for referral **51**. As the cumulative post-test odds rise to or above the threshold, the system approves the referral **60**. If the threshold is not met and checklist items are exhausted, the referral is not approved.

In certain embodiments, the threshold database **50** can also include criteria for rejecting a proposed medical action if the calculated probability of patient having the suspect medical condition falls below a pre-determined minimum probability level. Preferably, this is in addition to the threshold approval criteria discussed above. For example, a checklist of data points for approval of a proposed medical action, such as a referral or a procedure, is generated based upon the estimated initial probability of a medical condition. As the requested data for each checklist item is entered by the user, the system calculates the posterior probability of the suspect condition according to probability theory. This posterior probability of the condition

is then compared to both an approval threshold and a rejection threshold. If the posterior probability exceeds the approval threshold, then the proposed medical action satisfies the system's criteria, and an approval is returned. On the other hand, if the posterior probability drops below a certain minimum probability level, or
5 rejection threshold, then the system will return a rejection of the proposed medical action. If the posterior probability is neither greater than the approval threshold, nor less than the rejection threshold, then the process is repeated for the next item on the checklist until all items are exhausted.

According to another aspect, as each successive data point is entered into the
10 checklist, the inference engine can use the change in the patient's probability level to reassess the value of remaining data points on the clinical care pathway, and dynamically modify the number and sequence of subsequent data points on the checklist to account for these changed probabilities.

Figure 19 is a schematic showing use of a checklist over multiple visits and
15 assembly into a temporary episode record. A Bayesian-derived checklist is a unique representation of the best, and most minimal, (efficient and effective) decision guideline for the management of an episode of care for a given condition. As a clinician enters the process of care at specific transition points (referral to specialist, request for further tests, and request for approval for a procedure), the checklist is
20 structured to act like a lock, and meeting the checklist criteria represents the key to open the gate at that point. Clinical actions take place as part of a series of patient visits, first with the primary care clinician and then with specialists after the patient has been referred. While the checklist is formally accessed at those visits corresponding to a transition point **61, 62, 63** the checklist represents an integrated
25 series of steps on the optimal path of care, integrating actions throughout the process, like a kind of value chain, in which additional input moves the patient along a path towards resolution of the condition. Data could be entered at any encounter of the patient with the system of care, but only at the specified transition points are the answers to the checklist items treated like a key to open the gate to the requested
30 action. Thus, the collection of checklist responses, as they are progressively entered, becomes a type of medical record of medical work up transactions, albeit in

a truncated, skeletal form. This collection of checklist elements across all encounters and arranged in temporal sequence is stored as a temporary episode record in a secure database 64.

Figure 20 is a flow diagram showing feedback loops to a primary care
5 clinician to provide data for that clinician to monitor and manage specialist care. As a patient's care evolves 65 over a clinical episode, a sequence of stages and transitions takes place 67. These stages represent progress along a sequence between referral and resolution of the problem episode, much like different staging points on the assembly line of an automobile. These stages are heralded by a transition in
10 management, usually based upon reaching a point in a decision process where the probability threshold is reached that makes the transition appropriate. The work up consists of undertaking linked actions (examination, history, tests, and procedures) each of which contributes cumulatively to the probability of the condition. In this system, progress can be marked through the use of a checklist that is keyed to the
15 proposed transition to the next stage. At this transition point, criteria justifying the transition may be met or not. The system tracks the patient's progress. At these transitions the system automatically publishes the approval decision 68 - yes or no - to the referring primary care clinician, and provides the underlying checklist documentation if requested. The electronic episode record can also serve as the
20 communication vehicle for publishing results of consultations and reports back to the referring primary care clinician. 69

Figure 21 shows a high-level block flow diagram showing the feedback and monitoring mechanism for one embodiment of the system. Using any interface, a specialist 68 accesses the patient's temporary episode record from the database 64.
25 The specialist responds interactively to the checklist 69, ordering and adding data either manually or automatically. At a transition to another stage, the system presents the specialist with a lock, which the checklist data either opens or not, authorizing the patient's movement to the next stage. These transactions are monitored and tracked automatically 70 and are posted to a tracking database 71.
30 The tracking database can be accessed automatically at the time of login of the referring primary care clinician 73, who receives, via a user interface, a

representation of the status of all his or her patients active in the specialist sector 72. Concerns, discrepancies, disputes, or problems can be communicated via the system 74 as asynchronous messages to the specialist and operated upon in text form by the specialist, as needed.

5 Figure 22 depicts the primary care specialist tracking summary screen. This screen, on any GUI, encapsulates the status of all patients currently active in the specialist sector 76. Status of the patient is summarized using a color-coded (red, orange, green) designation 75 of the patient with serious discrepancies or problems through to one whose care and decisions are on track. Descriptive data such as
10 length of time in specialist care 77 and discrepancies between checklist and actual data are highlighted. By double clicking on the colored status summary button 75, a detailed chart of visits and checklist items is displayed (Figure 23).

 While this invention has been particularly shown and described with references to preferred embodiments thereof, it will be understood by those skilled in
15 the art that various changes in form and details may be made therein without departing from the scope of the invention encompassed by the appended claims.

CLAIMS

What is claimed is:

1. A method of converting evidence-based clinical decision support guidelines into a prescriptive patient-specific checklist of actions to satisfy process and outcome requirements for care of a specific diagnosis and episode of illness comprising:
 - deconstructing a guideline into its constituent symptom, physical exam finding, test, or treatment datum inputs;
 - subjecting each datum input to Bayesian test characteristic analysis using, when available, the sensitivity and specificity of each datum input with respect to a suspected medical condition, and the prior probability of the suspected medical condition, and calculating post-test probability of a positive or negative result for each datum input;
 - based upon the test characteristic analysis, creating plurality of protocols, each protocol associated with a prior probability of a patient's diagnosis, each protocol representing the optimal number and sequence of datum inputs for the care of the clinical condition through to resolution; and
 - based on the protocols, extracting the datum input or combination of datum inputs at each decision step of the guideline, and constructing its medical representation, the totality of the medical representations constituting the checklist.
2. The method as claimed in Claim 1, wherein the prior probability of a patient's diagnosis is determined by a decision algorithm that estimates a patient's prior probability of a diagnosis based upon at least one, or more, elements of patient data, information from the medical literature, and analysis of the accumulated experience of a plurality of patients represented in an episode data base.

3. The method as claimed in Claim 1, wherein the prior probability of a patient's diagnosis is determined by assigning the patient to a prior probability level.
- 5 4. The method as claimed in Claim 1, wherein the estimate of prior probability generates a unique checklist workup protocol for the specified patient's episode of illness care by specialists.
5. A method of managing a patient's episode of specialist care through using a temporary, integrated medical episode record that is based upon an
10 algorithmically constructed checklist that specifies and tracks decisions about care comprising:
 - at a referring user interface, selecting a medical specialty;
 - from a data base, based on the selected medical specialty, returning to the referring user interface a set of condition-specific queries for patient
15 information, the patient information comprising at least one of symptoms, physical exam finding, tests, or treatment data;
 - at the user interface inputting patient information in response to the queries;
 - at the data base, receiving the patient information and, based on
20 decision logic, determining the patient's probability of a medical condition and comparing this probability to a threshold probability for authorizing or refusing referral to a specialist within the selected medical specialty.
6. The method of Claim 5, further comprising:
 - at a specialist user interface, receiving patient information input
25 through the referring user interface and selecting a procedure to be performed;
 - from a data base, based on the selected medical specialty, returning to the referring user interface a set of condition-specific queries for patient

-23-

information, the patient information comprising at least one of symptoms, physical exam finding, tests, or treatment data

at the specialist user interface, inputting patient information in response to the queries;

5 at the data base, receiving the patient information and, based on decision logic, determining the patient's probability of a medical condition and comparing this probability to a threshold probability for authorizing or refusing authorization for the proposed medical procedure.

7. The method of Claim 6, further comprising:

10 at the data base, storing the referring and specialist patient data in a linked temporary transaction record that documents the patient's care process and progress.

8. A method as claimed in Claim 5 wherein the database is behind an insurer's, a practice's, or a hospital's privacy and HIPAA privacy compliant fire wall.

15 9. The method as claimed in Claim 5 wherein the database returns to the referring user interface a list of eligible specialists, one of which is selected at the user interface.

10. A method as claimed in Claim 9 wherein the specialists in the list who have access to the database are highlighted in the list.

20 11. A method as claimed in Claim 5 wherein a web-based GUI hypertext referral form from primary care to specialty doctors incorporating checklist protocols is created in a point and click format.

12. A method as claimed in Claim 6 wherein a specialist may customize the decision logic to include procedures to be performed by a referring medical
25 practitioner.

13. A method as claimed in Claim 6 wherein patient insurance information is delivered to at least one of the referring and specialist user interfaces.
14. A method as claimed in Claim 5 wherein the database receives information about the patient from another electronic information database.
- 5 15. A method as claimed in Claim 5 further comprising automatically generating a referral note from the referring user to a specialist.
16. A method as claimed in Claim 6 wherein the database provides evidence-based decision guidelines, relevant articles, and expert commentary to each of the user interfaces upon request.
- 10 17. A method as claimed in Claim 5 wherein the database returns patient care recommendations through the referring user interface.
18. A method as claimed in Claim 17 wherein the recommendations include procedures to be performed by a referring medical practitioner to assist the specialist.
- 15 19. A method as claimed in Claim 17 wherein the recommendations include patient information about location and other special advice regarding the consultation
20. A method as claimed in Claim 6 whereby the sequence of medical decisions and data are aggregated into a temporary electronic episode record linking
20 the checklist data of all clinicians and documenting transactions and incremental progress.

21. A method as claimed in Claim 6 wherein the database returns to the referring user interface patient information input at the specialist user interface concerning the care including tests and procedures and outcomes.
22. A method as claimed in Claim 21 wherein the database identifies
5 discrepancies between expected check list expected items and values and the information entered through at least one of the referring user interface and the specialist user interface.
23. A method as claimed in Claim 6, further comprising extracting tracking
10 information about the patient's progress on the check list and communicating deviations from the check list protocol back to the referring user.
24. A method as claimed in Claim 22 wherein discrepancies relating to at least one of timing, location, completion of check list items, and values of checklist items are published as a visual scorecard for primary care doctors and/or patients.
- 15 25. The method as claimed in Claim 5, wherein the active episode record is stripped of patient identifying data and stored in a relational data base of check list elements of all patient, doctor and insurer users of the system and wherein the data base performs analysis of referring and/or specialist
20 physicians' and insurer's performance over plural doctors, plural patients and plural insurers.
26. A patient referral management data processing system, comprising:
a referring user interface by which a medical practitioner identifies a specialty to which he intends to refer a patient and inputs patient information;
and
25 a referral data base process which, based on the selected specialty, returns to the referring user interface a set of condition-specific queries for

-26-

- 5 patient information, the patient information comprising at least one of symptoms, physical exam findings, tests, or treatment data, and, based upon the patient information entered at the referring user interface, determines the patient's probability of a medical condition and compares this probability to a threshold probability for authorizing or refusing authorization for a referral to a specialist within the selected medical specialty.
- 10 27. The system of Claim 26, wherein the data base process receives patient information from the referring user interface and, based on deviation from the patient's checklist protocol, notifies the referring user interface of the availability of backup explanation and further recommendations.
28. The system of Claim 26, wherein the database process returns to the referring user interface an insurer's approval and authorization to proceed from an insurance data base, based on concordance with the check list.
- 15 29. The system as claimed in Claim 28 wherein an accounts payable data bank initiates payment by the insurer to the doctor for the referral process.
30. A procedure approval data processing system wherein the intended action is a specialist clinical procedure comprising:
- 20 a specialist user interface by which a specialist identifies an intended procedure for which he seeks approval and inputs patient information;
- a procedure approval data base process which, based on the selected procedure, returns to the referring user interface a set of condition-specific queries for patient information, the patient information comprising at least one of symptoms, physical exam findings, tests, or treatment data, and, based upon the patient information entered at the specialist user interface,
- 25 determines the patient's probability of a medical condition and compares this probability to a threshold probability for authorizing or refusing authorization for the selected procedure.

31. The system of Claim 30, wherein the procedure approval data base process receives patient information from the specialist user interface and, based on deviation from the patient's checklist protocol, notifies the specialist user interface of the availability of backup explanation and further
5 recommendations.
32. The system of Claim 30, wherein the procedure approval database process returns to the specialist user interface an insurer's approval and authorization to proceed from an insurance data base, based on concordance with the check list.
- 10 33. The system of Claim 32, wherein an accounts payable data bank initiates payment by the insurer to the doctor for the approved procedure.
34. A method of managing an episode of medical care in a data processing system, comprising:
at a user interface, selecting a proposed medical action;
15 from a database, based upon the selected medical action, returning an interactive checklist of data points for the episode of care, the data points comprising representations of decision nodes of an evidence-based clinical decision support guideline associated with the proposed medical action;
at the user interface, inputting data into a data point of the checklist;
20 using the data input for the data point, calculating a probability of a medical condition associated with the proposed medical action based upon a prior probability of the condition, the sensitivity of the data point with respect to the condition, and the specificity of the data point with respect to the condition;
25 comparing the calculated probability of the medical condition to a pre-determined threshold probability of the condition that is associated with the proposed medical action; and
based upon the comparison, authorizing the proposed medical action,

refusing authorization of the proposed medical action, or requesting additional data input into the checklist.

35. The method of Claim 34, wherein the pre-determined threshold probability comprises an approval threshold, and the proposed medical action is authorized when the calculated probability exceeds the approval threshold.
36. The method of Claim 34, wherein the pre-determined threshold probability comprises a rejection threshold, and the proposed medical action is refused authorization when the calculated probability is less than the rejection threshold.
37. The method of Claim 34, wherein the calculated probability is compared to both an approval threshold and a rejection threshold, the proposed medical action being authorized when the calculated probability exceeds the approval threshold, and refused authorization when the calculated probability is less than the rejection threshold.
38. The method of Claim 34, wherein the proposed medical action comprises a referral to a specialist physician.
39. The method of Claim 34, wherein the proposed medical action comprises a medical test or examination.
40. The method of Claim 34, wherein the proposed medical action comprises a medical or surgical diagnostic or treatment procedure.
41. The method of Claim 40, wherein the proposed procedure comprises surgery.
42. The method of Claim 34, wherein data input into data points on the checklist

comprises at least one item of items of medical history, physical examination findings, medical tests, and medical procedures.

43. The method of Claim 34, further comprising determining an initial prior probability of the medical condition for a patient based on at least one of
5 presenting symptoms, physical examination findings, the patient's personal medical history, information from medical literature, the frequency of the condition within a population of which the patient is a member, and an analysis of the accumulated experience of patients stored in a database accessible by the data processing system.
- 10 44. The method of Claim 43, wherein determining an initial prior probability comprises assigning the patient to an initial prior probability level.
45. The method of Claim 43, wherein the checklist returned is associated with a particular initial prior probability level.
46. The method of Claim 45, wherein at least one of the number and sequence of
15 data points on the checklist is determined based upon the initial prior probability associated with the checklist.
47. The method of Claim 46, wherein the checklist is generated by calculating, for each decision node of the evidence-based clinical decision support guideline associated with the proposed medical action, the probability of the
20 existence of a particular medical condition based upon the initial prior probability level, the sensitivity of the decision node with respect to the condition, and the specificity of the decision node with respect to the condition, and, based upon these calculations, determining an optimal sequence and number of data inputs to reach a pre-selected probability of the
25 existence of the condition.

48. The method of Claim 47, wherein from each evidence-based clinical decision support guideline, a plurality of checklists are generated, each checklist associated with a different initial prior probability level.
49. The method of Claim 47, wherein the sequence and number of data inputs is optimized with reference to at least one of the cost, the risk, and the change in probability level associated with each data input.
50. The method of Claim 34, wherein for each data point on the checklist, the prior probability of the condition is determined by the probability calculation for the preceding data point.
51. The method of Claim 34, wherein the threshold probability of the condition is determined based upon an analysis of risks and benefits associated with the proposed medical action.
52. The method of Claim 34, wherein the probability calculation and comparison steps are repeated for each data point on the checklist until the proposed medical action is authorized or refused authorization, or all data points on the checklist are exhausted.
53. The method of Claim 34, wherein the user interface accesses the database remotely via a computer network.
54. The method of Claim 53, wherein the network comprises the world wide web.
55. The method of Claim 53, wherein the database is located behind a privacy firewall of a health insurance provider such as an insurance company, a government insurer, or a self-insured employer.

56. A medical care data management system comprising:
- a user interface by which a physician proposes a medical action;
 - an interactive checklist of data points for the episode of care, the data points comprising representations of decision nodes of an evidence-based clinical decision support guideline associated with the proposed medical action, the checklist permitting the input of data into the data points via the user interface;
 - a database process which, based on the selected medical action, returns the checklist to the user interface, uses data input into a data point of the checklist to calculate the probability of a medical condition associated with the proposed medical condition, the probability calculation being based upon a prior probability of the condition, the sensitivity of the data point with respect to the condition, and the specificity of the data point with respect to the condition, compares the calculated probability of the medical condition to a pre-determined threshold probability, based upon the comparison, authorizes the proposed medical action, refuses authorization of the proposed medical action, or requests additional data input into the checklist.
57. The system of Claim 56, wherein the pre-determined threshold probability comprises an approval threshold, and the proposed medical action is authorized when the calculated probability exceeds the approval threshold.
58. The system of Claim 56, wherein the pre-determined threshold probability comprises a rejection threshold, and the proposed medical action is refused authorization when the calculated probability is less than the rejection threshold.
59. The system of Claim 56, wherein the calculated probability is compared to both an approval threshold and a rejection threshold, the proposed medical action being authorized when the calculated probability exceeds the approval threshold, and refused authorization when the calculated probability is less than the rejection threshold.

60. The system of Claim 56, wherein the proposed medical action comprises a referral to a specialist physician.
61. The system of Claim 56, wherein the proposed medical action comprises a medical test or procedure.
- 5 62. The system of Claim 61, wherein the procedure comprises a surgical test or procedure.
63. The system of Claim 56, wherein the data input into data points comprises at least one item of items of medical history, physical examination findings, medical tests, and medical procedures.
- 10 64. The system of Claim 56, wherein the database process further comprises a prior probability database process which determines an initial prior probability for the medical condition based upon at least one of presenting symptoms, physical examination findings, the patient's personal medical history, information from medical literature, the frequency of the condition
15 within a population of which the patient is a member, and an analysis of the accumulated experience of patients stored in a database, and wherein the database process uses the initial prior probability to calculate the probability of the condition for an initial data point on the checklist.
- 20 65. The system of Claim 64, wherein for each subsequent data point on the checklist after the initial data point, the prior probability of the condition is determined by the probability calculation for the preceding data point.
- 25 66. The system of Claim 64, wherein the database process further comprises a checklist database process which receives an initial prior probability for the medical condition from the prior probability database process, and returns a checklist associated with the initial prior probability.

67. The system of Claim 66, wherein at least one of the number and sequence of data points on the checklist is determined based upon the initial prior probability associated with the checklist.
68. The system of Claim 67, wherein the checklist is generated by calculating, for each decision node of the evidence-based clinical decision support guideline associated with the proposed medical action, the probability of the existence of a particular medical condition based upon the initial prior probability level, the sensitivity of the decision node with respect to the condition, and the specificity of the decision node with respect to the condition, and, based upon these calculations, determining an optimal sequence and number of data inputs to reach a pre-selected probability of the existence of the condition.
69. The system of Claim 68, wherein from each evidence-based clinical decision support guideline, a plurality of checklists are generated, each checklist associated with a different initial prior probability.
70. The system of Claim 68, wherein the sequence and number of data inputs is optimized with reference to at least one of the cost, the risk, and the change in probability of the condition associated with each data input.
71. The system of Claim 56, wherein the database process further comprises a threshold probability database process which, based on the proposed medical action, returns a threshold probability value associated with the proposed medical action.
72. The system of Claim 71, wherein the threshold probability value is determined based upon an analysis of risks and benefits associated with the proposed medical action.

73. A method of managing an episode of medical care in a data processing system, comprising:
- at a referring user interface, selecting a medical specialty and inputting patient information;
 - 5 at a database, receiving the selected medical specialty and the patient information, and determining an initial prior probability of a medical condition associated with the selected medical specialty;
 - from the database, based upon the initial prior probability, returning to the user interface an interactive checklist of data points for the episode of
 - 10 care, the data points comprising representations of decision nodes of an evidence-based clinical decision support guideline associated with the medical specialty;
 - at the user interface, inputting data into a data points of the checklist;
 - and
 - 15 at the database, using the data input into the data points of the checklist to determine whether a referral to a specialist physician is authorized.
74. The method of Claim 73, further comprising:
- at a specialist user interface, receiving patient information input
 - 20 through the referring user interface, inputting additional patient information, and selecting a medical or surgical diagnostic or treatment intervention; and
 - at the database, using the patient information input through the referring user interface and the specialist user interface, determining whether the selected medical procedure is authorized.
- 25 75. The method of Claim 74, further comprising:
- at the database, determining an initial prior probability of a medical condition associated with the selected medical procedure; and
 - from the database, based upon the initial prior probability, returning to the specialist user interface an interactive checklist of data points for the
 - 30 episode of care, the data points comprising representations of decision nodes

of an evidence-based clinical decision support guideline associated with the selected medical procedure; and

5 at the specialist user interface, inputting data into the data points of the checklist, wherein the checklist data points are used with the patient information input through the referring user interface, the specialist user interface, and interfaces with other data sources laboratories and patients, for example.

76. The method of Claim 75, further comprising:
 at the database, storing the referring and specialist checklists and
10 patient information in a temporary episode record.
77. The method of Claim 76, wherein the referring user, patient, or other authorized user can access the temporary episode record to track the progress of patient care.
78. The method of Claim 76, further comprising:
15 from the database, reporting information entered by the specialist back to the referring user.
79. The method of Claim 78, wherein the information reported back to the referring user comprises discrepancies between information entered by the specialist physician and an expected treatment protocol.
- 20 80. The method of Claim 73, wherein the database is located behind a privacy firewall of an insurer, and authorization for the referral and the medical procedure is provided by the insurer.
81. The method of Claim 76, wherein, upon completion of an episode of care, the temporary episode record is stripped of patient identifying data and
25 stored in a database.

-36-

82. The method of Claim 73, further comprising:
upon authorization of a referral, returning to the referring user
interface a list of eligible specialist physicians.
83. The method of Claim 82, further comprising:
5 at the referring user interface, selecting an eligible specialist
physician; and
at the database, using checklist data to automatically generate a
referral note from the referring user to the selected specialist.

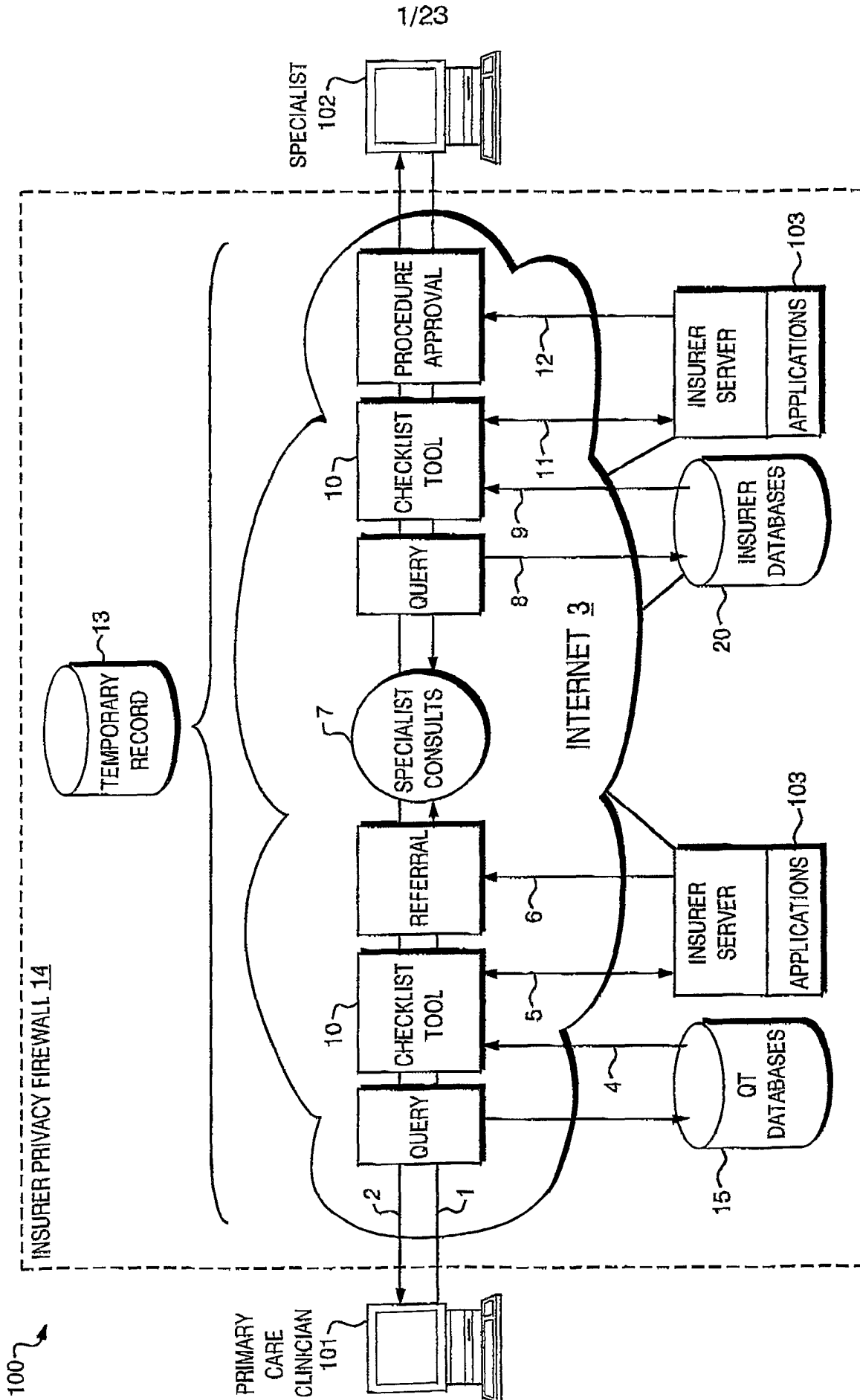


FIG. 1

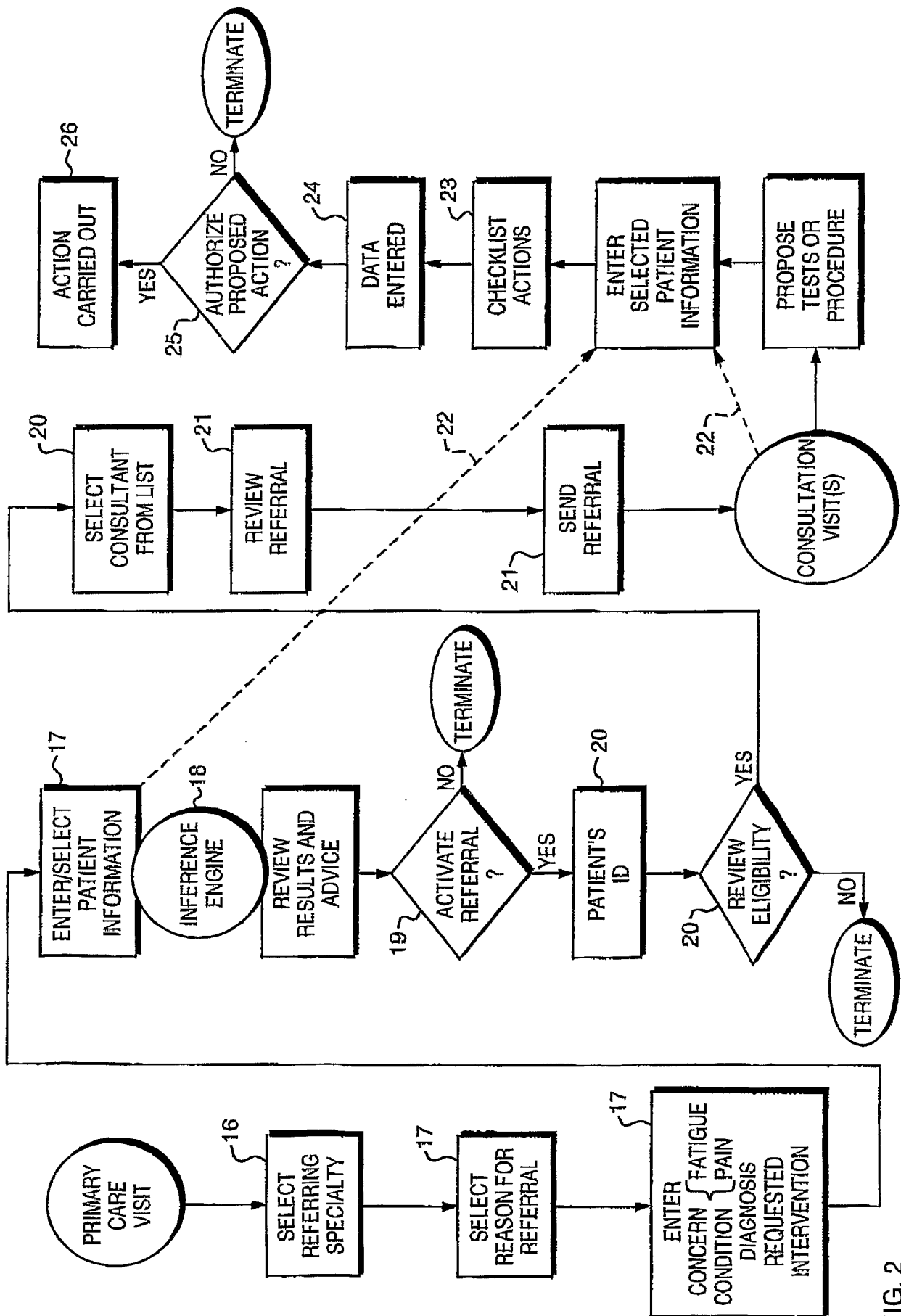


FIG. 2

3/23

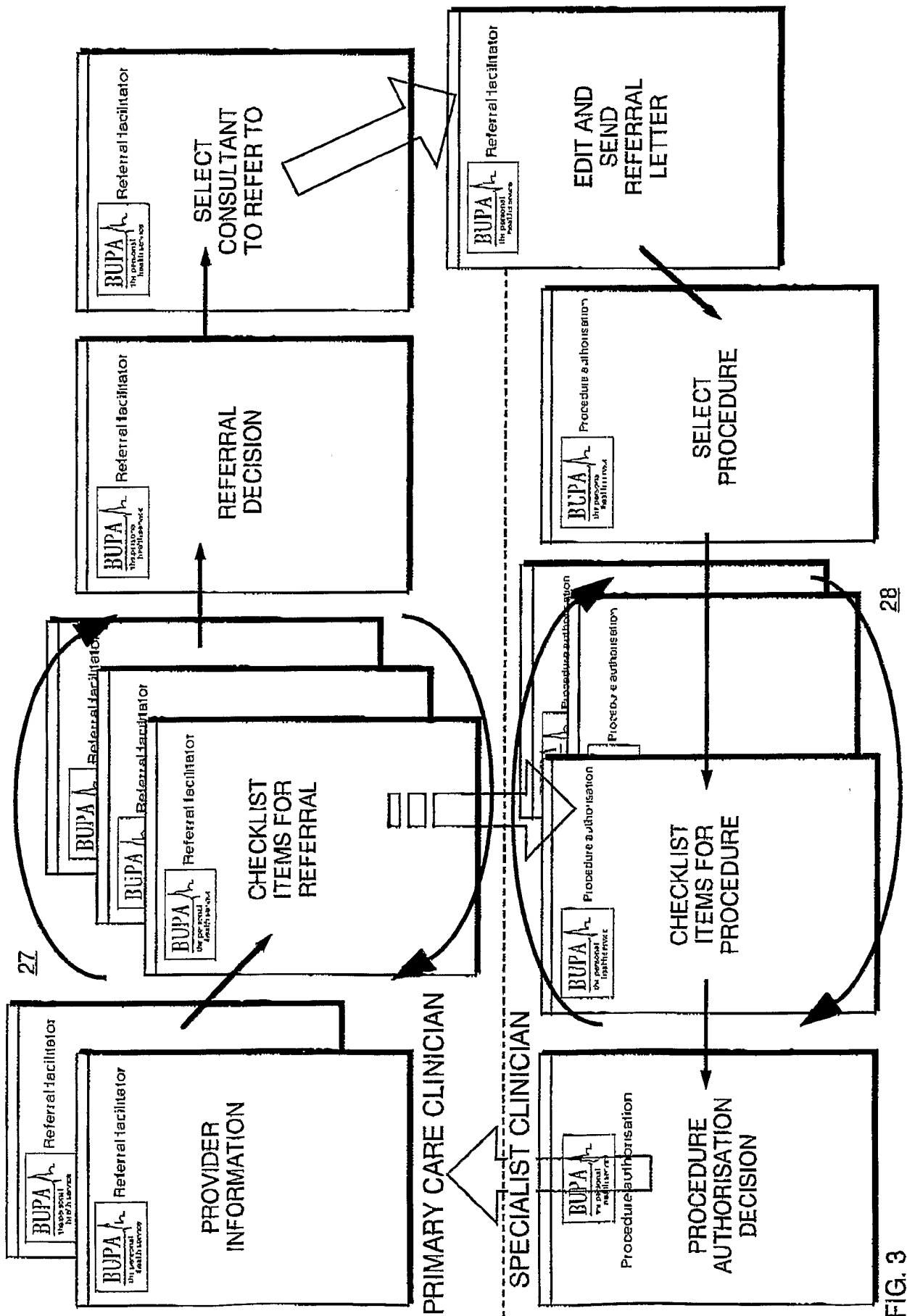


FIG. 3

4/23

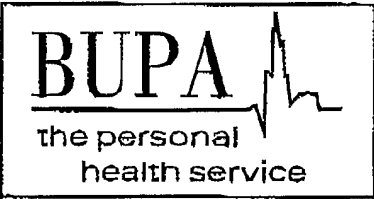
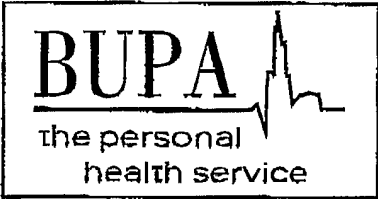
Referral guideline tool	
<div><h1>Referral facilitator</h1></div>	
Provider Information	
ID	<input type="text"/>
Name	<input type="text" value="John Billingsworth"/>
Telephone	<input type="text" value="207-453-7187"/> <input type="button" value="Edit"/>
Fax	<input type="text" value="207-453-7188"/> <input type="button" value="Edit"/>
Email	<input type="text" value="Billingsworth@bupa.org.uk"/> <input type="button" value="Edit"/>
Street Address	<input type="text" value="13 James St."/> <input type="button" value="Edit"/>
City	<input type="text" value="London"/> <input type="button" value="Edit"/>
Postal Code	<input type="text" value="NW3.1JA"/> <input type="button" value="Edit"/>
Reimbursement to	<input type="text" value="Curretil a/c 253.2381059, Barclays Ba"/>
Reimbursement will be made into your account upon completion of this fo	
<input type="button" value="Submit"/>	

FIG. 4

5/23



Referral facilitator

Demographic data and referral reasons

Menopausal status	<input type="text" value="Pre-menopausal"/>
Bleeding with intercourse	<input type="radio"/> Yes <input checked="" type="radio"/> No <input type="radio"/> Don't Know
Heavy bleeding	<input checked="" type="radio"/> Yes <input type="radio"/> No <input type="radio"/> Don't Know
Pelvic Pain	<input type="radio"/> Yes <input checked="" type="radio"/> No <input type="radio"/> Don't Know
Size of uterus in weeks	<input type="text" value="10"/>
History of taking tamoxifen	<input type="radio"/> Yes <input checked="" type="radio"/> No <input type="radio"/> Don't Know
History of polycystic ovaries	<input type="radio"/> Yes <input checked="" type="radio"/> No <input type="radio"/> Don't Know
Prior genital tract cancer	<input checked="" type="radio"/> Yes <input type="radio"/> No <input type="radio"/> Don't Know
Intermenstrual bleeding	<input type="radio"/> Yes <input checked="" type="radio"/> No <input type="radio"/> Don't Know
<input type="button" value="Submit data"/>	

FIG. 5

6/23

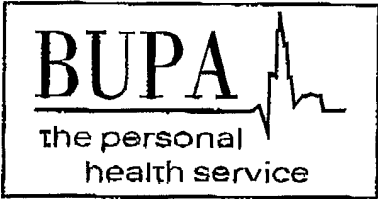
Referral guideline tool		<input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/>	
		Referral facilitator	
Patient findings			
Has pregnancy been out?	<input checked="" type="radio"/> Yes <input type="radio"/> No <input type="radio"/> Don't Know	<input type="button" value="▲"/>	
Patient has desire to maintain fertility?	<input type="radio"/> Yes <input checked="" type="radio"/> No <input type="radio"/> Don't Know		
Bimanual exam completed?	<input checked="" type="radio"/> Yes <input type="radio"/> No <input type="radio"/> Don't Know		
Pap Smear	<input type="button" value="Not done ▼"/>		
Medical risks assessed?	<input checked="" type="radio"/> Yes <input type="radio"/> No <input type="radio"/> Don't Know		
Psychological risks assessed?	<input checked="" type="radio"/> Yes <input type="radio"/> No <input type="radio"/> Don't Know		
Evidence of Anemia	<input checked="" type="radio"/> Yes <input type="radio"/> No <input type="radio"/> Don't Know		
Blood count obtained?	<input checked="" type="radio"/> Yes <input type="radio"/> No <input type="radio"/> Don't Know		
Has patient had trial of antifibrinolytic?	<input type="radio"/> Yes <input checked="" type="radio"/> No <input type="radio"/> Don't Know		
Trial of OCP or progestogen releasing IUD completed?	<input type="radio"/> Yes <input checked="" type="radio"/> No <input type="radio"/> Don't Know		
<input type="button" value="Submit data"/>		<input type="button" value="▼"/>	
<input type="button" value="◀"/>		<input type="button" value="▶"/>	

FIG. 6

7/23

Referral guideline tool

BUPA
the personal
health service

Referral facilitator

Referral decision


- The guideline recommends that you continue treating this patient in your practice.
- Please click on the 'Manage patient locally' button for recommendations on management of this patient.

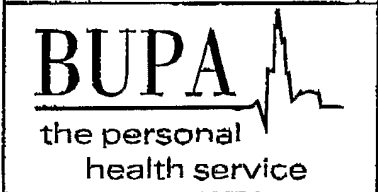
However, you still may choose to refer this patient. Please select the 'Refer' button.

Would you like to **Refer this patient** **Manage this patient locally**

FIG. 7

8/23

Referral guideline tool



Referral facilitator

Select consultant to refer to

The following consultants are available in and around London, NW3 .1JA

Fox, Dr. Anthony	<input type="radio"/>
Kirk, Dr. James T.	<input type="radio"/>
Pollock, Dr. Bruce	<input checked="" type="radio"/>
Smith, Dr. Grant	<input type="radio"/>

29

Select consultant

◀ ▶

FIG. 8

9/23

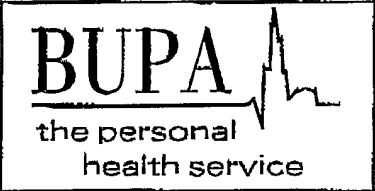
Referral guideline tool			
<div></div>		Referral facilitator	
Edit and send referral letter			
<p>I am referring Emelia Axelrod, a BUPA insured 45 year old mother of three to you for assessment of menorrhagia and fibroids. She has no major medical problems. Over the past two years, she has had mild back pain, arising when she has been on her feet all day. This responds nicely to paracetamol. She has not noted pelvic or back pain associated with intercourse. She denies weight loss or anorexia, polycystic ovaries, and has not been on tamoxifen. Her menstrual history has been normal until one year ago. Her menses usually last about four days and are quite regular. She bleeds extremely heavily for the first two days, saturating a pad every two hours. She has had three pregnancies, the last four years ago. She and her husband do not wish to have more children. On examination in my surgery last month, she was found to have an intrauterine, midline enlargement consistent with a pregnancy of about 10 weeks. The uterus is movable and firm, not hard. She has a hemoglobin of 12, a normal urinalysis, and has had a normal Papanicolou smear done three months ago. I have given her a course of Tranexamic acid 1 g tds but her bleeding has continued.</p> <p>Please see and advise about management.</p> <p>With best regards, Dr. John Billingsworth General Practitioner</p>		<div>△</div> <div>▽</div>	
<div>Send by email</div>		<div>Print letter</div>	
<div>◀</div>		<div>▶</div>	

FIG. 9

10/23

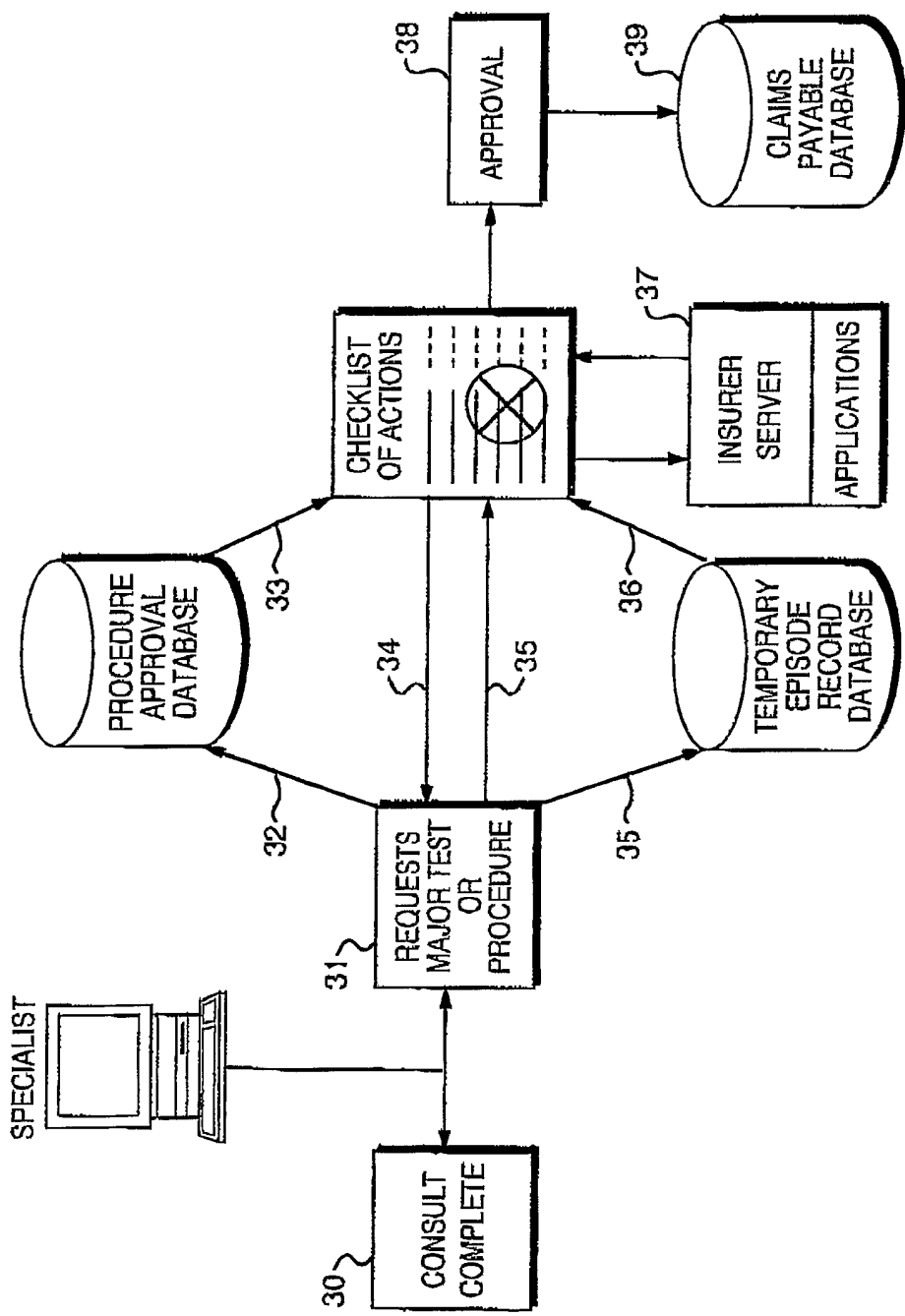
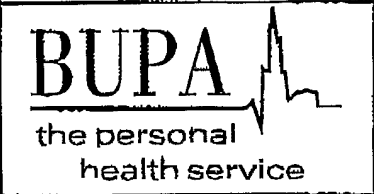


FIG. 10

11/23



Procedure authorisation

Select procedure

Hysterectomy
Dilation and curettage
Prolapse repair
Oophorectomy

Select

FIG. 11

12/23

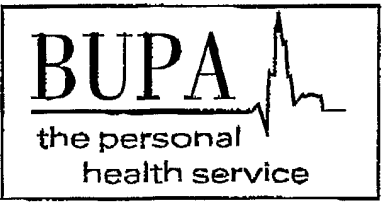
Procedure authorisation tool	
	Procedure authorisation
Reasons for procedure	
Dysfunctional uterine bleeding	<input type="radio"/> Yes <input checked="" type="radio"/> No <input type="radio"/> Don't Know
Uterine fibroids	<input checked="" type="radio"/> Yes <input type="radio"/> No <input type="radio"/> Don't Know
Malignancy or suspected malignancy of reproductive tract	<input type="radio"/> Yes <input checked="" type="radio"/> No <input type="radio"/> Don't Know
Ovarian cysts	<input checked="" type="radio"/> Yes <input type="radio"/> No <input type="radio"/> Don't Know
Endometriosis	<input type="radio"/> Yes <input type="radio"/> No <input checked="" type="radio"/> Don't Know
Adenomyosis	<input type="radio"/> Yes <input type="radio"/> No <input checked="" type="radio"/> Don't Know
Pelvic inflammatory disease	<input type="radio"/> Yes <input type="radio"/> No <input checked="" type="radio"/> Don't Know
Uterovaginal prolapse	<input type="radio"/> Yes <input type="radio"/> No <input type="radio"/> Don't Know

FIG. 12

13/23

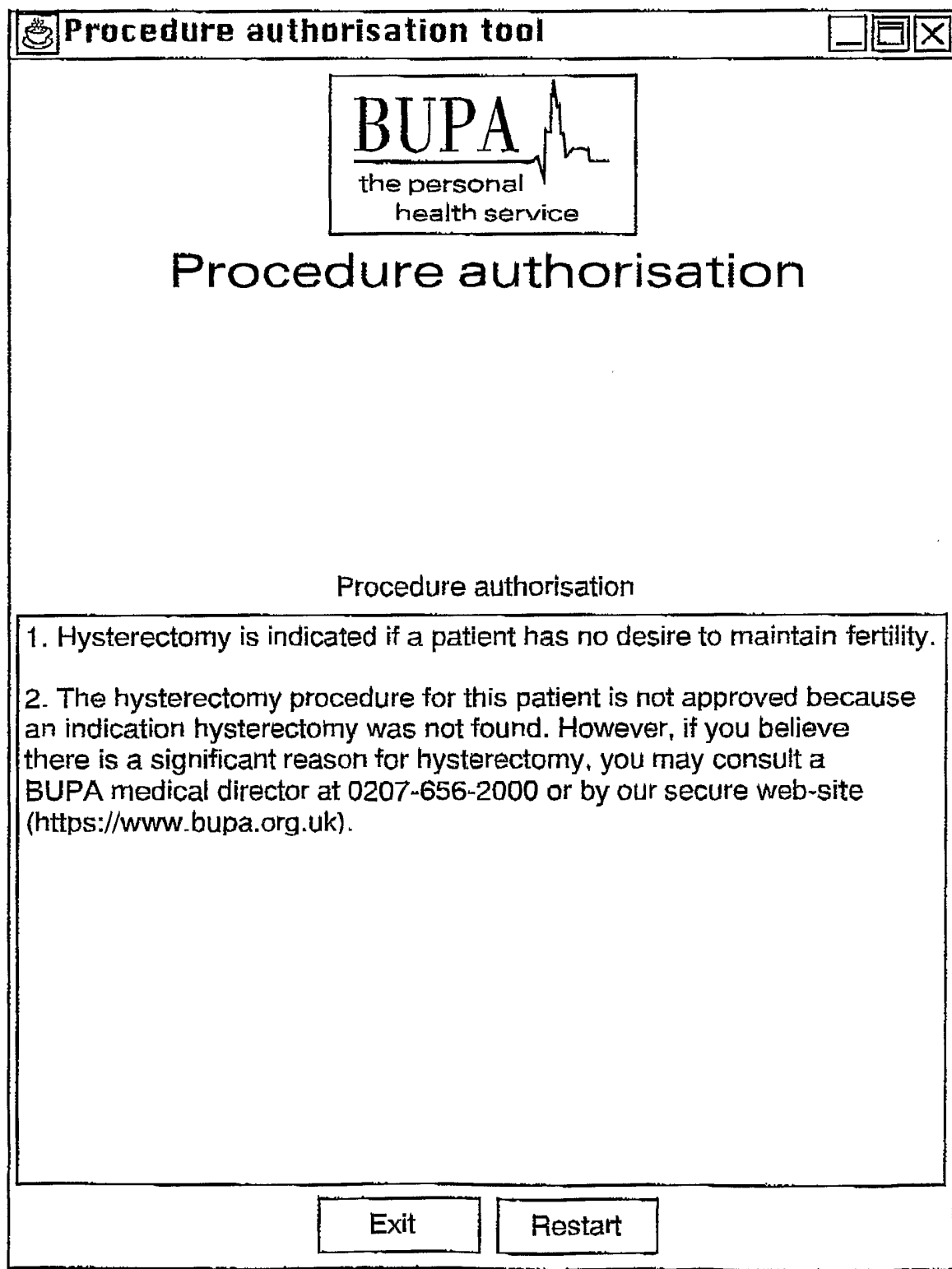


FIG. 13

14/23

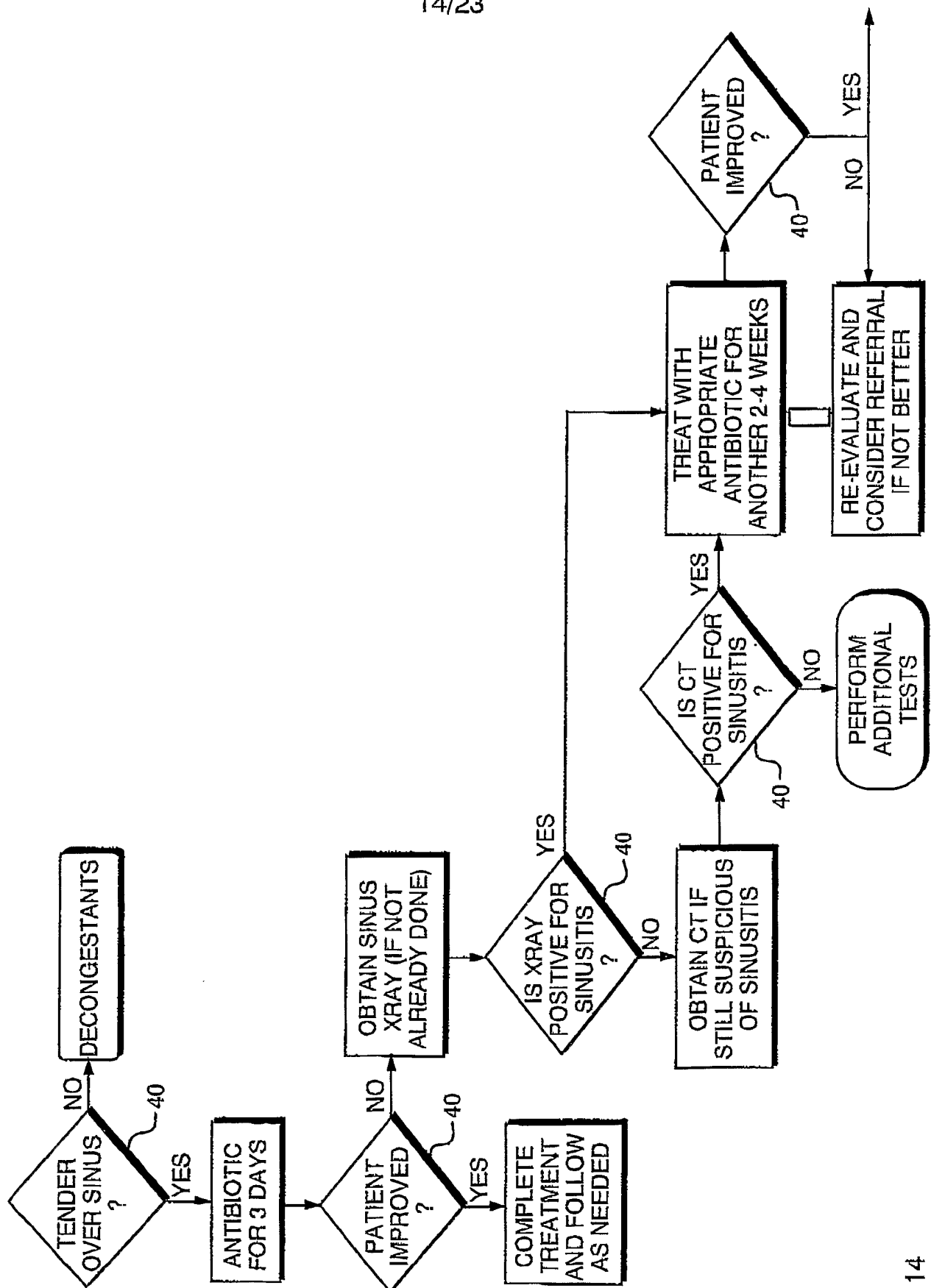


FIG. 14

15/23

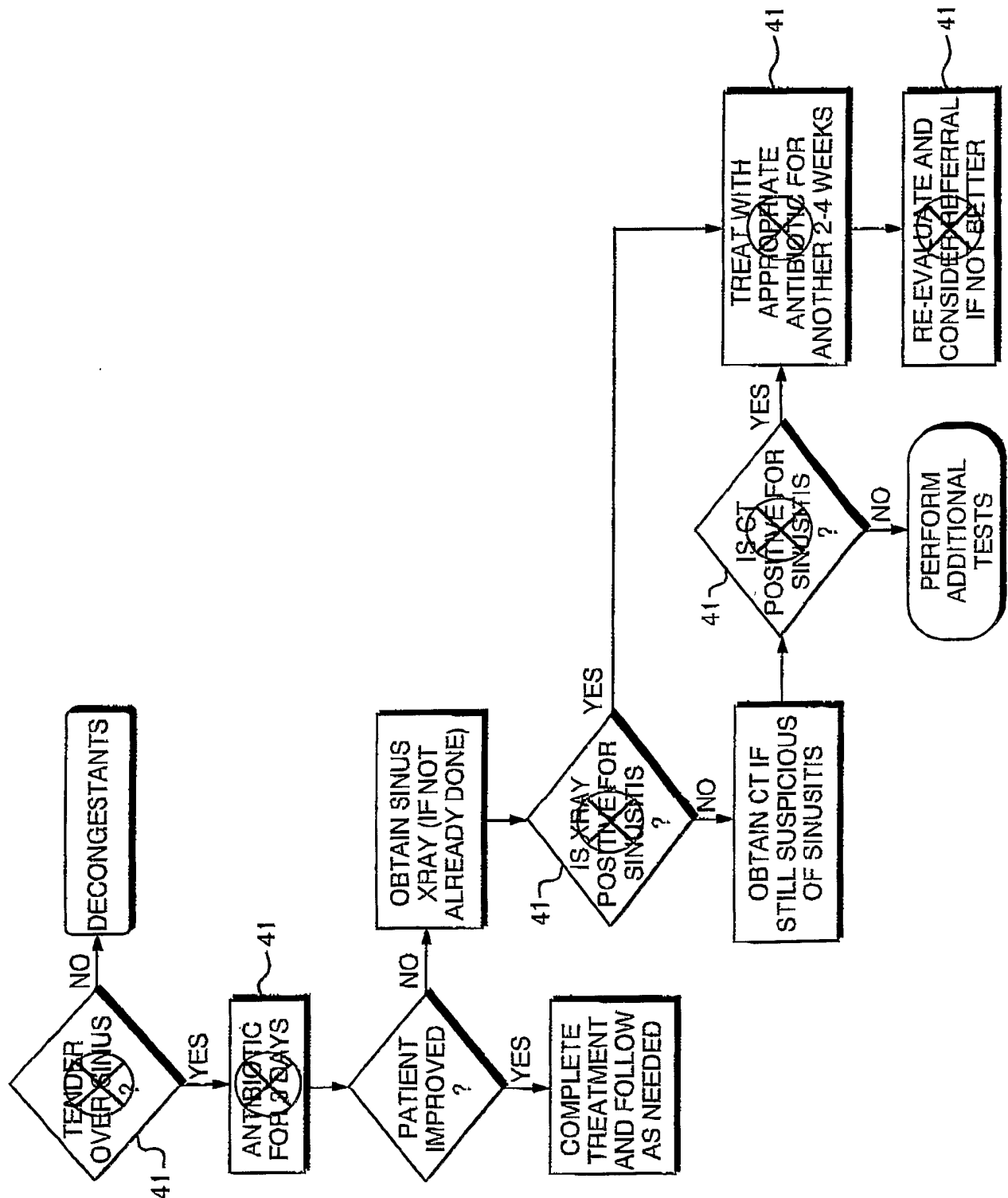


FIG. 15

16/23

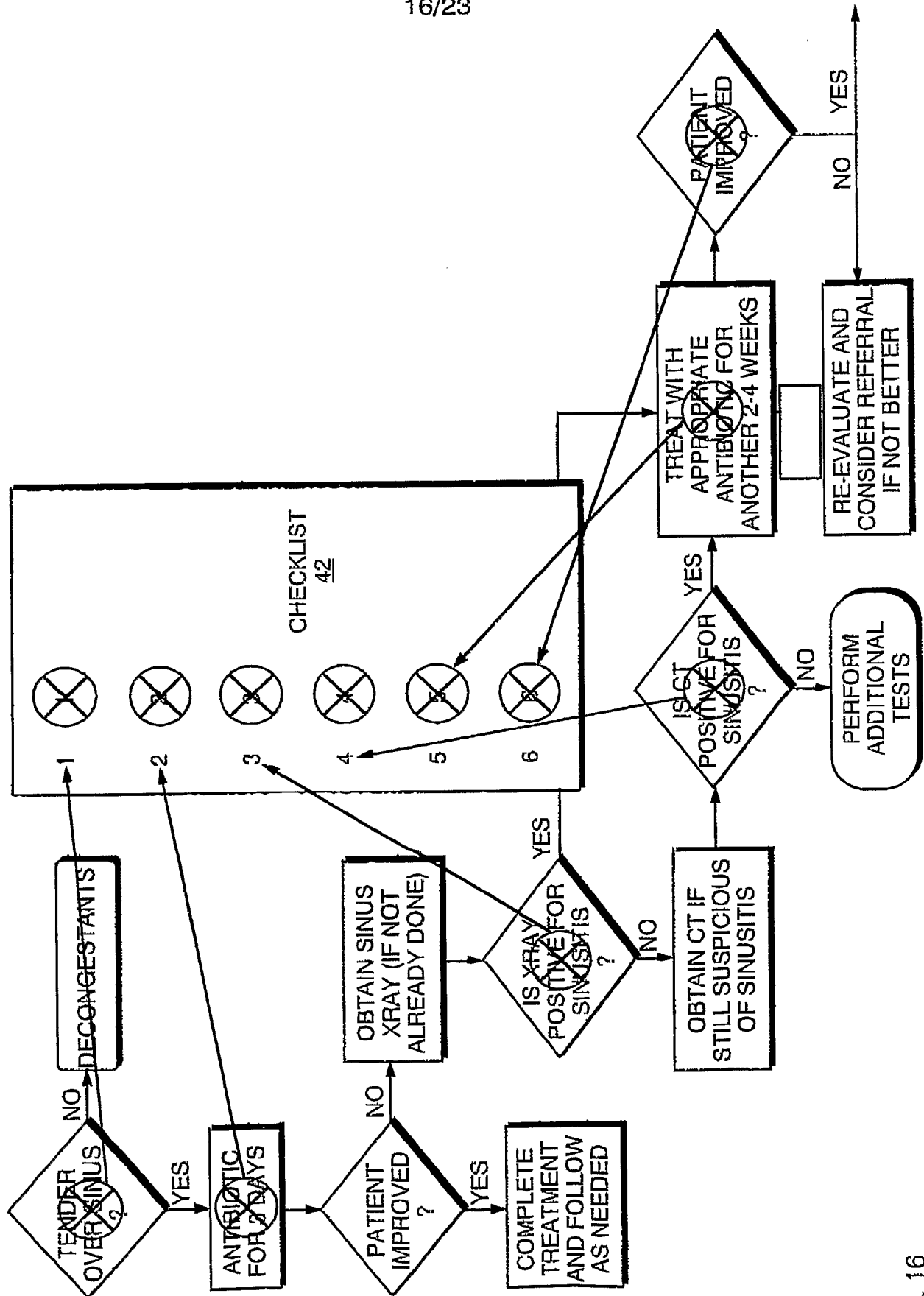


FIG. 16

17/23

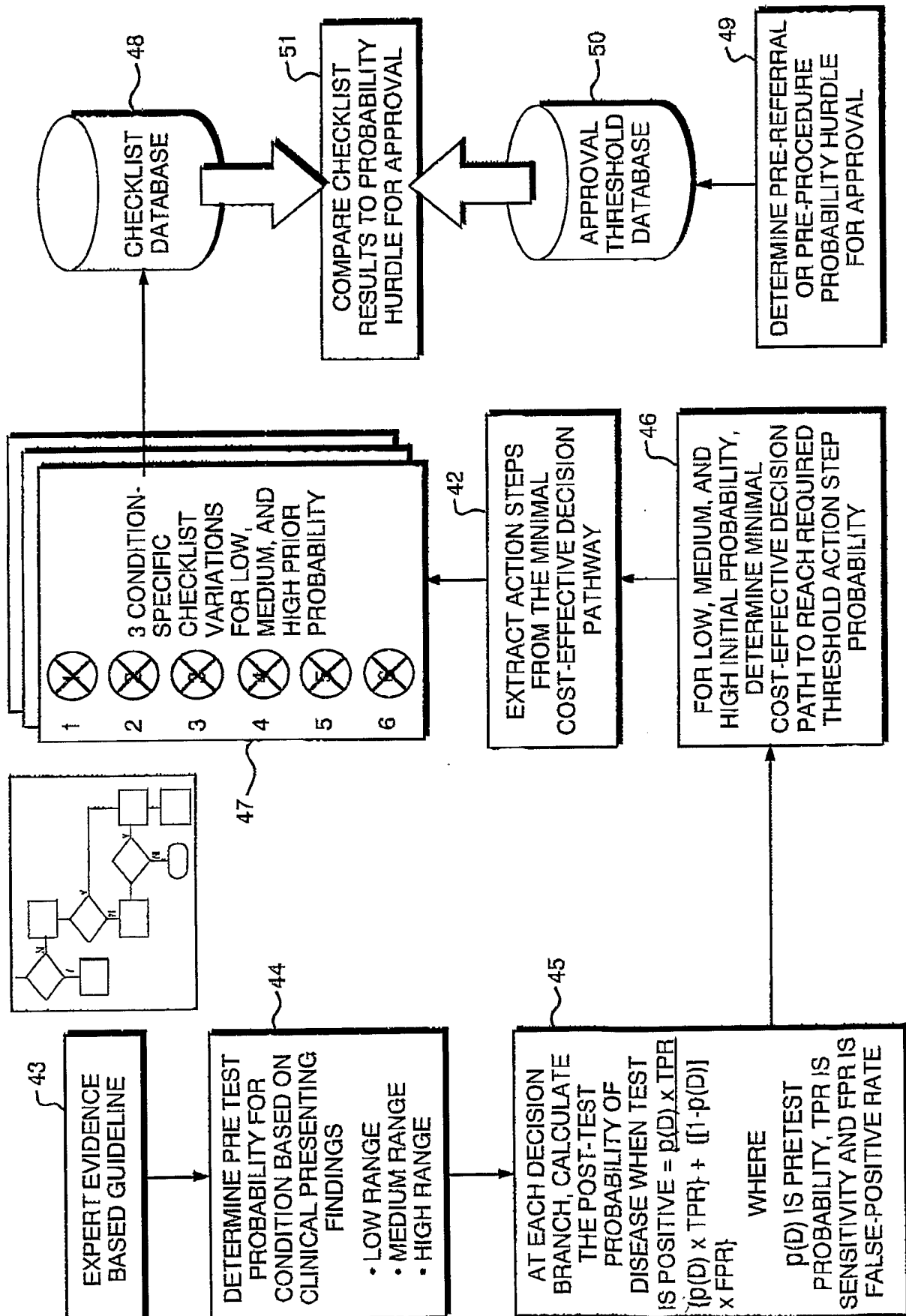


FIG. 17

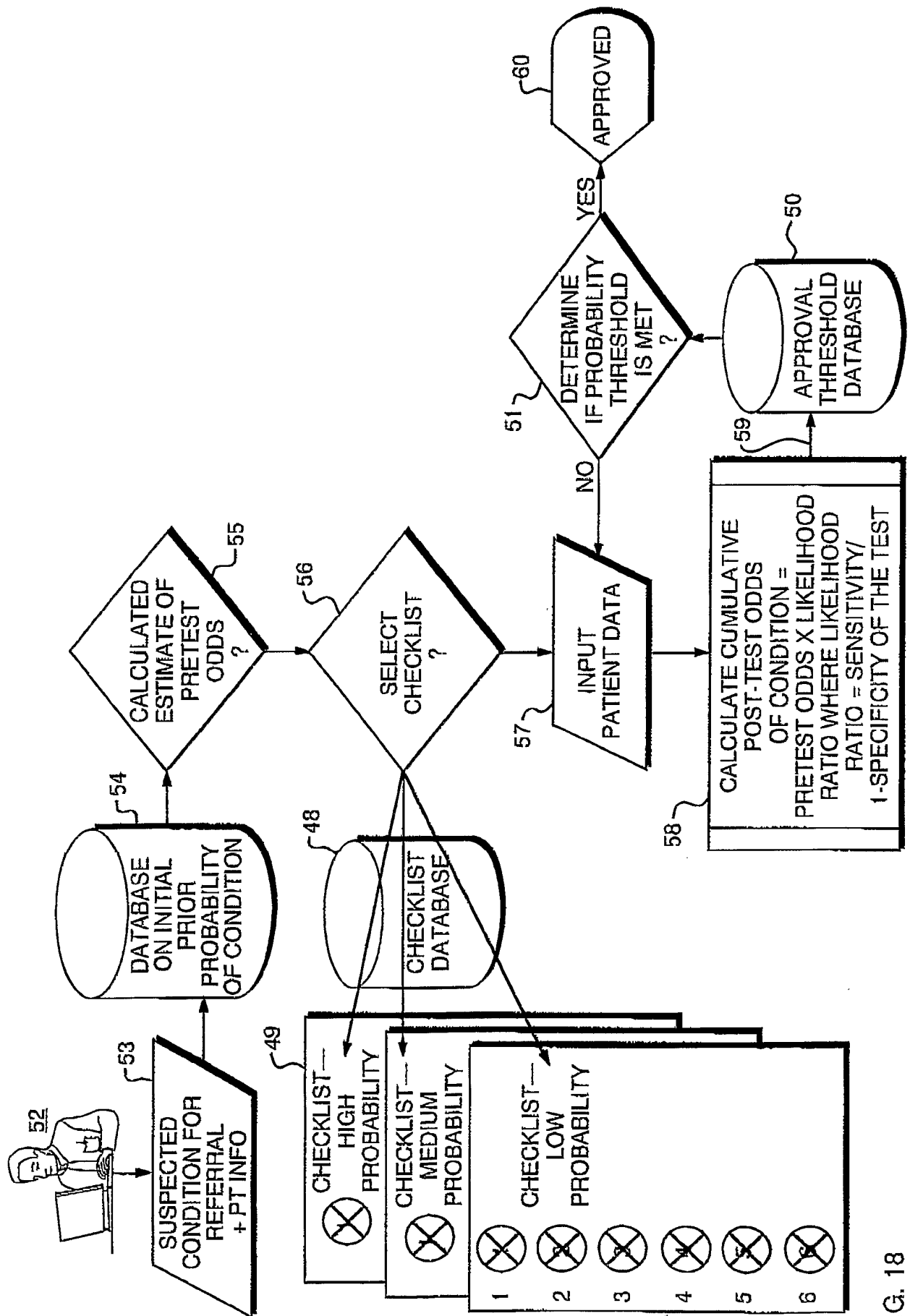


FIG. 18

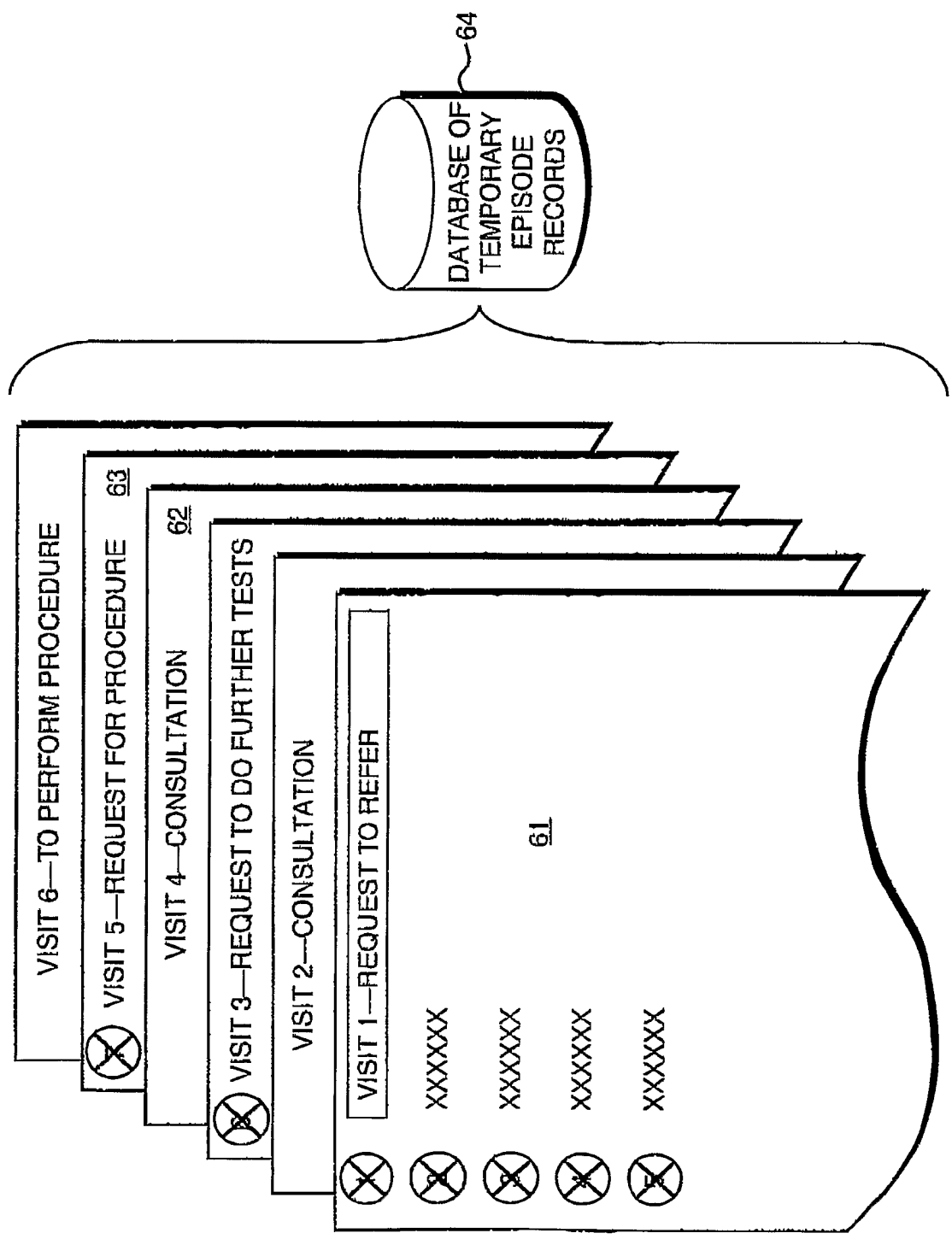


FIG. 19

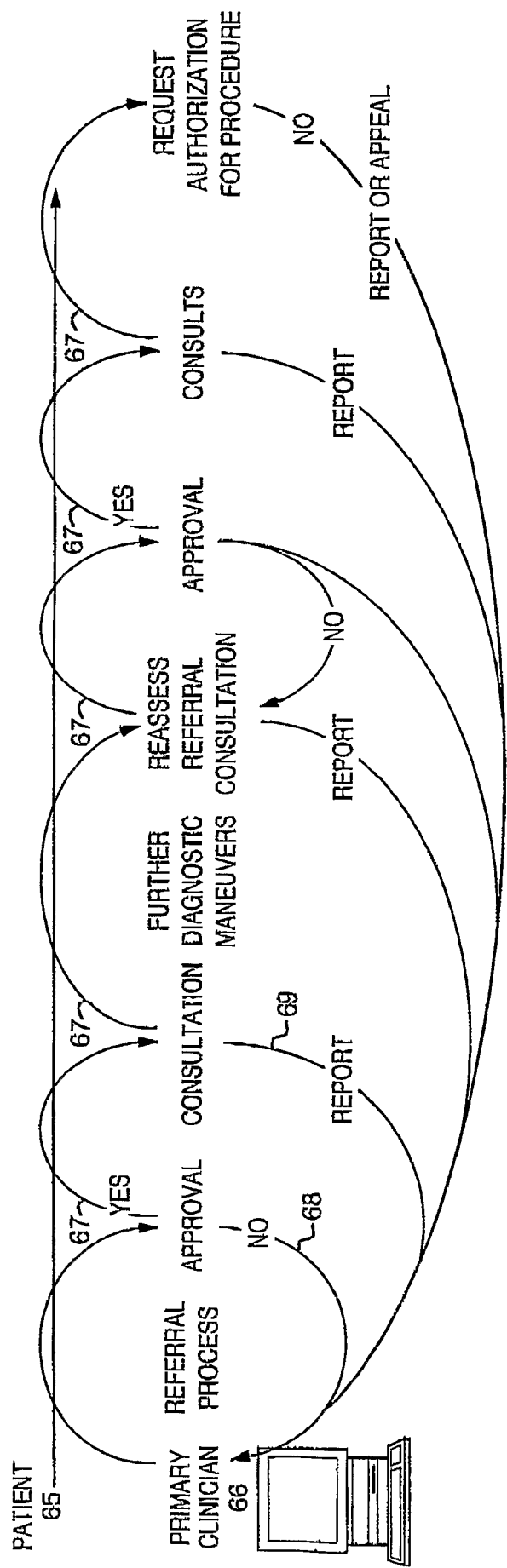


FIG. 20

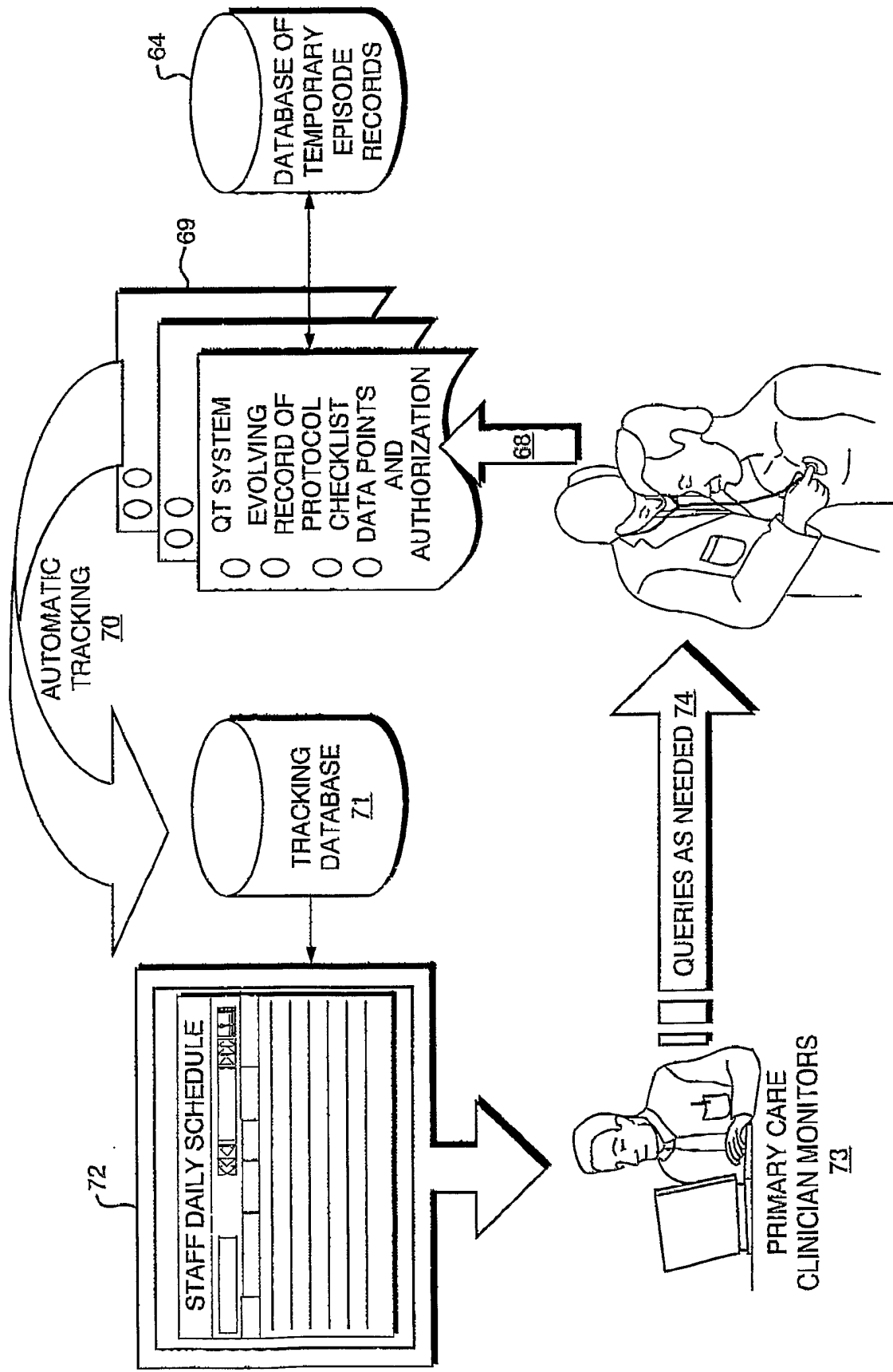


FIG. 21

REFRESH SCHEDULE

FOR DAY

02/13/2002 (WED)

112

SPECIALIST STATUS REPORT

STATUS	PATIENT	MED REC #	LENGTH	LOCATION	CHECKLIST GAP
<input checked="" type="checkbox"/>	VAZ,MANUEL J	78261	30	COMP: 7:49 AM	No SGOT
<input checked="" type="checkbox"/>	BOOKER,JOYCE C	496263	20	COMP: 8:55 AM	
<input type="checkbox"/>	BOYDEN,JOHN P	2449677	30	COMP: 8:50 AM	
<input checked="" type="checkbox"/>	HEATHMAN,VIVIAN R	194832	20	COMP: 9:03 AM	MRI, Rx
<input checked="" type="checkbox"/>	ANDERSON,SAMUEL L	144479	20	COMP: 10:04 AM	
<input checked="" type="checkbox"/>	ELLIS,WALTER J	44030	30	COMP: 9:04	
<input checked="" type="checkbox"/>	ALACH,JAMES	450824	20	COMP: 10:11 AM	
<input checked="" type="checkbox"/>	ELBRUS,L YUBOV	494554	20	COMP: 10:07 AM	Hct, BUN Rx Rx
<input checked="" type="checkbox"/>	LEFORT,AIDA C	184312	30	NO SHOW	
<input type="checkbox"/>	WAITERS,HATTIE B	86856	20	COMP: 11:08 AM	
<input checked="" type="checkbox"/>	RISMAN,BARBARA	418235	30	COMP: 1:24 PM	0

75

76

77

78

79

FIG. 22

23/23

ENCOUNTER HISTORY					ENCOUNTER	LABORATORY	IMAGING
DATE	TYPE	DEPARTMENT	PROVIDER	DESCRIPTION			
03/25/2002	TELEPHONE	KENOBG	PARKER, DIANE RN	DYSFUNCTIONAL UTERINE BLEEDING			
03/21/2002	TELEPHONE	KENOBG	PARKER, DIANE RN	DYSFUNCTIONAL UTERINE BLEEDING			
03/18/2002	TELEPHONE	KENOBG	PARKER, DIANE RN	DYSFUNCTIONAL UTERINE BLEEDING			
03/04/2002	TELEPHONE	KENOBG	DOWLING, DOROTHY	NO SHOW			
03/04/2002	APPOINTMENT	KENOBG	DOWLING, DOROTHY	DYSFUNCTIONAL UTERINE BLEEDING			
03/01/2002	TELEPHONE	KENOBG	PARKER, DIANE RN	DYSFUNCTIONAL UTERINE BLEEDING			
02/27/2002	TELEPHONE	KENOBG	PARKER, DIANE RN	DYSFUNCTIONAL UTERINE BLEEDING			
02/27/2002	ORDERS ONLY	KENOBG	PARKER, DIANE RN	DYSFUNCTIONAL UTERINE BLEEDING			
02/27/2002	TELEPHONE	KENOBG	PARKER, DIANE RN	DYSFUNCTIONAL UTERINE BLEEDING			
02/27/2002	APPOINTMENT	KENOBG	PARKER, DIANE RN	NO SHOW			
02/25/2002	TELEPHONE	KENOBG	LUCEY, ANNE RN	DYSFUNCTIONAL UTERINE BLEEDING			
02/19/2002	TELEPHONE	KENOBG	PARKER, DIANE RN	TEST RESULTS ONLY			
02/19/2002	TELEPHONE	KENOBG	PARKER, DIANE RN	DYSFUNCTIONAL UTERINE BLEEDING			
02/13/2002	OFFICE VISIT	KENOBG	DOWLING, DOROTHY	DYSFUNCTIONAL UTERINE BLEEDING			
02/13/2002	OFFICE VISIT	KIM4E	MOORE, GORDON T	PREGNANCY EXAM / TEST			
					CLICK ON TAB TO DISPLAY DETAILS		

FIG. 23