UNDERSTANDING WORKFLOW AND INFORMATION FLOW IN CHRONIC DISEASE CARE

By

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CHAPTER I

INTRODUCTION

Over 90 million people in the United States, or 30% of the population, live with one or more chronic diseases (1). Chronic diseases have significant personal and financial impacts, felt both by individuals and by society with both direct and indirect costs. Individuals with chronic disease consume consume a disproportionate share of overall healthcare expenditures because they have greater healthcare needs. Caring for people with chronic diseases consumes 75% of annual U.S. healthcare expenditures (1). Since chronic disease affects a higher proportion of the elderly, who are covered by government-financed healthcare programs such as Medicare, society bears the direct cost (2) (3). Numerous indirect costs are also imposed on patients, their families, and society including: lost time from work, loss of earnings, premature death, and caregiving costs incurred by family members (2).

The already substantial problems related to chronic disease are expected to increase in coming years as the overall age of the U.S. population increases (3). In addition, many diseases that were once thought of as fatal such as HIV, type 1 diabetes, and some cancers have, with advances in medicine, been converted to chronic diseases and these diseases are costly to treat (3). These trends are expected to continue. Hoffman and colleagues estimated that by 2030 there will be 148 million people or 41% of the U.S. population with one or more chronic diseases and that the direct cost of their care will be $798 billion yearly (2).

Numerous challenges impede improvements in chronic disease treatment. Modern medical care is still primarily focused on managing acute care episodes rather than chronic conditions. The limited time available during most patient-provider interactions is consumed by dealing with immediate needs, leaving little time to discuss overall health status or prevention of chronic disease or their sequelae, despite published care guidelines (4). This approach, referred to as the "tyranny of the urgent", results in deferral of care for long term chronic conditions (5). Time available for chronic disease prevention and management is further constrained by governmental and institution mandated care and documentation requirements. Moreover, healthcare's current reimbursement structure fosters the emphasis on acute care. The current fee-for-service model pays for performing individual procedures rather than chronic disease management. Services, such as patient treatment in a hospital for an acute episode, are usually well compensated. Management activities, such as calling patients to discuss their disease status, are not covered (6).

The Chronic Care Model (CCM) identifies information technology as an important part of a strategy to improve chronic disease care (5). The CCM consists of six interdependent elements: community resources and policies, health care organization, self-management support, delivery system design, decision support, and clinical information systems (7). Information technology plays a role in self-management support, decision support, and clinical information systems. Self-management support enables patients to manage aspects of their disease. Decision support facilitates the use of evidence-based clinical practice guidelines. Clinical information systems (CIS) provide reminder systems to assist with decision support. CIS also provide feedback to providers and to practices about their effectiveness in managing chronic conditions and include registries for planning individual care and for implementing population-based care.

This study was intended as a first step towards development of effective informatics tools for chronic disease care. Jakob Nielsen stated in *Usability Engineering*, "The first step in the usability process is to study the intended users and use of the product"(8). In order to learn about the intended users and their environment, this study investigated workflow and information flow in three chronic disease clinics: multiple sclerosis, cystic fibrosis, and diabetes. The hypothesis tested in the study was that workflow and information flow during management of different chronic diseases share core similarities, but also have some crucial differences. The specific aim was to evaluate and compare the workflow and information flow of providers across three chronic disease domains in the ambulatory care environment.

This report is divided into seven chapters discussing different aspects of the study. Chapter II describes how the three chronic disease clinics were selected for inclusion in the study. Chapter III provides an overview of the disease processes for the three diseases and also discusses the role of informatics thus far in each disease. Chapter IV explains how the qualitative methods used in the study were selected and applied. Chapter V explains the six research themes that were extracted from the observation and interview data. Chapter VI discusses the meaning of the data, implications for the design of informatics tools for chronic disease care, and study limitations. Chapter VII summarizes the study and discusses future research directions.

CHAPTER II

CLINIC SELECTION

Fifteen ambulatory clinics at Vanderbilt University Medical Center (VUMC) specializing in chronic disease care were evaluated for study inclusion (Table 1). After preliminary screening, interviews were conducted with key clinic personnel to evaluate study appropriateness. Several clinics chose not to participate in the initial interviews due to lack of provider interest and ongoing informatics projects.

Table 1. Chronic disease clinics evaluated

Clinic	**Interview conducted?**
Anticoagulation management (Cardiac Clinic)	Yes
Anticoagulation management (Coumadin Clinic)	Yes
Chronic renal failure	Yes
Cystic fibrosis (adult)	Yes
Diabetes (adult and pediatric)	Yes
Heart failure	Yes
Hyperlipidemia	Yes
Multiple sclerosis	Yes
Rheumatoid arthritis (pediatric)	Yes
Asthma (adult)	No
Asthma (pediatric)	No
Chronic obstructive pulmonary disease	No
HIV/AIDS (adult)	No
Parkinson's disease	No
Rheumatoid arthritis (adult)	No

After the initial interviews with key personnel, the 9 clinics were evaluated using the Strengths, Weaknesses, Opportunities, Threats (SWOT) framework (9). SWOT Analysis is most often used in strategic planning and evaluation of decisions for businesses (10) (11) (12) (13), public and social programs (14) (15) (16) , and education (17) (18). In SWOT analysis, lists of internal strengths and weaknesses and external opportunities and threats for each area under consideration are compiled. The process results in a more complete understanding of the benefits and risks associated with decisions and supports the comparison of different options. SWOT Analysis has been applied to the medical domain for multiple purposes including: evaluating learning environments in medical education (19), assessing the impact of the implementation clinical pathways in a hospital (20), and examining the value of virtual-reality approaches for physical rehabilitation (21).

In evaluating the chronic disease clinics for study inclusion, strengths and weaknesses were factors internal to the clinic such as clinic accessibility, existing use of technology, and clinic organizational structure. Opportunities and threats were factors external to the clinic such as trends in care, existing informatics projects, and department and medical center policies.

Three adult subspeciality clinics were selected for the study based on the SWOT analysis: multiple sclerosis (MS), cystic fibrosis (CF), and diabetes mellitus (DM). Table 2 presents a summary of the SWOT analysis for the three selected clinics.

Table 2. SWOT analysis of selected domains

Clinic	Strengths	Weaknesses	Opportunities	Threats
Multiple Sclerosis	• Existing use of informatics tools • Small staff with large patient load, interested in finding tools to help	• Much documentation still on paper, although scanned in • Disease measurement variables are non-numeric	• Goal of 'umbrella of care' to improve long term care processes and patient satisfaction	• Concerns about IRB and HIPAA issues
Cystic Fibrosis	• Existing use of informatics tools • Strong opinions on software functionality • Some numeric disease measurement variables (PFT results)	• Requested features may be challenging to implement	• Quality improvement perspective has potential for large impact on quality of care	• Difficulty in getting data from medical devices to EMR in usable format
Diabetes Mellitus	• Existing use of informatics tools • Joint pediatric/ adult clinic • Numeric disease measurement variables (HbA1c, glucose)	• Existing VUMC informatics projects • Clinic size and activity level may cause access difficulties	• New challenges due to new clinic space • Looking for sustainable informatics solutions	• Difficulty in getting data from medical devices to EMR in usable format • Significant informatics work already done in this domain

Data regarding clinic characteristics were also collected during the initial interviews (Table 3).

Table 3. Study clinic characteristics

Characteristic	**Multiple sclerosis**	**Cystic fibrosis**	**Diabetes**
Total patients	3000	140	6000
Attending physicians	2	2	10
Other physicians	Varies, residents and fellows on occasion	Varies, 2-3 fellows	Varies, residents and fellows
Nurses	1 full-time nurse 2 part-time nurses	1 full time CF nurse 2 intake nurses	5 intake nurses 2 nurse educators
Ancillary providers	None	1 dietitian 1 social worker	2 dietitians
Other personnel	1 clinical receptionist	3-4 clinical receptionists 1 administrative assistant	5 clinical receptionists >5 administrative assistants
Physical location	Clinic in rehabilitation hospital	Basement of main clinic building	Upper floor of clinic building
Dedicated exam rooms	4	4-5	15
Recommended minimum visit frequency	Every 6 months	Every 3 months	Every 3 months

The three clinics were selected in large part because of the diverse nature of the diseases, patient populations, number of patients, and number of staff. All of the included clinics had been using StarPanel, the VUMC electronic medical record (EMR), for several years, although usage patterns varied between the clinics. A physician within each clinic expressed interest in the study and in the use of informatics tools to support patient care. The variables described in the SWOT analysis (Table 2) and in the clinic characteristics (Table 3) resulted in the inclusion of the three clinics in the study.

In contrast, various characteristics resulted in clinics being excluded from the study after initial interviews were conducted. The reasons for exclusion are summarized below in Table 4.

Table 4. Reasons for clinic exclusion

Clinic	**Category**	**Characteristic(s)**
Anticoagulation management (Cardiac Clinic)	Weakness	High degree of satisfaction with existing processes and vendor-based informatics tools, lack of interest in changes
Anticoagulation management (Coumadin Clinic)	Threat	Existing project underway to design and implement new informatics tools to meet clinic needs
Chronic renal failure	Weakness	Lack of clear direction for study in the environment
Heart failure	Weakness	Interest in informatics for research studies rather than clinical applications
Hyperlipidemia	Weakness	Limited scope of patient follow-up, interest in informatics for research studies rather than clinical applications
Rheumatoid arthritis (pediatric)	Weakness	Limited scope of patient follow-up

The characteristics of each of the three selected clinics are summarized on the following pages. Information about the three clinics will be presented throughout this document in the order the clinics were studied: MS, CF, and DM.

Multiple Sclerosis Clinic

The Vanderbilt Multiple Sclerosis (MS) Clinic is located in a rehabilitation hospital which is physically separated from all other ambulatory clinics. This physical separation translates to separation from the services readily available to clinics with greater proximity to the main clinic area and a greater willingness to attempt to resolve problems before requesting support. The clinic provides continuing care to approximately 3000 patients with a staff of two physicians, one full-time registered nurse, one clinical receptionist, and several part-time nurses and administrative personnel. Fellows and residents occasionally work in the clinic. Most patients in the clinic have multiple sclerosis, although a small number of patients with other neuroimmunologic disorders are also seen.

Patients come to the clinic for routine care at ~6 month intervals and more frequently during disease exacerbations. Tests are routinely conducted to evaluate disease progression and to ensure chronic medications are not causing organ damage. Magnetic resonance imaging (MRI) plays an important role in the initial diagnosis of MS and is also used to assess disease progression.

During the initial interview, the clinic represented itself as "fully electronic". The MS clinic has been using StarPanel for several years and also uses EPIC software for scheduling visits and for billing.

Adult Cystic Fibrosis Clinic

The Vanderbilt Adult Cystic Fibrosis (CF) Center is located in the Pulmonary and Infectious Disease clinics in the basement of The Vanderbilt Clinic (TVC). The physical location of the clinic results in easy access to support services including a laboratory for phlebotomy and an informatics support center. The clinic provides continuing care to approximately 140 patients. Clinic staff include two attending physicians, 2-3 fellows, two intake nurses, one full-time CF nurse, and several clinical receptionists and administrative staff. During the course of the study, staff turnover resulted in the CF nurse role being filled by temporary staff. A social worker and a dietitian are available during clinic hours. Outside of clinic hours, a part-time CF registry administrator tracks clinic compliance with Cystic Fibrosis Foundation (CFF) guidelines and submits information to the CF Registry. The adult CF clinic is held 5-6 afternoons per month. Only adult patients are seen in the study clinic, with the transition from pediatric to adult care occurring some time after the patient turns 18.

Patients come to the clinic for routine care at 3 month intervals and more frequently due to illness. Follow-up visits are typically held 2 weeks after the completion of an infection treatment regimen. The CF registry administrator compiles information on a paper form regarding patient care requirements to meet the CFF guidelines before each patient visit. Patients see the social worker at least once each year. Patient weight determines the frequency of dietitian visits. CF patients are regularly tested for nutrition and pulmonary function. After each clinic day, the CF registry administrator updates the CFF registry to include tests or treatments completed during clinic.

The director of the Adult CF Clinic has been active in the development of the StarPanel EMR system. She designed and implemented several of the StarPanel templates used in the CF clinic and is interested in how technology can be used to enhance patient care. All of the clinic staff use StarPanel for patient documentation. EPIC is also used for scheduling patient visits.

Adult Diabetes Mellitus Clinic

The Vanderbilt Eskind Diabetes Clinic is located on the 8th floor of a clinic tower at VUMC. The clinic provides care for approximately 6000 patients. Both pediatric and adult patients are seen in the clinic for diabetes as well as for other endocrine problems. Like the CF Clinic, the physical location of the DM clinic provides easy access to support services. Physical space for pediatric and adult care is loosely divided, with separate waiting rooms and different designated exam rooms within the clinic. Providers in the adult clinic include approximately 10 attending physicians, five nurse practitioners, two nurse educators, and two dietitians. Several residents and fellows also see patients in the clinic. The clinic staff also includes approximately five intake nurses, two triage nurses, five clinical receptionists, call center staff, and administrative assistants.

Frequency of routine visits varies dependent on disease stability and patient needs.

Many patients are seen at 3-month intervals. Glucose meter results are downloaded during clinic visits. Tests to monitor the disease are performed on a routine basis.

All of the providers and staff in the clinic use StarPanel for patient documentation and intra-clinic communication. EPIC software is used for scheduling appointments.

CHAPTER III

DISEASE CHARACTERISTICS

The information described in this chapter summarizes the information the investigator had prior to data collection. An overview of each of the three chronic diseases was prepared prior to beginning observation in each clinic. The overviews detail the prevalence of each disease, diagnostic approaches, effects of the disease, and current treatments. In addition, informatics tools that have been developed for each disease domain are discussed.

Multiple sclerosis disease overview

Multiple Sclerosis (MS) is an autoimmune neurological disorder resulting in damage to myelin sheaths surrounding axons as well as direct damage to axons (22). Myelin sheaths act as high resistance, low capacitance insulators on axons, speeding the conduction of action potentials on the axons and protecting the integrity of the signal (23). In MS, an unknown mechanism leads to neuronal inflammation resulting in demyelination, axon injury, and eventual axon loss. Myelin damage causes slowing and deterioration of action potentials and even complete signal conduction failures (23). One in 1000 people will develop MS (23). The diagnosis is typically made in the late 20s or early 30s. Both genetic and environmental factors are involved in development of the disease (24). MS is more common in people of northern European heritage and also in people who live farther from the equator. Twice as many women as men are affected. Some type of infection may trigger the onset of the disease, but the reason is unknown.

There is no gold standard for diagnosis of MS (24). While MRI scans are used to track progression of the disease and can be used to confirm potential diagnosis, MRI does not provide a definitive diagnosis. Types of lesions, number of lesions, and how lesions display on the MRI both with and without contrast agent are all disease measures. Diagnosis is clinical and based on signs and symptoms. Common symptoms include tingling, pain, visual impairment, weakness, bladder dysfunction, dizziness, and loss of coordination. However, a variety of other conditions mimic these symptoms (24). Several other tests such as analysis of cerebrospinal fluid are used for research purposes, but a definitive marker for MS has not been identified(23). Communication between provider and patient is critical during both diagnosis and treatment (25). Providing immediate access to information, timely and direct communication, and anticipating the types of information patients with MS might need are important in allaying fear.

MS is classified based on the clinical progression of the disease (23). Relapsing-remitting MS is the most common form, affecting 85% of newly diagnosed patients. This form of MS is marked by relapses or flares of sudden neurological disturbances such as: loss of coordination, visual disturbances, numbness/tingling in a body part, or weakness of a body part. After a relapse, the problem becomes stable. Lost function may recover to baseline status, recover only partially, or not recover. One-half of patients with relapsing-remitting MS eventually enter a state of secondary progressive MS. Secondary progressive MS is characterized by flares where function is permanently lost. Some patients begin in a primary progressive form of MS, where flares always result in permanent loss of function. The overall course of disease is highly variable, both between and within types of MS. Progress of MS is tracked on several different measures (26). The most commonly used scale is the Kurtzke Extended Disability Status Scale (EDSS), although it is difficult to use consistently and lacks sensitivity to small changes. A second scale originally developed for use in clinical trials is the MS Functional Composite Score (MSFC). Scores on the MSFC are standardized against reference population scores.

Three distinct types of treatment are important in management of MS: treatment to manage symptoms, treatment to manage relapses, and treatment to slow disease progression. Managing symptoms is important because untreated symptoms can worsen or lead to other symptoms (27). Spasticity contributes to disability associated with MS (24) (27). It can be treated through exercise, including range of motion exercise, aerobic exercise, and relaxation methods. More significant spasticity can be treated with medication, specifically antispastic drugs. Fatigue is the most commonly reported symptom in MS and substantially affects the quality of life (27). Treatment includes decreasing secondary sources of fatigue such as depression and sleep disturbances as well as teaching energy conservation techniques through occupational therapy (OT). Medications such as CNS stimulants and calcium channel blockers can also be used to deal with fatigue (24). Cognitive dysfunction in MS is typically restricted to specific functions such as recent memory, attention, and information processing rather than global dysfunction (27). Techniques include using OT and speech and language therapists to teach patients how to compensate for specific cognitive defects. Cholinesterase inhibitors, currently used for dementia, are being evaluated for use with MS (27). Depression is another common symptom of MS and treatment includes counseling and prescription of anti-depressants such as selective serotonin reuptake inhibitors (SSRIs) (24). Both acute and chronic pain are reported by MS patients and anticonvulsants are typically used for treatment (27). Bladder dysfunction is common (24). For urinary urgency and frequency, anticholinergic drugs are the standard treatment. For urinary retention, medication is typically ineffective and intermittent self-catheterization is a solution. Bowel symptoms are aggressively managed through various techniques, included adding fiber to the diet. Sexual symptoms are managed through counseling, minimization of medication side-effects, and medications such as Viagra.

Flares or relapses are typically treated with high doses of adrenal corticosteroids to decrease inflammation and reduce symptoms (24). Physical therapy can be used to regain some of the lost functionality. Supportive care in the form of OT, counseling, and patient support groups can also be important.

Treatments to slow disease progression are also referred to as disease modifying agents (DMA) (24) (26). Three types of DMA are approved for different stages of MS. In the relapsing-remitting form of MS, beta interferons are the first line of treatment. Beta interferons are naturally occurring cytokines that have immunomodulating and antiviral effects. In clinical trials, beta interferons have been shown to reduce relapses and inflammatory lesions and increase quality of life and cognitive function. The side effects are normally mild, disappear over the course of treatment, and infrequently cause discontinuation of the therapy. Glatiramer is another DMA for use in relapsing-remitting MS. It is a polypeptide mixture made up of four amino acids and designed to mimic myelin basic protein. In clinical trials, Glatiramer has been shown to reduce relapses and inflammatory lesions and is generally well tolerated with few side effects. Mitoxantrone is approved only for use with the progressive form of MS. As a chemotherapeutic agent, it is an immunosuppressive drug with immunomodulatory properties. Due to cardiotoxicity problems, mitoxantrone has a lifetime limit that allows for 2-3 years of use for MS treatment. In clinical trials, it has been shown to reduce MRI measures of disease activity. Current recommendations of the MS Foundation are to initiate treatment with DMAs early in the disease, since irreversible axon damage may occur early in relapsing-remitting MS. However, few long-term studies have been done to show extended safety and efficacy of these treatments.

Informatics research and development for MS

Most informatics research and development for MS involves databases for research collaboration, although some applications were developed for clinical uses (Table 5).

Table 5. MS-related informatics projects

Product	**Intended use**	**Functionality**
MS COSTAR (28)	Research, Clinical	Database, calculated EDSS score electronically using neurological exam data
EDMUS (29)	Research	Database, concise description of disease status targeted toward collaborative multi-center studies, automatic EDSS calculation using input data
iMed (30)	Research	Database, part of the Italian MS database network
MUSIS (31)	Clinical	Clinical information system for MS centers
MS-CANE (32)	Clinical	Computerized version of the EDSS

The main goal of the research databases is to standardize and systematize data to facilitate multi-center research studies. Database applications also provide some limited clinical functions, such as automatic calculation of the EDSS based on the input data. As of 2004, more than more than 200 MS centers in over 28 countries used the EDMUS database. Barriers related to the use of existing database systems include the amount of data required, interest from clinicians, financial support, customizability, and flexibility (33).

Applications with more clinically-related functionality such as MUSIS have been adopted by some centers (34). The usability of such tools and ensuring that the data collection processes required by the software are appropriate to the workflow in MS clinics is generally missing. No clinical monitoring informatics tool has been widely adopted or acknowledged as a standard approach to collecting MS data.

Two contrasting ideas can be developed based on the current state of informatics development in the MS domain. One possibility is that MS providers do not have unique needs and thus current general informatics tools are adequate for them. A second possibility is that little attention has been directed at this domain and thus the needs of MS providers have not been understood and are not being met by currently available tools. This study addresses this question by examining workflow and information flow in MS care in comparison to other chronic disease domains.

Cystic fibrosis disease overview

Cystic fibrosis (CF) is an autosomal recessive genetic disease caused by mutations in one gene on chromosome 7 (35). The gene that causes cystic fibrosis was sequenced in 1989. To date, more than 1000 mutations for chromosome 7 have been identified, most of which cause cystic fibrosis (36). Mutations result in production of an abnormal form of the cystic fibrosis transmembrane regulator (CFTR) protein. This protein is critical in the regulation and transport of sodium and chloride in epithelial cells (37). Due to the abnormal protein, epithelial cells in CF have decreased chloride secretion and increased sodium absorption (38). This produces sweat with higher sodium and chloride concentrations, viscous airway secretions, and pancreatic insufficiency. There are approximately 30,000 patients with cystic fibrosis in the United States and 1:3500 children are born with CF (39). As of 2003, the median age at diagnosis is 6 months and median survival age is 32.9 years. While genetic testing is used to classify the mutations involved post-diagnosis, the gold standard for CF diagnosis is a sweat test (37). In the sweat test, localized sweat production is stimulated, the sweat is collected, and the sodium and chloride concentrations are analyzed. If sodium and chloride concentrations are elevated, the test is repeated to confirm the diagnosis.

Respiratory failure is the leading cause of death in CF. Pulmonary function declines progressively, with intermittent exacerbations characterized by increased cough, sputum production, anorexia, and malaise (40). In the lower respiratory tract, CF is characterized by progressive cycles of infection and inflammation. Stagnation of viscid secretions and inability to clear bacteria trapped in the secretions cause infection (40).

Infection results in an excessive inflammatory response that actually promotes continuing infection (40). Over 57% of CF patients are infected with pseudomonas aeruginosa (39), a highly adaptable bacteria that can develop resistance to multiple antibiotics (40). Damage to the lungs is the eventual outcome of the infection/inflammation cycles. As the lungs become damaged, a restrictive-obstructive lung function pattern develops. The end result in almost all patients with CF is respiratory failure.

Although respiratory problems are the main problem in CF, the disease affects multiple organ systems. In the pancreas, lack of fluid secretion in the pancreatic ducts causes protein secretion and eventual ductal blockage (35) (36). Pancreatic insufficiency causes maldigestion and malabsorption of fats and proteins. Young CF patients often have growth retardation due to a combination of pancreatic insufficiency and the higher caloric demands of fighting infection and breathing difficulties (38). As the median survival age for CF patients has increased, the incidence of CF-related diabetes mellitus (CFRDM) has also increased. Rarely seen in children under 14, CFRDM is present in 24% of CF patients at age 20 and 76% of CF patients at age 30 (35).

Since there is no cure for CF, current treatments focus on slowing the progression of airway damage, improving growth patterns, and treating associated symptoms. Respiratory therapy is critically important and consists of diverse treatments (35). The thick, viscous airway secretions are difficult to clear. Natural mechanisms for secretion removal must be mechanically assisted on a regular basis using various forms of chest physical therapy (PT) and devices. Chest PT techniques include: postural drainage, percussion and vibration of the chest, breathing exercises, and directed cough (38). Mechanical devices developed to assist with chest PT include: the flutter valve, positive airway pressure masks, and high-frequency chest compression vests. Regular physical exercise also helps encourage secretion removal (36).

Several types of medication are important in treatment of CF. Antibiotics are used on a regular basis, both prophylactically and to treat recurrent lung infections (35). The type of antibiotic and its method of administration (inhaled, IV, oral) are all dependent on bacteria cultures. While antibiotic treatment will not completely eradicate all bacteria in a CF patient, by reducing the burden of infection it improves quality of life. DNase (alfa dornase) is an enzyme that selectively cleaves neutrophil-derived DNA thereby reducing sputum viscosity (38). Use of ibuprofen to fight the inflammatory response in the lungs appears effective in some situations (36). Broncodilators are also used by some patients with CF to increase lung function (36). Lung transplantation is the final approach to irreversible respiratory failure. Since 1988, more than 1500 lung transplants have been performed in patients with CF (39). Patients with the best chance of survival have a body weight greater than 80% of normal and no multi-drug resistant respiratory tract organisms (37).

Pancreatic insufficiency is treated with pancreatic enzyme replacement therapy. The therapy dose needs to be carefully balanced to avoid side effects, but is successful for many patients (36). CFRDM is treated with regular insulin injections.

The Cystic Fibrosis Foundation (CFF) developed standardized guidelines for CF care (39) (Table 6). Compliance with these recommendations varies between juvenile and adult CF patients.

Table 6. Care recommendation of the Cystic Fibrosis Foundation

Area	**Recommendation**
Clinic visits	At least every 3 months
Pulmonary Function Tests (PFTs)	At least every 6 months
Respiratory culture	At least once per year
Creatinine level	At least once per year
Glucose level	At least once per year for all patients over age 14
Liver enzyme levels	At least once per year

Several predictors of longer survival have been identified (Table 7). Overall, patients receiving early, aggressive care based at a CF center have better outcomes (38).

Table 7. Predictors of longer survival

Predictor	**Relationship**
Pulmonary status	Better status linked to longer survival
Pancreatic status	Pancreatic sufficient patients have better pulmonary function and longer survival
Infection agents	Patients infected with pseudomonas aeruginosa have worse outcomes
Aerobic fitness	Better fitness level linked to longer survival
Socioeconomic status	Patients in households with lower incomes tend to have poorer lung function and worse nutrition
Nutritional status	Better nutritional status linked to longer survival
Environmental factors	Exposure to secondhand smoke and other environmental factors is a negative predictor
Gender	Female patients have lower survival rate than males

Many treatments for CF are being developed or investigated (38). After the CF gene was identified, gene therapy seemed promising. However, progress on gene therapy has been slow. Better success has been seen with protein repair therapy, a process of delivering functional CFTR protein to the cell membrane. Ion transport modifiers also show promise by their ability to improve the ion transport properties of epithelial cells. Finally, telemedicine extends the range of CF clinics making care for geographically remote patients easier and of higher quality (38).

Informatics research and development for CF

The main impact of informatics in the treatment of CF patients thus far has been development of disease registries. The CFF maintains a registry of a majority of the 22,000 CF patients treated at accredited centers in the United States (39). All accredited centers participate in the registry, but patients are able to opt out. The database contains key data on each patient and is updated annually. Similar registry databases exist in Canada (41), the UK (42), Australasia (43), and France (44). Differences in data elements, data collection processes, data analysis, and information presentation between the registries generate difficulties in comparing data between countries (44). The American CF Foundation has also developed "instant reports" to assist clinics in communicating important disease status information to patients and families (39). However, there are no data on the use of these reports.

Several non-registry informatics applications have been developed for CF as well. The applications and their general functionality are shown in Table 8.

Table 8. CF-related informatics applications

Application	**Intended use**	**Functionality**
Hanover CF Record (45)	Research, Clinical	Quantitative disease data record with a print out of patient history for physicians before appointments
Electronic EDIC (Early Detection and Intervention Criterion)(46)	Clinical, Self-management	Home-based system involving paper forms sent in to clinical center and entered into a statistical decision-making system to detect exacerbations
Hopkins Teen Central (47)	Self-management	Electronic support group for teenagers with CF

Both the EDIC and Hopkins projects related to self-management of CF. The Hanover CF record had some components useful in the clinical environment, but was mainly intended for research purposes.

While the national registry applications are important in research and in ensuring compliance of CF centers with guidelines, little progress has been made in developing applications intended for clinical purposes in CF care. As in the MS domain, one possible reason for lack of clinical applications for CF is that CF providers do not have unique needs and general informatics tools adequately address their needs. In contrast, it is also possible that the needs of CF providers are not well understood and are not addressed by existing tools. This study examines this question and seeks to determine if CF care has unique elements and if this issue is not adequately addressed by current systems.

Diabetes Mellitus Disease Overview

Diabetes mellitus is a group of metabolic diseases characterized by hyperglycemia (48). The disease results from defects in insulin secretion, insulin action, or a combination of the two. In a normal system, the α-cells and β-cells in the Islets of Langerhans in the pancreas maintain glucose homeostasis through hormone secretion (48). The α-cells secrete the hormone glucagon to increase levels of blood glucose, while β-cells secrete insulin and amylin to decrease blood glucose levels.

Diabetes mellitus is divided into several groups, with Type 1 and Type 2 being most common. Type 1 diabetes mellitus is marked by an absolute insulin deficiency due to the autoimmune destruction of β-cells (49). There is a genetic predisposition towards Type 1 diabetes but it is also believed that a trigger such as a viral infection starts the β-cell destruction process. Onset of Type 1 diabetes is typically sudden and can occur any time from childhood through adulthood. Type 1 diabetes represents 5-10% of all cases of diabetes (50).

Type 2 diabetes mellitus can involve either a relative insulin deficiency, insulin resistance, or both (49). Insulin deficiency is caused by β-cell dysfunction. Insulin resistance occurs when cells are less sensitive to insulin. Risk factors for development of Type 2 diabetes include increased age, overweight, lack of physical activity, family history of diabetes, and race. Those over age 40 have a higher risk, as do minorities. Type 2 diabetes represents ~90% of all cases of diabetes (50). Diabetes can also be caused by pregnancy, cystic fibrosis, medications, and illness in a small percentage of cases (51).

Diabetes is a significant and growing problem both in the United States and worldwide. In 2002, an estimated 6.3% of the US population, or ~18.2 million people, had diabetes (50). Diabetes was the 6th leading cause of death in the US in 2000 (50). The prevalence of diabetes has increased 4-8 fold over the last 40 years. The increase is expected to continue, with prevalence projected to increase from 4.4% to 9.7% in the U.S. between 2000 and 2050. One of every three people born in the US in 2000 are projected to develop diabetes at some point in their lifetimes (50). Diabetes is projected to increase worldwide as well, with prevalence projected to increase from 2.8% to 4.4% between 2000 and 2030 (52). The worldwide increase is due to a number of factors, including population growth, aging population, urbanization, changing diets, and increases in obesity and physical inactivity (52).

Diagnostic criteria for diabetes are listed in Table 9 below. Any of the three criteria can be used for diagnosis. A positive diagnostic test should be repeated on a different day to confirm diagnosis.

Table 9. Diagnostic criteria for diabetes mellitus

Criteria (51)
Diabetes symptoms (polyuria, polydipsia, unexplained weight loss) AND casual blood glucose ≥200 mg/dL
Fasting blood glucose ≥126 mg/dL
During an oral glucose tolerance test, 2-hour postload glucose ≥200 mg/dL

The diagnosis of Type 1 diabetes is usually straightforward due to acute symptoms of elevated blood glucose levels. Type 2 diabetes may go undiagnosed for many years, as it is often symptomless in early stages (51). Complications frequently begin to develop before a clinical diagnosis is made. Early detection and treatment of Type 2 diabetes may decrease the later disease-related complications (48) (53).

Diabetes is associated with a number of chronic and acute complications. Chronic complications occur on both the macrovascular and microvascular levels. On a macrovascular level, individuals with diabetes have a higher risk of developing cardiovascular disease (49). Atherosclerosis of the large blood vessels of the heart, brain, and legs is common. Risk factors for developing macrovascular complications include: systolic hypertension, elevated cholesterol, smoking, and consistently poor control of blood glucose levels (50).

On a microvascular level, capillaries throughout the body are affected, commonly including the eyes and the kidneys (49). This causes long-term damage and ultimately organ failure. Long term microvascular complications include retinopathy, neuropathy, and nephropathy (48). Visual impairment and blindness are common complications of diabetic retinopathy. Diabetic nephropathy is the most common cause of chronic renal failure. Peripheral neuropathy combined with atherosclerosis leads to minor injuries which can become infected and require lower-extremity amputations (50). Poor glycemic control and hypertension are risk factors for development of microvascular complications (50). Development of chronic complications of diabetes can be slowed through control of blood glucose levels, blood pressure, and lipids (49).

Acute complications of diabetes are seen in both types of diabetes. Diabetic ketoacidosis is more of a problem in Type 1 diabetes and is marked by an extreme insulin deficiency (48). A hyperglycemic, hyperosmolar state is more common in Type 2 diabetes and includes insulin deficiency and severe hyperglycemia but without ketosis (48). Hypoglycemia is a common acute complication caused by injecting too much insulin, exercising more than food and insulin intake allows, and skipping meals (49).

Therapy for diabetes depends on type. Insulin injections are required for survival in Type 1 diabetes (48). Therapy for Type 2 diabetes changes based on disease stage. As each type of treatment loses its ability to provide adequate glycemic control, new therapies are added (54). Lifestyle changes such as diet and exercise may be enough to treat Type 2 diabetes in its early stages (53). Insulin sensitizers including metformin and thiazolidinediones (TZD) such as Avandia are used as the disease progresses (54). Metformin and TZDs are commonly used in combination to take advantage of the differing mechanisms of action of the drugs. There is a low risk of hypoglycemia associated with insulin sensitizers. The next agent added to the treatment regiment is frequently a secretagogue (54). Secretagogues such as Glimepiride cause the release of additional amounts of insulin regardless of blood glucose levels. Studies have shown that patients who do not achieve good glucose control on maximum doses of both insulin sensitizers and secretagogues may be helped by exenatide, sold as Byetta (55). Byetta improves glucose regulation and also provides some weight loss benefits. The dysfunction of β-cells increases over time and oral medications will become inadequate for good glycemic control. Insulin is then added to the treatment regimen either in addition to or in place of the earlier oral agents (53). The dose of insulin is adjusted over time to meet glycemic control needs.

The American Diabetes Association (ADA) guidelines, updated annually, include recommendations for values for key physical parameters and recommended frequency for different types of care (56) (Table 10). The ADA advocates diabetes care provided by a physician-coordinated team that includes physicians, nurse practitioners, nurses, podiatrists, optometrists, dietitians, pharmacists, mental health professionals, and other providers as appropriate. The physical parameter guidelines include targets for glycemic control, blood pressure, and lipids. The primary target for glycemic control is glycosylated hemoglobin (HbA1c) which reflects average of blood glucose levels over 2-3 months.

Table 10. ADA recommendations for physical parameters

Parameter	**Recommendation**
Glycosylated hemoglobin (HbA1c)	<7.0%
Preprandial blood glucose	90-130 mm/dL
Peak postprandial blood glucose	<180 mg/dL
Blood pressure	<130/80 mmHg
Low-density lipoprotein (LDL)	<100 mg/dL
Triglycerides	<150 mg/dL
High-density lipoprotein (HDL)	>40 mg/dL

Recommended frequency of routine diabetes visits depends on individual disease status. Several tests are recommended on a routine basis (Table 11).

Table 11. ADA recommendations for test frequency

Parameter	**Recommended testing frequency**
HbA1c	Every 6 months if stable, every 3 months if not meeting glycemic control goals
Blood pressure measurement	Every routine diabetes visit
Lipid testing	At least annually
Microalbuminuria & serum creatinine tests	At least annually

Eye exams are recommended on an annual basis or every 2-3 years if the eye exam is normal. A comprehensive foot exam and foot self-care educations should be done on a yearly basis although there are also recommendations that the patient's feet be examined every visit to prevent serious problems. An exam for distal symmetric polyneuropathy should be conducted annually. The influenza vaccine should be administered annually. Patients with diabetes should see diabetes educators and dietitians as needed.

Informatics research and development for DM

In contrast to CF and MS, many informatics tools have been developed for the diabetes domain and the majority of these tools are for clinical purposes (Table 12).

Table 12. Diabetes-related informatics applications

Application	Intended use	Functionality
DM-PEP (57)	Clinical	Diabetes registry with rankings according to needed services, part of a larger population management trial
DARTS (58)	Research, Clinical	Diabetes registry with added audit and practice improvement functions
COSTAR diabetes module (59)	Clinical	Web-based EMR with diabetes care features
DEMS (60) (61)	Clinical	Patient registry, structured clinical data entry, chronic disease management flowsheets
DREAM (62) (63)	Research, Clinical	Disease registry with added functions for evidence-based guidelines, appointment prompts, and patient feedback
EPIC EMR Enhancement (64)	Clinical	Added diabetes-specific flags and reminders to commercially available EMR
Partners Health Care diabetes reminders (65)	Clinical	Added five evidence-based guidelines for diabetes to existing EMR application

IDEATel (66) (67)	Self-management, Clinical	Self-management using telemedicine for underserved rural and urban patients, provided patients with home telemedicine units
D-Net (68)	Self-management	Behavioral intervention over the internet using a dedicated PC, featured access to a coach and educational materials
Living with Diabetes (69)	Self-management	Allowed patient to review medical record, provided feedback to patient through online diary, and educational materials
DAILY (70)	Self-management	Provided PDA with wireless modem featuring diabetes game to youth, transmitted data wirelessly to research team

Each of these applications saw limited success when used in study environments. None of the approaches taken by the applications has been adopted on a wider scale or accepted as a standard approach to design of these types of applications. Several of the projects only addressed limited portions of diabetes care. DM-PEP focused on disease registries, DREAM focused on guidelines, and the EPIC EMR enhancement and Partners diabetes reminders focused on reminders and flags. The lack of significant changes in patient metrics may be linked to the limited scope of the projects. Without taking other aspects of chronic disease care such as support for patient self-management and overall EMR design into account, it is difficult to see how limited projects can have major effects. Many of the applications, including DM-PEP and the COSTAR diabetes module, were directed only at physicians, failing to take the important role other members of the care team play into account. The main exception to this was the DEMS project, which identified that all members of the care team from nurses to physicians must benefit from informatics tools. However, the DEMS project also argued that care delivery processes needed to be reorganized in order for their software to be used effectively. Because the DEMS project was part of a larger care delivery redesign, it is difficult to determine the actual impact of the informatics tool on care.

Consistent problems in the studies were the lack of user input in the design process and the lack of attention to software usability. The DARTS project is the main exception. Users were involved throughout the software development process. However, the development team failed to address user-identified barriers to system implementation in the design process. The users identified several barriers, including: lack of time, access to equipment and training, fear of computers, and anxiety over data validity. These barriers were not addressed by the system. The DEMS project also involved users throughout the software development process. The drawbacks of the DEMS project were discussed earlier. User input was also sought in the DREAM project but input was limited to the development of localized practice guidelines. Even with user input, after system implementation, users complained that the system added to their workload and that the guidelines were not customizable enough.

The lack of end user input in the design of the four self-management tools is surprising. Previous studies by Forsythe (71) (72) showed that clinician opinions of patient education needs and processes for asking for information were starkly different than actual patient opinions and processes. In the four diabetes-related studies above, users were not involved in selecting the functionality of the software, nor were they involved in the design of the interface. The idea that actual patient needs differ from what experts say patients need was not addressed in the design process. This is especially problematic since the main purposes of these systems is to educate and motivate patients. Self-management systems cannot deliver on this goal if they do not involve patients in the design process.

In addition to diabetes tools developed outside Vanderbilt, StarTracker, a disease registry and reminder system for use in primary care clinics, is currently under development at VUMC (73).

Clearly, many applications have been developed to address the needs of diabetes care both from a provider perspective and from a patient perspective. However, the majority of these applications are tailored specifically to diabetes care and do not extend to other chronic disease domains. Tools developed specifically for one environment and one disease, especially a disease as prevalent as diabetes, can be valuable. This study seeks to move beyond single-disease informatics development by looking for generalizable patterns across multiple chronic diseases. Informatics tools designed to address the general needs of chronic disease care would have a wider reach than tools to address the needs of one disease. In addition, the importance of understanding user needs and barriers to informatics tool adoption are highlighted by the limited adoption of these applications. This study also seeks to address this issue.

CHAPTER IV

METHODS

This chapter discusses the rationale for selecting the qualitative methods and modeling approaches used in the study. Other applications of these methods to research in informatics are described. The design of the study, which included two iterative phases, is outlined. Details of the observation and semi-structured interviews, including the hours and type of observation and the number and type of interviews, are presented. Finally, the rationale and the process of model development are explained in detail.

Selection of methods

Qualitative methods were chosen for this study as the most appropriate way to understand behavior in the natural work environment. Data from direct observation were organized through the extraction of themes and development of workflow and information flow models. The accuracy of subsets of the models was evaluated through the use of semi-structured interviews, which also augmented the results of the observations. Generalized models of workflow and information flow in chronic disease care were developed by comparing the three chronic disease clinics.

Direct observation

Direct observation was chosen as the initial approach in order to understand the activities of individuals in their environment. The direct observation technique involves watching behavior in a natural setting and recording notes to describe both the setting and the observed behavior (74). Nielsen described observation as "the simplest of all usability methods since it involves visiting one or more users and then doing as little as possible in order not to interfere with their work." (8) Approaches to observation can vary in multiple dimensions, as shown in Table 13 below (75).

Table 13. Dimensions of observation

Dimensions of observation	**Study specifics**
Role of observer	Onlooker
Perspective	Outsider
Study personnel	Solo researcher
Disclosure of study purpose	Full disclosure
Duration	Several months, multiple observation periods per site
Focus	Evolving over time

Individuals are immersed in their work environment. Activities that are part of daily work can become routine and can be missed when people are interviewed or complete a survey (76). People may be unaware of the processes and patterns underlying their work (77). There was little formal information about the workflow and information flow in the three clinics at the beginning of the study. Observation provided many of the specific details on how activities were performed and how people interacted with other people, processes, and technology.

Semi-structured interviews

The investigator asked questions to clarify observations and understand the reasons for behaviors as time allowed during observation periods. However, the nature of the environment prevented extensive questioning. Semi-structured interviews were chosen as an additional method to gather data. The interviews were primarily to get feedback on the workflow models in order to validate and augment the models. Individual semi-structured interviews involve a face-to-face discussion with a set of questions as a guideline for interview topics (74). Additional unscripted questions can be asked to expand on the interviewee's answers. The semi-structured nature of the interviews allowed the investigator to start with a common set of questions across subjects and then delve more deeply into details of specific responses. The interview format allowed time to ask questions to understand the rationale behind actions and identify exceptions from the observed behavior. The interviews served as a method for model validation and augmentation.

Qualitative methods in informatics

Previous studies have used qualitative methods to understand workflow and other aspects of the healthcare environment. Studies typically apply multiple qualitative methods to gain a broader perspective on the study objectives. Kindberg et al (78) studied information exchange between providers and patients in diabetes care using observation and interviews. The study was part of a larger investigation during the development of software to support collaborative work through shared workspaces. The investigators gained an understanding of information acquisition and transfer in diabetes care and highlighted the amount of duplication of effort between different providers in the care process. Observational and interview data informed the application development process.

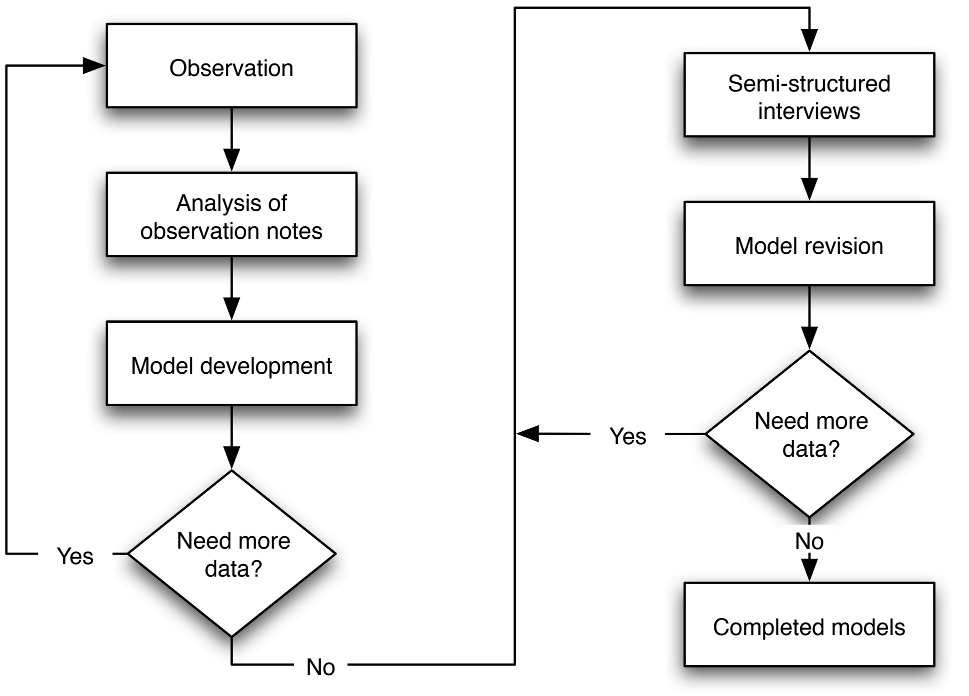
Two studies used different approaches to examine workflow in radiology. Symon et al (79) studied coordination of work in a hospital setting, with a focus on the radiology department. The study used both observation and interviews, as well as documentation analysis. Paper forms were tagged and followed through the hospital process. Individuals who interacted with the forms were interviewed to discuss their role in the process. Work activity in the radiology department was also observed, with a focus on information transfer. The study revealed variation across the hospital in how work was coordinated and the contrast between formal procedures and informal processes. Bardram et al (80) also looked at work processes in a hospital radiology department, but with a focus on the use of an informatics application. A hospital radiology order system was deployed but was not readily adopted. The goal of the study was to understand the reasons for lack of system adoption. The investigators studied documents, observed daily work and meetings, and conducted interviews. The results highlighted the importance of work coordination and synchronization, functions that were not adequately supported by the software. Features that the developers had considered minor such as billing turned out to be very beneficial for some users. Adoption was also impeded by the narrow view of work processes taken in the system design and not accounting for the broad work spectrum of the intended users.

Other studies used observation and interviews to examine workflow and information management in critical care units. Effken et al (81) studied information use and behavior in the ICU to facilitate design of clinical displays. Observation was used to understand the different roles in the ICU and how individuals in the different roles interacted with clinical displays. They found that nurses and physicians took different approaches toward the displays. The study findings were used to tailor the design of the clinic displays toward assisting in treatment decisions. Reddy et al (82) studied information management in the surgical intensive care unit (SICU). Using observation, interviews, and documentation reviews they explored the impact of temporal rhythms on information seeking behavior and found differences in the use of explicit information (e.g. charts and reports) and implicit information (e.g. the configuration of people and equipment). Temporal flow was divided into large scale temporal rhythms such as nursing shifts and fine grained temporal rhythms such as processing of lab orders. Malhotra et al (83) studied workflow in the adult ICU using observation and interviews. The observation was conducted in a two-phase approach, with general data collection as the first phase and observations targeted to specific time periods identified in the first phase as the second phase. The investigators developed a cognitive workflow model of the ICU, which could be used to extract organizational approaches to resolving errors.

The description of the studies above shows the type of information that can be obtained through observation and interviews. These studies showed that qualitative methods can yield valuable information about workflow and information flow in healthcare. The application of qualitative methods in the current study is similar to approaches taken in previous studies, however, while the studies described above are limited to a single domain such as diabetes, radiology, or the ICU, the current study examines multiple clinics in an attempt to form conclusions generalizable to chronic disease care as a whole. The current study builds on the methods and goals of these previous studies and seeks to extend the reach of qualitative methods in healthcare.

Study design

Data were collected over a 10-month period using direct observation, semi-structured interviews, and iterative workflow and information flow modeling (Figure 1).



First 8 months of study

Final 2 months of study

Figure 1. Study design

The first eight months of the study consisted of data collection through direct observation and development of workflow models. The final two months of the study consisted of data collection through semi-structured interviews and revision of workflow models.

Direct observation

Over 150 hours of observation were conducted, spread across the three clinics as shown below in Table 14. Observation was conducted largely sequentially, starting in the MS clinic, continuing in the CF clinic, and finishing in the DM clinic.

Table 14. Observation distribution

Clinic	**Hours of observation**	**Study period**
MS	56	December 2005-February 2006
CF	44	March-April 2006 July-August 2006
Diabetes	52.5	August-September 2006
Total	152.5	

A variety of providers and staff were observed in each clinic (Table 15). Observation was conducted in clinic work areas, hallways, and in exam rooms during patient visits.

Table 15. Types of providers observed

Clinic	**Provider types**
MS	Clinical receptionist Nurse Physician (attending) Physician (resident)
CF	Intake nurse Physician (attending) Physician (fellow) CF Nurse Dietitian Social worker
Diabetes	Clinical receptionist Intake nurse Nurse educator Nurse practitioner Physician (attending) Dietitian

Similar types of activities were observed across all three clinics (Table 16).

Table 16. Types of activities observed

Types of activities observed
Check-in process
Intake process
Patient visit
Patient exam
Patient education
Check-out process
Emergency care processes
Intra- and inter-clinic communication
Hand-offs between providers

The focus of observation was the interaction between people, processes, and technology. This included observation of various technologies used in the clinic - what, how often, and in what manner they were used. A particular interest was variation in technology use within the clinic, both between and within provider types. The flow of information and the temporal work flow of the clinic were illuminated. Data collection was not directed by a pre-observation hypothesis, but rather with the goal of attaining an unbiased understanding of current clinic workflow and information flow.

Verbal assent was obtained from staff and providers who were being observed prior to observation periods. Verbal assent was also obtained prior to observing patient-provider interactions. The observer stood or sat in a non-interfering location during observation, preferably with a view of the computer screen when present. Outside of the exam room as time and the situation allowed, the observer asked the provider questions to clarify observations. Detailed notes were recorded during observation using a Logitech io2 digital writing system. The system uses an ink pen with an optical sensor to capture information written on patterned paper for later upload to a computer. After upload to the computer, handwritten notes were transcribed by computer program to text files and then transferred to a fully-indexed electronic notebook. Blank copies of all relevant paper artifacts used by each clinic were obtained for analysis. Recurring and important themes were periodically extracted from the observation notes.

Semi-structured interviews

Semi-structured 30-45 minute interviews were conducted with providers in each of the three clinics. A small incentive was given to each participant. Nine interviews were conducted with the distribution shown in Table 17 below.

Table 17. Interview distribution

Clinic	Interview subjects
MS	Physician (attending) x1
CF	Dietitian x1 Physician (attending) x1 Physician (fellow) x1
Diabetes	Nurse x1 Nurse practitioner x2 Dietitian x1 Physician (attending) x1

Verbal assent was obtained from each participant prior to the start of the interview. The goal of the interviews was model validation and augmentation. Individual interviews focused on that subject's portion of the clinic-specific task and workflow model (i.e. the diabetes nurse was asked about the role, tasks, and information uses of nurses in the diabetes clinic). As time allowed, the interviewer asked additional questions related to other portions of the clinic-specific model and to individual workflow. The inteview instrument is included in Appendix A. Interviews were audio-taped and transcribed.

Model development and revision

Modeling of clinical workflow began during clinic observation, with progressive refinement as more data were collected. Modeling was based on a systems engineering approach to understanding task and information flow in each clinic (84) and also incorporated elements of Soft Systems Methodology (SSM) (85). SSM utilizes the concept of "human activity systems", which are activities directed towards a purpose. Actors are the individuals who carry out the activities within the system (86). Model development was an iterative process. Gaps in knowledge of clinic workflow were identified as each model was developed, which guided the focus of subsequent observation periods.

Three distinct types of models were developed. The initial models, used in the semi-structured interviews, were individual clinic models of task and workflow. The modeling approach was similar to Hierarchical Task Analysis (HTA) . In HTA, each individual process is divided into sub-processes and each sub-process is further divided until all elements of the workflow are accounted for (87) (88). The task and workflow models identified the details and sequences of care processes in each clinic, including all aspects of care and perspectives of different types of providers. A generalized model of task and workflow in chronic disease care was developed based on common attributes across the individual clinic models. The generalized model also identified exceptions that were specific to each clinic's individual workflow.

The second task was to model information flow, which was influenced by both Checkland (85) and Barwise (89). Information flow models should capture both the information required to perform an activity as well as the information generated by performance of the activity (85). The information flow models show how information flows between different actors in the care process as well as between actors and information repositories. A single generalized information flow model was developed that depicted clinic-specific with information flow patterns on separate layers.

Chronic disease care is an ongoing process. Each disease has a recommended frequency of tests, procedures, and appointments. Clinic-specific temporal flow diagrams captured this temporal rhythm. The modeling process for temporal flow was influenced by approaches to temporality described by Orlikowski (90) and Reddy (91). The temporal flow models demonstrate temporal aspects of workflow and information flow on daily time scales as well as yearly time scales.

The clinic-specific models were revised based on the information gathered during the semi-structured interviews. The majority of the changes were minor, typically involving reordering events based on cognitive processes rather than visible ones. Clarifying notes were added to the models to capture provider opinions on the nature of processes. Several changes were more substantial, particularly regarding communication between providers within each clinic. All modifications were annotated to indicated changes stemming from the interviews

The models provided structure for the qualitative data and also presented the information in a format accessible to software designers, software developers, and clinicians interested in process improvement.

CHAPTER V

RESULTS

Research Themes

Based on the observational and interview data, six research themes were developed. The themes are shown below in Table 18.

Table 18. Observed themes

Observed Themes	Description
Clinic	
Task and workflow patterns	Each clinic has an overall task and workflow pattern. Variations existed between and within provider types.
Communication	Effective communication between and among physicians, nurses, patients, and administrative staff is critical to chronic disease care.
Temporal flow	Temporal aspects of workflow and information flow play an important role in chronic disease care and are dependent on disease and person-specific factors.
Information - Systems/Technology	
Information flow	Chronic disease management relies on the collection, organization, and synthesis of information from disparate sources.
Variation in use	Informatics applications are used for three main functions: information access, information input, and communication. Different types of users employ different subsets of these three functions.
Technology as a partner	The effective use of technology should enable better disease management in chronic disease care.

The six themes were used to organize the presentation of the results in this chapter.

Task and workflow patterns

The task flow and workflow in each clinic were organized by segmenting the overall process into subprocesses. Each subprocess was further divided into specific tasks. The handoffs between tasks and between people were shown in detail. The flowcharts graphically present each clinic's workflow.

MS Clinic

Figure 2 below shows the overview task and workflow for the MS clinic. The subprocesses in this clinic were: appointment preparation, check-in, patient intake, hand-off from nurse to physician, physician workup and treatment, make follow-up appointment, appointment completion, and between appointment activities.

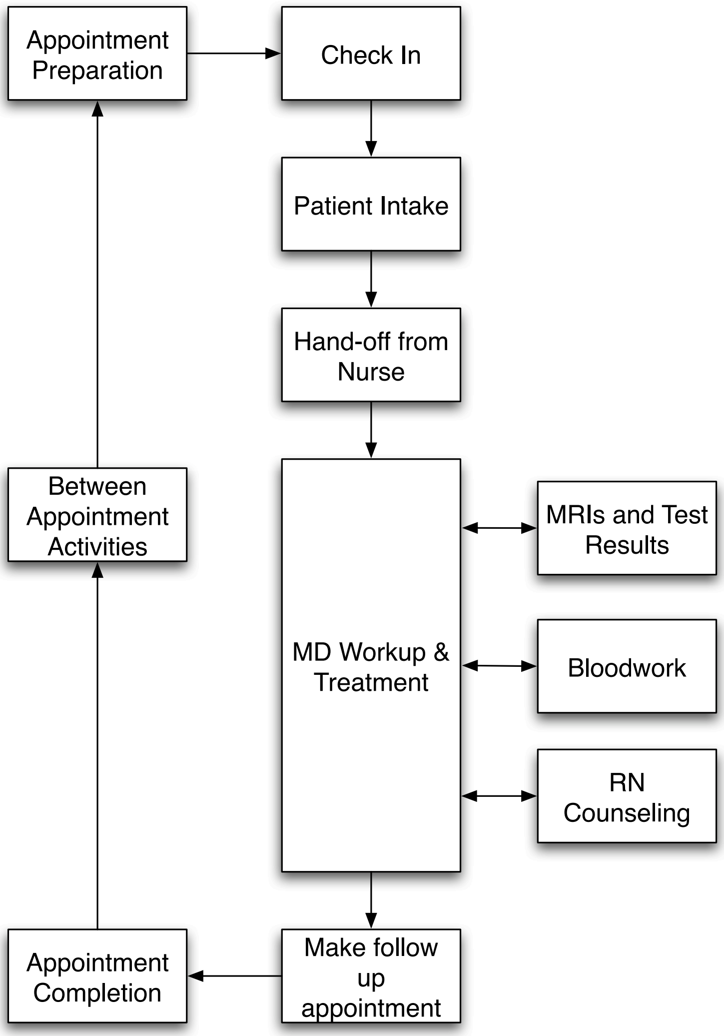


Figure 2. Workflow overview in MS clinic

Several of the unique aspects of workflow in the MS clinic related to the clinic's use of paper charts and extensive use of paper forms. The paper chart process added a layer onto appointment preparation, with the paper charts for the day's appointments being pulled by an administrative assistant at the start of each day and brought to the clinic. Forms were also sent to new patients to fill out prior to their first appointment, and all patients were asked to fill out forms related to current medical status. During each patient exam, the physician used a domain-specific assessment form. These forms were later scanned into StarPanel, but were also placed back in the paper shadow chart.

The providers in the MS clinic primarily used qualitative data in the form of status reports from patients and patient gait and balance while walking to monitor disease progression. MRI scans were also used to diagnose new patients and to track returning patients' disease progression and response to therapy. The physicians in the clinic preferred to view the MRI scans themselves rather than relying on reports from radiologists because they were looking for specialized information regarding central nervous system lesions. This was sometimes challenging for scans performed outside of Vanderbilt and available only on electronic media. When patients brought disks with electronic copies of scans, problems were encountered with accessing the scans because of format and software issues. In addition to the qualitative walking test performed by physicians, the nurses performed a timed walking test, where patients were asked to walk a certain distance and were timed using a stop watch. Quantitative data such as laboratory values can be graphed in the current informatics tools, providing easy access to longitudinal data. However, the graphical display of longitudinal qualitative data is currently not supported.

Hand-offs of the patient from the clinical receptionist to the nurse to the physician were also observed to have occasional problems. During the study period, the clinical receptionist sometimes placed the patient in an exam room and marked that information on a whiteboard in the hallway of the clinic. However, the nurse frequently missed this information and was unaware that a patient was ready for intake. Once intake was completed, the nurse marked the patient availability on the whiteboard, but the physicians generally did not consult this whiteboard. In addition, the sequence in which patients arrived and had intake completed was not shown on the whiteboard, so patients were often seen out of appointment time or arrival sequence. The clinical receptionist placed a printout of the clinic's schedule inside the charting room and nurses sometimes highlighted patient names after patient check in.

The full task and workflow flow chart for the MS clinic is in Appendix B.

CF Clinic

Figure 3 below shows the overview task and workflow for the CF clinic. The subprocesses in this clinic were: appointment preparation, check-in, pre-appointment tests, patient intake, hand-off from nurse, treatment, make follow-up appointment, post-appointment tests, appointment completion, and between appointment activities.

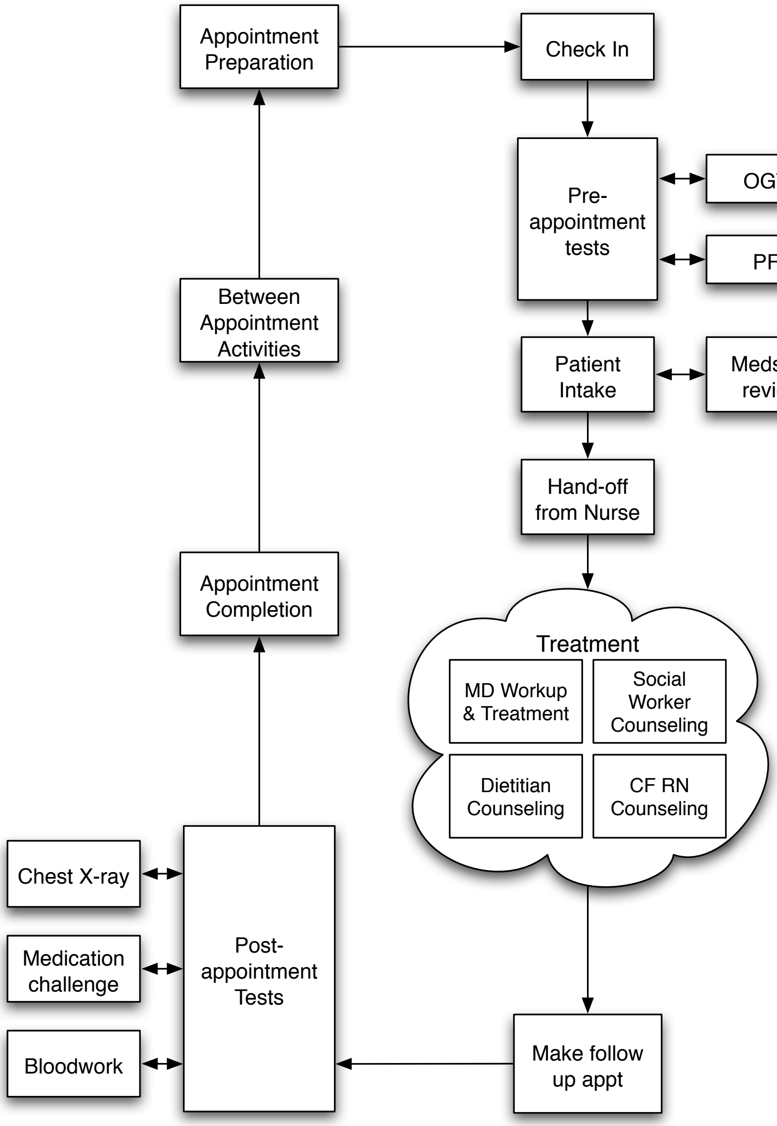


Figure 3. Workflow overview in CF Clinic

Several aspects of workflow in this clinic were unique. Patients completed pre-appointment testing in the majority of cases. Prior to most types of appointments, patients completed pulmonary function tests (PFT). Respiratory therapists in the pulmonary clinic conducted the tests, which provide measures of lung capacity and function. Providers in the clinic consulted the PFT results extensively while making treatment decisions, so it was important that the test be completed prior to the appointment. In addition, an oral glucose tolerance test (OGTT) was performed once a year for patients not diagnosed with CFRDM. The tests were typically scheduled during the morning before a clinic visit, mainly for the convenience for patients. OGTT results had less immediate impact on treatment decisions than PFT results.

The structure of the treatment subprocess of the workflow was unique to the CF clinic. CFF guidelines recommend visits with a physician at least every 3 months and counseling with a dietitian and social worker at least once a year. During each clinic day, all patients needed to see a physician but only a subset of patients needed to see the dietitian and social worker. Thus, the physicians were the constraining resources in the clinic. Visits were structured loosely, to allow maximum flexibility for physicians. Patients had a set appointment time for the PFT and for the overall visit, but specific times were not assigned to the different types of providers. The patient remained in an exam room and the providers moved between exam rooms to visit the patients.

The treatment workflow was complicated by the presence of fellows in the clinic. The portion of the treatment workflow specific to fellows is shown below in Figure 4.

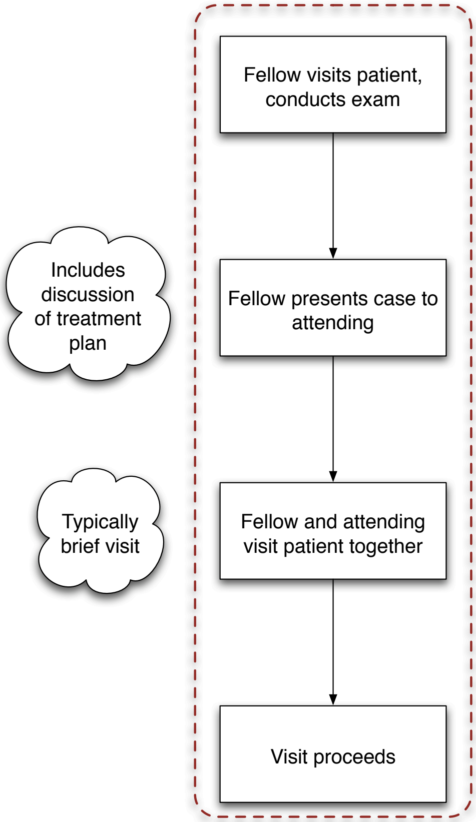


Figure 4. Workflow overview of fellows and residents

The flowchart shows that the main constraining resources were the attending physicians. The clinic has two attending physicians; one or both are present for all clinic hours. The number of fellows present for clinic varied from none to three.

The major drawback of the current treatment workflow was a persistent problem with providers entering the exam room while another provider was seeing the patient. For example, the physician would sometimes walk into the room while the dietitian was visiting the patient. Patient hand-offs between the different providers had little explicit notification and required monitoring and guesswork, particularly on the part of the ancillary providers and the nurses. The visit flow occasionally resulted in patients waiting in the exam room longer than necessary when providers were unaware the patient was available.

Between-appointment activities in the CF clinic were largely coordinated by a CF nurse. Patients were able to contact the nurse via phone call or MyHealth@Vanderbilt and the nurse would resolve the question or refer it to physicians or ancillary providers as needed. The CF nurse also occasionally saw patients during clinic hours to deal with specific visit-related needs. During the course of the study, the CF nurse left Vanderbilt. In her absence, the role was filled on a temporary basis by different nurses.

The clinic adopted several non-electronic measures in an attempt to manage workflow. Patient paperwork was placed in bins in the hallway near the nurses' station when the patients were ready for intake to the CF clinic. The intake nurses would check the bins to monitor for patients ready for intake. The intake nurses placed a printout of the clinic's schedule for the day on a bulletin board in the charting room. The CF nurse placed a sticky note on the printout with a list of patients who needed to see the ancillary providers. When patient intake was completed, the intake nurse came to the charting room, highlight the patient name, and mark the exam room number on the sheet. When a physician selected to see a particular patient, the physician typically put their initials next to the patient name on the printout. The nurses placed the patient's paperwork on the filing cabinet outside the charting room. Providers watched the cabinet to see if any new papers were added. Ancillary providers had a difficult time knowing when a patient was available and spent time monitoring to try to find the most efficient time to see each scheduled patient.

The full task and workflow flow chart for the CF clinic is in Appendix C.

Diabetes clinic

Figure 5 below shows the overview task and workflow for the diabetes clinic. The subprocesses in this clinic were: appointment preparation, check-in, patient intake, hand-off from nurse, provider workup and treatment, make follow-up appointment, RN counseling, labwork, appointment completion, and between appointment activities.

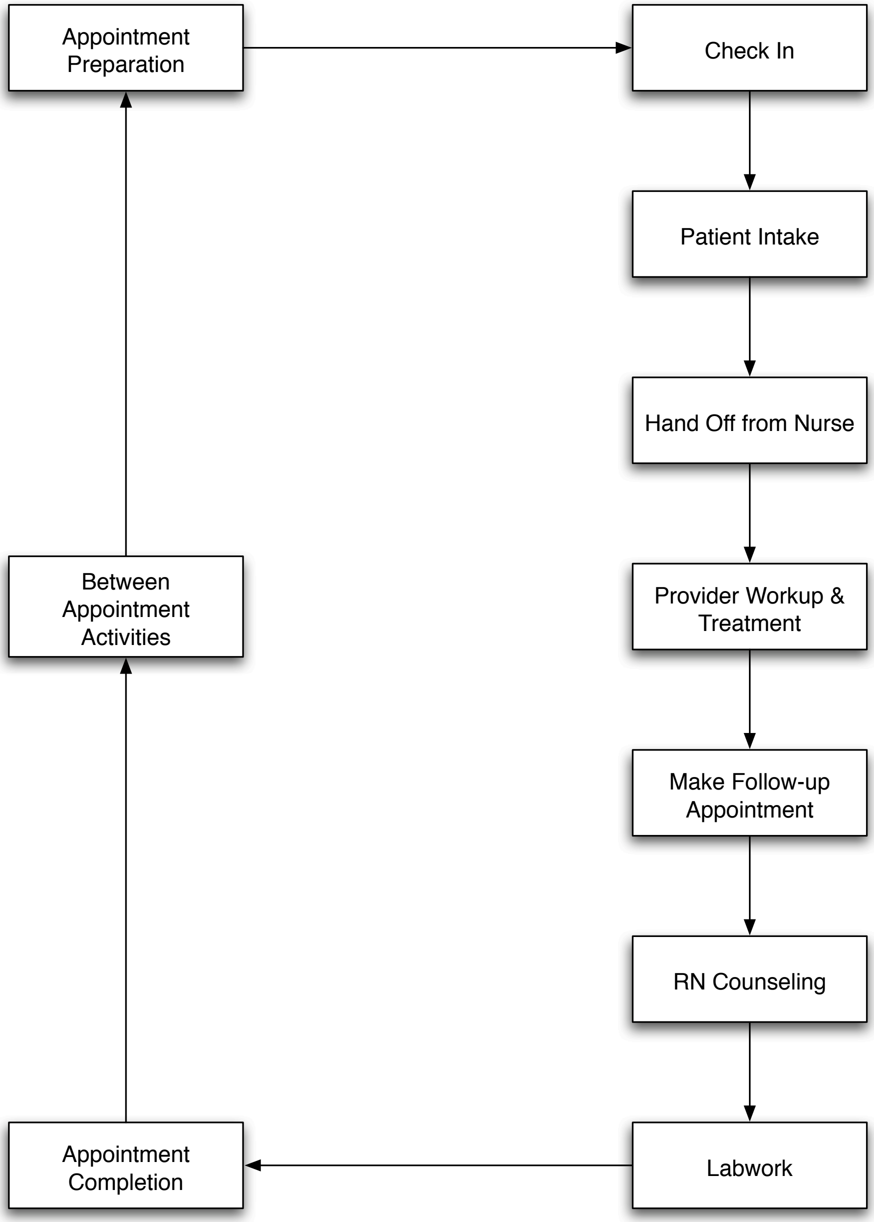


Figure 5. Workflow overview in diabetes clinic

The diabetes clinic was larger than both the CF clinic and the MS clinic in terms of number of providers, number of patients, and amount of physical space. The flow of patients through the clinic was sometimes not smooth, or was perceived as being that way by providers. Several providers in the clinic felt that the check-in and intake processes were "bottlenecks". The comments regarding reasons for this perception included the amount of information collected during check-in and intake as well as perceived inefficiencies in the process flow. The intake nurses were largely responsible for determining the order of patient intake. Because of clinic volume, it was not unusual during the study period for up to eight patients to have completed check-in and be waiting for intake. Intake nurses juggled several factors in determining order including: if a provider already had patients waiting with intake completed, if a patient was early/late, how early/late the patient was, provider preferences, and the number of intake nurses available at that time. These decisions were made on the fly, with no consistent set of rules.

Providers felt that too much extraneous information was collected during intake. Near the end of the observation period, responsibility for conducting diabetes foot exams was transitioned to the intake process. Since the foot exam involves patients removing their shoes and socks and then putting them back on after the exam, it also adds time to the intake process. Another time-consuming portion of the intake process was performing the point-of-care (POC) HbA1c test. Many providers requested the test be performed on intake but the actual processing of the test takes 6 minutes. Even when the test was started at the beginning of intake, it occasionally took longer than the intake process and nurses then delivered the result to an exam room or office.

As in the CF clinic, patients sometimes saw multiple providers during a single visit. This usually consisted of a visit to a nurse practitioner and a dietitian or occasionally to a physician and a dietitian. Patients were never scheduled to see both a physician and a nurse practitioner in the same visit for reimbursement reasons. Unlike the CF clinic, the providers remained in their offices or assigned exam rooms and the patients rotated between the providers. The hand-off from the intake nurse to the first provider was normally smooth, with the intake nurse paging the provider to let them know the patient was ready. Several providers reported that hand-offs between providers was occasionally a problem area, when they were not aware that the other provider was finished with the patient or were left wondering where the patient was.

The check-out process in the diabetes clinic was unique. Patients checked out after seeing all the providers they were scheduled to see. Part of the check-out process included making their next appointment, which providers recorded on the billing forms and clinical receptionists set using the EPIC Hyperspace system. After checkout, if the provider had requested any education activities or lab work, the patient was called back into the clinic. If both education and labwork were ordered, the sequence depended on availability. RN counseling typically took the form of education regarding a new device or new treatment. Nurse educators taught patients how to use a new glucose meter, how to administer insulin shots, and about a variety of other devices and treatments. Lab samples, both serum and urine, were collected in the lab room in the clinic. Some laboratory analysis was also performed in the clinic's laboratory. If HbA1c tests were ordered at the end of the visit by a provider, the test was performed as a point-of-care (POC) test by the intake nurses after check-out.

Handling of patient contact between appointments varied according to provider. Some providers, especially nurse practitioners, gave patients their direct phone number in case of any questions or problems. For other providers, the calls were filtered through a call center and then forwarded to administrative assistants to make appointments or to triage nurses to fill refills or handle triage. Many of the providers in the clinic also used MyHealth@Vanderbilt. Incoming messages in this case were typically filtered through the provider's administrative assistant.

The clinic used several paper-based artifacts to assist in workflow management. During check in, labels with patient name and medical record number were printed by the front desk. The labels were stapled to patient paperwork and were used to mark paper reports and forms, such as glucose meter downloads and lab order forms. After check in was completed, front desk staff placed patient paperwork in a bin on the end of the administrative area near the intake area. Intake nurses looked through the bin to determine which patient to bring back next, as well as to evaluate the number of patients waiting for check in. For physicians, nurses placed a printout of each provider's schedule on a shelf outside the exam rooms assigned to the provider. Intake nurses highlighted the patient's name on the form when intake was completed and the patient was placed in an exam room. The physicians occasionally checked this sheet. The intake nurse placed patient paperwork in a bin near the door to the exam room . After checkout, front desk staff placed lab order forms and requests for nurse counseling in bins near the lab area. The lab technicians and nurses marked papers with tape flags if a patient needed both lab work and nurse counseling to ensure that the patient received all necessary services.

The full task and workflow flow chart for the diabetes clinic is in Appendix D.

Inter-clinic workflow similarities

Workflow diagrams from the individual clinics were assessed and a generalized workflow diagram was generated based on the similarities between clinics. Figure 6 below shows the overview of the generalized workflow diagram.

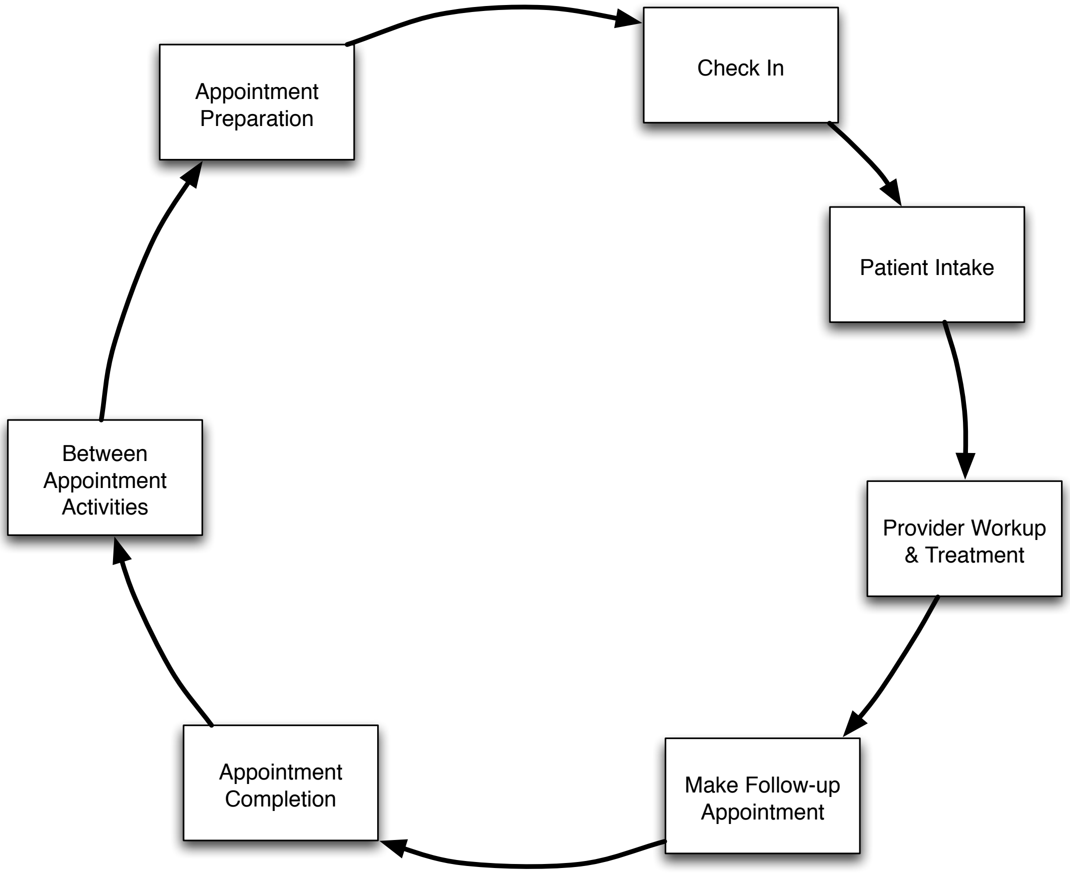


Figure 6. Generalized chronic disease workflow overview

The generalized chronic disease workflow diagram captures elements of workflow that were common between the three clinics. Chronic disease care is a cyclical process, regardless of disease. Patients are always either preparing for an appointment, having an appointment, completing an appointment, or conducting activities between appointments like contacting providers with questions. The importance of capturing these common elements of workflow is explained in greater detail in the Discussion chapter, especially in the discussion of Guideline 1 and Guideline 2.

The full version of the generalized workflow diagram is in Appendix E.

Communication

Multiple communication methods are used for various purposes through the three clinics. Table 19 presents different modalities used in the three clinics, the nature of the communication, and summarizes the communication participants.

Table 19. Communication modalities

Communication modality	**Asynchronous or Synchronous**	**Notification that message is received**	**Used by**
Face-to-face conversation	Synchronous	n/a	Everyone
Telephone	Synchronous	Yes	Patient-provider, admin-provider, provider-provider
Voicemail	Asynchronous	No	Patient-provider, admin-provider, provider-provider
Pager	Asynchronous	No	Admin-provider, nurse-provider
StarPanel Message Basket	Asynchronous	Yes, able to check that message was read	Admin-provider, provider-provider, nurse-provider
Email	Asynchronous	No	Admin-provider, provider-provider, nurse-provider, patient-provider
Patient portal messages	Asynchronous	For provider, yes. For patient, no.	Patient-provider
Fax	Asynchronous	No	External provider-provider
Paper forms	Asynchronous	No	Admin-provider, provider-provider, nurse-provider

Face-to-face conversation was commonly used for informal resolution of questions and as a method to direct workflow. Administrative staff in all three clinics would locate providers during slower periods to ask questions or ask for direction on specific issues. Providers with questions or concerns would locate other providers to request their feedback. In the MS clinic, if a patient needed lab tests or RN counseling, the providers would find a nurse in the charting room and ask the nurse for assistance. Although synchronous communication provided fast answers, it also often interrupted the work of others as was previously discussed by Coiera (92).

The use of asynchronous communication modalities without notification of receipt caused problems in several cases. In the diabetes clinic, intake nurses normally page providers to notify them that intake was complete. Providers complained several times that pages were not sent, but the nurses in question insisted that the provider had been paged. This disconnect led to patients waiting for longer than needed, delays in provider schedules, and tension between nurses and providers. Patients also complained that phone calls handled by the call center in the diabetes clinic were not returned. Patients using the patient portal do not receive notification that their messages have been read, although providers are notified if a patient does not retrieve a message within a set period of time. In addition, asynchronous communication modes can also be interruptive. Providers in the diabetes clinic noted that when nurses page them to notify them patient intake is completed, it serves as a prompt to wrap up their current visit and move on. Even though the page required no direct action on the provider's part, it still interrupted their workflow and modified their behavior.

Numerous paper artifacts are used in communications processes in all three clinics. These paper forms present some opportunities for error, but also cause additional work and frustration. The most prevalent paper-based communications system is the process for ordering tests. Different individuals are responsible for filling out the forms depending on clinic. Lab order forms are filled out by physicians in the CF and diabetes clinics, while a nurse fills out the forms in the MS clinic. Multiple domain-specific forms are used, such as the three forms used on the diabetes clinic - one for serum, one for urine, and a special form for cholesterol tests. Although most order forms relate to laboratory tests to be conducted immediately, in the CF clinic an order form is filled out for the patient's next PFT exam and for an OGTT test if needed during their current visit. This allows the clinical receptionist to schedule these additional pre-appointment tests during patient check out. Multiple subjects commented that the ordering process was time-consuming and that they would prefer an electronic outpatient order entry system. Additional treatment related communications artifacts included pharmaceutical company injectable medication start forms in the MS clinic and prescription pads, which were used in all three clinics. Most providers who routinely used the electronic prescription writer continued to use handwritten prescriptions when necessary for medications and treatments that they felt were not well covered by the tool.

Paper artifacts were also used in the CF and diabetes clinics as quality improvement tools. The Diabetes and Endocrinology Clinic Form was part of a legacy quality control database that was reportedly being phased out. A researcher printed the form off for each diabetes patient with an appointment the next day. The form contained information on the dates of last services or tests, such as foot exams, cholesterol tests, and HbA1c tests. The forms were delivered to the front desk, where clinical receptionists alphabetized the forms and placed them in a cart. The clinical receptionist would find the form on patient check-in and add it to the papers given to the intake nurse. At the completion of the visit, some providers gave the form back to the research technician who then updated the database.

The CF clinic used a CF Clinic Checklist as part of a process to encourage compliance with CFF recommendations. The paper checklist was filled out prior to each clinic day by a CF registry technician. The technician would write dates of last service or test by each CFF recommendation and then highlight items that were due. She also placed a colored sticker on each form to indicate the patient's BMI status. The technician used the CFF registry, the EMR, and other data to compile the information on the form. The forms were placed on a cabinet outside the charting room at the start of each clinic. As patients checked in, intake nurses combined the forms with other patient paperwork. The clinic checklist was used as a guideline by providers to ensure that needed services and tests were completed on schedule. After each clinic day, the CF registry technician updated the CFF registry with the latest information on service and test completion.

Paper artifacts were also used to communicate educational information to patients in all three clinics. Various flyers, handouts, brochures, booklets, and books were provided to patients in each clinic.

Paper artifacts were also used extensively in administrative purposes, such as billing. This included regulatory related forms such as HIPAA forms and agreements to participate in research studies. Several forms related to billing were used in all three clinics. The forms, which were generally blue or pink in color so they were easy to identify listed treatment codes appropriate to the speciality. Providers marked the ICD-9 codes for each visit and administrative staff input the data into billing systems. Additional information was documented on the form, such as the interval to the next visit as set by the provider. In the diabetes clinic, providers would also record a note if RN counseling was needed on the current visit. An additional form was used in the diabetes clinic to document POC testing. The POC testing forms were maintained by the intake nurses and were sent to a POC testing group at the end of each day. The POC testing group would input the data manually into the EMR and also handle billing for the tests.

The various forms used for communication throughout the clinic can create opportunities for problems. An example would be the POC testing form in the diabetes clinic. The intake nurse manually recorded data, including HbA1c results and glucose test results, on the form. The form was then faxed to another group, where a technician manually input the data into the EMR. The data could be accidentally modified at any point in the process, which would skew the ability to track these lab values over time. The majority of the other communications processes using paper forms did not present direct hazards to patients, but were time-consuming and occasionally frustrating processes for staff. Examples of this include test order forms and billing forms. The quantity of test order forms and the process of filling them out was repeatedly highlighted as a annoyance for many providers. Administrative staff often had problems determining which ICD-9 codes were selected on the billing forms.

Temporal Flow

Reddy, Dourish, and Pratt discussed the concept of temporal rhythms and temporal horizons in medical work (91). They define temporal rhythms as the collective time-based characteristics of work such as re-occurring patterns. Every environment has a dense temporal fabric composed of the multiple temporal rhythms of different people and activities. Temporal horizons characterize how individuals respond to the broader temporal rhythms that are part of their environment. Although Reddy et al applied these temporal flow concepts to the surgical intensive care unit (SICU), such rhythms can be readily examined in the ambulatory chronic disease care environment.

Disease-related temporal rhythms

The nature of chronic disease care, regardless of domain, is cyclical. Patients are expected to return for routine visits at intervals dependent on disease- and person-specific factors. Specific tests and treatments are also conducted at regular intervals. Annual temporal flow scenarios are presented in Figures 7-9. The diagrams present patient-centric disease-related scenarios over the course of a year. Actors in the process, including informatics systems, are listed along the left hand side. Routine events, such as routine appointments, are shown in the main portion of each diagram. Events that do not occur on a routine timetable, such as disease exacerbations, are also shown. Causal links between events are marked by the lines along the top of the diagram and unplanned events that interrupt temporal rhythms are marked by arrows. Actors who participate in each event have a filled-in circle by the event. This type of diagram can be constructed for various anticipated or observed scenarios.

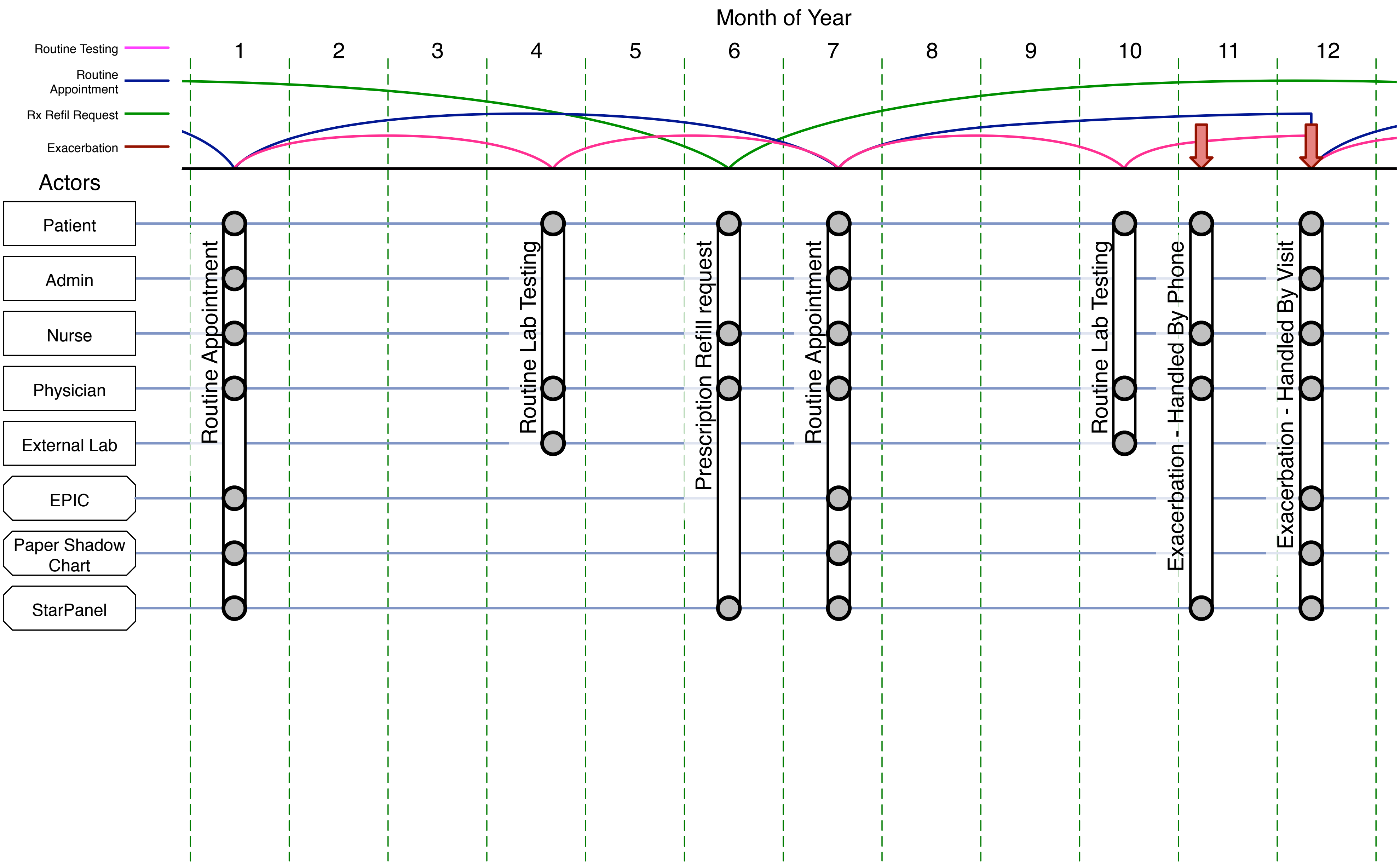


Figure 7. Annual Temporal Flow Scenario: MS Clinic

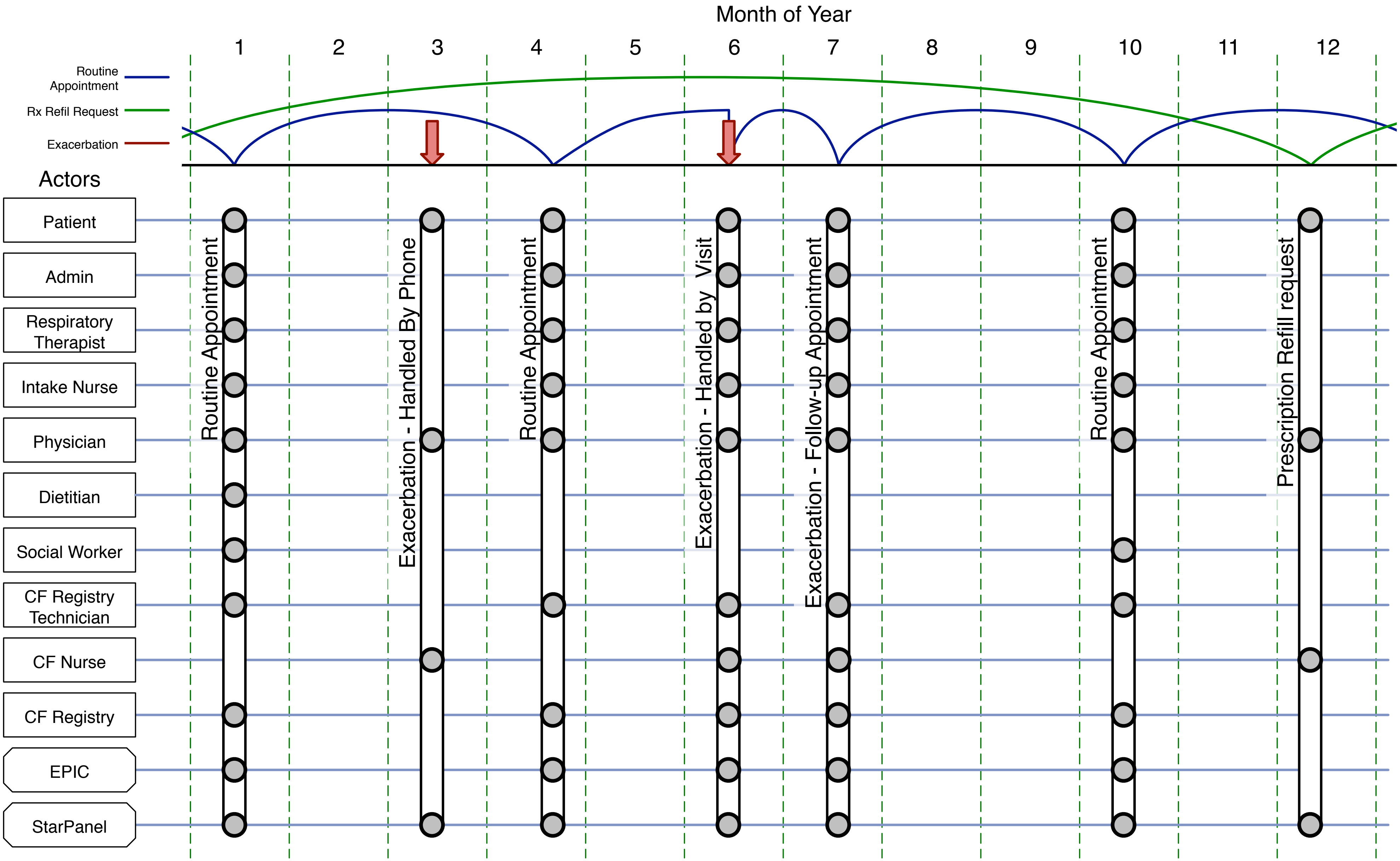


Figure 8. Annual Temporal Flow Scenario: CF Clinic

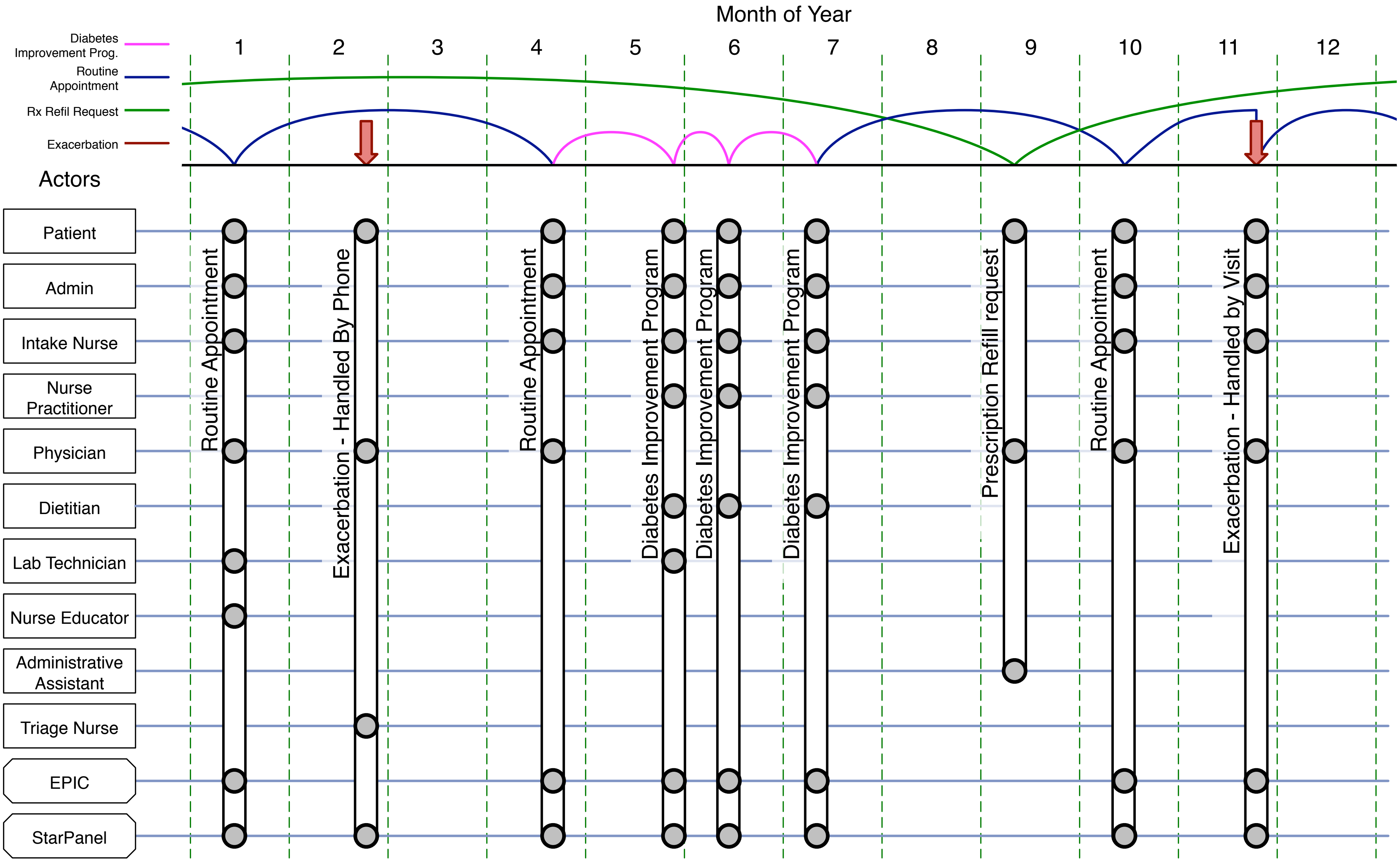


Figure 9. Annual Temporal Flow Scenario: Diabetes Clinic

The standard of care for each disease with regard to the intervals of tests and treatments was discussed in the background section. There was a great deal of variability between these recommendations and what happens in practice. The initial basis for variability was clinician preference. Individual clinicians decided the level of importance for tests and treatments for their patients. For example, there was substantial variation in HbA1c test frequency in the diabetes clinic. Some providers felt that HbA1c tests should be done on a monthly basis, while others ordered the test on a quarterly basis. An additional degree of variability was introduced by how these interval preferences were interpreted by others. Although intake nurses were aware of the providers' preferences for the frequency of HbA1c testing, in many cases the tests were performed every visit, which could be as often as every other week.

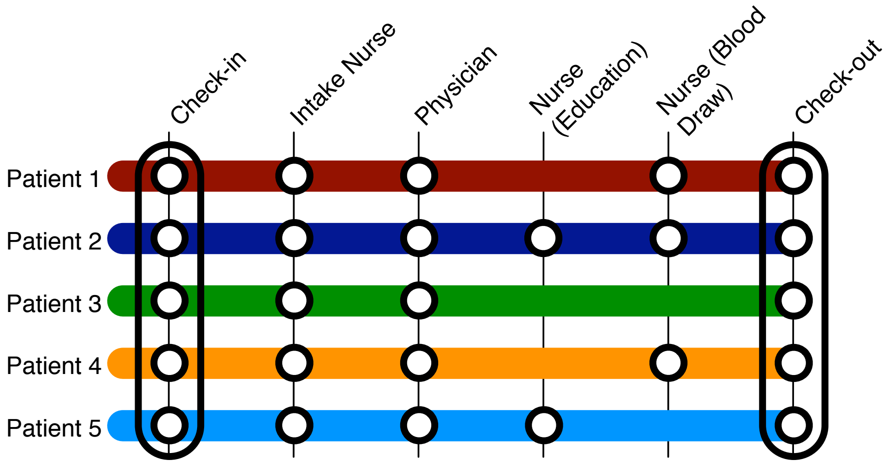
Provider type also affected visit frequency. In the CF clinic, dietitians and social workers saw patients at least one time per year, while physician visit occurred at least every 3 months. Patients in the Diabetes Improvement Program were seen by a nurse practitioner and dietitian as often as every other week initially and then less frequently as the patient developed better diabetes control.

Individual patient preferences, needs, and disease status introduced an additional source of variability. Disease stability is a key factor in visit and testing frequency. Patients with stable disease are routinely seen less frequently in all three clinics. In the CF clinic, patients in yellow and red BMI zones are seen by the dietitian more frequently than patients with a BMI in the green zone. Some physicians in the diabetes clinic may choose to see some patients every six weeks if they have very unstable disease, every three months if their disease is moderately stable, or every six months if they have excellent glycemic control. Many of the physicians in the diabetes clinic referred patients with disease control problems to the Diabetes Improvement Program, for a more intense schedule of visits with both nurse practitioners and dietitians. In the MS clinic, patients with progressive disease or with treatment problems were seen more frequently than patients with stable relapsing-remitting MS. Factors such as insurance concerns and distance patients needed to travel to Vanderbilt also played a role in the frequency of routine visits.

Patients in all three clinics were often seen more frequently than the minimum schedule of visits due to disease exacerbations. Disease exacerbations were largely unpredictable, although there were factors for each disease and for individual patients that increase the frequency of exacerbations. Between patient visits to the clinic, patients contacted the clinic via telephone or by electronic means to request information, medication refills, or assistance with specific problems. Requests for medication refill prescriptions had a temporal rhythm, as most recurring medications were prescribed for a 12-month period. The nature of between-visit patient contact affected the temporal horizons of the clinic staff, with added work due to patient contact on an unpredictable schedule.

Clinic-related temporal rhythms

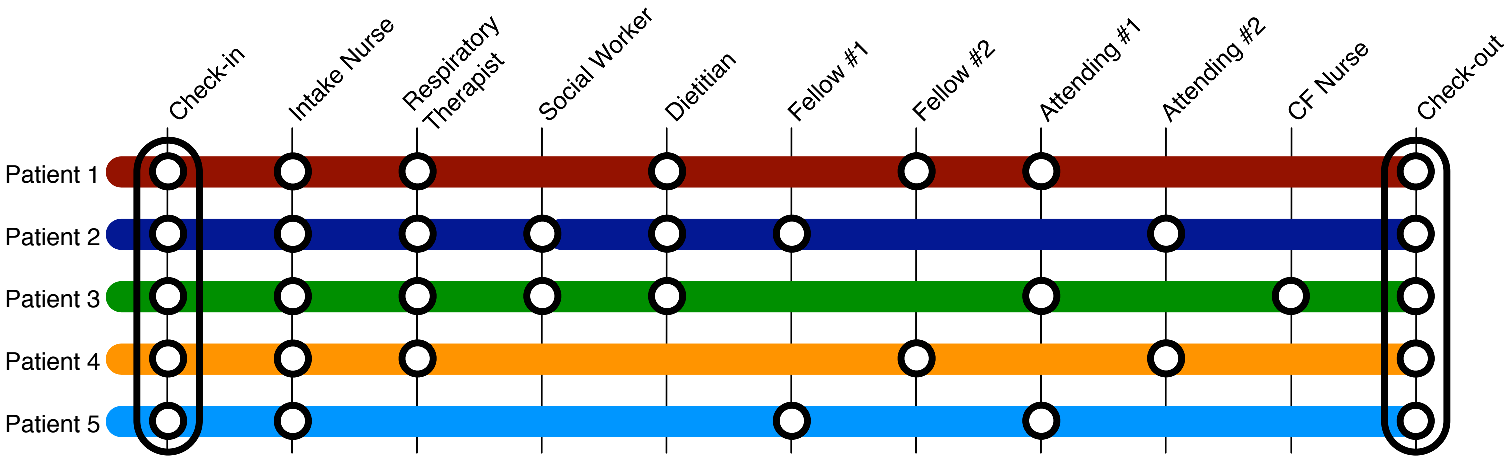
Daily temporal flow scenarios for each clinic are shown on the following pages in Figures 10-12. The diagrams present a patient-centric snapshot of a portion of a clinic day. Patients are listed along the left hand side of the top portion of each diagram. Potential care providers that they may interact with are listed along the top, and actual patient-provider interactions are marked with circles. The table portion of the figure lists each patient and each provider and shows the different temporal horizons within the clinics. The times listed in the table are provided for illustration only. Staff and providers adjust their temporal horizons based on when the patient arrives, which providers are involved in their care, and what types of procedures the patient requires during the visit. These figures illustrate the temporal aspects of workflow and augment the workflow diagrams shown earlier in this chapter.



	Appointment Time	Check-in	Intake Nurse	Physician	Nurse (Education)	Nurse (Blood Draw)	Check-out
Patient 1	9:00	9:20	9:25	10:10	n/a	10:40	10:50
Patient 2	9:30	8:45	9:05	9:30	10:05	10:05	10:20
Patient 3	10:00	10:20	10:30	10:50	n/a	n/a	11:25
Patient 4	10:45	10:40	10:50	11:35	n/a	12:05	12:15
Patient 5	11:00	11:00	11:10	12:10	12:50	n/a	1:10

Note: Times listed are for illustration.

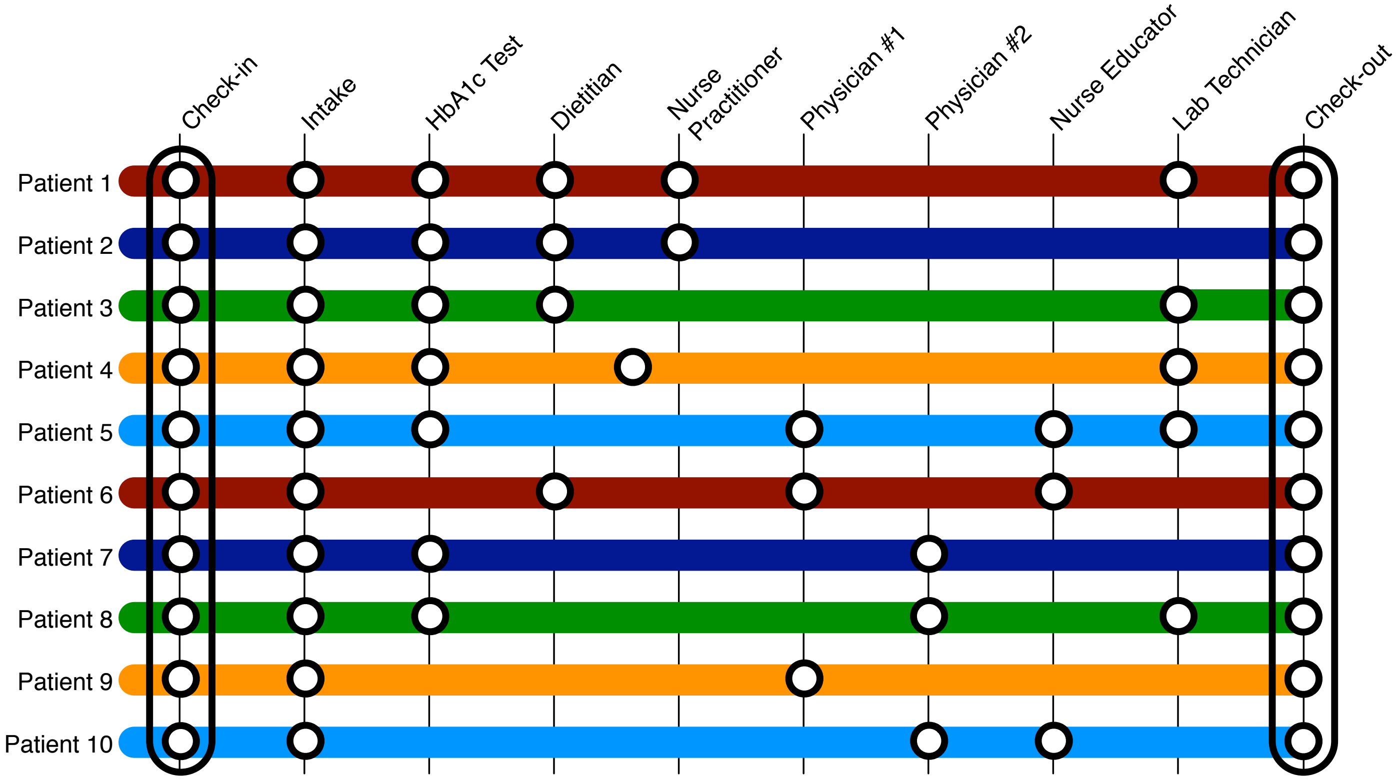
Figure 10. Daily Temporal Flow Scenario: MS Clinic



	Appoint. Time	Check-in	Intake Nurse	Respiratory Therapist	Social Worker	Dietitian	Fellow #1	Fellow #2	Attending #1	Attending #2	CF Nurse	Check-out
Patient 1	13:00	11:00	12:45	11:10	n/a	13:25	n/a	13:05	13:40	n/a	n/a	13:55
Patient 2	13:00	11:20	12:55	11:40	14:00	14:20	13:10	n/a	n/a	13:40	n/a	14:35
Patient 3	13:30	13:40	14:30	13:50	15:45	15:25	n/a	n/a	14:40	n/a	16:00	16:10
Patient 4	13:30	12:20	13:15	12:30	n/a	n/a	n/a	13:50	n/a	14:20	n/a	14:35
Patient 5	14:00	12:35	13:45	12:50	n/a	n/a	13:55	n/a	14:20	n/a	n/a	14:40

Note: Times listed are for illustration.

Figure 11. Daily Temporal Flow Scenario: CF Clinic



	Appoint. Time	Check-in	Intake	HbA1c Test	Dietitian	Nurse Practitioner	Physician #1	Physician #2	Nurse Educator	Lab Tech	Check-out
Patient 1	08:30	08:50	09:10	09:10	09:50	09:15	n/a	n/a	n/a	10:15	10:10
Patient 2	09:00	08:40	08:50	08:50	08:50	10:20	n/a	n/a	n/a	n/a	10:50
Patient 3	09:00	08:40	08:55	08:55	09:20	n/a	n/a	n/a	n/a	n/a	09:50
Patient 4	10:00	09:30	09:40	09:40	n/a	09:45	n/a	n/a	n/a	10:25	10:20
Patient 5	09:00	08:40	08:45	08:45	n/a	n/a	09:00	n/a	09:45	10:00	09:30
Patient 6	09:30	09:20	09:25	n/a	10:10	n/a	09:35	n/a	10:15	n/a	10:05
Patient 7	10:00	09:55	10:00	10:00	n/a	n/a	n/a	10:10	n/a	n/a	10:45
Patient 8	10:30	10:40	10:50	11:50	n/a	n/a	n/a	11:00	n/a	11:35	11:25
Patient 9	10:00	09:50	10:00	n/a	n/a	n/a	10:10	n/a	n/a	n/a	10:35
Patient 10	11:00	11:15	11:20	n/a	n/a	n/a	n/a	11:30	12:10	n/a	12:00

Note: Times listed are for illustration.

Figure 12. Daily Temporal Flow Scenario: Diabetes Clinic

In addition to temporal rhythms related to disease-specific factors, there are temporal rhythms specific to each clinic. Major factors in clinic-related temporal rhythms include clinic size and organizational structure. The number and type of staff and providers in each clinic directly affected the number of patients that can be seen in a given time period. This also indirectly affected the length of time each stage of the visit takes, the number of delays in the providers' schedule, and response time to messages from patients. For example, if multiple patients arrived at the same time to check in and the number of clinical receptionists was limited, patients had to wait to check in which introduces a delay into their visit schedule. Even if there were enough clinical receptionists to check everyone in at once, if the number of intake nurses was limited, patients had to wait for intake to be completed introducing additional delays. If a patient needed to wait for both check-in and intake, then the delay compounded.

Delays were also created when patients arrived late for appointments. In the diabetes and MS clinics, several providers had a policy that if a patient is more than 30 minutes late, the provider would not see them unless there are other openings on that day. Even if patients arrived less than 30 minutes late, delays were created in the schedule that impacted provider workflow throughout the day, even outside of clinic hours. Providers in the CF clinic did not follow this policy and would normally see patients even if they are more than 30 minutes late. Problems in this area were exacerbated by the limited amount of parking at Vanderbilt, difficulty in navigating the parking areas, and the extended geographic distance that some patients travel.

As part of the discussion of temporal horizons, Reddy et al discussed how individuals must deal with multiple temporal horizons and shift the order of activities to organize upcoming work. The intake process in the diabetes clinic was an excellent example of this process. Intake nurses received input from clinical receptionists in the form of paperwork for checked in patients. The papers were placed in a bin on the intake side of the administrative area and nurses prioritized the order of patient intake. The nurses applied a complex mental heuristic for prioritization that involved knowledge of the current status of providers and availability of exam rooms. Patient order was prioritized by the time the patient arrived, the time of the patient's appointment, if the provider they are seeing already has a patient, if one of the provider's exam rooms is available, how many other intake nurses are available and other factors. This delicate balancing act did not always result in intake being completed in the order patients arrived or the order of appointments, although it did take those factors into account. The intake nurses reacted to multiple temporal horizons and attempted to prioritize patients in order to balance the needs of multiple providers as well as patients. Several providers pointed to the check in and intake process as a bottleneck, in contrast to the rapid pace of work in the area and the continuous flow of patients through the intake process. Difficulties in balancing temporal horizons of different providers may account for some of this disparity.

Temporal horizons also include the amount of time required to complete documentation. Providers who completed all or most of their notes in the exam room during patient visits spent limited time outside of clinic hours documenting patient visits. Providers who used the computer for documentation in a limited amount or not at all in the exam room spent extensive amounts of time documenting patient visits. Several providers mentioned spending time in the evenings and weekends completing documentation. Little attention was paid to this hidden temporal aspect of patient care because the work is completed outside of normal hours. In addition to documentation time, all providers spent time writing patient lab letters, communicating with other providers, and answering patient questions and problems.

Information flow

The transfer of information between actors is a key element of the healthcare process. Actors range from external providers to patients to nurses to providers within the clinic. Information in a wide range of types flows into the clinic from a variety of sources. The information is stored in repositories ranging from paper notes to paper charts to electronic medical records. Providers need to take this disparate information from a wide time-range and integrate it into a usable and informative narrative. The role of existing informatics tools in supporting information presentation and synthesis varied within and between clinics.

Information flow in chronic disease care

Figures 13-15 on the following pages show information flow in each of the three clinics individually. Exceptions to the flow presented in the figure will be discussed in this section. Similarities in information flow were noted and a generalized diagram for information flow was developed. This generalized information flow diagram is shown in Figure 16 following the three individual clinic diagrams.

Scenarios were developed to ensure that important elements of the care process were accounted for in the model. The scenarios were based on the action set discussed by Essaihi and colleagues (93). The following action-based scenarios (Table 20) were tested against the model. The flow of information related to each scenario was traced through the model to ensure the model covered all aspects of the scenario. The model was revised as missing details were uncovered.

Table 20. Action-based scenarios for model evaluation

Scenarios	
Prescribe treatment	Admit patient
Prescribe medication	Request follow-up appointment
Order therapeutic procedure	Refer patient to another provider
Patient education	Diagnose patient
Order lab testing	Monitor patient status over time
Order treatment	Record information
Requesting information from the patient	Send report elsewhere

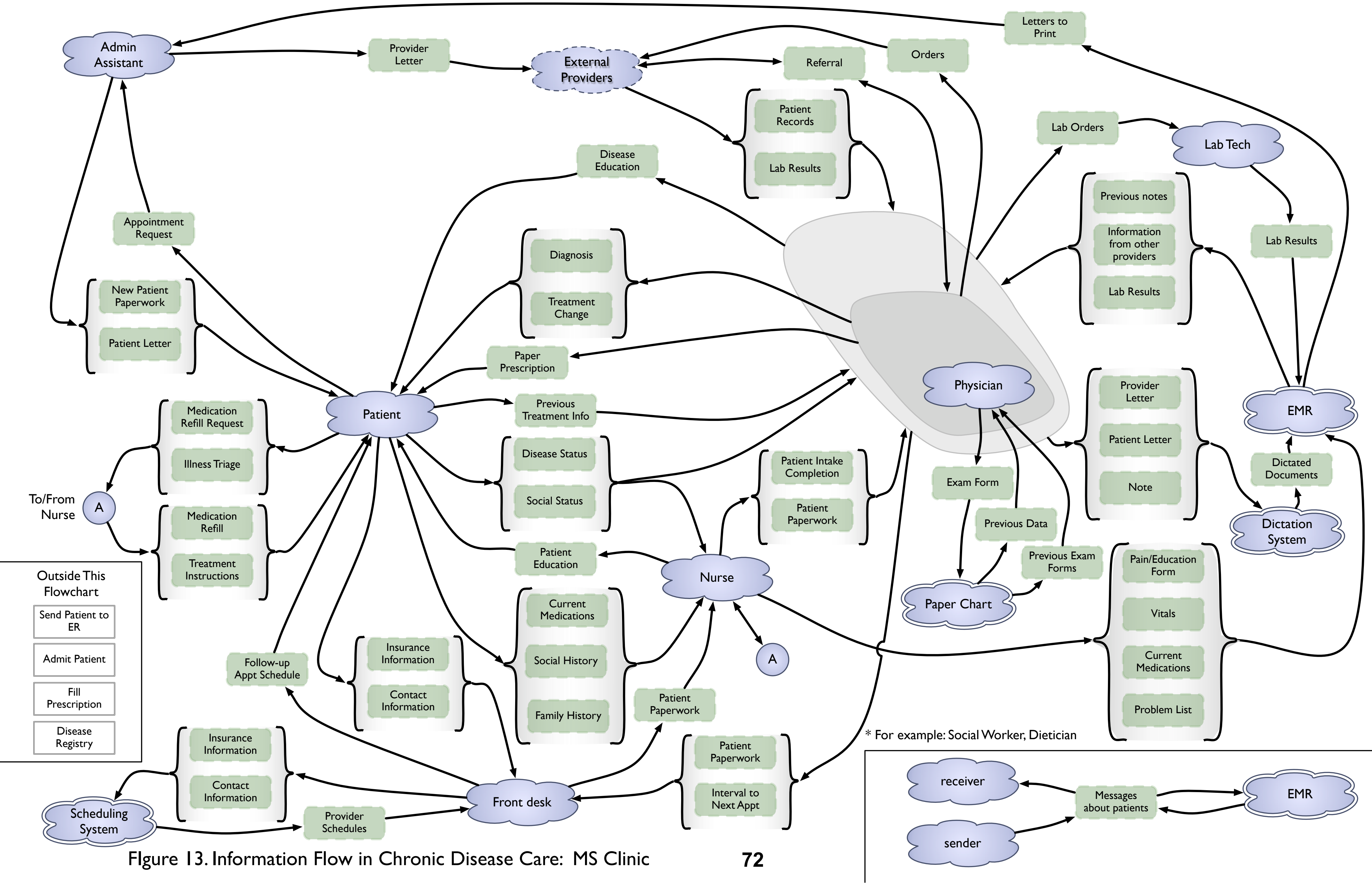


FIgure 13. Information Flow in Chronic Disease Care: MS Clinic

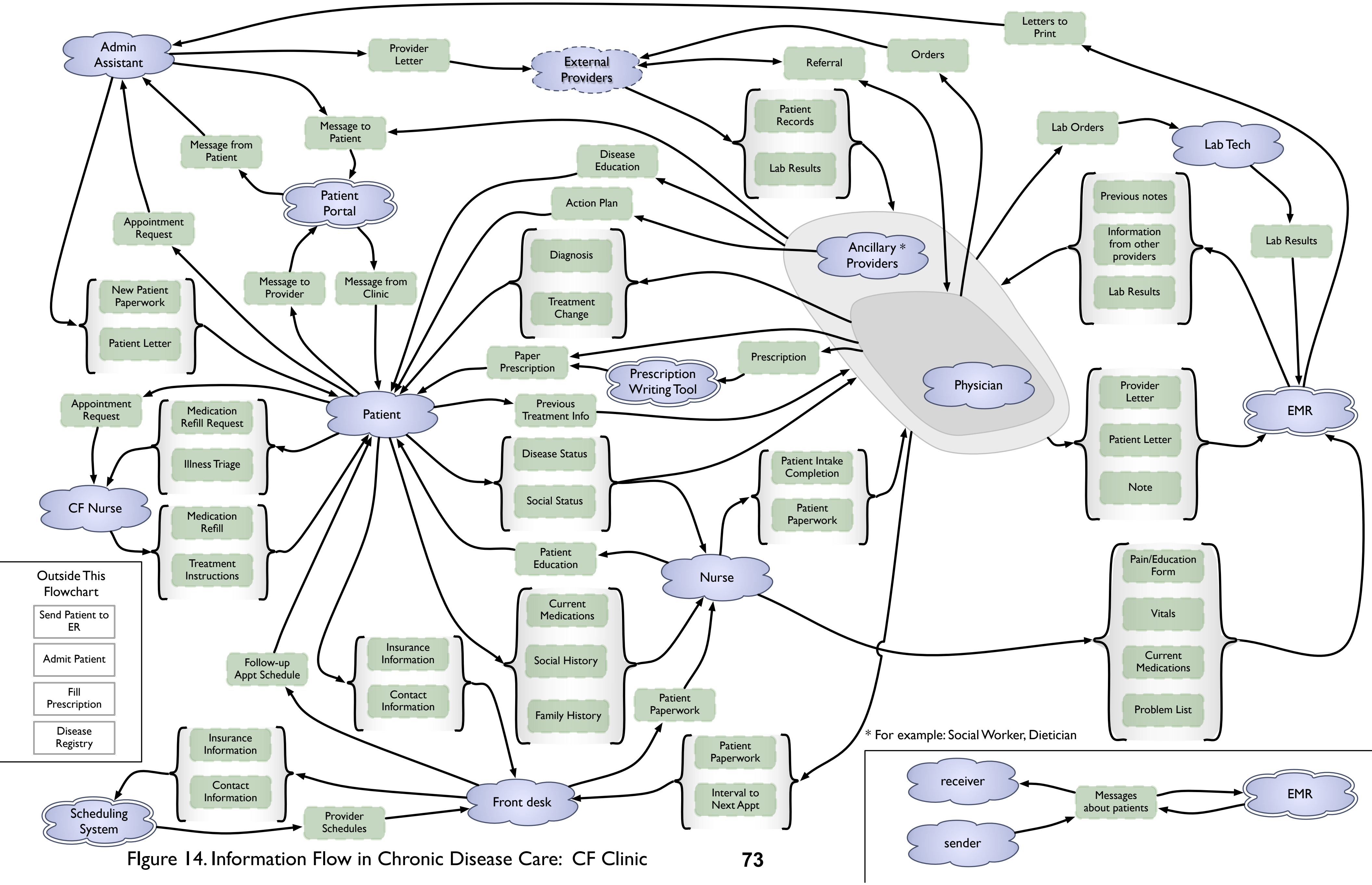


FIgure 14. Information Flow in Chronic Disease Care: CF Clinic

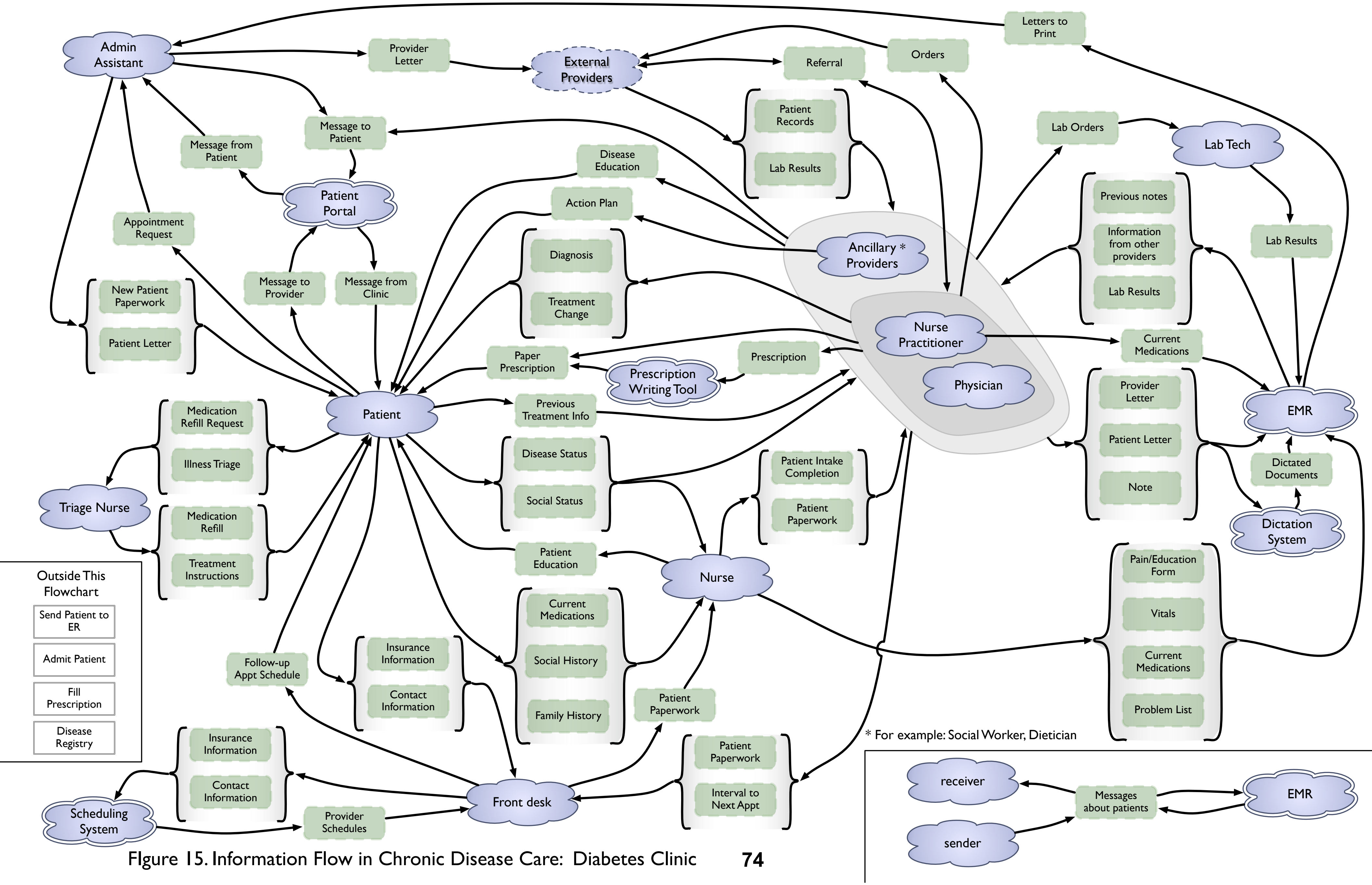


FIgure 15. Information Flow in Chronic Disease Care: Diabetes Clinic

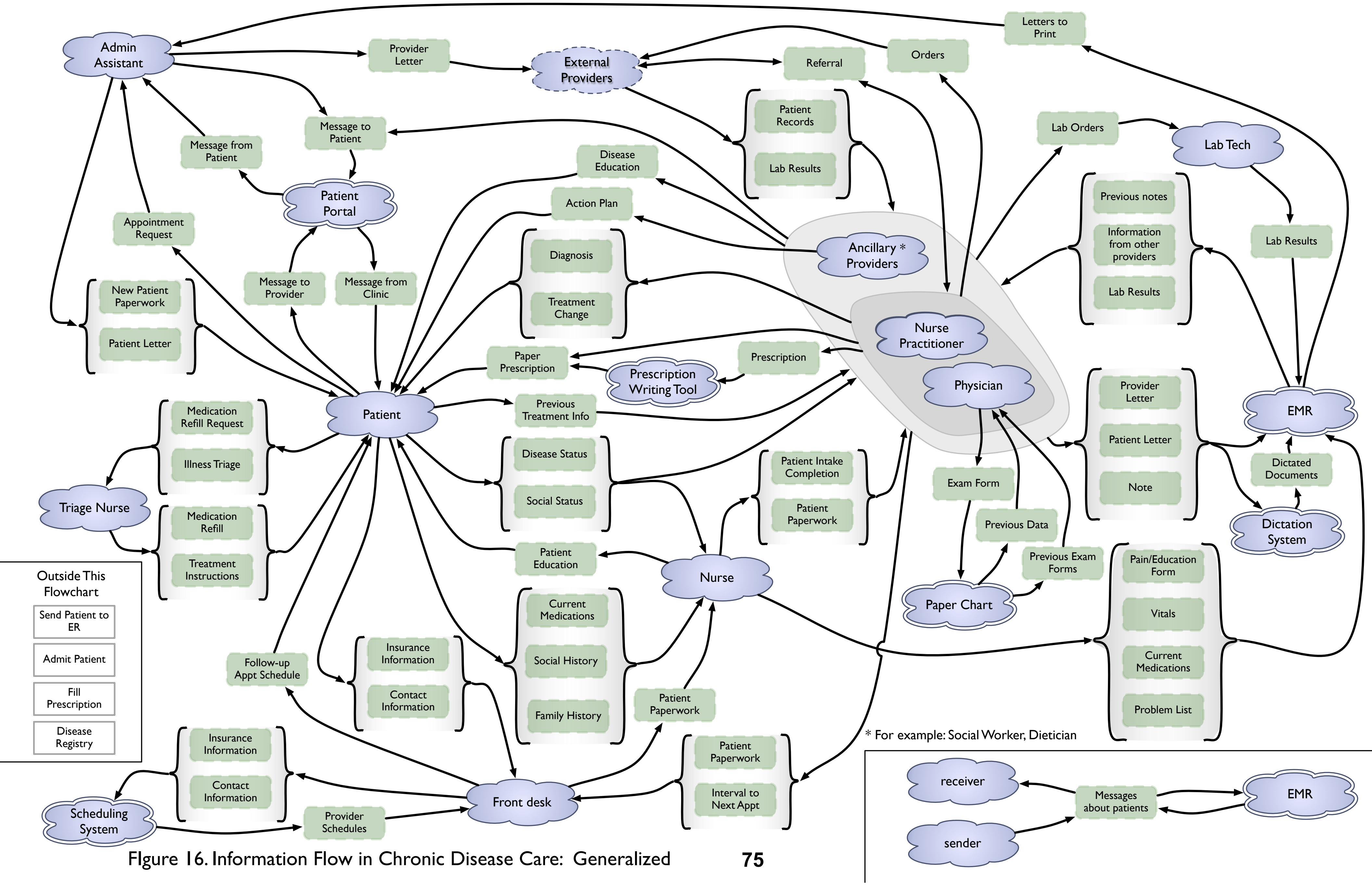


FIgure 16. Information Flow in Chronic Disease Care: Generalized

The information flow models treat each piece of information as having the same value. Although the model shows who is using and who is providing each type of information, the model does not capture frequency of use or a default information flow. Data on frequency of information use were not collected as part of the study. It is also important to note that information that is not part of a default information flow or that is used infrequently can be critical to patient care. For example, if a patient needs to be admitted to the hospital or sent to the emergency department from the ambulatory clinic, the information related to this process is as critical to patients as routine care information although it is needed much less frequently. When designing informatics systems for ambulatory chronic disease care, flow of all types of information needs to be supported regardless of how often that information is needed.

Types of information

The types of information gathered and used were similar between the three clinics (Table 21).

Table 21. Types of information

Information type	CF	Diabetes	MS
Laboratory results	Yes	Yes	Yes
Radiology images	Yes	No	Yes
Other test results	Yes	Yes	No
External medical records	Yes	Yes	Yes
Internal medical records	Yes	Yes	Yes
Status information from patient	Yes	Yes	Yes

The major difference in types of information used related to testing. Both the CF and MS clinics routinely used radiology images both for diagnostic and treatment purposes. Chest x-rays were performed for each patient in the CF clinic on a minimum 3-year interval. MRI scans of the brain and spinal column were used in the MS clinic for purposes of MS diagnosis as well as for monitoring the effect of therapy and disease progression. The diabetes clinic rarely used radiology images and relied to a greater degree on laboratory results.

Sources of information

Information flowed into each clinic through a variety of modalities, many of which were common across all three clinics (Table 22).

Table 22. Sources of information

Information source	CF	Diabetes	MS
EMR	Yes	Yes	Yes
Paper chart	No	No	Yes
Fax	Yes	Yes	Yes
Mail	Yes	Yes	Yes
Email	No	Yes	No
Brought by patient	Yes	Yes	Yes
Report from device	Yes	Yes	No

All three clinics used the available EMR, although level of use varied between providers and clinics. Results for laboratory tests conducted at Vanderbilt were routinely reviewed using the EMR. Results for laboratory tests conducted outside Vanderbilt arrived via faxes, email, and postal mail. Many of the laboratory results from external locations were scanned into the EMR. Even when scanned, these external results were not available through the same process as reviewing internal lab results and were only accessible by looking at the scan in PDF form or if a provider copied information from the report into a note.

Radiology images for studies conducted at Vanderbilt were viewed through the PACS-

WEB electronic viewing system. Radiology images for studies conducted outside Vanderbilt were typically brought in by patients and were either hardcopies or electronic files. As previously discussed, electronic radiology images from outside Vanderbilt were often difficult or even impossible to view. Radiology images brought from outside Vanderbilt were typically returned to the patient and a copy was not retained.

Both the CF and diabetes clinic obtained data from devices and printed reports for use by providers. In the CF clinic, hardcopy reports were generated from PFT equipment. These results were typically scanned into the EMR after the visit. The diabetes clinic downloaded data from patient-managed devices including glucose meters, insulin pumps, and continuous glucose monitoring devices. Glucose meters were downloaded at every appointment if the patient remembered to bring the meter and the software was able to download from that type of meter. Reports were then printed and given to each provider the patient was seeing as well as to the patient. Most providers chose to scan the glucose meter download report into the EMR after the visit, although some providers chose to scan only portions of the report or summarized the report in their note and then did not scan the report at all. The downloaded data was never imported directly into the EMR.

Glucose logs kept by hand were also sent in to providers in the diabetes clinics. Logs kept on paper forms were mailed, faxed, or brought in by patients. Logs kept electronically were either emailed to providers or printed and faxed.

External medical records were typically sent in hardcopy form and were mailed or faxed by the external provider or were brought in by patients. If a patient were referred to the clinic by an external provider, the medical records were sometimes augmented by a note from the provider explaining the reason for referral. The external records were often in part or whole scanned into StarPanel.

Internal medical records differed between the three clinics. In addition to the EMR, a paper shadow chart was maintained by the MS clinic for exclusive clinic use. New information added to the paper record was also normally scanned into to the EMR. All three clinics used the EMR for communication and to retrieve information from other Vanderbilt providers. Providers in the CF and diabetes clinics used the EMR to review information from previous visits as well.

Use of information

Information in chronic disease care was used for three main purposes: diagnosis, prognosis prediction, and disease management.

Disease diagnosis was the most common use of information for new patients in the MS clinic. Patients were often referred to the clinic for a second opinion or for diagnosis of MS with less clear signs and symptoms. New patients referred to the diabetes clinic generally already had a diagnosis of diabetes. Tests were often performed on new patients to determine if they had Type 1 or Type 2 diabetes, which was used in determining treatment approaches. New patients in the CF clinic were already diagnosed with CF and were typically either transferring from pediatric to adult care or from another CF center. Information was used to diagnose returning patients in the clinic with additional CF-related complications, such as CFRDM.

Prognosis prediction was another, less routine, use of information in all three clinics. Overall prognosis in the MS clinic was predicted based on the type of MS, history of exacerbations and disease progression, response to treatment, and literature evidence. Information used in the CF clinic for prognosis prediction included nutritional status, types of CF-related genetic mutations, history of exacerbations, response to treatment, compliance with treatment, and literature evidence. Overall prognosis in the diabetes clinic was typically linked to glycemic control, as measured by glucose meter logs and HbA1c tests.

The main use of information for both new and returning patients was disease management. Disease management in all three clinics included impeding disease progression, addressing specific symptoms, and assisting with lifestyle issues. The specific details of treatments to impede progression, the types of symptoms encountered, and the scale and types of lifestyle issues varied based on the disease and the patient.

Use of paper artifacts

Paper artifacts were used in all three clinics for both information access and information input. The observed use of paper artifacts for information access was limited. In the CF clinic, a checklist was used to monitor compliance with recommended tests and treatments. The checklist, which was compiled for each patient by the CF registry technician before each clinic day, allowed providers to rapidly and simply review when tests and treatments were last completed for each patient. In the diabetes clinic, some providers asked the nurses to print out previous notes and the updated problem list. The providers would look over this printed information rather than looking at the information online. In the MS clinic, the paper shadow chart was the primary resource used by providers during the patient exam. Providers would look through previous neurology exam forms as well as other longitudinal data recorded in the paper chart.

Use of paper artifacts for information input can be divided into two categories: permanent recording of data and temporary recording of data. The largest category of paper artifacts used for permanent recording of data were reports and forms that were later scanned into the EMR. In all three clinics, this included laboratory reports from external sources. In the CF clinic, this also included PFT reports printed by the PFT equipment. In the diabetes clinic, this typically included paper glucose logs kept by patients as well as reports from glucose meter downloads. The paper glucose logs were provided to patients by nurse practitioners and physicians. After the patient completed the log for a set period, the patient would fax, mail, call, or drop off the forms. They were used by providers to evaluate treatment and to get a picture of glucose levels during treatment changes. Glucose meter download reports were printed by intake nurses using glucose meter download software. The downloads were used by providers to assess patient disease control and to suggest treatment changes based on patterns in the report. Most providers chose to scan the reports in whole or part into the EMR, while others summarized the report in their note and did not scan the report. In the MS clinic, forms filled out by patients about medical history and current medical status were also scanned into the EMR. In addition, the neurology exam form in the MS clinic was both scanned into the EMR and placed in the paper shadow chart.

Use of paper artifacts to temporarily record data was common. Artifacts in this category included anything where information recorded on paper is later entered into the EMR as part of a note, summary, or problem list and the paper is then discarded. Patients sometimes brought in computer print outs or handwritten lists of medications. The intake nurse would typically use these lists to update the medication list in the problem list. Paper was used for temporarily recording notes in both the CF and diabetes clinics by some providers and in some situations. Both clinics provided some paper forms for taking notes. Use of the paper forms varied extensively within each clinic. Paper artifacts were also used to capture data for later input into the EMR. Examples include a paper form used in the diabetes clinic by the intake nurse to record POC HbA1c results and transfer the information to the provider, food logs kept by patients and sent to dietitians for evaluation in the diabetes clinic, and hard copies of MRI scans in the MS clinic.

Variation in use

There was substantial variation in the usage models for existing informatics tools, both within and between clinics. The usage modes for the existing informatics tools can be categorized into three distinct types:

- Information access: using the EMR to examine data already present in the record
- Information input: using the EMR to alter existing data or enter new data

- Communication: using functions of the EMR to communicate with others

Providers used informatics tools to access information for similar purposes across all three clinics. Table 23 below shows typical information access related functions as well as the types of providers who used each function in each clinic.

Table 23. Use of existing tools for information access

Function	**MS**	**CF**	**Diabetes**
New test results	MD	MD	MD, NP
Previous test results (trends)	MD	MD	MD, NP
Reviewing diagnostic images	MD	MD	No
Reviewing previous notes	No	MD, Ancillary providers	MD, NP, Ancillary providers
Reviewing notes from other providers	MD	MD, Ancillary providers	MD, NP, Ancillary providers
Reviewing medications	MD	MD, Ancillary providers	MD, NP, Ancillary providers

Use of the EMR for review of new and previous test results was similar across all three clinics. Test results review in the CF and diabetes clinics was directed at understanding trends in disease-related metrics. In the MS clinic, test results were reviewed for diagnostic purposes as well as for ensuring disease-related medications were not causing liver damage. Radiology images in the CF and MS clinics were reviewed electronically when performed at Vanderbilt. The diabetes clinic rarely used diagnostic images, although physicians who also saw endocrinology patients did. Providers across all clinics also used StarPanel to review notes from other providers who used StarPanel for documentation, including notes related to hospitalizations. The case of reviewing previous notes was one area where the MS clinic differed from the CF and diabetes clinics. Although previous notes were reviewed on occasion, the providers in the MS clinic consulted the neurology exam form in the paper chart more frequently than the EMR.

Usage of information input functions varied more than information access functions, both between the different clinics and between providers in the same clinic. Table 24 below shows information input-related functions and how they were used in the three clinics.

Table 24. Use of existing tools for information input

Function	**MS**	**CF**	**Diabetes**
Check-in (EPIC)	Clinical receptionist	Clinical receptionist	Clinical receptionist
Documenting patient vitals	Intake nurse	Intake nurse	Intake nurse
Documenting disease specific variables	Intake nurse	Intake nurse	Intake nurse
Updating problem list (including medication list)	Intake nurse	Intake nurse	Intake nurse, NP
Downloading glucose meters	No	No	Intake nurse
Downloading insulin pumps and continuous glucose monitors	No	No	NP
Writing notes	No	MD, ancillary providers	MD, NP, ancillary providers
Receiving glucose logs in MS Excel format from patients (E-mail program)	No	MD	MD, NP, dietitian
Attesting to notes of residents/fellows	MD	MD	MD
Making appointments (EPIC)	Clinical receptionist, administrative assistant	Clinical receptionist, administrative assistant	Clinical receptionist, administrative assistant
Check-out (EPIC)	Clinical receptionist	Clinical receptionist	Clinical receptionist
Writing prescriptions using RxStar	No	MD	MD, NP

All three clinics used versions of EPIC software for patient check-in, check-out, and making appointments. Intake nurses in all three clinics recorded general patient vitals as well as disease specific vitals in StarPanel. The timing of recording vitals varied from clinic to clinic and from nurse to nurse. Nurses in the diabetes clinic consistently input vitals information during the intake process. In the CF and MS clinics, while the data was always eventually entered, nurses occasionally recorded the information on sheets of paper and input them at a later point. The driving force behind this decision appeared to be time pressure to complete the intake process so the physician could see the patient more quickly.

The StarPanel problem list includes a medication list, a diagnosis list, and a listing of any drug allergies. The task of updating the problem list generally fell to the intake nurses. The major exception to this was in the diabetes clinic, where the nurse practitioners were expected to update the list. Interestingly, some of the nurse practitioners seemed unaware of this expectation and when they were aware, reported focusing exclusively on the diabetes portion of the problem list, especially the medication list, due to time constraints. In the CF and diabetes clinics, the physicians occasionally edited the problem list to clarify information or to add content that was not captured during intake. Providers rarely updated the medication list at the time new medication was prescribed or an existing treatment was changed, with the exception of insulin and insulin pump related changes which were updated more frequently at the time changes were made.

Software programs were used to download several patient devices in the diabetes clinic. Glucose meters were downloaded by the intake nurses. Each intake nurse had a computer set up for meter download, with multiple connectors for different kinds of meters. Most meters were downloaded using Glucose32 software, although a few exceptions used different programs. Insulin pumps were downloaded on occasion by nurse practitioners to examine patient pump use over time. In addition, nurse practitioners downloaded data from continuous glucose monitors for the small number of patients in the clinic currently using the devices.

The process of writing notes in StarPanel was more variable than any other information input function. Provider use of the computer in exam rooms for input of data varied from never using the computer to almost always using the computer. If a provider used the computer in the exam room to input data at all, they either completed their notes during the exam or completed the note after the exam. Several providers commented that their goal was to complete the note in StarPanel during the patient visit, but that they rarely met this goal. Providers who normally recorded data in the computer during the visit would occasionally chose not to use when needed based on patient situation.

In the diabetes clinic, several of the physicians used a voice recognition software program, Dragon NaturallySpeaking, to dictate their notes. The dictation software was able to place the dictated information directly into StarPanel. Physicians in the MS clinic had also considered using the dictation software, but were not using it at the time of the study. At the time of the study, physicians in the MS clinic dictated their notes on the phone and the transcribed dictation was later transferred into StarPanel.

In the CF and diabetes clinics, some providers started using a prescription-writing program within StarPanel called RxStar. Roll-out of the tool was on-going during the course of the study, with more providers starting to use the software. Providers frequently commented regarding interface and speed issues. Within the diabetes clinic, several providers were not aware the tool was available even though other providers were using the tool extensively.

Traditional communication tools such as phones and pagers were still used in all three clinics in addition to informatics tools. Table 25 below shows the communications-related functions of the existing informatics tools.

Table 25. Use of existing tools for communication

Function	MS	CF	Diabetes
Message basket communication	MD, nurse, front desk	MD, ancillary providers, nurse, front desk, admin assistant	MD, NP, ancillary providers, nurse, front desk, admin assistant
Checking schedule to see if patients have arrived	MD	MD	MD, NP, dietitian
Reviewing notes from other providers	MD	MD	MD, NP, dietitian
Writing patient letters	No	MD	MD, NP
Reminders to self	No	No	Dietitian
Communication with patients	No	MD, nurse	MD, NP, ancillary providers

The most widely used informatics communication function was the StarPanel Message Basket (SPMB) functionality. The message baskets allow StarPanel users to send messages to any other StarPanel user. Message baskets can also be shared between users based on roles, such as a single message baskets for all nurses in a clinic. Monitoring of message baskets can be transferred to other users when people are out of the office to ensure continuity of care. All types of staff and providers in all three clinics used the message basket functionality. Message baskets were used to communicate within the clinic and with other areas within VUMC. The overall feeling towards SPMB was positive, with most people commenting that it was an important part of communication in each clinic. There were some complaints regarding the volume of messages, however, and one user described the message baskets as a "time sucking hole".

Multiple modalities were used to track patient progress through each clinic. Each provider or clinic, depending on set-up, has a list of patients for the day. Before the patient arrives, the list shows their name and medical record number, along with a brief reason for the appointment. The patient status is changed to show their arrival time once patient check-in is completed. This view of patients for the day was used by most providers across all three clinics to know if patients had shown up for their appointment. The major drawback of the view was the lack of information regarding completion of intake or visits with other providers. The limited information was useful, but did not provide the full amount of information most providers were interested in.

Providers in the CF and diabetes clinics used a template in StarPanel to compose patient letters. An example of a reason for patient letter would be to inform the patient of the test results from their last clinic visit. After the provider finished composing the letter, they typically transferred it to an administrative assistant to print out and send to the patient. Physicians in the MS clinic dictated their letters on the phone and the transcribed letter was sent to the patient.

Technology as a partner

The three clinics described in this study utilize several different informatics tools. The tools were designed to support care processes and assist in documenting patient care. After three years of general availability the main EMR tool, StarPanel, has not achieved the status of a partner in care. Several areas related to adoption and integration were observed and discussed with interview subjects.

Usability

Several issues related to usability of the EMR system. Several subjects commented that they felt they could use the EMR more effectively, but they were simply unaware of the full features of the software. This topic was of special interest to one provider, who had recently attended a demonstration of the prescription writing application. While the informatics instructor was demonstrating new features, she also showed the group how to use multiple features of StarPanel that they were unaware of and that the provider felt could improve her efficiency in using the tool. However, when the provider was asked to discuss these features several days later, she was unable to determine how to access the features in the EMR. The lack of documentation describing different features and the sheer number of features and approaches to accessing features complicated the use process. Learning new features that were added to the EMR was challenging in several cases. Providers who had recently started using the prescription writing tool in both the CF and diabetes clinics described a steep learning curve and difficulty in becoming efficient in tool use. One provider indicated that patients became restive while she was trying to write a prescription using the prescription writing tool because she was still learning how to use the tool. As a result, she switched back to handwritten prescriptions and commented that lack of time to learn and become proficient with new tools was a problem.

Some providers also commented on the difficulty of locating the information they were looking for in the EMR. The EMR collects data from everyone the patient sees and includes information that is not of interest to clinicians. Data related to patient hospitalizations are especially numerous in the record. In a single hospitalization, a patient accrues notes and other data from multiple providers. Some providers were unaware of the tools currently available to limit the information that is displayed and were dissatisfied with current record search abilities. Providers in both the diabetes and MS clinics commented that they felt the notes recorded in StarPanel used too much template language and too little specific information on the case.

Organization of the medication list in the EMR's problem list consistently slowed the medications update process in all three clinics. The medication list is not alphabetized and has no internal organization; it is a free text list. While this makes initial data entry easy, updating the list to add or modify medications is a challenge both for intake nurses and patients. Providers also commented that when medication changes were made, the medication list was not immediately updated to reflect this change which presented a special challenge if the patient was seeing multiple providers. If another provider from another clinic added or changed a medication, they would typically document the information in their note, but not in the problem list. Providers would need to locate and read through the other provider's note to understand the rationale for the change or addition. Information in the list is automatically populated when using the prescription writer tool, which assists with updating but also presents information differently than the manually entered medications.

Workflow

Aspects of workflow in some areas were complicated by, rather than complemented by, the EMR. In the MS clinic, use of both the paper shadow chart and the EMR resulted in duplication of effort. In all clinics, providers needed to spend time outside of clinic hours, including evenings and weekends, documenting patient visits in the EMR. This was especially true for providers who wrote short handwritten notes during patient visits and then translated that information into electronic notes in the EMR. Some providers in the diabetes clinic commented that they tried to use the computer for documentation in the exam room after the clinic moved to new facilities, but found that that data entry process simply did not fit their workflow.

The EMR assists with workflow in some ways. A list of the clinic's or provider's schedule for the clinic is available and clinicians find the feature useful. However, because the view only documents when the patient checked in and does not show if patient intake is completed or if the patient is currently with another provider, it has limited utility. For example, in the CF clinic, the patient is checked in for the PFT as much as an hour or two before their clinic appointment. The check-in time is shown, but no information about whether the patient had completed the PFT or if intake is completed is shown. The same situation applies to multiple provider visits in the diabetes clinic. If the patient is seeing both a nurse practitioner and a dietitian, the handoff process between the providers is not supported by the existing tools.

Finally, lack of awareness of current workflow on the part of informatics tool developers hinders adoption of new tools. Adoption of new tools is tied to providing tools that are as efficient as current processes or that provide clear benefits to either the provider or in terms of patient safety. In the diabetes clinic, one provider described his reasons for not using the prescription writing tool. His process for patient refills was very specific. If a patient requested a medication refill during a visit, the provider instructed the patient to call his administrative assistant who in turn provided the prescription. Because the provider himself does not write prescriptions in the exam room, using the prescription writing tool in that environment would actually result in extra effort and time. As a result, the provider is not interested in using the electronic prescription writer unless clear benefits in safety or efficiency can be demonstrated.

System constraints

A major constraint on use of the EMR is access to computers. Accessibility is both a problem of location as well as of numbers of computers. In both the CF and the MS clinics and in a few areas of the diabetes clinic, computers in exam rooms are located in positions that make it awkward to use the computer while talking to the patient. In the CF and MS clinics, the patient is generally either next to or behind the provider when they are using the computer in the exam room. Several providers mentioned that this made it difficult to use the computer to document. In some clinics, the number of available computers also presented a problem. In the CF clinic, space during clinic hours is normally shared with non-CF providers. All of the available computers were frequently in use, making access difficult for some of the ancillary providers.

A user-related constraint was the ability of the users to type. Users who were unable to type or who were slow typists had problems with computer use for documentation in the exam room.

Finally, some types of data were difficult to capture using the existing tools. The EMR has forms and templates available for provider use and tailored to specific clinic and provider needs. However, in the MS clinic, one of the key elements of the neurology exam form is a homunculus. The homunculus allows the provider to capture a gestalt view of patient status. However, use of graphical images for documentation is not readily available in the existing EMR and requires significant resources for implementation.

User expectations versus system performance

A source of surprise and consternation during the observation period in each clinic involved changes to the EMR without notice. In several cases, changes that were rolled out resulted in modified system behavior but users were not aware of the change until they tried to use specific functions. In the CF clinic, the view of previous notes and notes from other providers changed to move the summary section of the note to the top of the view. Users were initially disturbed by the change and pointed it out to the investigator. After a few minutes of use, the users noted that typically they would scroll through the note to the section that was now displayed at top anyway and found the behavior change useful. However, several minutes were spent discussing the change and acclimating to it. In the MS clinic, a form used by the nurses during intake changed with no notification. The clinic was also using a paper form to collect the information and the nurses would then input the patient information in the EMR. The form in the EMR changed without notice to the users and the layout and questions no longer matched the paper form used in the clinics. Replacement forms with the questions and layout were received several days later, but in the interim nurses had to bridge between the new EMR form and the old paper form.

Users also commented on frustration in the time it took pages to load in the EMR as well as in the time it took to enter information. Providers in the CF and diabetes clinic noted that the EMR system as a whole slowed down during certain time periods on certain days. Users were not aware of reasons for this slow down and did not know of any workarounds. System reliability also presented a challenge. Users commented that as a whole, they felt the system was very reliable but that during time periods when the EMR was down or significantly slowed down, it was difficult to maintain clinic flow. It was difficult or impossible during these time period to access patient data and to enter new information, changing the care process in the clinics.

Finally, the features of the system in many ways are a double edged sword for the end users. Users felt they liked many features of the EMR, such as the message basket function, but found them time-consuming to learn and time-consuming to use.

Framework for informatics design

Eleven guidelines were developed based on observations and interviews. These guidelines could be characterized as an architectural framework for the design and development of informatics solutions for the chronic disease care environment. The eleven guidelines are:

1. Applications should be designed to support shared needs and behaviors in chronic disease care.
2. Applications should be designed to allow for customization for disease-specific needs.
3. Applications should allow customization to meet the needs of different types of users.
4. New paradigms for information input into the EMR should be explored.
5. Efficient transfer of data from medical devices into the EMR should be supported.
6. Information scanned into the system should be searchable, quickly viewable, and more accessible.
7. The EMR should be designed so that users are able to search through the EMR quickly and easily to filter out important information.
8. Alternate methods of displaying the longitudinal data for individual patients should be investigated to determine if they assist in cognitive processing of electronic data.
9. New tools and processes should be as efficient as existing approaches or yield significant benefits to users to promote adoption.
10. The reasons behind organizational and personal resistance to technology should be addressed in order to promote adoption.
11. Models of workflow, information flow, and temporal flow should be used to guide

software development, to locate inefficiencies and error-prone areas, and to improve processes.

CHAPTER VI

DISCUSSION

This study identified similarities in workflow and information flow between three chronic disease clinics. Differences between the clinics and within each clinic were also identified and causes for the differences were proposed. The study examined the breadth and depth of adoption of existing informatics tools in the ambulatory chronic disease environment. The results showed that the existing technology did not fully support users' workflow and needs and that adoption was impeded as a result. The study demonstrates the value of qualitative methods in understanding clinical workflow and information flow, in evaluating the impact of technology in the clinical environment, and in assessing the adoption of technology. Finally, the results suggest design guidelines for development of informatics tools that better support workflow and information flow in chronic disease care. These eleven guidelines provide the structure for this chapter.

Guideline 1. Core functionality to support shared needs

Guideline 1. Applications should be designed to support shared needs and behaviors in chronic disease care.

The three clinics shared many similarities in workflow and information flow, many of which were not supported by current informatics tools. The participation of patients was an important element of the care process in all three clinics. Compliance with provider recommendations is one area where patients' behavior affected chronic disease treatment. Lack of compliance with treatment plans was identified as a major problem by providers in all three clinics. Patients in all three clinics also provided important input regarding their disease progression, treatment history, and current status. This information was used to determine if the patient was having an exacerbation that required treatment changes or if their current symptoms were not well controlled. These details can also answer questions regarding why a particular therapy is ineffective or whether a proposed treatment may be effective. An example of this would be patient explanations of activities and food intake compared to glucose meter readings in the diabetes clinics. Thus, patients provide the background information essential to appropriate treatment decisions in chronic disease care. Providing care for chronic diseases seemed difficult if not impossible without patient-provider cooperation. Providers maintained awareness of patient status, abilities, and willingness to participate in certain types of treatment and tailored treatment plans accordingly.

The important role that patients play in chronic disease care has been discussed in several studies. The role of the patient in making everyday disease self-management decisions and in compliance with medical recommendations is well documented in the literature (94) (95). Patient-provided health status information and effective communication with providers contribute to the quality of care (96) (25).

Trends in diagnostic values and in patient status were important in all three clinics. The variables followed over time in the CF clinic included patient weight and PFT results. Decreases in either variable prompted intervention. In the diabetes clinic, HbA1c values were monitored over time. Weight was also an important variable for patients with type 2 diabetes. Providers also monitored patient-performed glucose testing on a shorter time scale to adjust treatment based on daily trends in glucose levels. The variables that were monitored in the MS clinic included a timed walking test performed in clinic, a qualitative assessment of balance and gait while walking, and lesions shown on MRI scans. Trends and status were monitored over time to make treatment changes and to assess patient needs.

Similar approaches to accomplishing functions not supported by current informatics systems were also observed in all three clinics. Each clinic had a similar paper-based interface for billing purposes. Paper forms were filled out by providers to capture ICD-9 billing codes. The forms differed in content, with information tailored to each domain, but embodied equivalent functionality. Administrative staff manually entered the billing information from the paper forms into electronic systems. The clinics also had similar approaches to ordering tests even though the typical tests ordered differed dependent on the domain. Providers often had to fill out multiple paper forms to order tests, because different forms were used for serum, urine, and cholesterol tests. These paper-based solutions produced additional work when they were not filled out in full or when administrative or lab staff had difficulty interpreting what was written. This resulted in a back-and-forth discussion between administrative staff and providers to ensure forms were interpreted correctly, leading to wasted time and universal frustration.

A problem in all three clinics was lack of current knowledge about patients' location in the clinic facility and which provider was with the patient. Although all three clinics had implemented different approaches to improve patient flow through the clinic, none of the methods seemed reliable. At times in all three clinics, patients spent more time waiting than necessary. For example, a new patient in the MS clinic was unsure if it was alright to leave after waiting for several minutes in the exam room after a visit with the physician. The patient was waiting to have blood drawn, but the nursing staff were unaware of this. This problem is unlikely to cause any direct harm to patients, but it can lead to patient frustration, irritation, and dissatisfaction with care. Patient participation in treatment is a key part of chronic disease care and issues that adversely impact the patient-provider relationship cause concern. Patient flow presented problems for providers as well, who were frustrated by not knowing patient location and timeline.

Multiple projects have been implemented both inside and outside VUMC to better track patient and provider locations. A computerized whiteboard system was developed and deployed in the VUMC emergency department to track patient location and status, length of patient stay in the ED, and wait times (97) (98). An electronic whiteboard system was also developed at VUMC for outpatient clinics to track scheduling information and patient movement through the clinic (99), although the system had not been deployed to any of the three clinics during the study period. The use of radio frequency identification (RFID) tags to track the location of supplies and patients in healthcare has also been investigated, although most often in the hospital setting (100) (101) (102).

The similarities in workflow and information flow between the three clinics lend themselves to a concept of modular design of informatics tools. A central core module could support the behaviors and needs shared by the clinics. Some of the functions that could be included in a core module are shown below in Table 26. The items in Table 26 marked by an asterisk are available in some form in the existing informatics tools at VUMC.

Table 26. Support for shared needs

Informatics tools to support shared needs	
Patient input of status details	Notes entry*
Patient location tracking*	Electronic prescription writing*
Status change tracking	Order entry
Previous treatments* and responses to them	Patient education materials*
Trend tracking*	Support for communication*

It is important to note that although there are existing approaches at VUMC to many of these shared needs, some of these tools are not available or are not in use throughout the ambulatory clinics including patient location tracking and electronic prescription writing. Users also expressed dissatisfaction with the implementation of some of the functions, such as notes entry and listing of previous treatments. In a full implementation of this modular approach to design, the functions listed in Table 26 would be smoothly integrated with one another, available throughout the environment, and designed and evaluated using principles of human factors engineering.

Guideline 2. Disease-specific customization

Guideline 2. Applications should be designed to allow for customization for disease-specific needs.

Despite the core similarities between clinics, workflow and information flow in each clinic have unique elements. Inter-clinic variability appeared to primarily stem from two sources: disease-related variability and clinic staff characteristics.

The most obvious source of variability is the disease itself. The types of diagnostic information and the nature of the data relevant to the management of each disease were different. Both CF and diabetes had clear markers for diagnosis, while diagnosis of MS was often less clear and relied more on the judgement of individual providers. The timeframe for diagnosis and the characteristics of the populations also differed between the three diseases. CF and type 1 DM is typically diagnosed in children, while type 2 DM and MS are typically diagnosed in adulthood. As a result, adults with CF and type 1 diabetes have been dealing with chronic illness from an early point in their lives. Their perspective on the process of chronic disease treatment may differ from patients who have been dealing with chronic illness for a shorter period of time. These differences in population characteristics may influence the approach of providers to patients.

The nature of the information to guide ongoing treatment also varied between the three diseases spanning a spectrum from quantitative to qualitative. Diabetes treatment primarily uses quantitative information from HbA1c tests and glucose meter readings. Some qualitative information such as foot exam results and patient self-reporting of status is used. CF treatment uses a blend of quantitative information, including PFT results and weight, and qualitative information such as patient self-reports of status. Ongoing treatment of CF also uses graphical images in the form of chest x-rays. MS treatment primarily uses qualitative information in ongoing treatment. Descriptive information such as reports of problems in activities of daily living provide much of the direction to treatment. Ongoing MS treatment also relies on graphical information in the form of MRI scans as well as patient symptom descriptions. A small amount of quantitative information, especially in the form of a timed walk, is also used to guide treatment.

There was variability between the clinics in the number of staff as well as the types of staff members. The number of staff members and the clinical hours set by the different providers directly affected the number of appointment slots available each day. In the diabetes and MS clinics, new patients often waited extended periods of time for an appointment slot and returning patients often faced challenges in setting up their next appointment in a timely fashion. The larger number of providers in the diabetes clinic introduced different difficulties, as nursing and administrative staff attempted to satisfy the preferences of each nurse practitioner and physician.

Clinics with ancillary providers such as dietitians and social workers provided additional disease-specific services, such as setting dietary goals specific to the disease process. Other services could have been useful in all three clinics, such as dealing with insurance and work-related problems. Neither the CF or MS clinics had any nurse practitioners on staff, while the diabetes clinic had multiple nurse practitioners. While the content of care was similar between nurse practitioners and physicians, the style of care differed. The different types of staff in the clinic affected patient contact processes as well.

An easily customizable modular approach could support both the common needs and the disease-specific needs. Elements of this approach were discussed in Guideline 1. A core module would provide common functions while custom modules would address needs unique to individual diseases. Some of the types of clinic-specific functions that could be addressed in this modular approach are shown below in Figure 17.

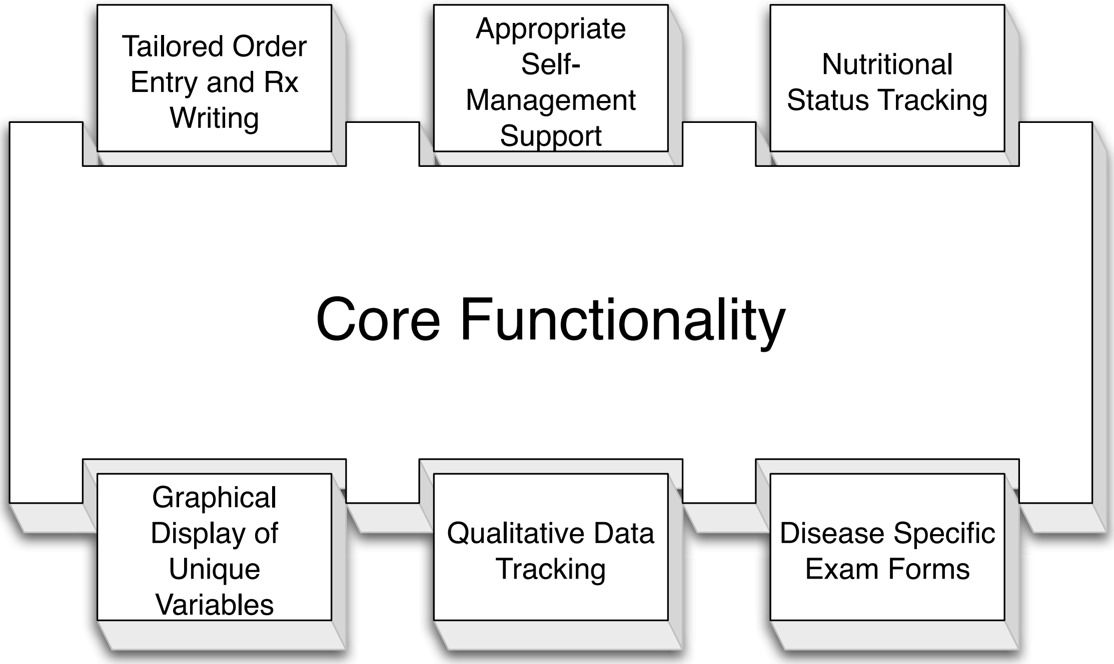


Figure 17. Customizable modular approach to software design

The clinic-specific modules would seamlessly integrate with the core module. A process to request new modules would need to be developed and users would need to be aware of how to initiate module development. Modules could be reused between clinics when appropriate. This modular approach could allow the software to meet the needs of the end users without adding extraneous functions for users in other clinics.

Guideline 3. User-specific customization

Guideline 3. Applications should allow customization to meet the needs of different types of users.

Information needs, care processes, and use of informatics tools varied within each clinic. Users collect and input different types of data and have different information needs depending on their role and responsibilities within the clinic. Input features of current informatics tools are tailored in many cases to roles. Intake nurses utilize specific forms for gathering patient vitals and other intake variables, while providers use other templates for input of visit notes. Information not of interest to specific types of users is mixed in with the information of interest. Users must filter through extraneous data when attempting to locate needed information.

Differences among providers' habits and preferences within a clinic can lead to confusion and extra work. This problem was especially apparent in the diabetes clinic, because of the large number of providers. The nurses maintained a list of the different providers and their individual preferences including testing frequency, paperwork, exam room use, and contact method. These differences could not be readily explained by differences in actual patient care needs.

Informatics tools that apply this guideline would present information differently depending on user role and preferences. Interfaces would be user customizable to tailor the informatics tools to support the workflow of individual users. Workflow diagrams, such as the ones shown in Figures 2-4 in the Results, could be used to establish a baseline for the design and then users could customize the interfaces to meet their needs.

The concept of customizing data and navigation in medical informatics applications based on user preferences was explored by Ghedira et al (103). The researchers modeled user behavior based on previous computer interaction and then applied these models to application behavior. Users were able to rapidly add and remove standard approaches of data presentation and navigation to customize the interface of a cardiology clinical workstation prototype based on their needs and preferences. This type of approach has great potential for improving individual satisfaction with informatics tools.

Guideline 4. New methods of input

Guideline 4. New paradigms for information input into the EMR should be explored.

While many providers already use computers for information input while with patients, users are not satisfied with current processes. Information input into the existing informatics tools is unduly difficult and there are barriers to data input during patient interactions. Users who are not proficient at typing find rapid keyboard input problematic. One provider commented during observation,

> "I hate typing notes. I didn't go to nursing school to be a typist, but I'm turning out to be one."

The importance of proficiency in typing in effective use of the EMR while with patients was also noted by a study of EMR use in primary care practices by Ventres et al (104).

Some clinicians are uncomfortable with typing on the keyboard while with patients and think it gives patients the impression they do not have their full attention. This was supported by reports of patient complaints by some providers. However, a study by Gadd and Penrod demonstrated that although physicians perceive that EMR use impacts the patient-provider relationship, patients do not actually share this opinion (105). One provider summarized these concerns during an interview with the comment,

> "It feels very awkward to me to sit there and type while they are looking over my shoulder and I can't look at them. I mean, I just think it impacts the relationship building to do that."

Providers who do not use the computer for information input in the exam room are currently penalized by taking notes down by hand and then needing to spend extensive periods of personal time completing notes in the computer. However, even providers who begin their notes while in the exam room can find themselves falling behind and completing notes on their personal time. One provider commented,

> "I'm ending up at the end of the day, if I've seen 11 or 12 patients, I may have 6-7 unfinished notes. And I'm taking it home and doing it. It's not good."

The design of the forms used to input notes might be part of the problem, but alternative methods to keyboard entry of data should also be explored. One alternative could be Tablet PCs, that could be held by the provider with data input using a stylus. Several studies have explored the use of Tablet PCs in healthcare, including examining questions related to workflow and usability (106) (107) (108) (109). Another alternative could be digital pen and ink systems, such as the Logitech io2 Digital Writing System (110). This approach uses an ink pen equipped with a small camera and special paper printed with a light pattern of dots (111). After writing information on the paper with the pen, the data can be downloaded from the pen to a computer where it can be analyzed. This technology was utilized by the researcher to take notes during observation. Previous studies have examined the use of digital pen and paper technology in the healthcare environment (112) (113) and in combination with an existing EMR system (114). Other new technologies that might make information input into the EMR easier should also be explored.

In addition to alternatives to the keyboard, graphical forms may be helpful for entry of data, especially for diseases that rely on qualitative data such as MS. McCullagh et al developed a graphical structured input form using a homunculus to record symptoms of MS (115). Users selected spots on the homunculus and then were able to record symptom descriptions for the selected areas. Although the form was highly structured, providers were able to enter free text to further refine the symptom descriptions. This approach to interface design, when combined with alternate methods of input such as Tablet PCs, may encourage some users to consider inputting data while in the exam room with patients.

Guideline 5. Data transfer from devices to EMR

Guideline 5. Efficient transfer of data from medical devices into the EMR should be supported.

Multiple medical devices and test equipment are used throughout the medical center, but efficient transfer of electronic data from these devices into the EMR is not supported. McDonald commented on the problem of compiling external data in the EMR and the importance of this external data in a complete understanding of the patient's health (116). The problem of external data applies to medical devices as well as to data from external providers, which is discussed further in Guideline 6. Examples of devices used in the study clinics include PFT equipment in the CF clinic and patient glucose meters in the diabetes clinic. In both cases, hardcopy reports are printed from the equipment and are commonly scanned into the EMR as a PDF. As a result, these data are not readily available for tracking trends in the patient status over time. It is also important to note that providers appreciate receiving paper copies of these reports, as they write notes on them or circle key points. Adjusting from a paper report to an electronic report could require effort and time and impact efficiency.

An example of how efficiency of processes could be improve through direct data transfer is the glucose meter download process in the diabetes clinic. The current process for download is shown on the left side of Figure 18. The right side of Figure 18 shows the process if the data were transfered directly into the EMR. With direct data transfer, the information would be available for automatic import into notes and forms, removing many of the manual steps providers currently follow. Paper reports could still be printed when needed, but the routine printing of paper reports could be eliminated.

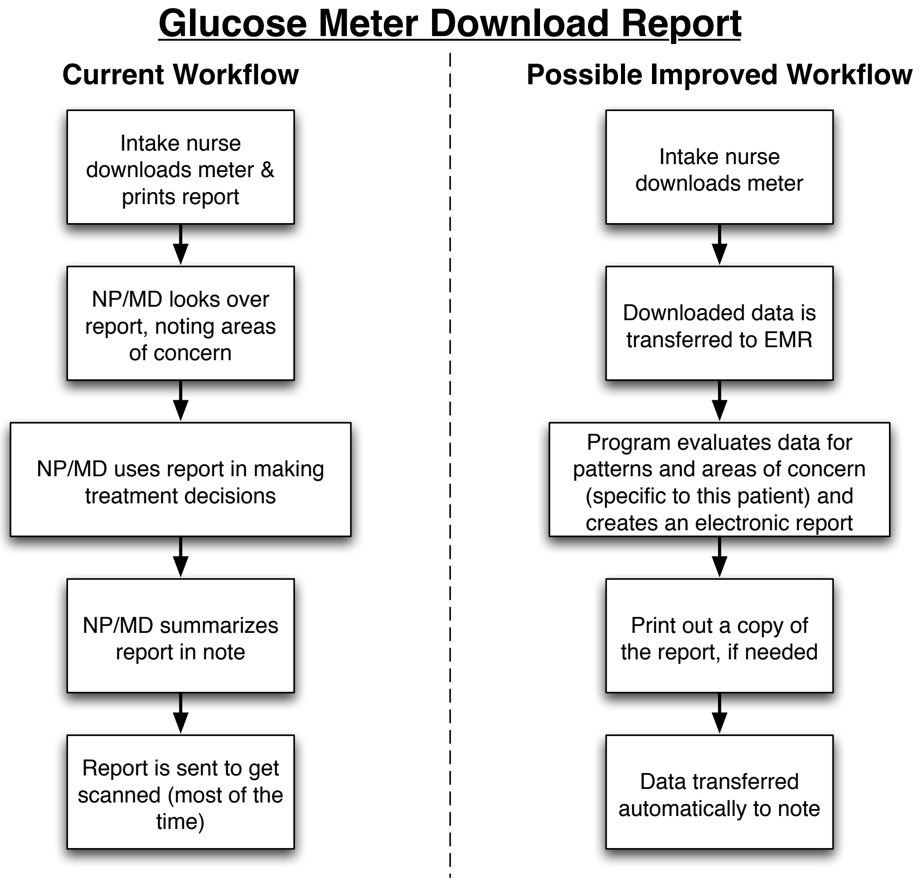


Figure 18. Glucose meter download process

There are many technical challenges to direct data transfer from devices to the EMR. In the case of glucose meters, there are many device manufacturers and several different software packages that are currently used to transfer the data from the meter. However, the value of making this data available to the EMR could make the effort of resolving technical barriers to direct data transfer worthwhile.

Guideline 6. Make scanned information usable

Guideline 6. Information scanned into the system should be searchable, quickly viewable, and more accessible.

Currently, paper is scanned into the EMR and is viewable in PDF format. As currently stored in the EMR, the PDF files are image files and as a result they are not searchable and cannot be parsed to extract trend data. Many clinics are regional disease centers that draw patients from a wide geographic area. This results in patients having tests performed at external facilities. The data from these tests needs to be an integral part of the record, as accessible as internal lab data. Scanned files could have optical character recognition (OCR) performed on them, which would enable searching and data parsing. The current process is shown on the left portion of Figure 19, while the proposed additional process is shown on the right side.

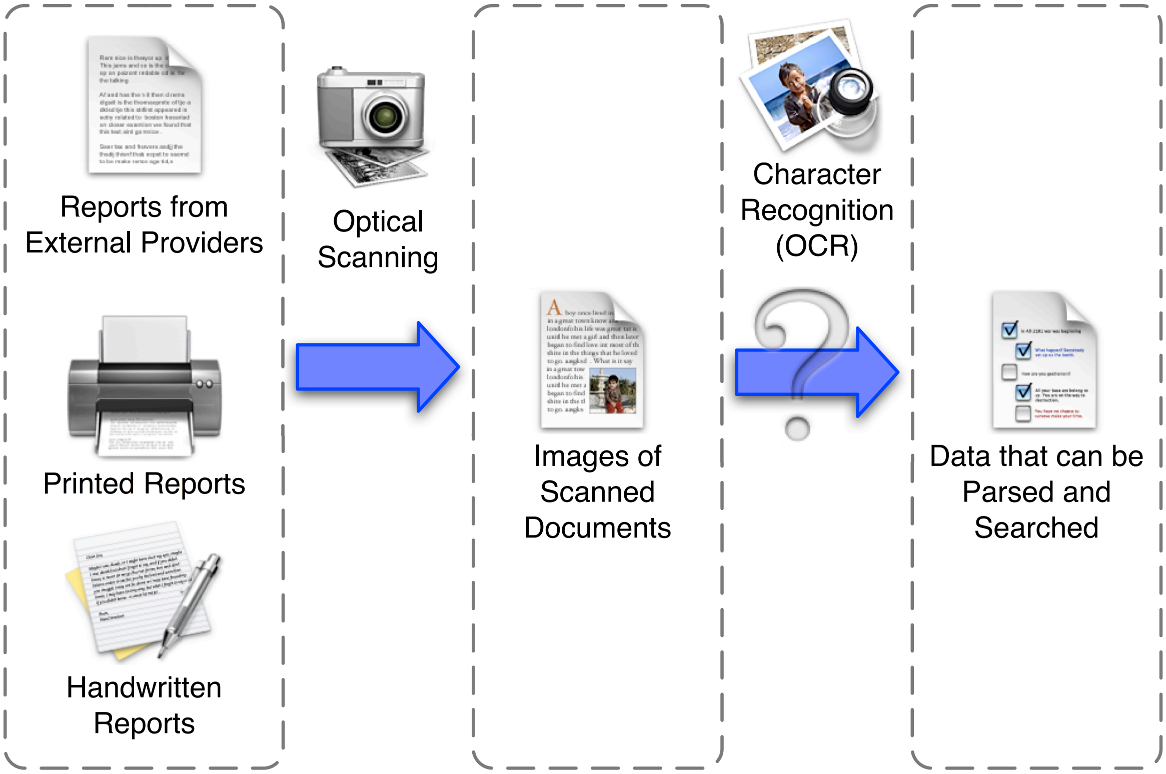


Figure 19. Scanning paper documents

Problems are also currently encountered with the speed with which PDFs open. Searching through multiple PDF files to find a piece of data can be a time-consuming and daunting task, with the result that providers seek alternate sources of information rather than continuing to manually search through PDF files. Alternate approaches are needed to make this information searchable and readily accessible.

Guideline 7. Searching and filtering

Guideline 7. The EMR should be designed so that users are able to search through the EMR quickly and easily to filter out important information.

Powsner et al suggested that the ability of computers to collect large amounts of data can actually be a disadvantage of EMRs and stressed the importance of searching capabilities (117). Providers are drowning in data in the current EMR. Information is input into the record by so many individuals for so many reasons that it is sometimes difficult to locate information of interest to a specific provider. This is especially true for patients with chronic diseases who may have multiple medical problems, see multiple providers on a regular schedule, and have multiple tests and therapies performed every visit. The problem is further compounded for patients with ER visits and inpatient stays. Some of the types of data included in the EMR are shown below in Table 27.

Table 27. Types of information in the EMR

Information in the EMR	
Vital signs from each visit	Notes from every visit with every provider
Medication list	Information from ER visits
Lab results	Information from inpatient stays
Clinic intake form	Scanned documents

Searching through all of the information in the EMR is like searching through a box of puzzle pieces to attempt to find the data that most interests the provider. Users must filter through both similar and dissimilar pieces of information to attempt to find the right data. Figure 20 below demonstrates the complexity of searching and filtering. The information the provider needs is colored blue, but they need to search through many similar pieces of information to find the right pieces.

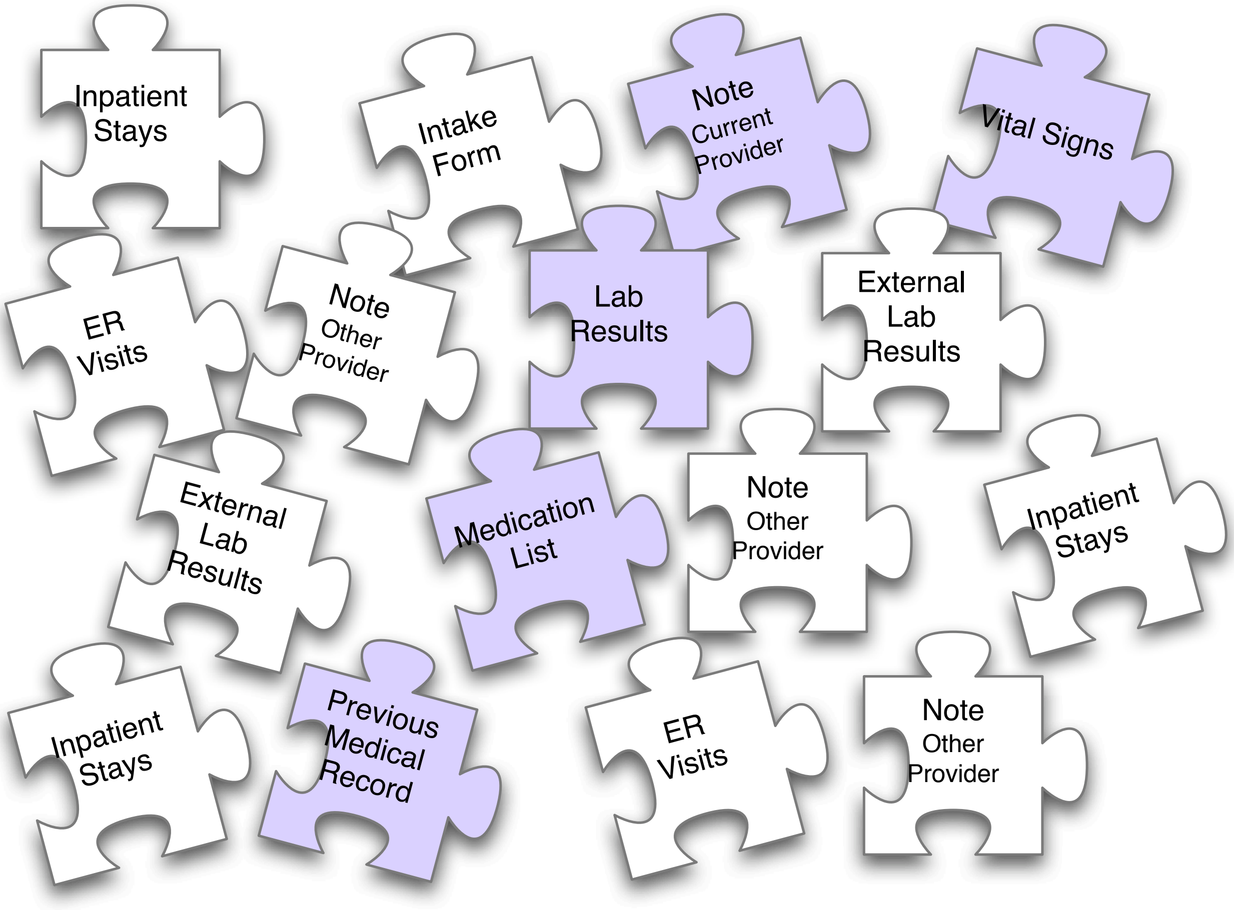


Figure 20. Searching and filtering through information in the EMR

Searching and filtering through the record are functions that all types of providers would use repeatedly. These functions will increase in importance as the size of individual electronic records increases.

Guideline 8. Longitudinal data display

Guideline 8. Alternate methods of displaying the longitudinal data for individual patients should be investigated to determine if they assist in cognitive processing of electronic *data.*

Patient care in chronic disease is a continuous process with a temporal rhythm dependent on disease and personal factors. While providers currently have access to the entire electronic record, synthesizing the electronic information over an extended time period is a difficult task. To extend the puzzle analogy from Guideline 9, once providers have located important information, they need to synthesize that information to formulate a coherent picture of patient status in order to make appropriate treatment decisions (Figure 21).

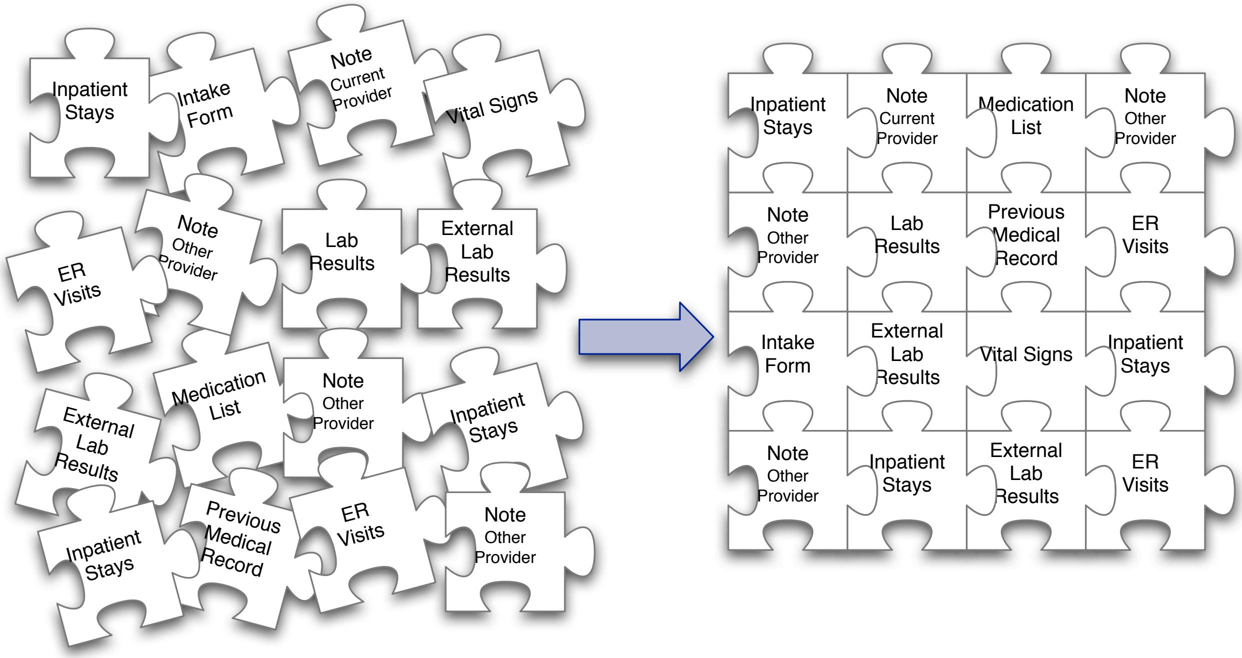


Figure 21. Synthesizing information

A longitudinal view of patient disease history could help clinicians process this important information. The longitudinal view would include key disease status variables as well as links to previous treatments that were tried and how patients responded to them.

One approach that might assist with the rapid synthesis of information is a graphical longitudinal display. Powsner and Tufte suggested using graphical summaries to help providers relate findings and treatments within a medical record (118). An example of how this might apply to chronic disease is shown below in Figure 22.

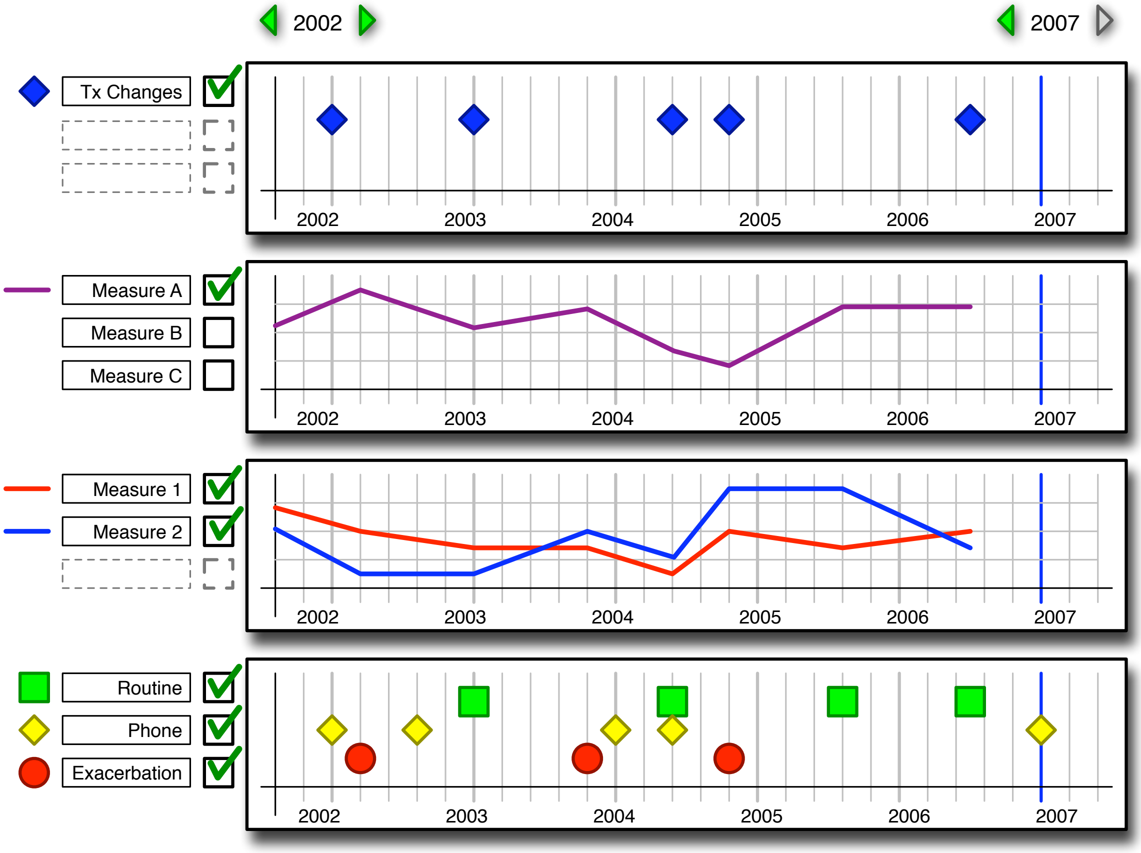


Figure 22. Sample graphical display of longitudinal data

This display shows routine visits, exacerbations, and phone calls. Each item can be clicked on to see a report or other information from that visit. In addition, treatment changes are clearly highlighted and are also linked to disease-specific variables so the effect of a treatment change on disease status is apparent. The use of appropriate metaphors to make the information rapidly usable by providers should be considered in the design of this type of interface (119). This approach does not replace the EMR, it acts as an overlay to make the information in the EMR more accessible.

Other studies have shown the value of this graphical approach to display of medical data. A group at Partners Healthcare has developed informatics tools called Smart Forms and Quality Dashboards to input and display data related to both acute and chronic care (120) (121). The tools are designed to make information both on a population and individual patient scale easily accessible to physicians. In the McCullagh study described in Guideline 4, the investigators also explored ways to graphically represent qualitative MS data (115). The system combined the graphical input with structured text to develop graphs of patient disease status over time. This type of approach may meet the needs of clinicians in areas like the MS clinic, where providers stated they preferred to flip through a paper chart to get a picture of patient status. By graphically representing this information on a single screen, the process of understanding patient status could be simplified. The system described in the paper was a prototype that was not deployed in the actual clinical environment. However, with rigorous usability testing, this type of approach could prove valuable for some disease domains.

Guideline 9. Tangible benefits without significant cost

Guideline 9. New tools and processes should be as efficient as existing approaches or yield significant benefits to users to promote adoption.

This study provided a snapshot of technology adoption approximately 3 years after the informatics tools were deployed in these clinics. Discrepancies existed between the workflow of each clinic and the workflow required by the informatics tools. Changes to the provider-preferred workflow required to use the informatics tools made some tasks more challenging to complete, decreased efficiency, and added work. Providers who did not change their workflow to use the tools to document patient care in the exam room spent additional time outside of regular work hours attempting to complete documentation. Providers in this situation repeatedly expressed their dissatisfaction with the process and a desire for changes to the informatics tools. Providers who attempted to change their workflow found that the new approaches did not meet their needs.

There are functions available within the existing informatics tools to streamline input processes, increase efficiency, and retrieve information more easily. However, most users were unaware of these capabilities. Some users admitted to having been shown some functions but did not use them because they had either forgotten about them or forgotten how to use them. This points both to problems in educating users about available features and to usability problems that make it difficult to learn how to use new features. The effort required to use new technology effectively may be greater than the effort required by existing processes. Users assess new capabilities or tools to determine what specific benefits they can derive from the new technology. If a tool imposes additional work on users or complicates existing processes, they may choose not to use the tool unless they can identify tangible benefits of tool use. Even if benefits are evident, if the learning curve for the new tool is too steep it may not be adopted because there is too little time is available for these learning activities.

Observational and interview data revealed some of the users' strategies when evaluating new functions or software. Users commonly ask the question "What can the tool do for me?" and will try to adopt features that may work for them. Features that require more time than existing processes and that do not have demonstrated advantages are rarely adopted proactively. Workarounds are created for software functions that do not fully meet user needs.

Two new informatics applications were deployed in the CF and DM clinics during the course of the study, enabling a closer look at the impact of new informatics tools. One of the new tools was RxStar, an electronic prescription writer. The tool was widely used in the CF clinic, in part due to the prompting of one of the attending physicians. This physician had readily adopted the prescription writer and encouraged fellows and other providers in the clinic to use the tool. In the diabetes clinic, however, some providers used the tool and found it to be extremely helpful, others attempted to use the tool and decided it was too time consuming, while a majority of providers had never even heard of it. One provider who had been using RxStar for several weeks commented,

> "I keep telling myself once I get all my favorites down, it will be faster... It's got to be better and I do choose to use it... but I don't know if it is as efficient as I want to be just yet."

Interview data suggest that the MS clinic providers had heard of the new tool but that they felt it could not be adapted to handle the medications they prescribed. The lack of understanding of the actual functionality and value of the tool points to problems in communication, training, usability, and functionality.

The second new tool was MyHealth@Vanderbilt, an electronic patient portal that enabled electronic communication between patients and providers. Many providers were enthusiastic about this functionality. One provider indicated that the tool was "a disaster", in particular for her elderly patients who had difficulty understanding how to use the tool. Another provider commented,

> "I just spend more and more time here every time that they roll out something wonderful, it just takes more of my time."

At the time of the study, it was not possible to send attachments through the patient portal. This presents a unique challenge in the diabetes clinic, where patients sometimes keep daily glucose reading logs in MS Excel format and send them to providers. Since this function is not supported by the official patient portal, providers adopted a workaround, using unsecured email to obtain the patient data as attachments.

Previous studies have demonstrated that adoption of new technology is often a difficult process. Providers are often concerned about the speed of informatics applications and are hesitant to adopt systems that are slower than existing work processes or require additional effort (122). Ash and Bates highlighted the concept that systems designed to fit clinician workflow have higher rates of adoption than systems that conflict with existing workflow (123). The importance of an EMR system fitting the workflow and nature of the environment was demonstrated in a pilot implementation of an EMR at the Cleveland Clinic (124). Many of the initial users of the system discontinued EMR use because of impact on workflow and the time required for use. Design changes were made to the EMR based on feedback from the pilot study. In another investigation, although a time-motion study confirmed that an EMR system did not require more time for use than equivalent paper-based systems, the majority of the end users of the system still perceived that the EMR system required more time for patient documentation (125). Perception of system impact on time and workflow can be as important in adoption as the actual impact itself.

Guideline 10. Barriers to adoption

Guideline 10. The reasons behind organizational and personal resistance to technology should be addressed in order to promote adoption.

It is difficult to persuade users to adopt new technology if there are organizational barriers or personal reasons for resistance. Understanding the source of the resistance as well as the rationale behind it is important to finding solutions that will work. Informatics tools do not exist in a vacuum; understanding the environment of use is critical to designing effective tools.

Multiple studies have discussed the organizational, technological, and personal barriers to adoption of new technology in healthcare. Karsh discussed organizational factors such as management support, amount of training on technology use, and level of user participation in system design as well as personal factors such as concerns about changes in work and self-efficacy related to new technology use (126). Meigs et al specifically designed their diabetes EMR intervention to address physician-level barriers to technology adoption (59). However, the study team found additional barriers not addressed in their design, such as lack of integration into the workflow, still limited adoption of their tool. Lorenzi has also extensively discussed the organizational barriers to informatics adoption (127) (128).

Observation revealed gaps between institutional expectations for EMR use and actual use. The EMR was intended to function as a care management tool that would replace paper charts. The MS clinic was described as "fully electronic" in an initial interview, but continues to use paper shadow charts for a variety of reasons. Differences in how the term "fully electronic" is understood by users versus developers and researchers reflect the need to be certain of terminology when requesting user input and feedback. Clinicians in all three clinics needed to be able to integrate clinical information from disparate sources to formulate an accurate picture of patients' current status. This was an important element that motivated the use of paper charts in the MS clinic. Providers felt it was easier to flip through the paper chart to review trends over time than to attempt to extract this information from the EMR. Providers in all three clinics noted the difficulty of rapidly synthesizing information distributed across visits and providers to gain temporal or other patterns of disease. The problems were compounded if the patient had multiple chronic conditions or hospital admissions.

There was also a gap between user expectations and system performance. Forms and functions within the EMR changed without notification of the end users. The sudden appearance of unannounced changes caused confusion and disrupted workflow until users adjusted. Users cannot always tell if the change is intentional or a malfunction. Users across all three clinics complained about speed issues, especially at certain times of day. There was little awareness of what might be causing the speed issues or potential ways to resolve the problem. The lack of help functionality within the EMR system prevented users from resolving simple problems themselves or from learning about additional ways to perform tasks.

Users also had conflicting feelings about some of the EMR features. The main example was differences in opinions on the Message Basket functionality. Many users found this communication tool to be invaluable and appreciated being able to rapidly communicate with others about patient-related issues. However, one provider who felt the tool was helpful called it a "time sucking hole" because of the volume of messages and the time required to respond to each message. Other providers commented on the high volume of messages and the challenges of responding to them in a timely fashion. In addition, the shared aspects of the message basket could cause duplication of effort. For example, two nurses in the MS clinic had the shared clinic nurses basket open and were unaware they were working on the same message.

The majority of the observational data pointed to general barriers to technology adoption, related to cognitive aspects of the EMR as well as design and implementation details. During the study period, none of the clinics used computerized guidelines to promote standardized care. Both the CF and DM clinic utilized manually managed databases and paper forms to remind providers about test and treatment frequency. If these guidelines were computerized, it would be important to consider the work of Patterson and colleagues regarding the many barriers related to computerized clinical reminders specifically (129) (130). Patterson et al found several barriers including workload, lack of time, and prevalence of inapplicable reminders.

Multiple barriers exist that limit or prevent adoption of EMR technology. These barriers exist on both an organizational level and on a personal level and can result in limited adoption and workarounds. Understanding and addressing the potential reasons for lack of adoption is important to widespread in-depth adoption of informatics tools.

Guideline 11. The role of models

Guideline 11. Models of workflow, information flow, and temporal flow should be used to guide software development, to locate inefficiencies and error-prone areas, and to improve processes.

The initial motivation for model development was to provide models for use in software designers. Using the general workflow model for chronic disease care and understanding clinic-specific exceptions to it, software that better meets the needs of chronic disease providers could be developed. The three types of models reveal where and how current informatics tools are being used as well as where paper-based processes are being used, which could be used to determine areas where new informatics tools are needed to support functions not included in the current tools. In addition, the models capture areas where effort is being duplicated by recording data both on paper and in the computer. Understanding reasons for this duplication could lead to the development of more user-centric approaches and interfaces. The temporal flow models could be used to understand the conflicting demands placed on users by exceptions in their workflow. The temporal flow models could be used to develop software to streamline the flow of patients through the clinics and support users in the face of conflicting demands on their attention.

Shepherd (88) and Preece (131) describe theoretical aspects of how hierarchical task analysis (HTA) can be used to apply principles of human factors engineering to software design. Models generated using HTA can be used to understand software requirements related to user behavior and needs. An example of how workflow models can be used for software design was a study conducted by Johnson et al. Activity diagrams were developed as part of the study to capture workflow of outpatient prescribing as a first step in designing electronic prescription writing software (132).

Another potential audience for these diagrams are individuals and groups interested in process improvement. During the semi-structured, several providers expressed interest in obtaining the workflow models for their clinics to better understand existing processes and to determine where process changes might have a practical impact. Bottlenecks in workflow, caused by processes or limited number of staff, could be identified using the workflow models in concert with the temporal flow models. Because the models cover all aspects of clinic workflow, they can also provide a wider understanding of clinic processes as a whole, rather than group or provider processes on their own.

The models could also be used in assessing errors and in planning responses to non-routine events. A modeling approach based on HTA was used to examine potential causes for errors in medication administration (133). This same type of approach could be used to look at sub-processes in clinics to identify areas where processes are prone to errors. Assessing scenarios using the models could also simulate how the clinic would respond to unanticipated events, such as an emergency weather situation. The models could help to predict the information that might be required as the clinic returns to normal status after the unanticipated event and also what kind of information might be lost in the process.

Finally, the models could be used to analyze the impact of new informatics tools in the clinic environments, including tools developed without using these guidelines. The workflow required by a new tool can be compared to the existing workflow in a clinic. Areas where the tool may modify workflow or require additional work can be evaluated prior to implementing the new system in the real world. In addition, the tool can be evaluated for workflow improvements. This process could help both in software design and in assessing off-the-shelf software for appropriateness for the environment. This technique is similar to an approach proposed by Borycki and colleagues (134). Borycki proposed using simulation to examine workflow before and after implementation of new software, for the purposes of improving software design and decision-making regarding informatics tools. This simulation approach could be used in chronic disease clinics, using the workflow models developed in this study as a basis for comparison.

The models developed in this study have a wide variety of potential applications for many different audiences. While the initial motivation for model development was directed towards software design, there are clearly many other areas that could benefit from examining the models.

Study limitations

This study provides a picture of workflow, information flow, and computer use in three chronic disease clinics based on qualitative methods. The process followed to select clinics for study inclusion presents a threat to internal validity of the study. Several clinics did not respond to requests for initial interviews and other clinics were not interested in study inclusion. The clinics represented in the initial interviews thus represent a convenience sample. The motivation for this lack of interest is unclear; clinics may have been convinced their workflow was significantly better or worse than other clinics or they may have had other reasons for not wanting to participate. This may have resulted in the study missing unique elements of chronic disease care. Validating the generalized workflow and information flow models by studying additional clinics including some that initially chose not to participate in the study may ameliorate these potential confounders.

The generalizability of this study to other chronic diseases may be limited since only clinic for each of three chronic diseases were evaluated. The number of providers that were studied was limited by the size of the clinics and by provider availability. The study was conducted at a single academic medical center with unique informatics tools developed in-house for use in this specific environment. Chronic disease care was only studied in disease-specific clinics, while some chronic disease care is provided by primary care physicians. Changes to policies, procedures, staff, and informatics tools were implemented during the course of the study. The dynamic nature of the work environment presents challenges in validating the results of this study.

Other limitations include the use of only qualitative methods and the potential for observation bias. Qualitative methods were selected as being most appropriate to the research goals. Quantitative methods could also have been used but seemed less appropriate to the research aims. However, in the future, quantitative methods such as time-motion studies, could significantly supplement the understanding of workflow in ambulatory chronic disease care. For example, timing data for different steps in the workflow could be used to identify bottlenecks and re-engineer processes to improve efficiency. The study was conducted by a single observer, which introduces the potential for bias. The observations were discussed extensively with others and interviews were conducted with clinic personnel to clarify observations and obtain feedback on the validity of observations and conclusions. The observer was aware of the risks and tried to maintain an open viewpoint to adjust for her personal biases.

The discussion of temporal horizons and rhythms and the temporal flow diagrams in the results section represent a preliminary application of these concepts. Further exploration and refinement of the topic could add value to the understanding of temporal aspects of workflow and information flow in chronic disease care.

CHAPTER VII

CONCLUSION

The hypothesis motivating this study was that workflow and information flow during management of different chronic disease share core similarities, but also have some crucial differences. The specific aim of the study was to evaluate and compare the workflow and information flow of providers across three chronic disease domains in the ambulatory clinic environment.

The multiple sclerosis, cystic fibrosis, and diabetes mellitus clinics were selected for study inclusion based on clinic characteristics and clinician interest in improving informatics tools. The study utilized qualitative methods, including direct observation, semi-structured interviews, and analysis of artifacts. The similarities in the findings across the clinics formed the basis of generalized models of workflow and information flow in chronic disease care. Sources of variability between the clinics and within each clinic were identified. The findings support the concept that informatics tools will be most readily adopted when their functionality and implementation support individual and team clinical workflow. Current processes of data input present difficulty for many users. The difficulty of utilizing a relatively flat EMR structure to provide longitudinal care was identified as a barrier to full adoption of informatics in the chronic disease environment. Gaps between how informatics tools are actually used and institutional expectations of use were identified, as were workarounds developed to deal with gaps between functionality and needs. Finally, the data have implications for the design of informatics tools for chronic disease care including design for chronic disease care, specific features needed in the environment, and guidelines to promote adoption of informatics tools.

Future directions for research include evaluating the generalizabilty of models developed in this study to other chronic disease clinics and outside of Vanderbilt

University Medical Center. The validated models can the be used as an empiric basis for designing and evaluating informatics tools. A modular approach could be taken to the design of informatics tools for chronic disease where core functionality applicable to a wide range of chronic diseases could be provided in a central module, with easily customizable add-on modules serving to meet the disease- and clinic-specific needs of individual clinics.

The results of the study also suggest the value of applying the qualitative methods and modeling approaches developed to other problems including process improvement, promotion of informatics tool adoption, and design of informatics tools for other care environments.

APPENDIX A

INTERVIEW INSTRUMENT

Looking at the role of the interviewee as described in the clinic specific workflow and information flow models:

- Is the description of your role accurate?
- Is there anything missing from the model?
- What kinds of non-routine events would change your typical workflow, as described here?
- Are there any nuances of your workflow that we are missing, such as exceptions or unusual situations?

Looking at the overall clinic specific models:

- Is this overall model of your clinic accurate?
- Is anything missing from the model?
- Are there any nuances that we are missing, such as exceptions or unusual situations?

Looking at the role of the interviewee as described in the general model of workflow and information flow in chronic disease clinics:

- Does the general model describe your role accurately?
- Are there differences between how {role of interviewee} work in this clinic and in other clinics?
- What causes these differences?

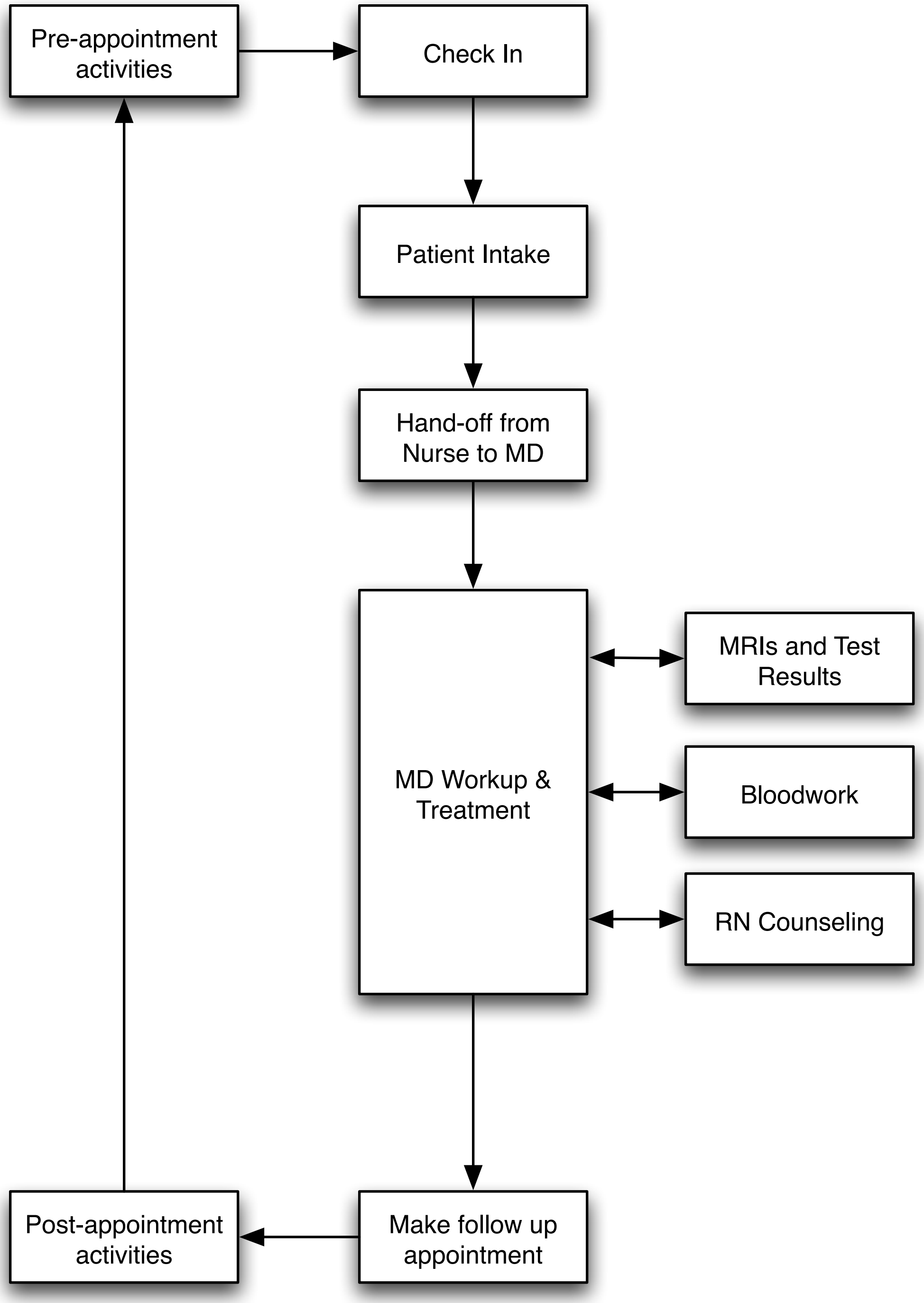
Looking at the overall general model:

- What do you think of this generalized model?
- Is it missing anything that is important for chronic disease care?
- Is there anything that you would suggest adding to the models?

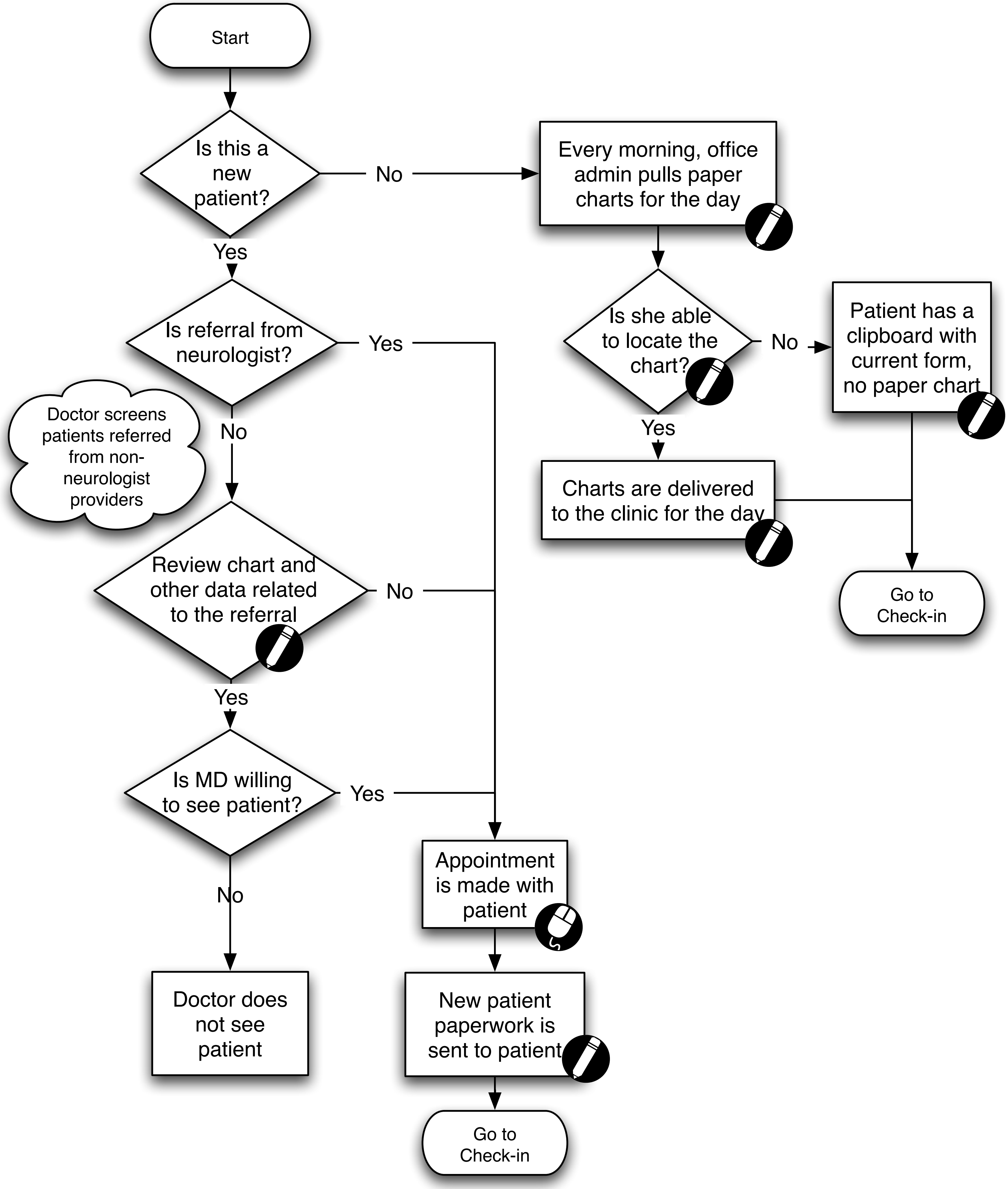
APPENDIX B

WORKFLOW IN MS CLINIC

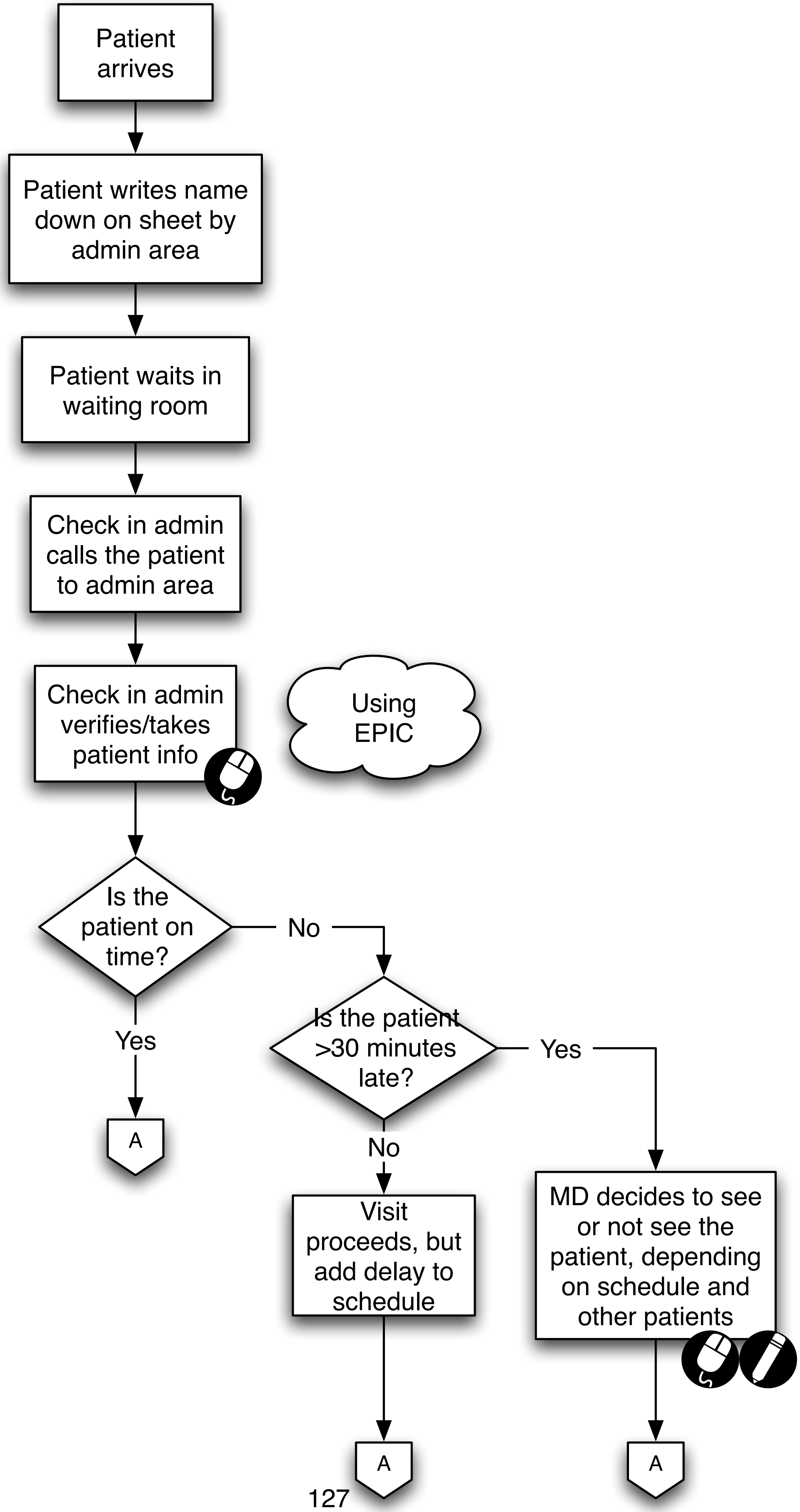
Overview

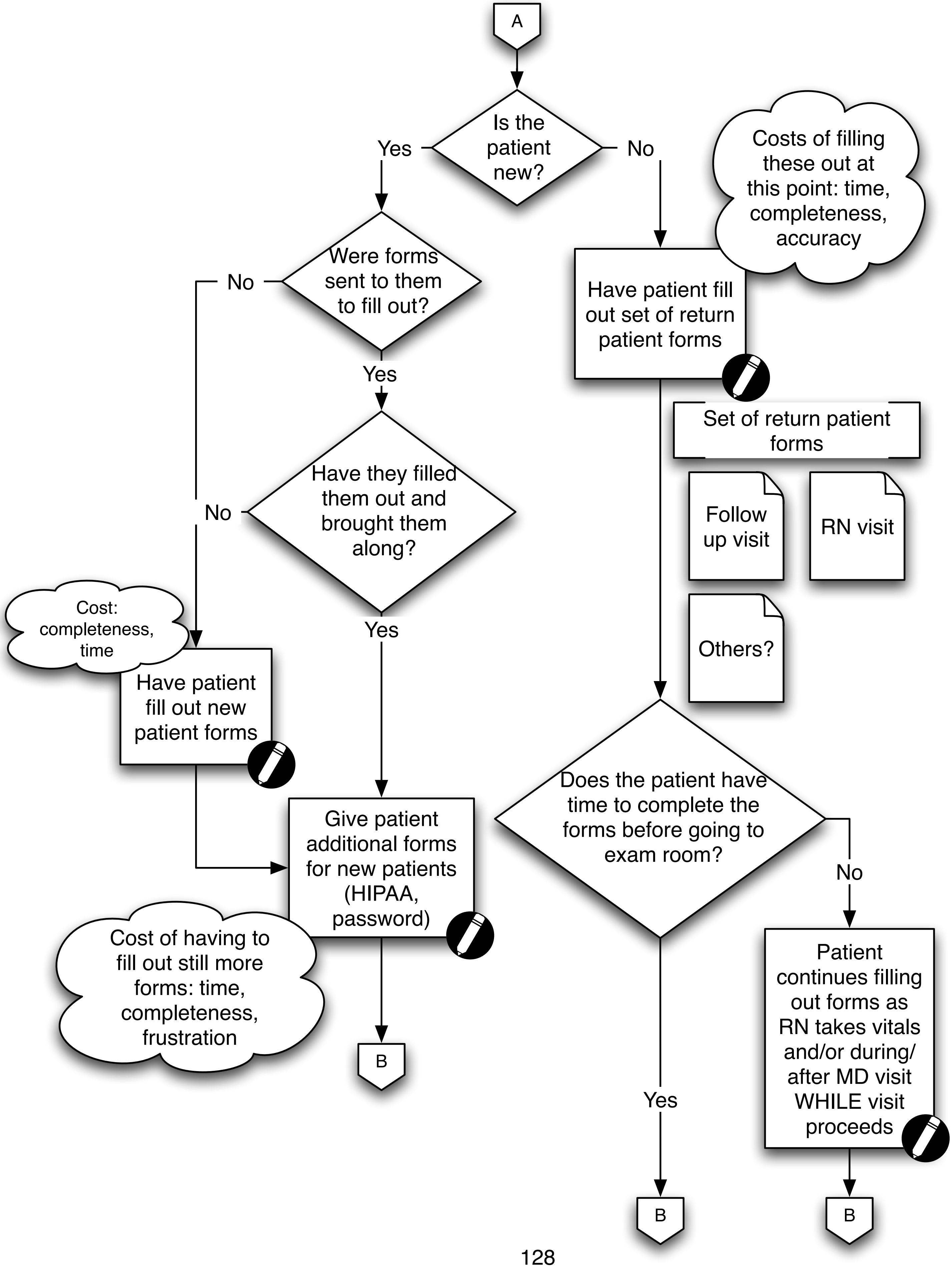


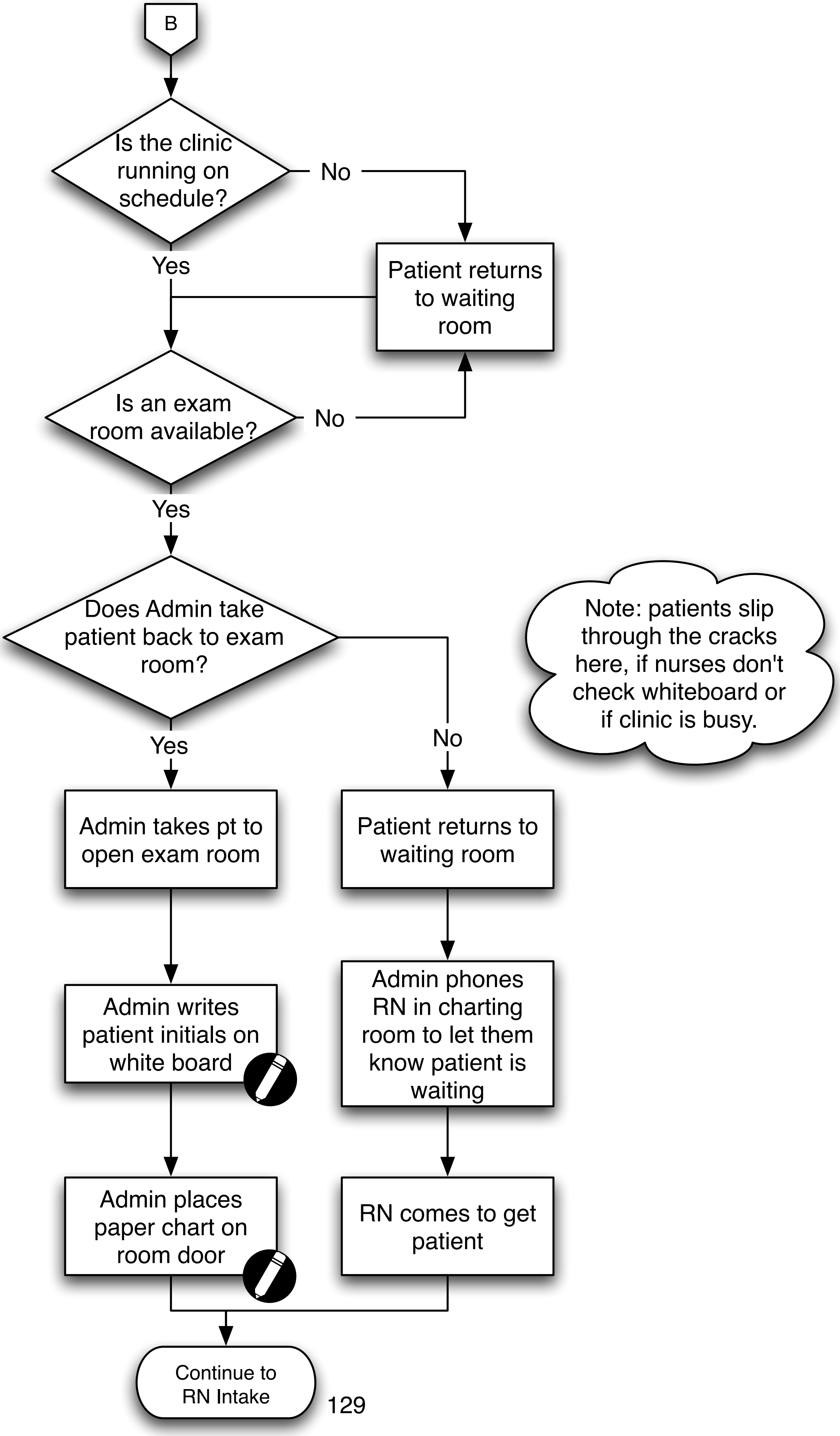
Pre-appointment



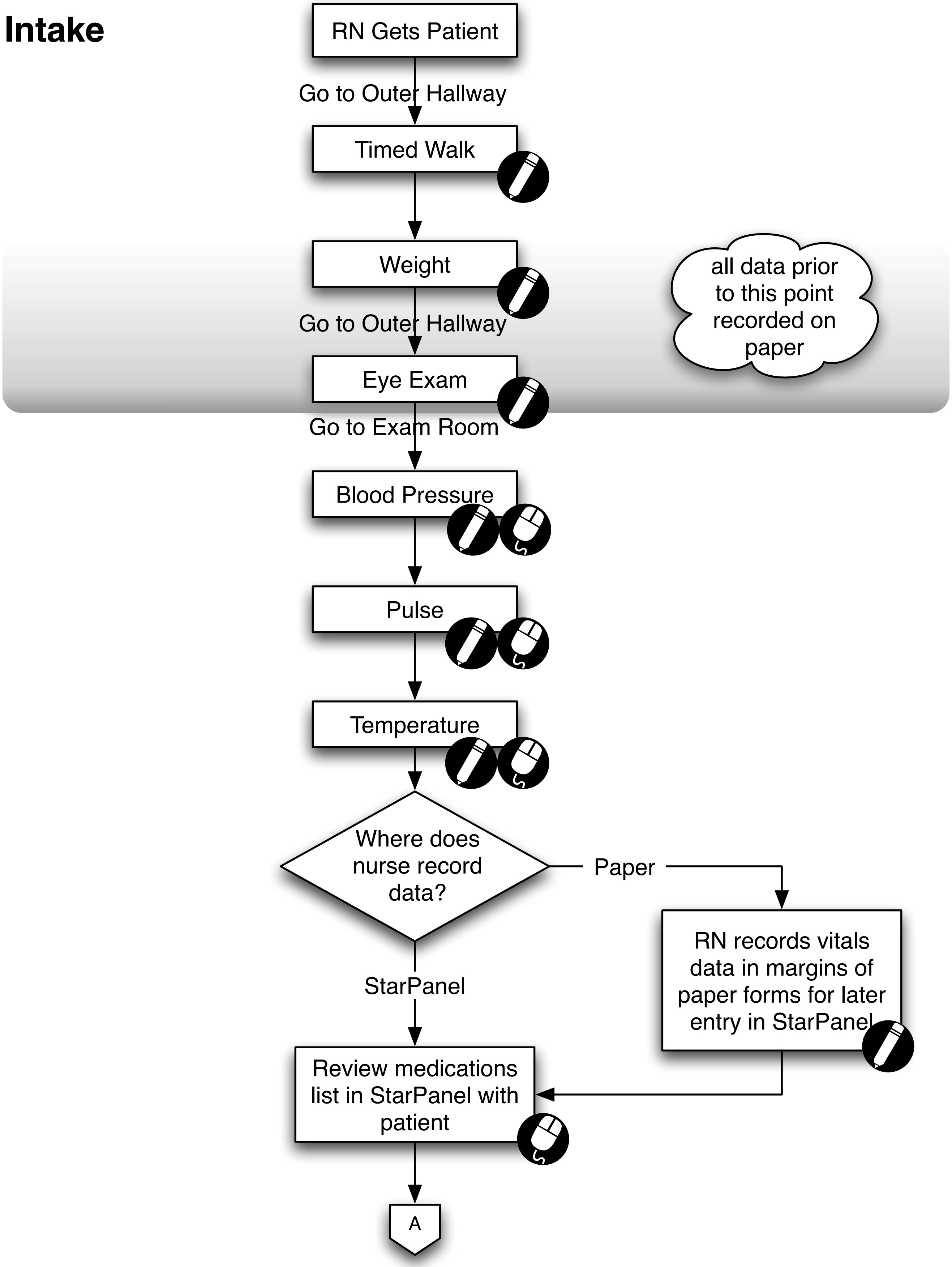
Check-in

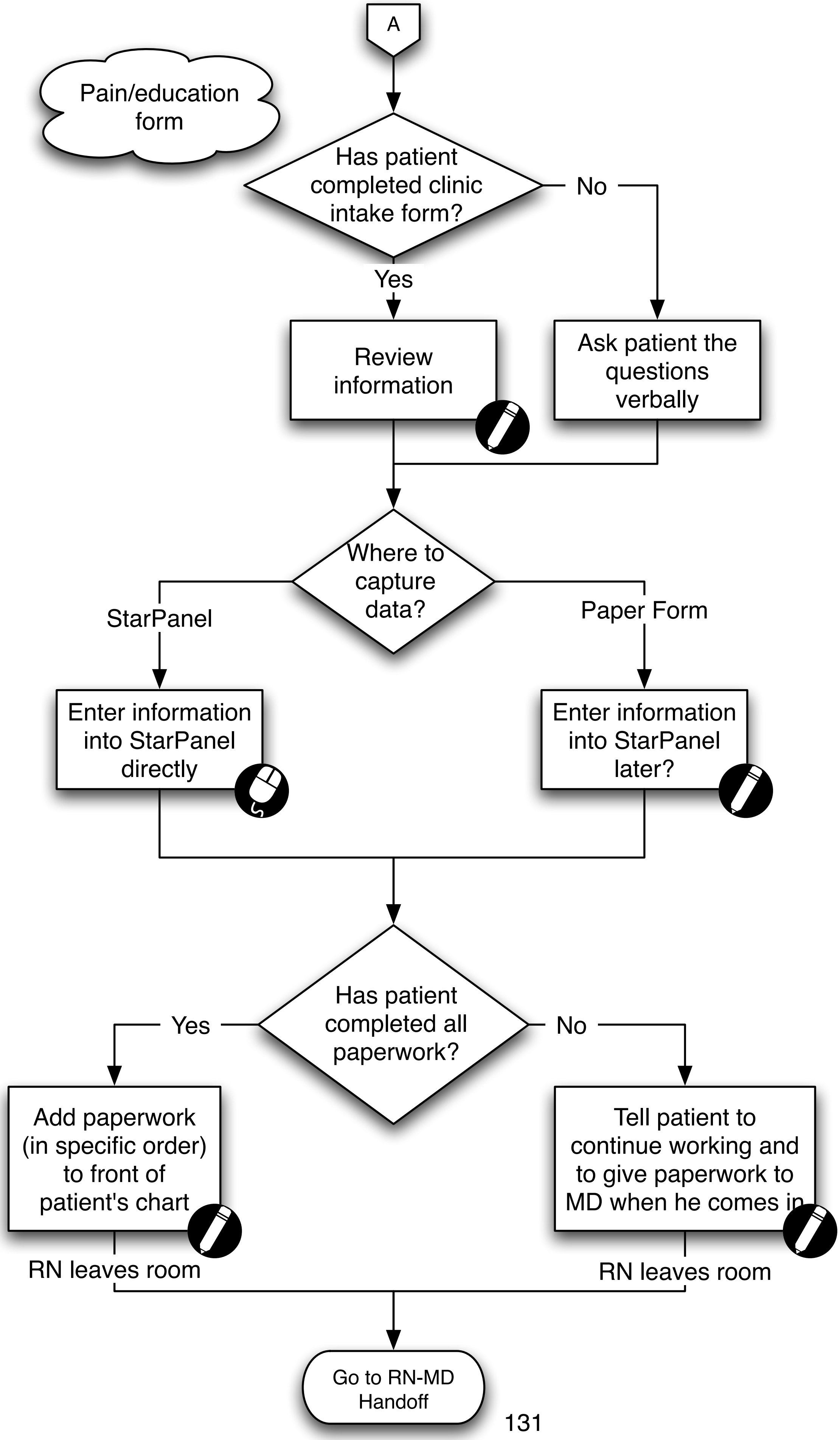

Patient arrives
Patient writes name down on sheet by admin area
Patient waits in waiting room
Check in admin calls the patient to admin area
Check in admin verifies/takes patient info
Using EPIC
Is the patient on time?
No
Yes
A
Is the patient >30 minutes late?
Yes
No
Visit proceeds, but add delay to schedule
MD decides to see or not see the patient, depending on schedule and other patients
A
A


A
Is the patient new?
Yes
No
Were forms sent to them to fill out?
No
Yes
Have they filled them out and brought them along?
No
Yes
Cost: completeness, time
Have patient fill out new patient forms
Give patient additional forms for new patients (HIPAA, password)
Cost of having to fill out still more forms: time, completeness, frustration
B
Costs of filling these out at this point: time, completeness, accuracy
Have patient fill out set of return patient forms
Set of return patient forms
Follow up visit
RN visit
Others?
Does the patient have time to complete the forms before going to exam room?
No
Yes
Patient continues filling out forms as RN takes vitals and/or during/ after MD visit WHILE visit proceeds
B
B

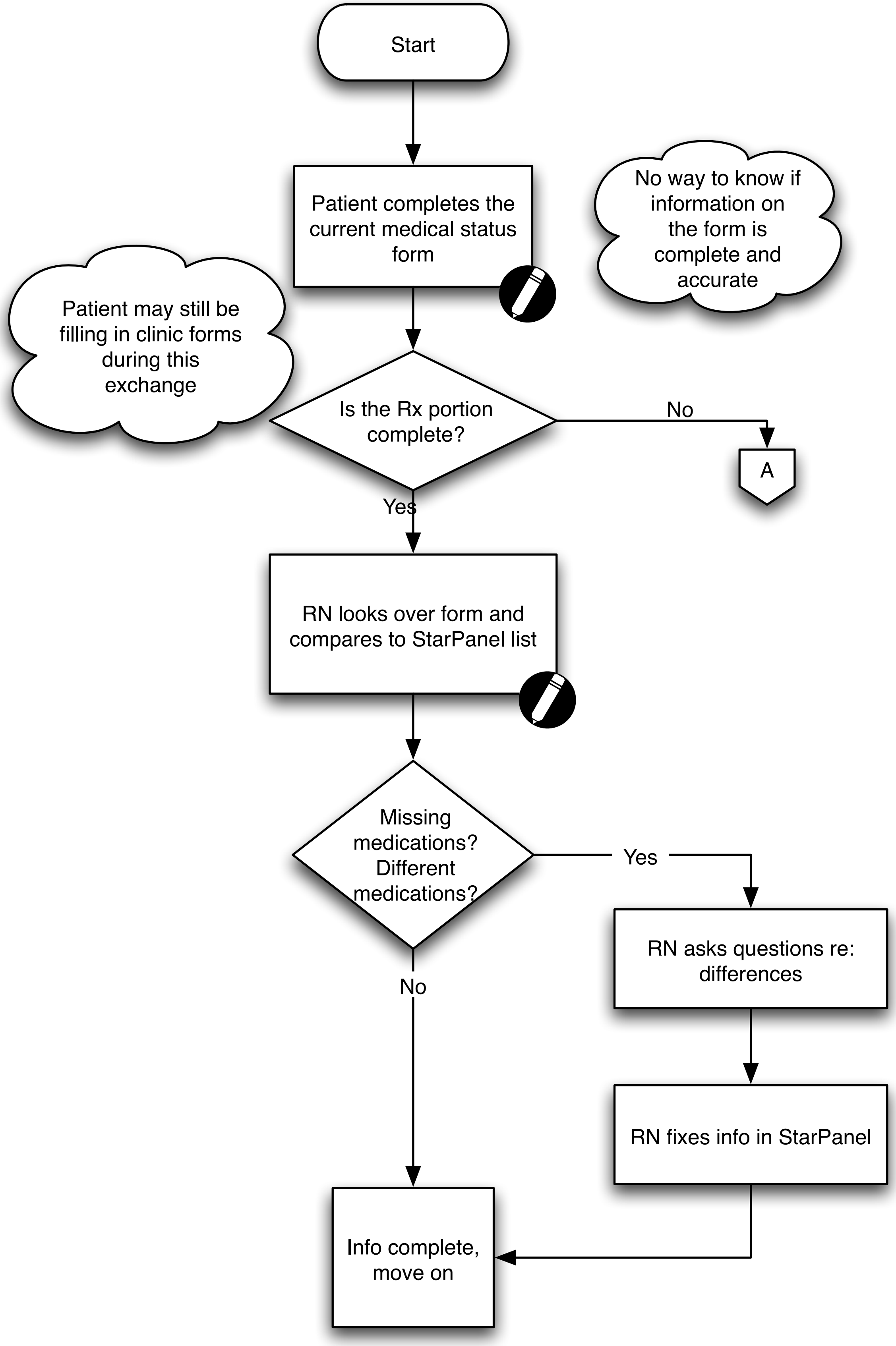

B
Is the clinic running on schedule?
No
Patient returns to waiting room
Yes
Is an exam room available?
No
Yes
Does Admin take patient back to exam room?
Yes
No
Note: patients slip through the cracks here, if nurses don't check whiteboard or if clinic is busy.
Admin takes pt to open exam room
Patient returns to waiting room
Admin writes patient initials on white board
Admin phones RN in charting room to let them know patient is waiting
Admin places paper chart on room door
RN comes to get patient
Continue to RN Intake

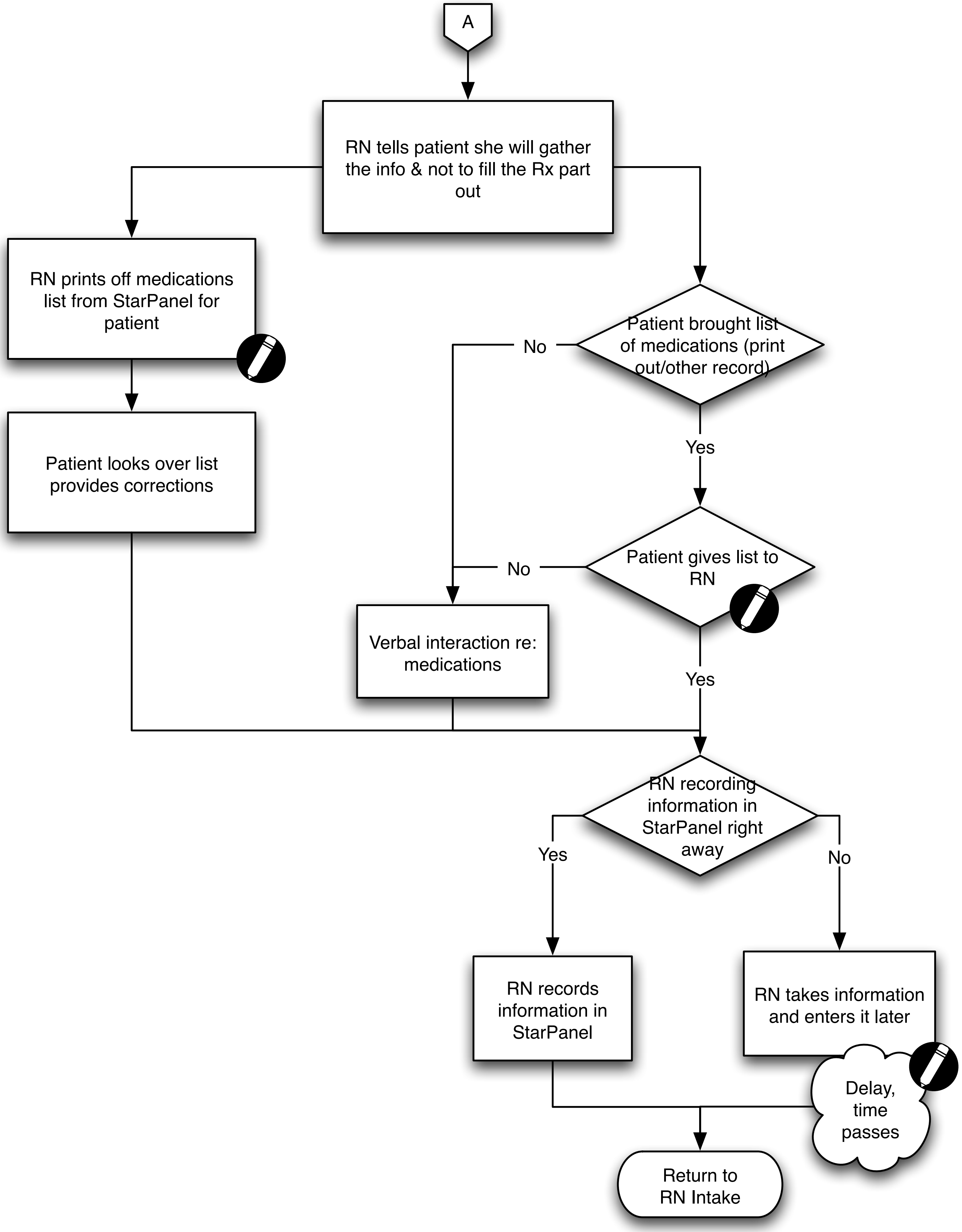
RN Intake


RN Gets Patient
Go to Outer Hallway
Timed Walk
Weight
Go to Outer Hallway
Eye Exam
Go to Exam Room
Blood Pressure
Pulse
Temperature
all data prior to this point recorded on paper
Where does nurse record data?
Paper
RN records vitals data in margins of paper forms for later entry in StarPanel
StarPanel
Review medications list in StarPanel with patient
A

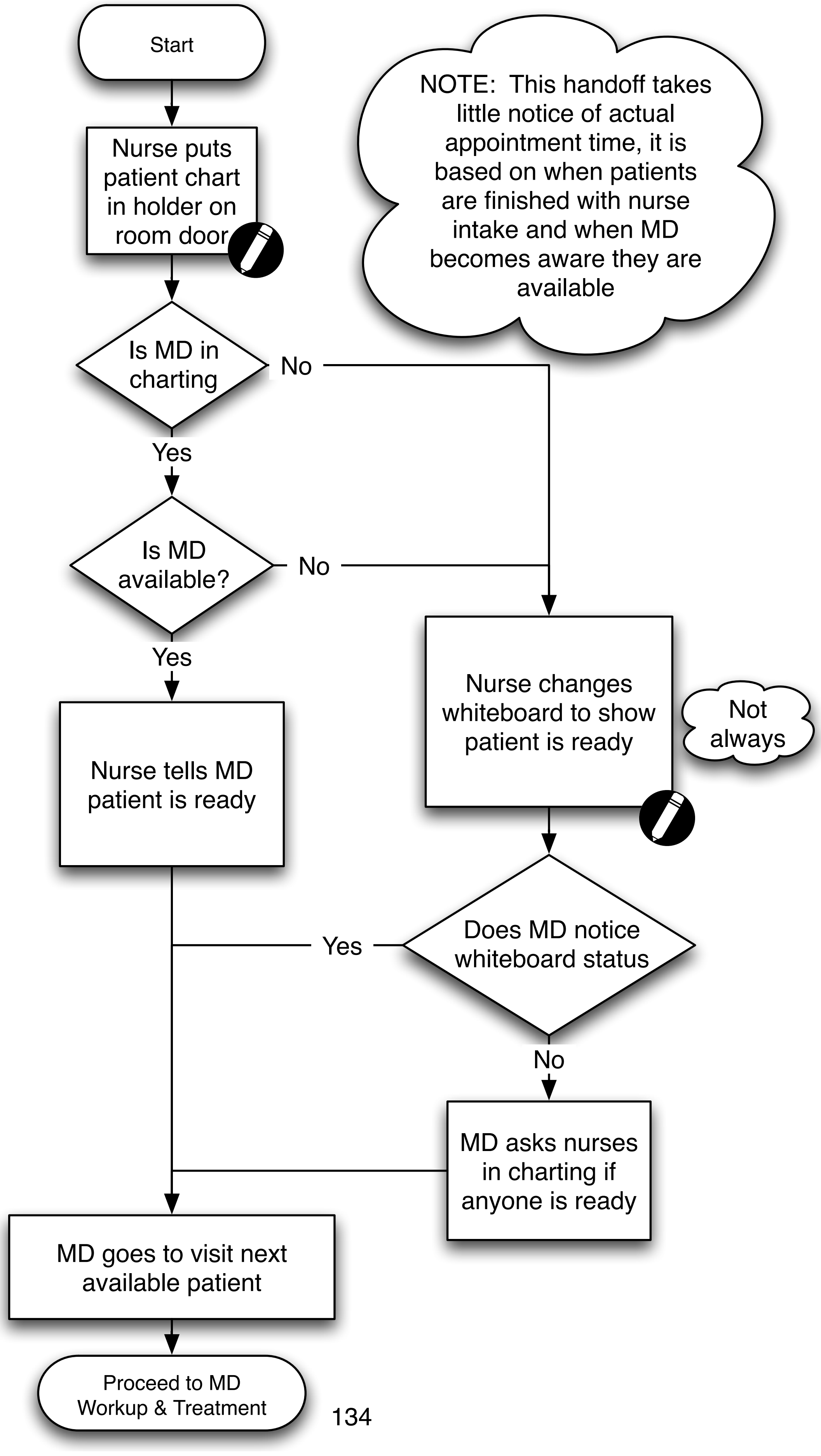

A
Pain/education form
Has patient completed clinic intake form?
No
Yes
Review information
Ask patient the questions verbally
Where to capture data?
StarPanel
Paper Form
Enter information into StarPanel directly
Enter information into StarPanel later?
Has patient completed all paperwork?
Yes
No
Add paperwork (in specific order) to front of patient's chart
Tell patient to continue working and to give paperwork to MD when he comes in
RN leaves room
RN leaves room
Go to RN-MD Handoff

Medication Review Routine

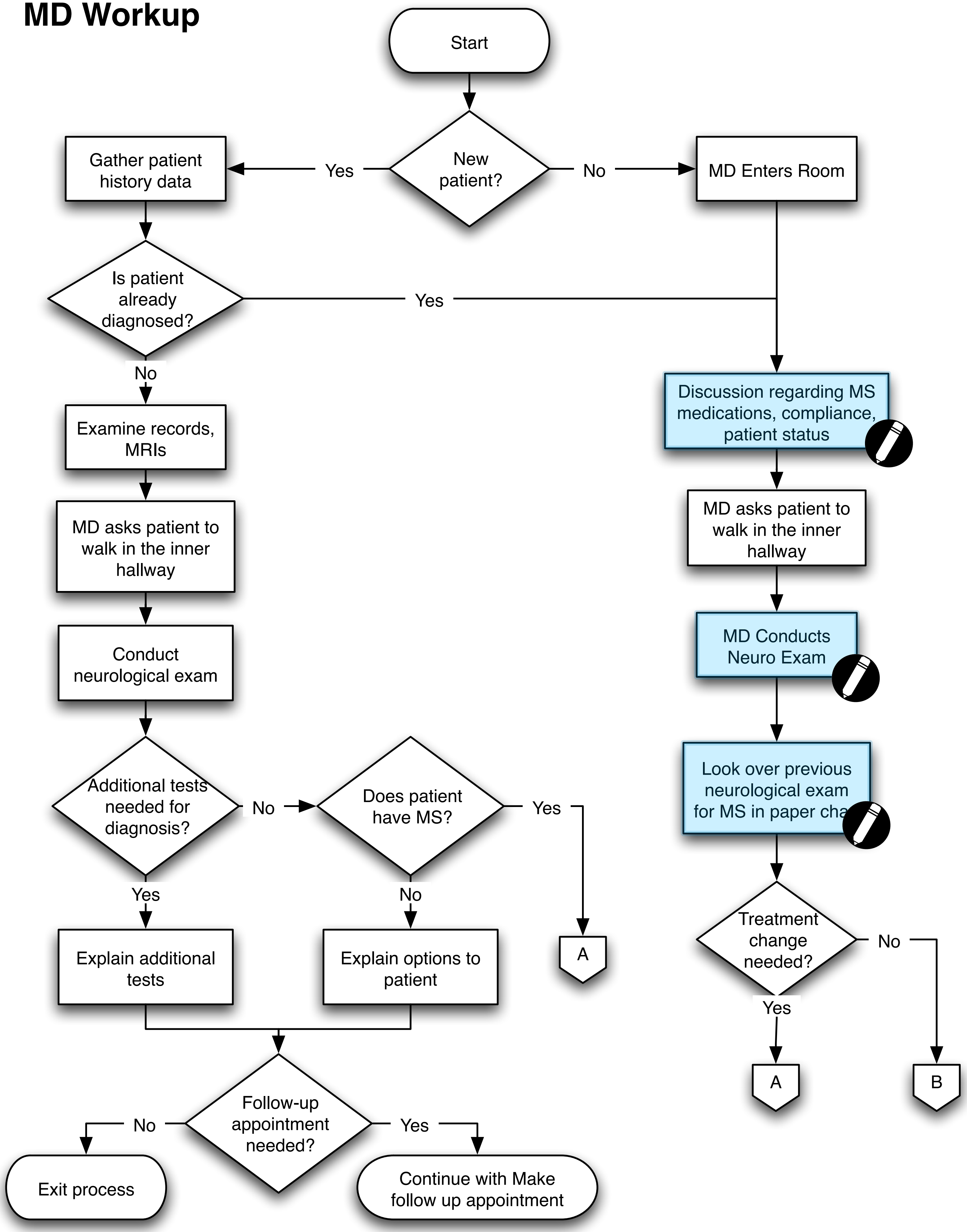


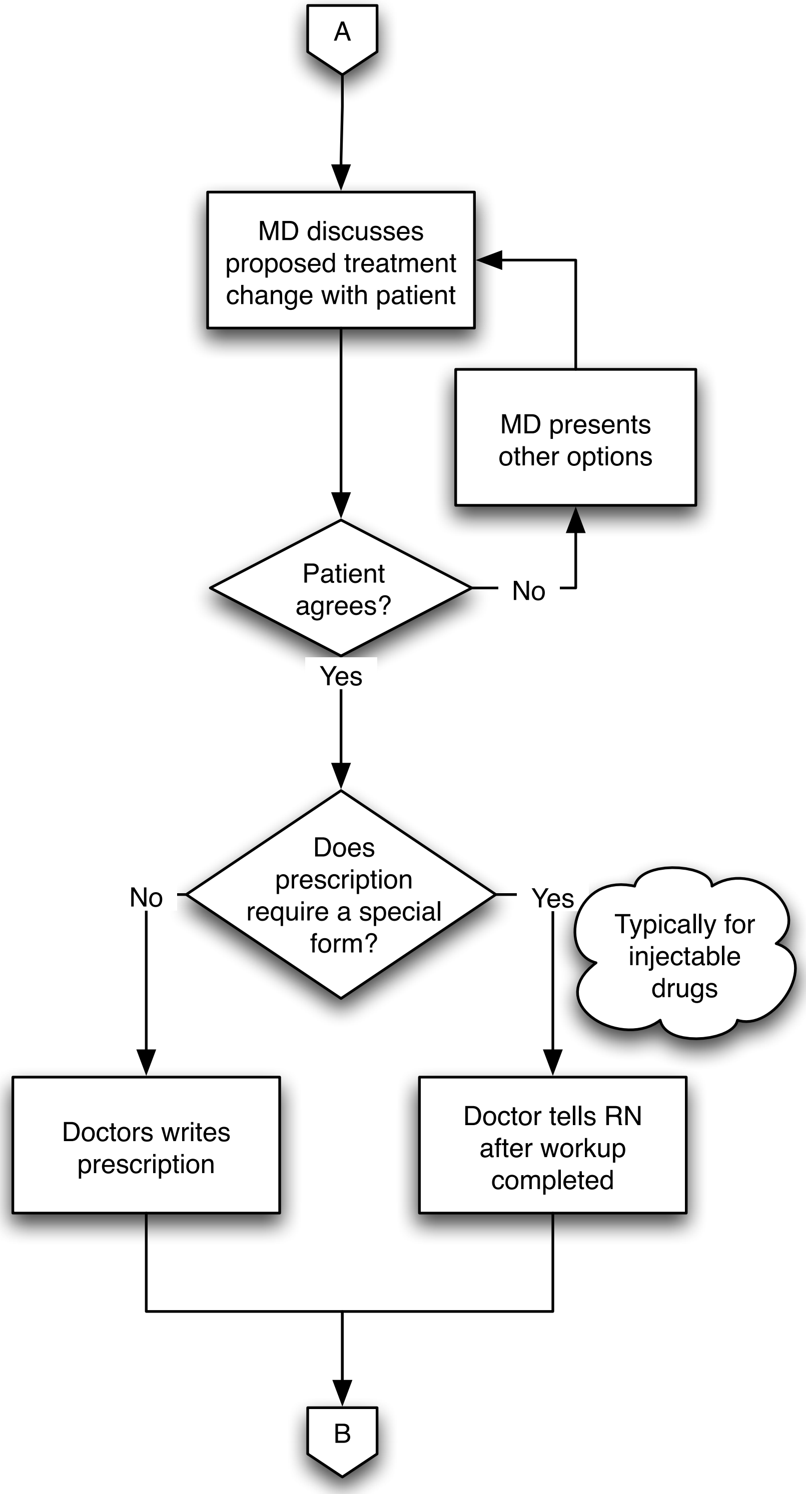

A
RN tells patient she will gather the info & not to fill the Rx part out
RN prints off medications list from StarPanel for patient
Patient looks over list provides corrections
Patient brought list of medications (print out/other record)
No
Yes
Patient gives list to RN
No
Yes
Verbal interaction re: medications
RN recording information in StarPanel right away
Yes
No
RN records information in StarPanel
RN takes information and enters it later
Delay, time passes
Return to RN Intake

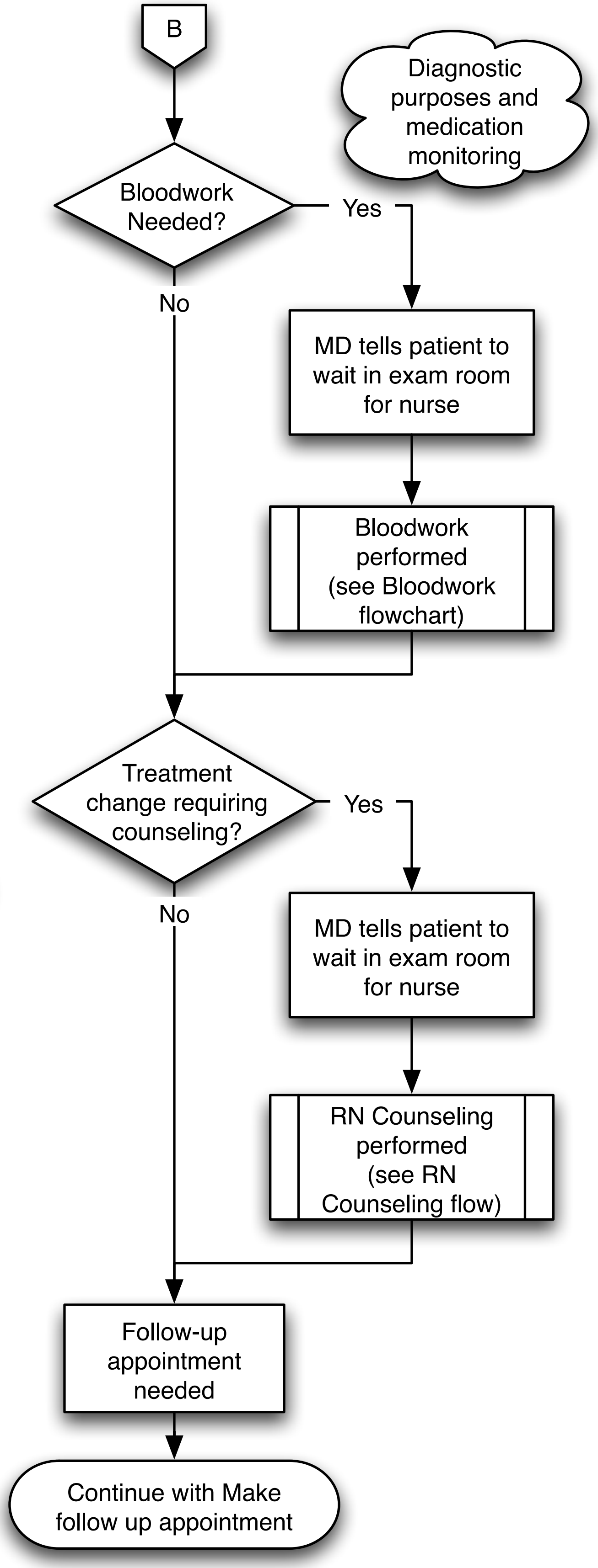
RN-MD Handoff



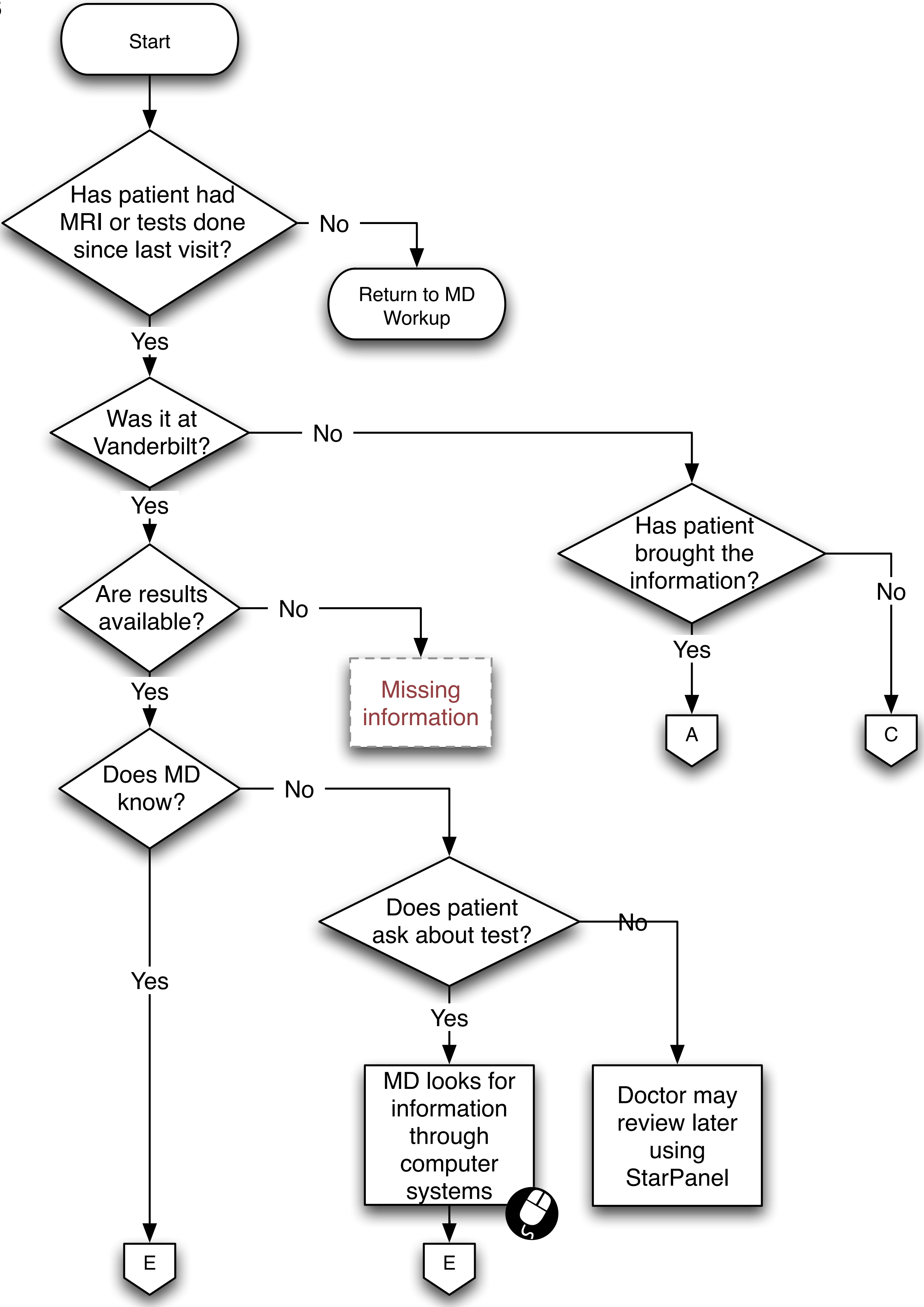
MD Workup

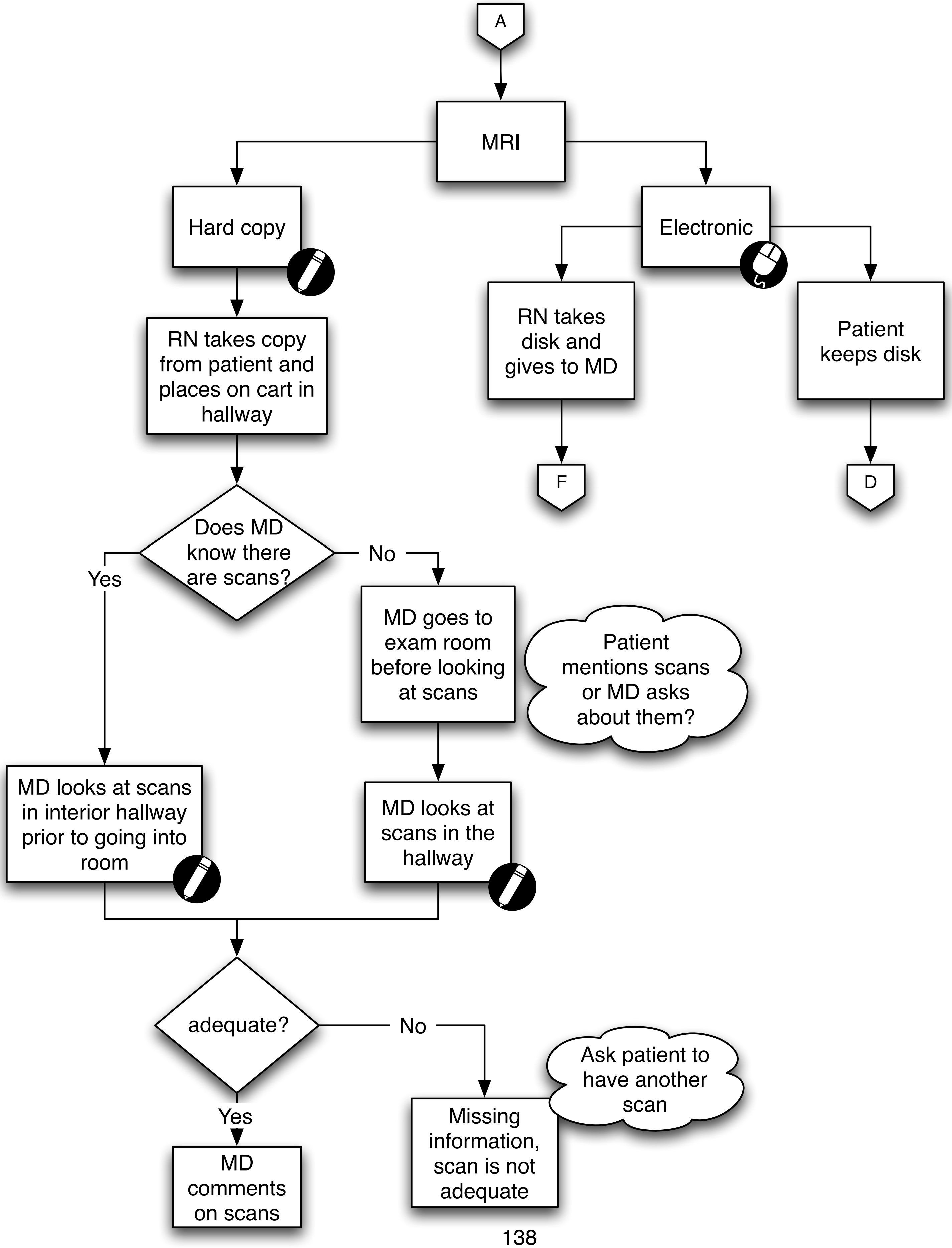

Start
New patient?
Yes
No
Gather patient history data
MD Enters Room
Is patient already diagnosed?
Yes
No
Discussion regarding MS medications, compliance, patient status
Examine records, MRIs
MD asks patient to walk in the inner hallway
MD asks patient to walk in the inner hallway
MD Conducts Neuro Exam
Conduct neurological exam
Look over previous neurological exam for MS in paper cha
Additional tests needed for diagnosis?
No
Does patient have MS?
Yes
Yes
No
A
Treatment change needed?
No
Yes
Explain additional tests
Explain options to patient
A
B
Follow-up appointment needed?
No
Yes
Exit process
Continue with Make follow up appointment

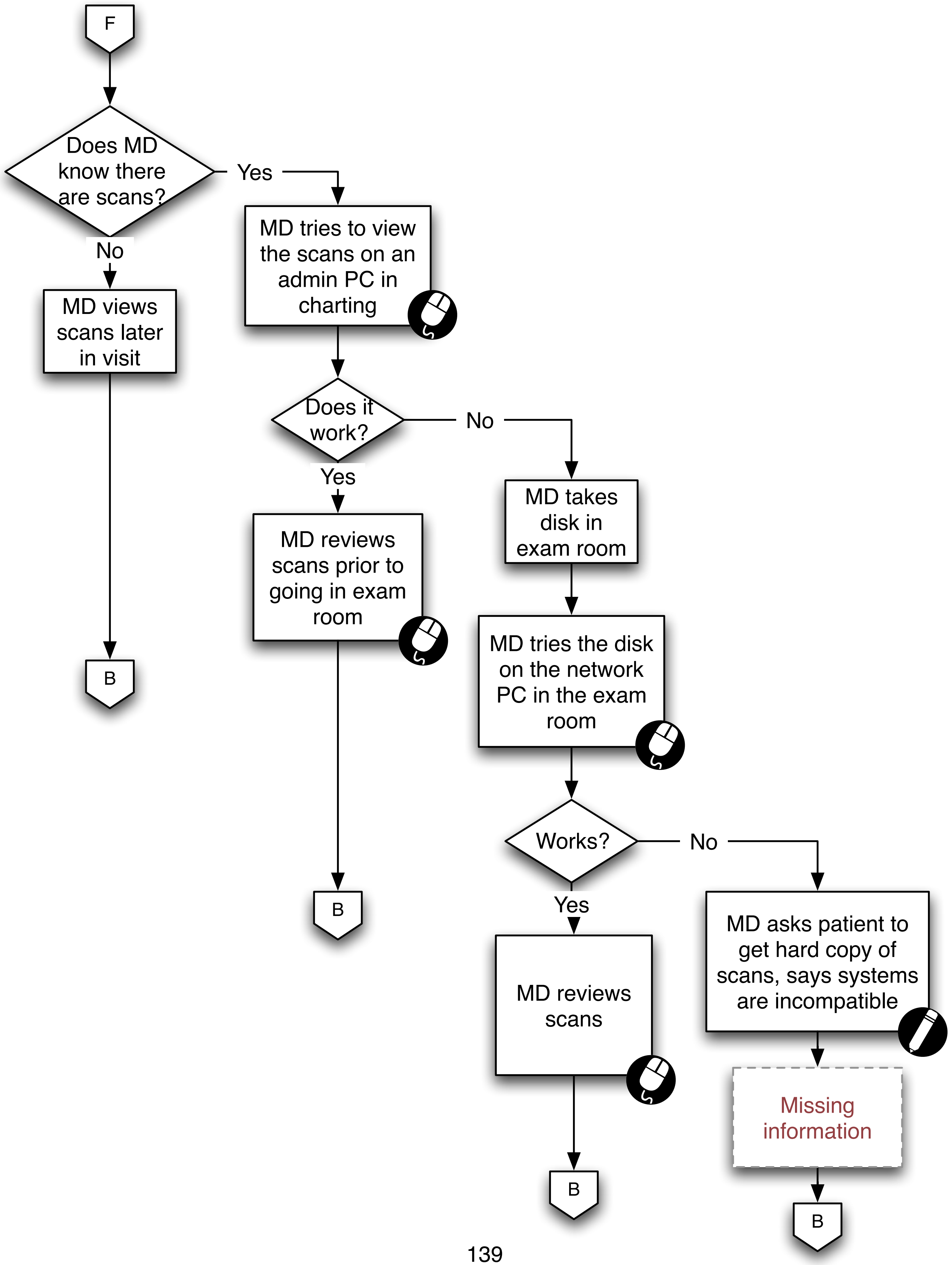

A
MD discusses proposed treatment change with patient
MD presents other options
Patient agrees?
No
Yes
Does prescription require a special form?
No
Yes
Typically for injectable drugs
Doctors writes prescription
Doctor tells RN after workup completed
B

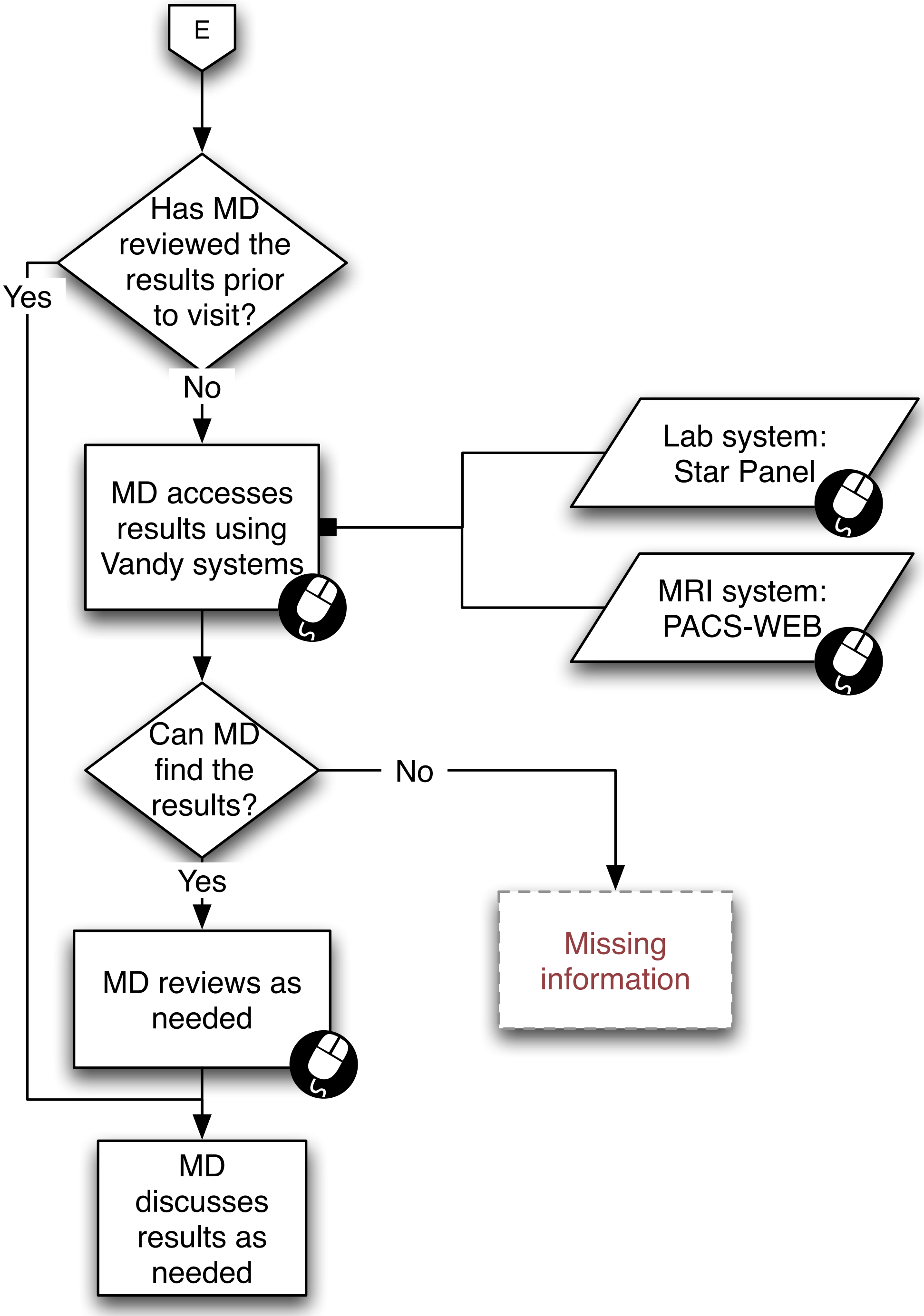

B
Diagnostic purposes and medication monitoring
Bloodwork Needed?
Yes
No
MD tells patient to wait in exam room for nurse
Bloodwork performed (see Bloodwork flowchart)
Treatment change requiring counseling?
Yes
No
MD tells patient to wait in exam room for nurse
RN Counseling performed (see RN Counseling flow)
Follow-up appointment needed
Continue with Make follow up appointment

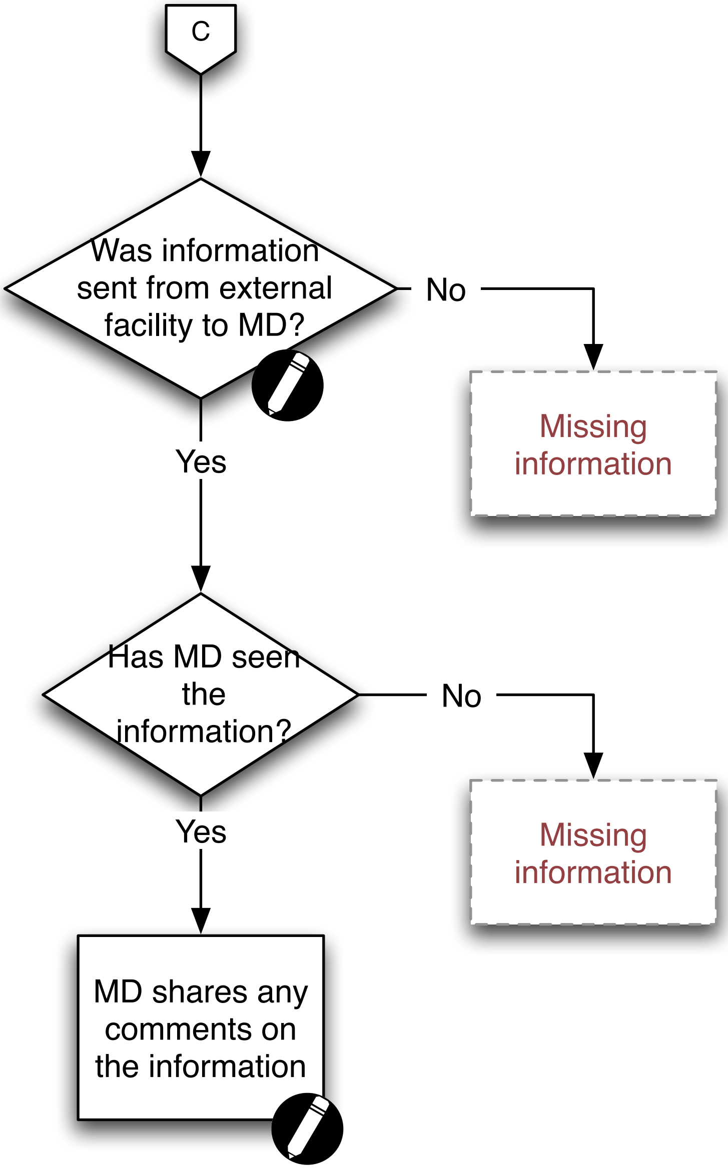
MRIs and test results

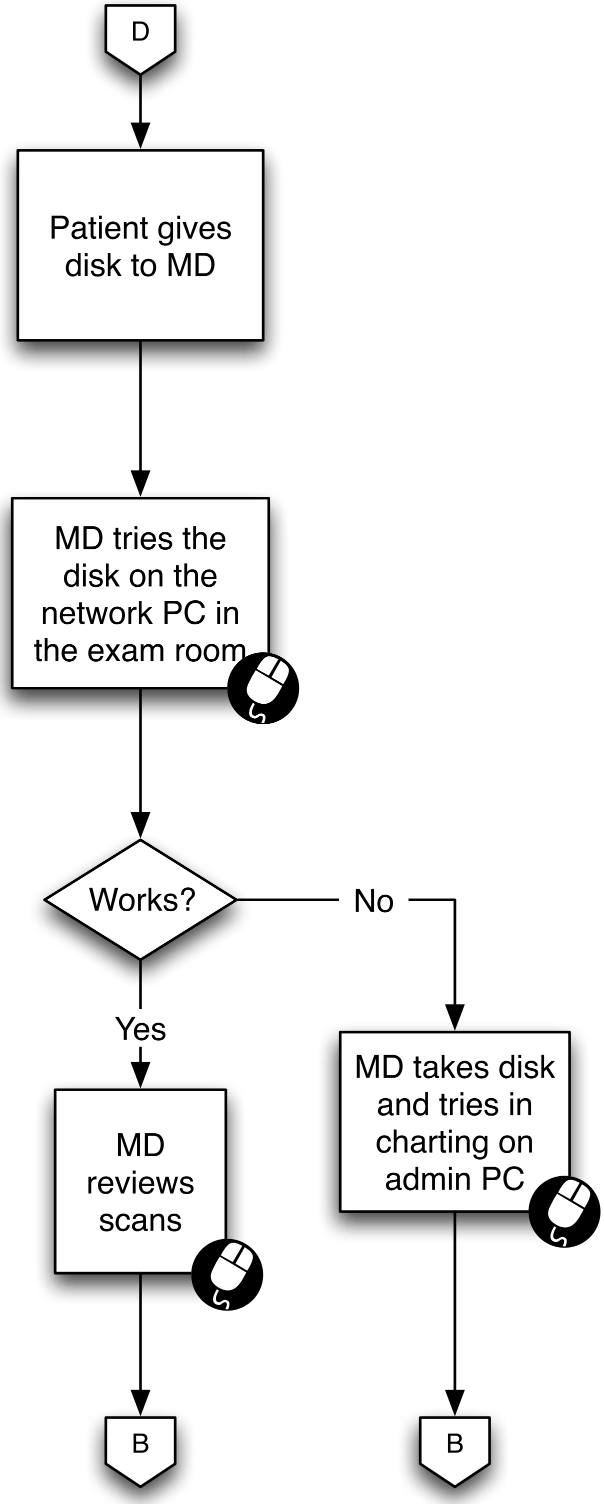


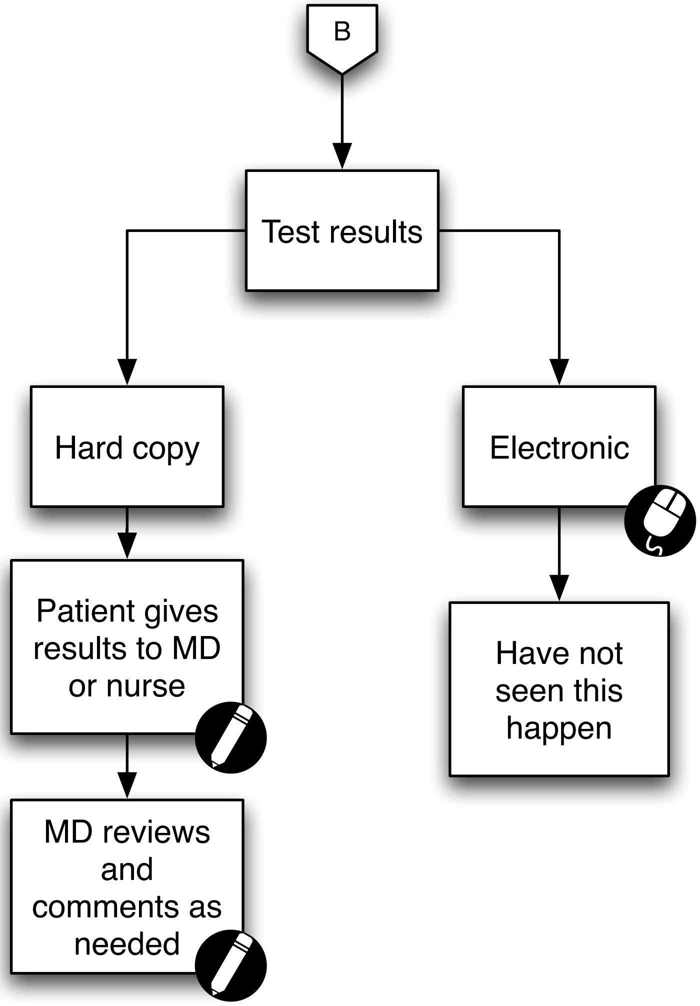

A
MRI
Hard copy
Electronic
RN takes copy from patient and places on cart in hallway
RN takes disk and gives to MD
Patient keeps disk
F
D
Does MD know there are scans?
Yes
No
MD goes to exam room before looking at scans
Patient mentions scans or MD asks about them?
MD looks at scans in interior hallway prior to going into room
MD looks at scans in the hallway
adequate?
No
Yes
Ask patient to have another scan
Missing information, scan is not adequate
MD comments on scans


F
Does MD know there are scans?
Yes
No
MD tries to view the scans on an admin PC in charting
MD views scans later in visit
Does it work?
No
Yes
MD takes disk in exam room
MD reviews scans prior to going in exam room
MD tries the disk on the network PC in the exam room
B
B
Works?
No
Yes
MD asks patient to get hard copy of scans, says systems are incompatible
MD reviews scans
Missing information
B
B

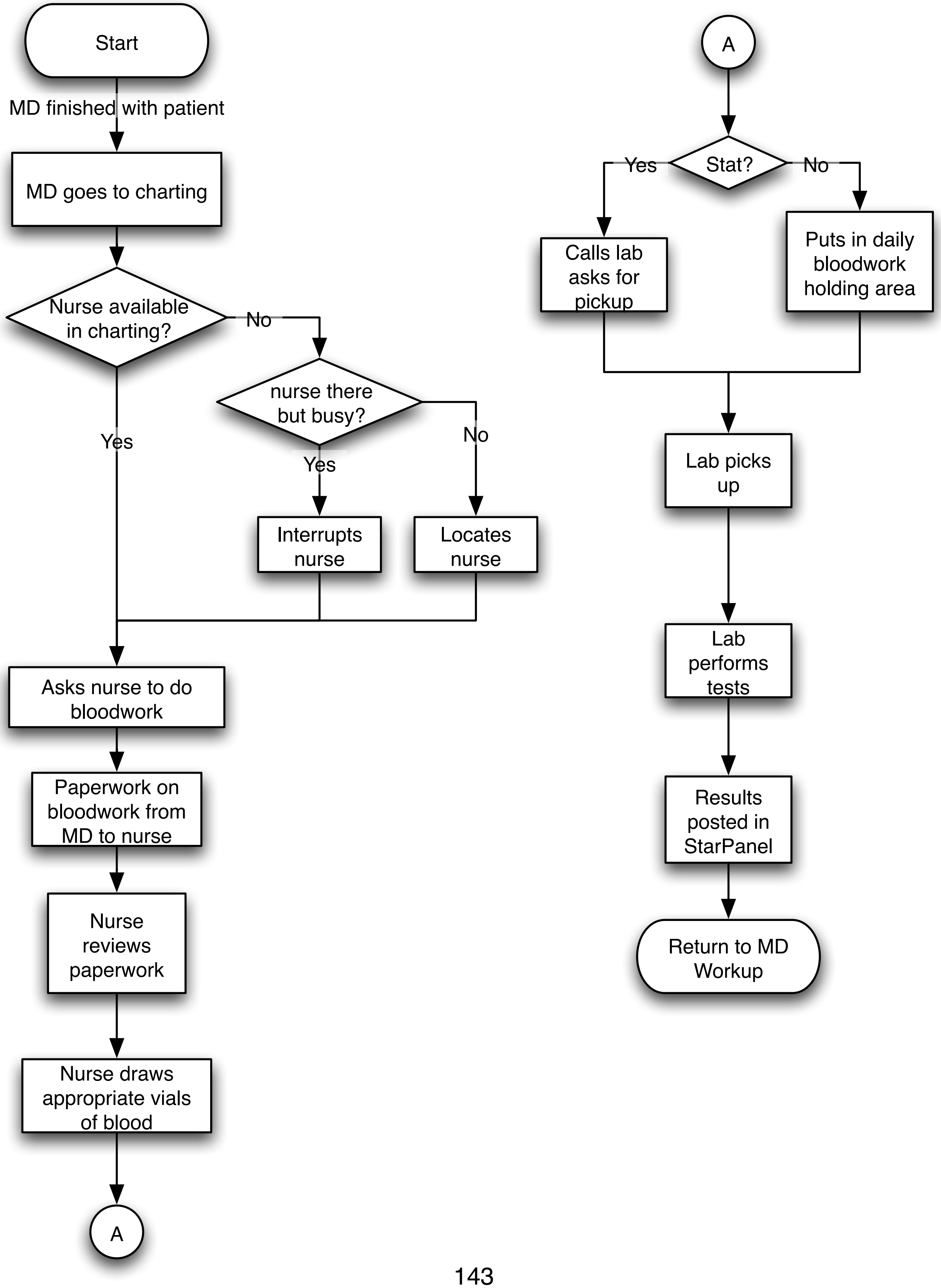

E
Has MD reviewed the results prior to visit?
Yes
No
MD accesses results using Vandy systems
Lab system: Star Panel
MRI system: PACS-WEB
Can MD find the results?
No
Yes
Missing information
MD reviews as needed
MD discusses results as needed


C
Was information sent from external facility to MD?
No
Missing information
Yes
Has MD seen the information?
No
Missing information
Yes
MD shares any comments on the information

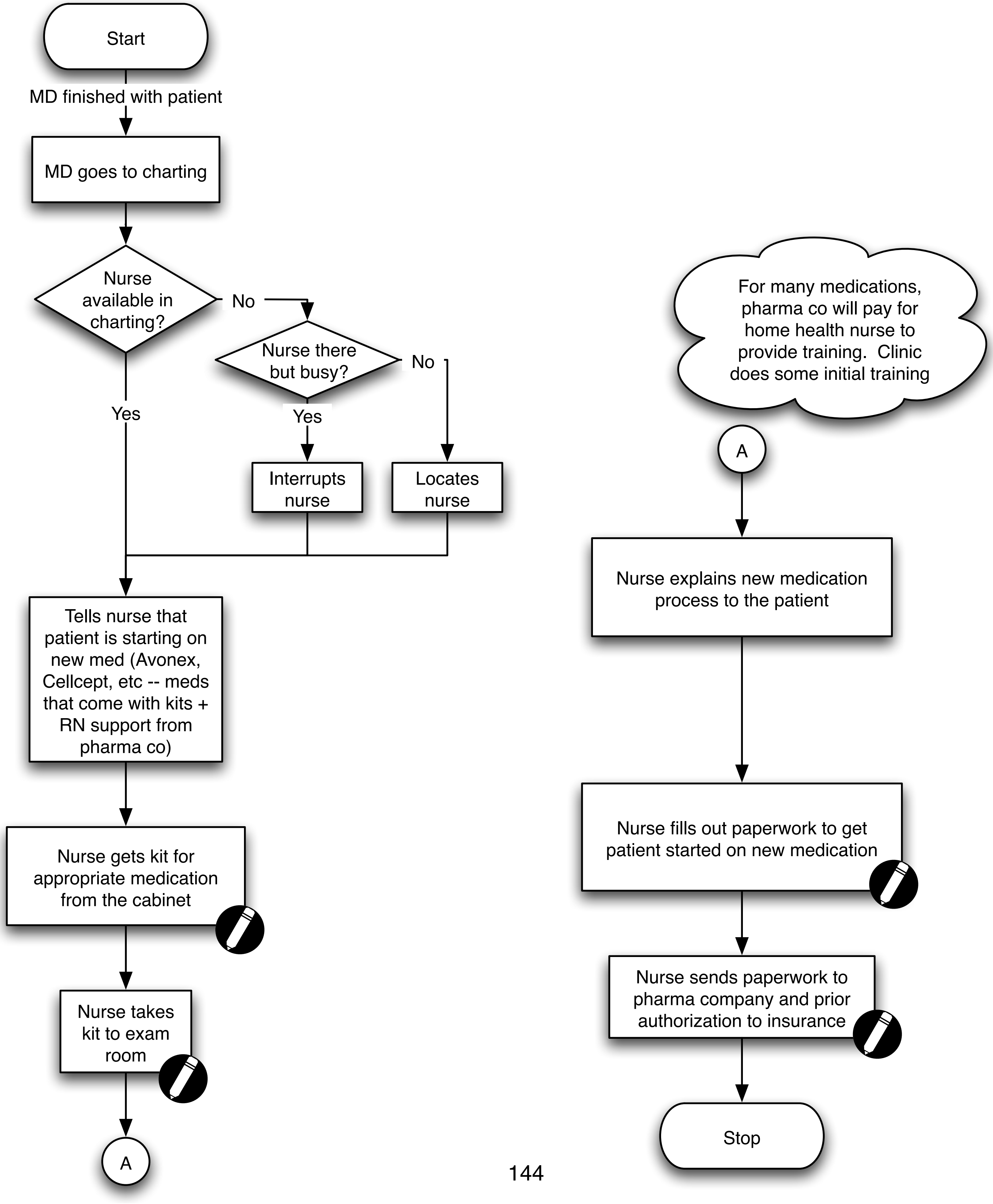

D
Patient gives disk to MD
MD tries the disk on the network PC in the exam room
Works?
No
Yes
MD reviews scans
MD takes disk and tries in charting on admin PC
B
B


B
Test results
Hard copy
Electronic
Patient gives results to MD or nurse
Have not seen this happen
MD reviews and comments as needed

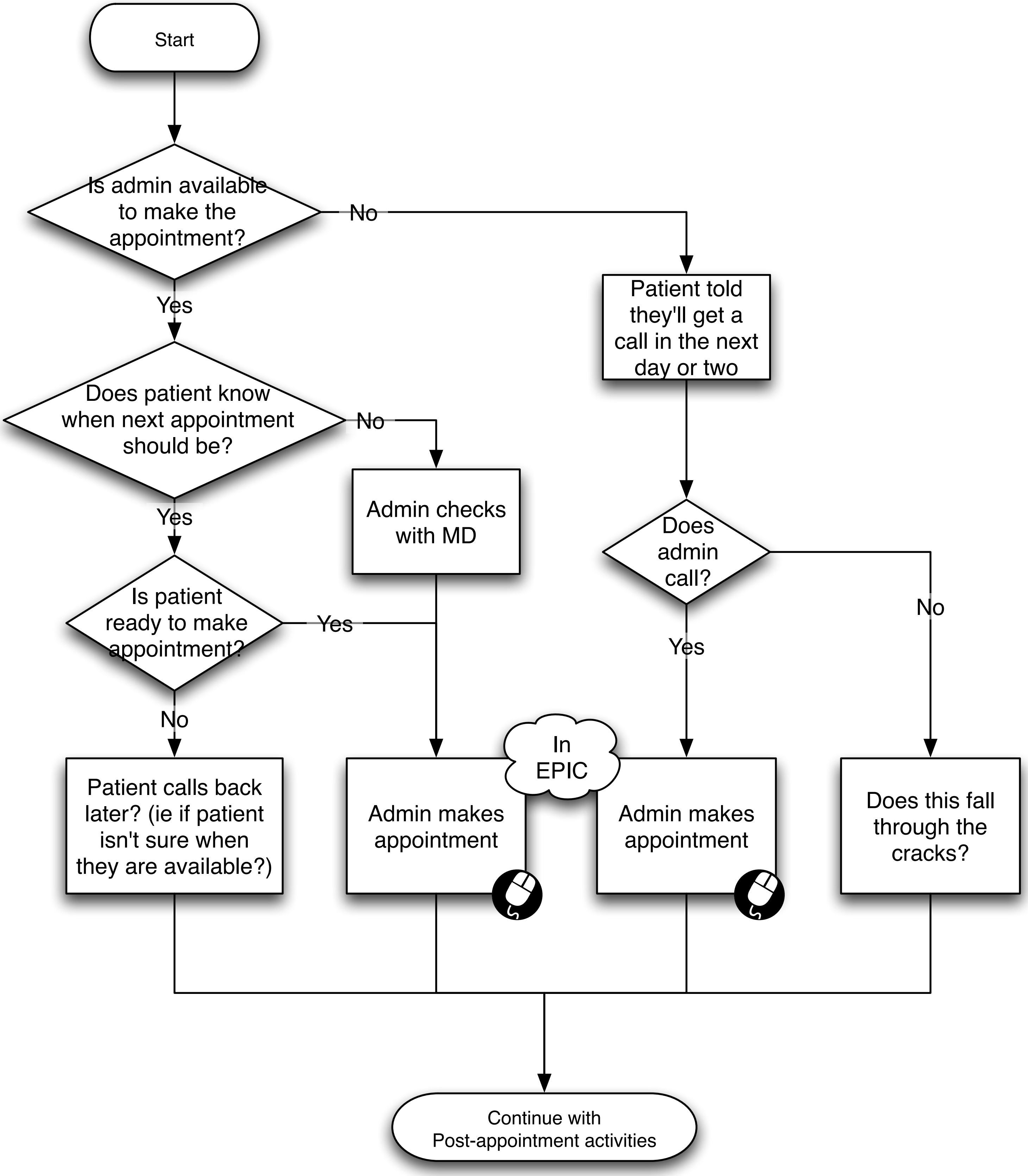
Bloodwork


Start
MD finished with patient
MD goes to charting
Nurse available in charting?
No
nurse there but busy?
Yes
Yes
No
Interrupts nurse
Locates nurse
Asks nurse to do bloodwork
Paperwork on bloodwork from MD to nurse
Nurse reviews paperwork
Nurse draws appropriate vials of blood
A
A
Stat?
Yes
No
Calls lab asks for pickup
Puts in daily bloodwork holding area
Lab picks up
Lab performs tests
Results posted in StarPanel
Return to MD Workup

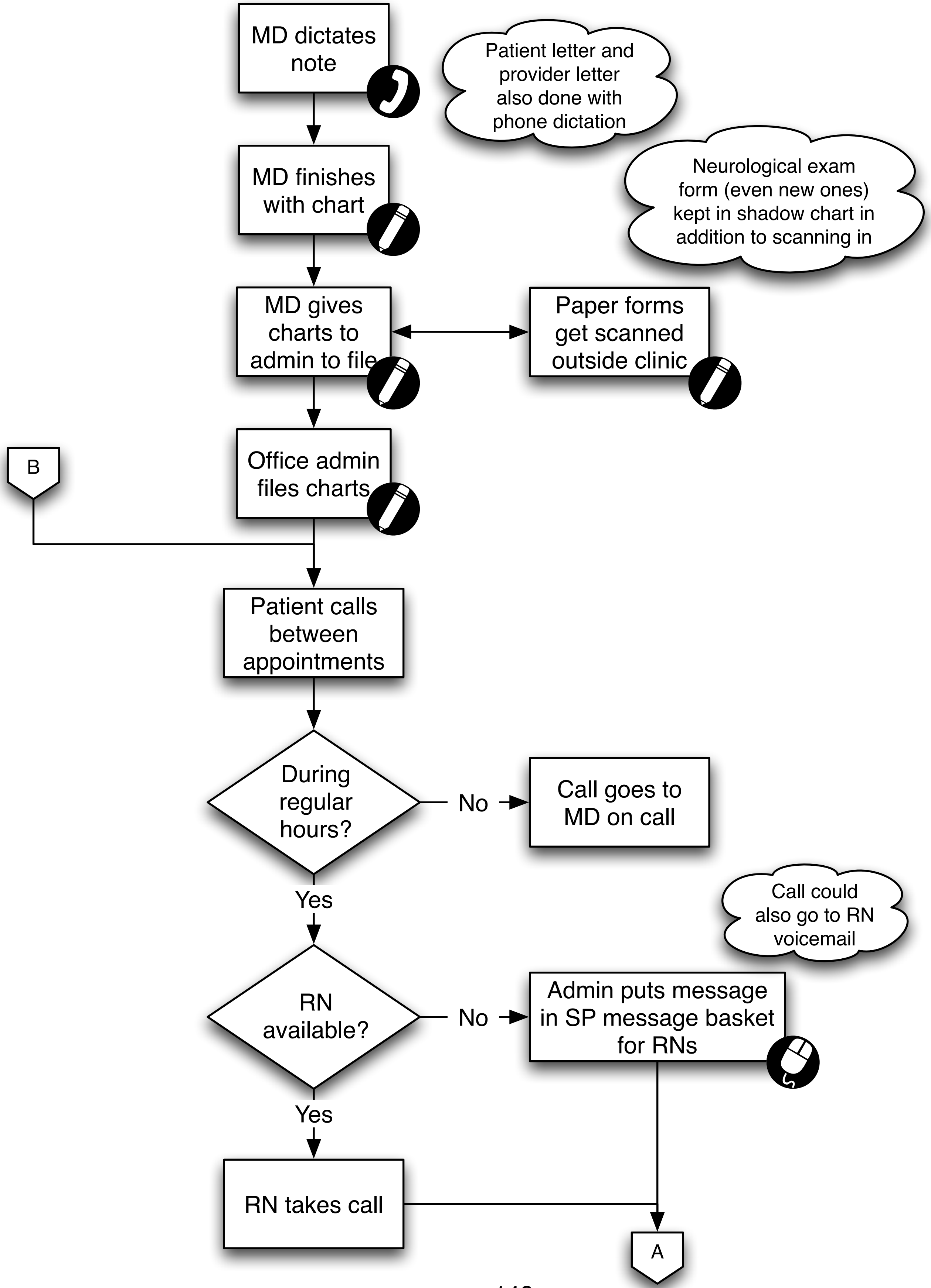
RN Counseling

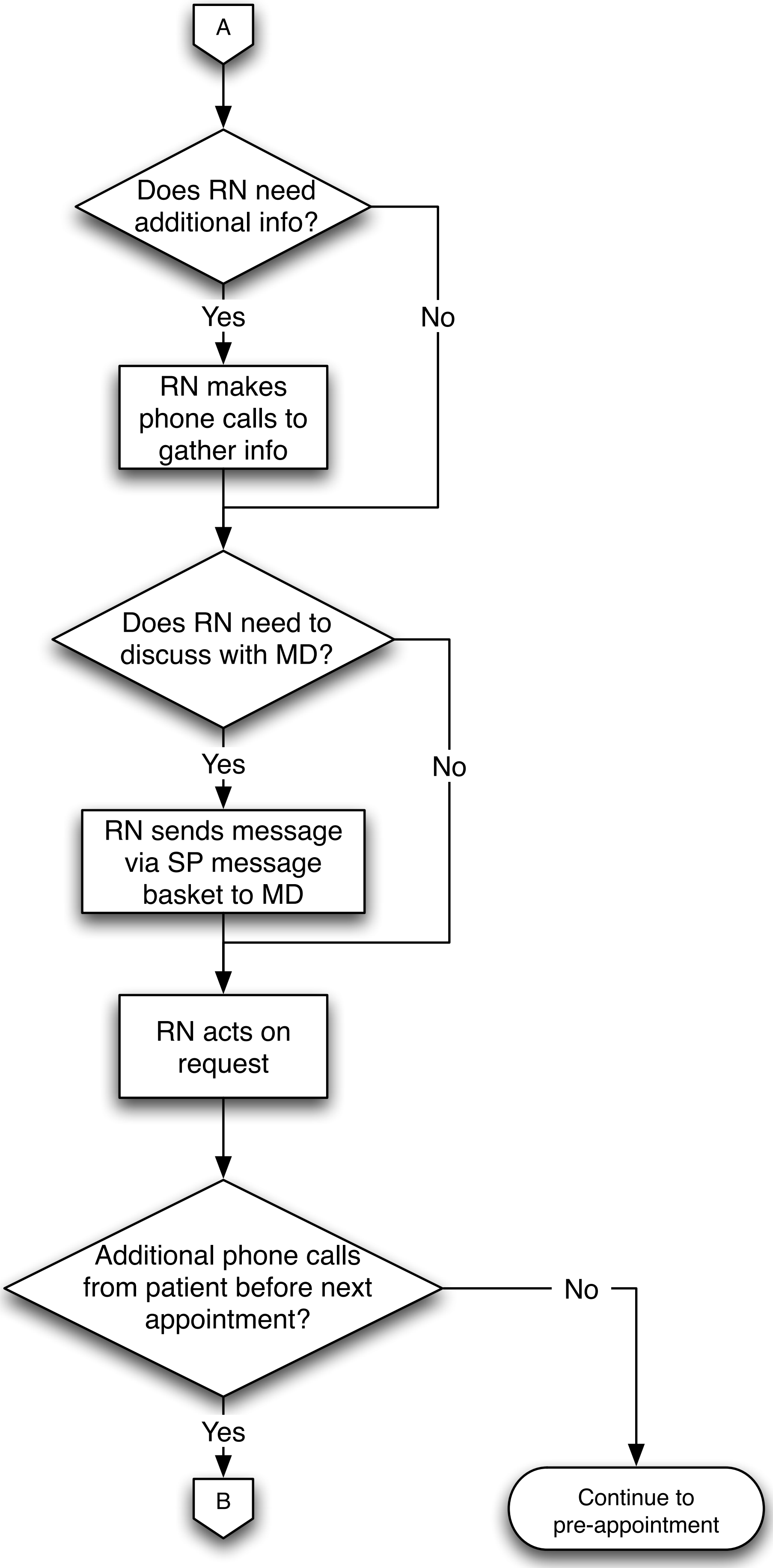


Follow-up Appointment



Post-appointment

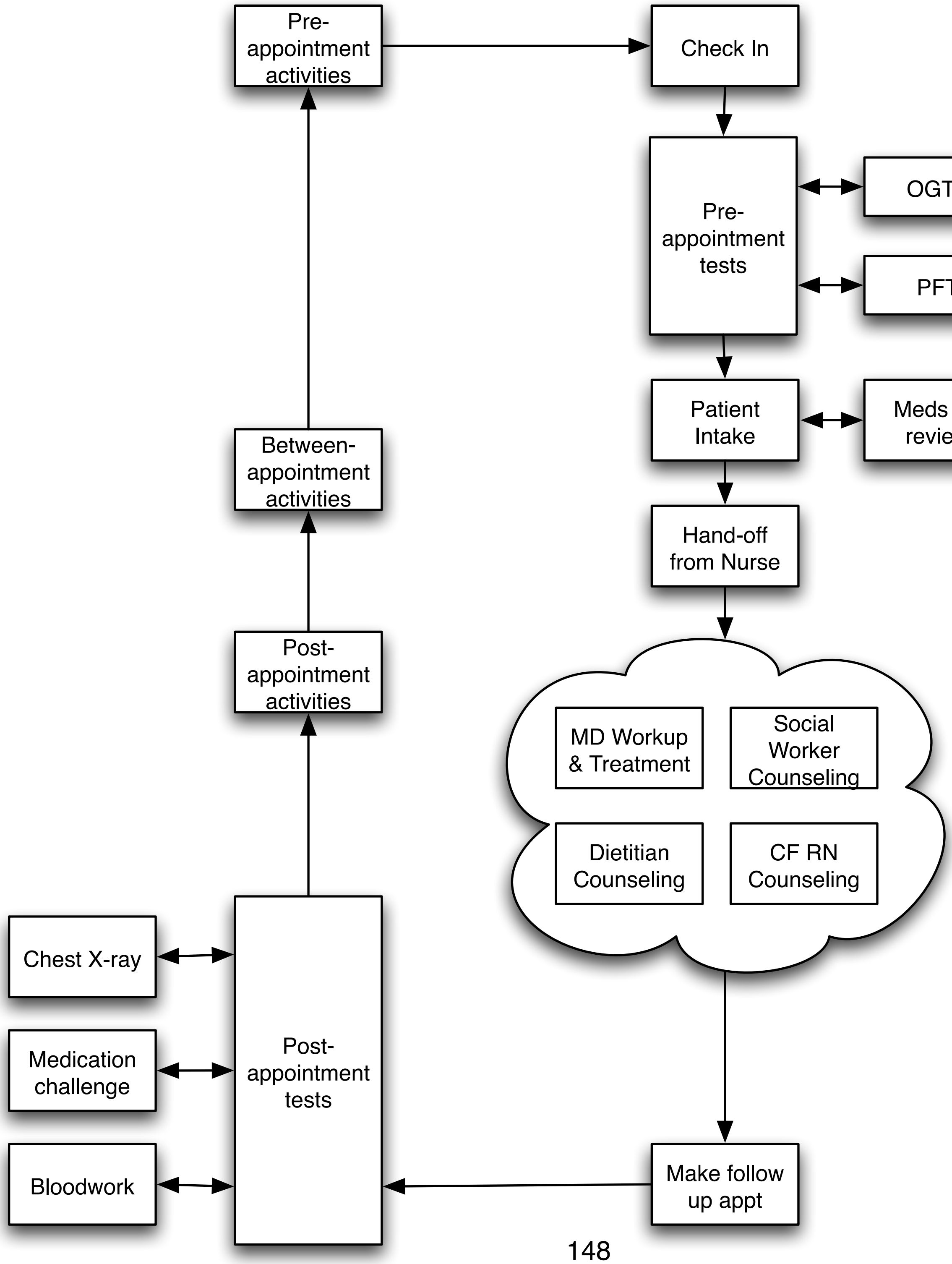



A
Does RN need additional info?
Yes
No
RN makes phone calls to gather info
Does RN need to discuss with MD?
Yes
No
RN sends message via SP message basket to MD
RN acts on request
Additional phone calls from patient before next appointment?
No
Yes
B
Continue to pre-appointment

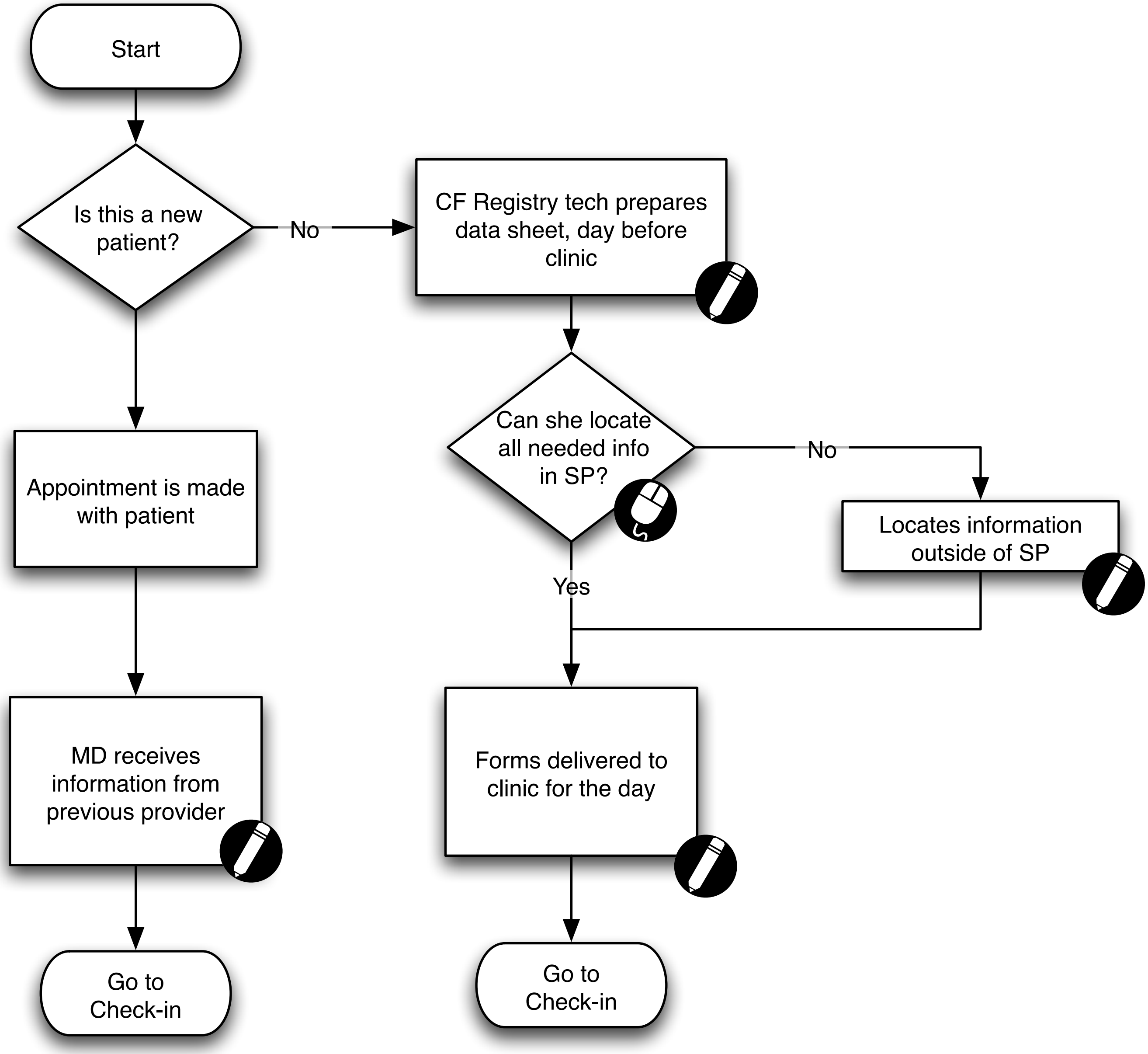
APPENDIX C

WORKFLOW IN CF CLINIC

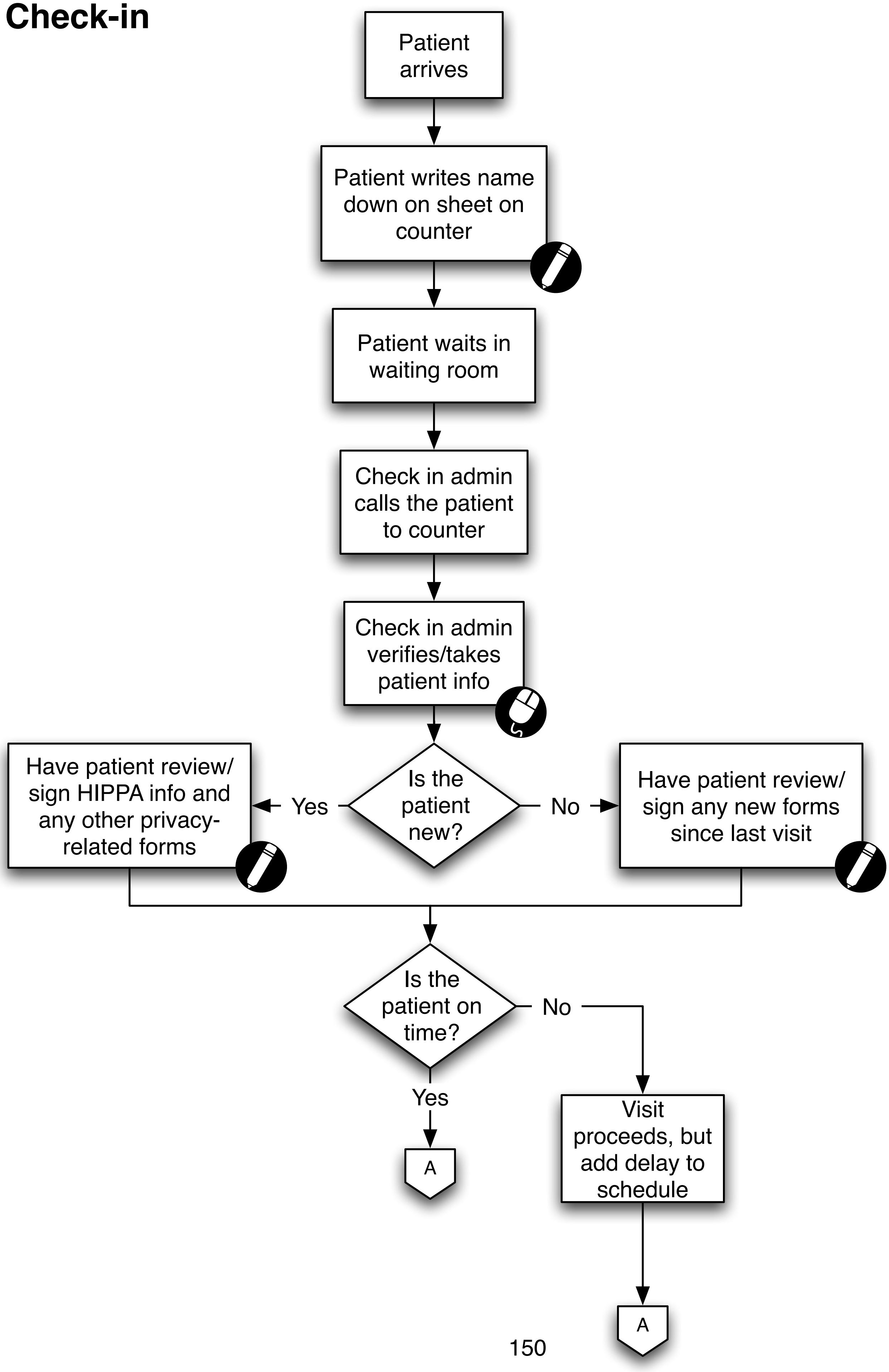
Overview

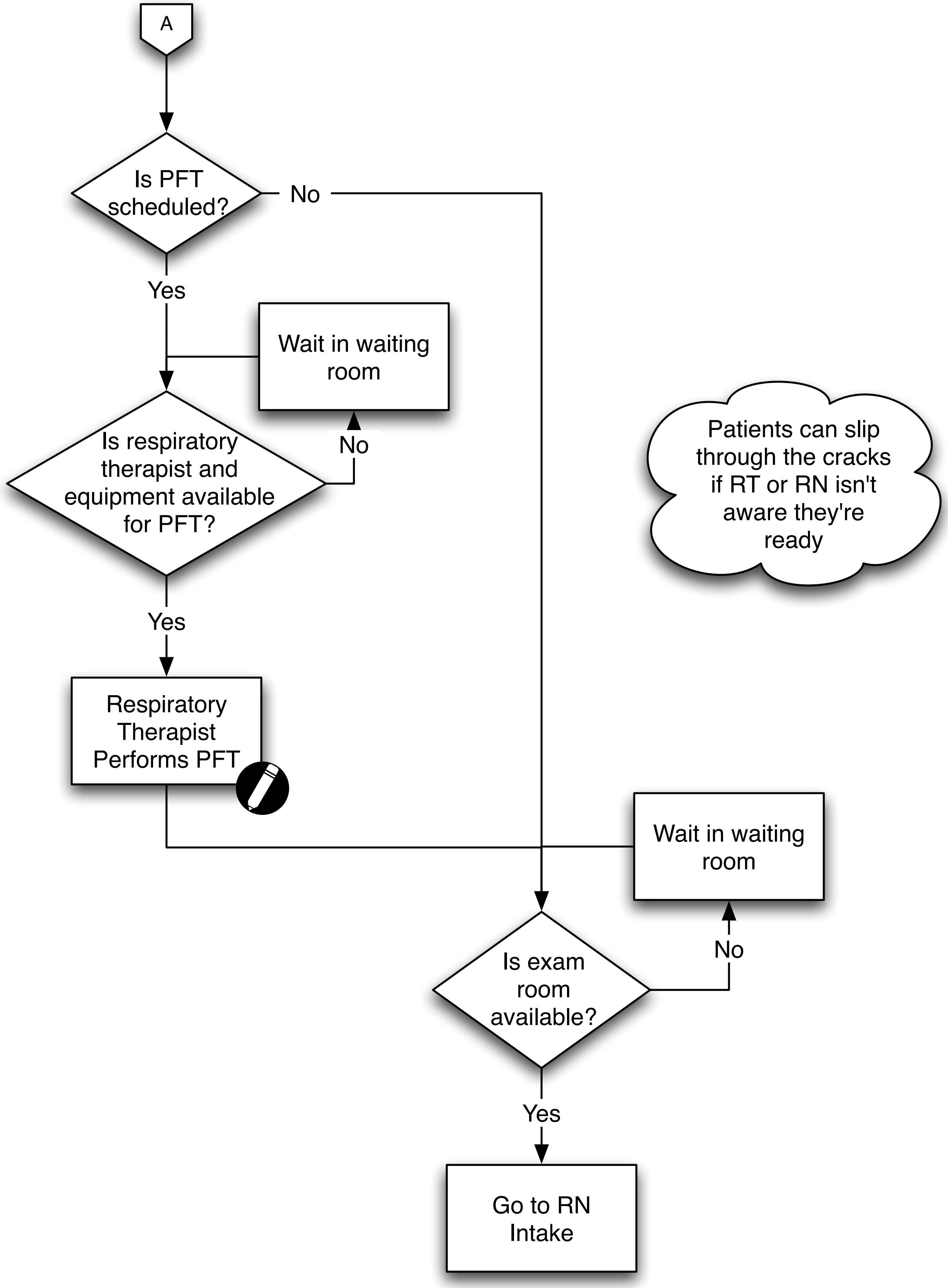


Pre-appointment

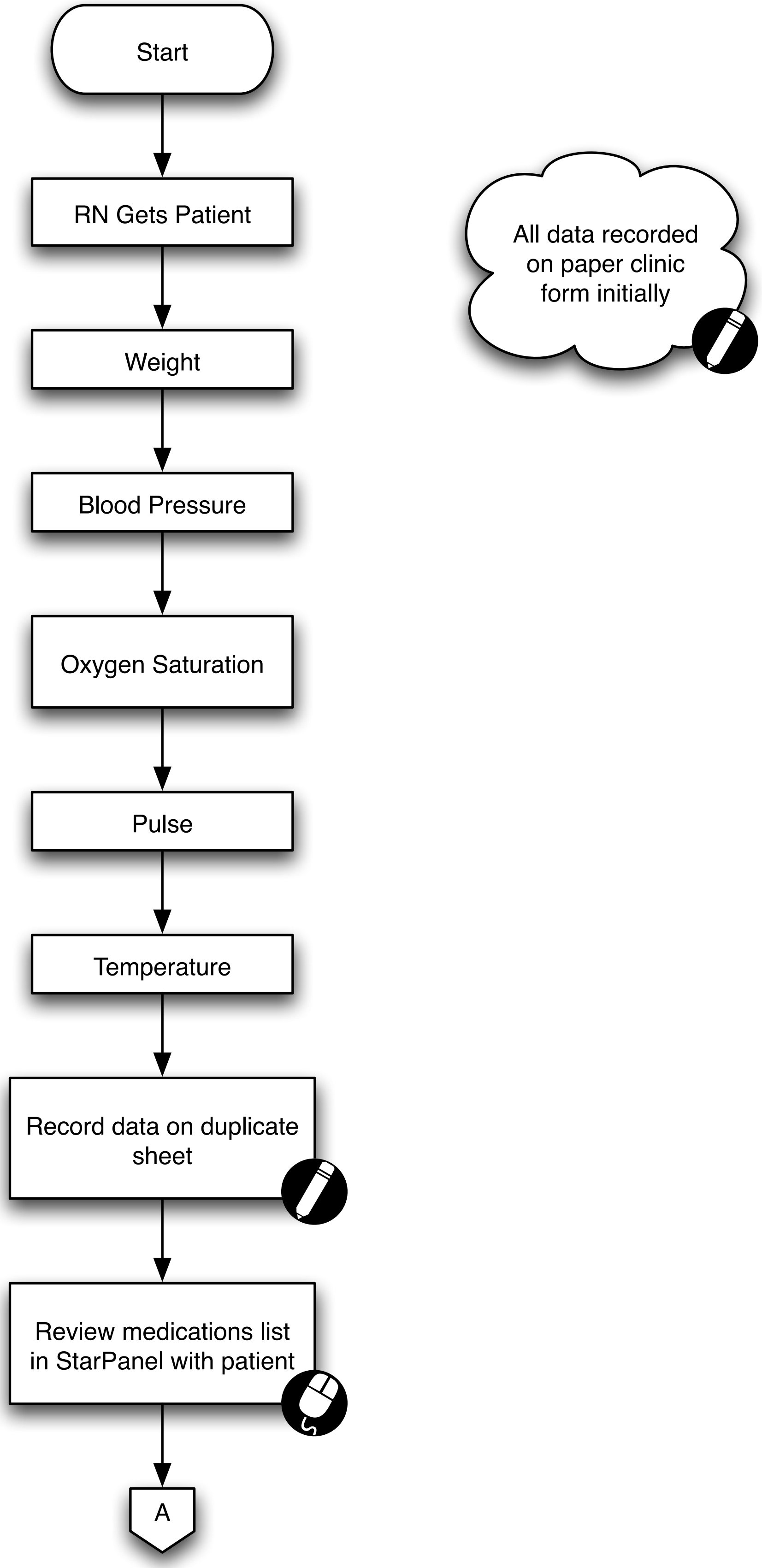


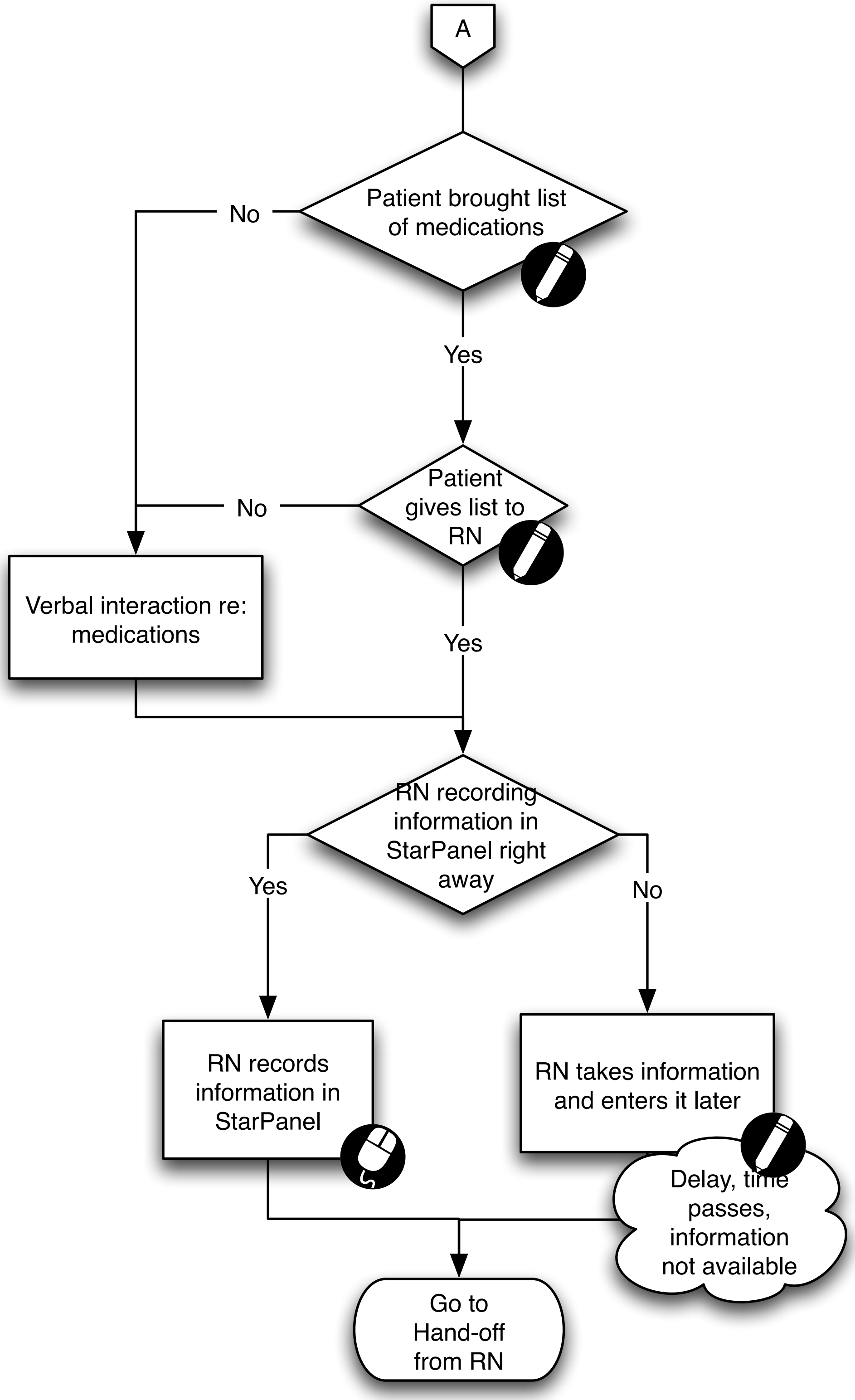
Check-in


Patient arrives
Patient writes name down on sheet on counter
Patient waits in waiting room
Check in admin calls the patient to counter
Check in admin verifies/takes patient info
Is the patient new?
Yes
Have patient review/ sign HIPPA info and any other privacy-related forms
No
Have patient review/ sign any new forms since last visit
Is the patient on time?
No
Visit proceeds, but add delay to schedule
Yes
A
A

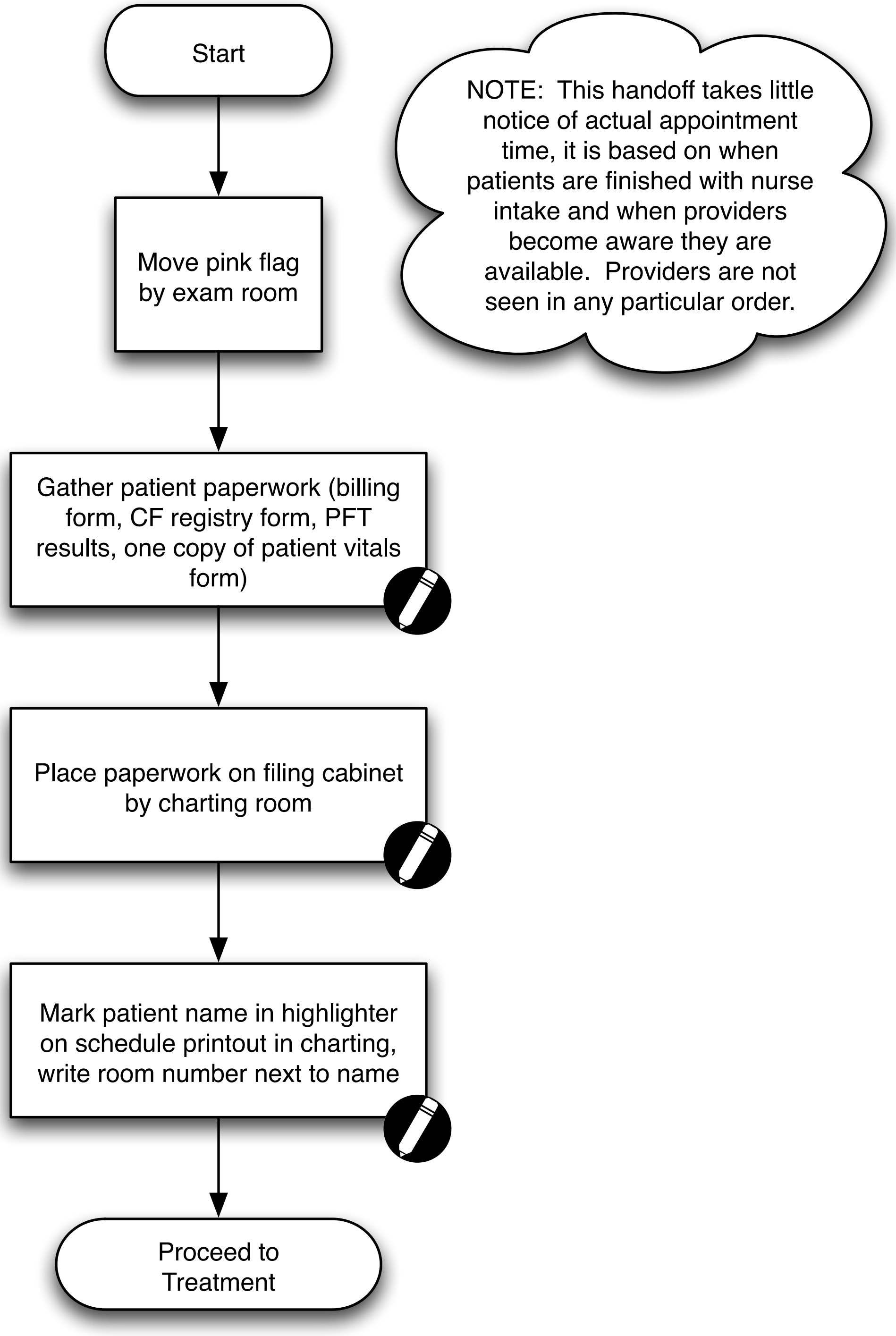

A
Is PFT scheduled?
No
Yes
Wait in waiting room
Is respiratory therapist and equipment available for PFT?
No
Yes
Respiratory Therapist Performs PFT
Patients can slip through the cracks if RT or RN isn't aware they're ready
Wait in waiting room
Is exam room available?
No
Yes
Go to RN Intake

RN Intake


Start
RN Gets Patient
All data recorded on paper clinic form initially
Weight
Blood Pressure
Oxygen Saturation
Pulse
Temperature
Record data on duplicate sheet
Review medications list in StarPanel with patient
A

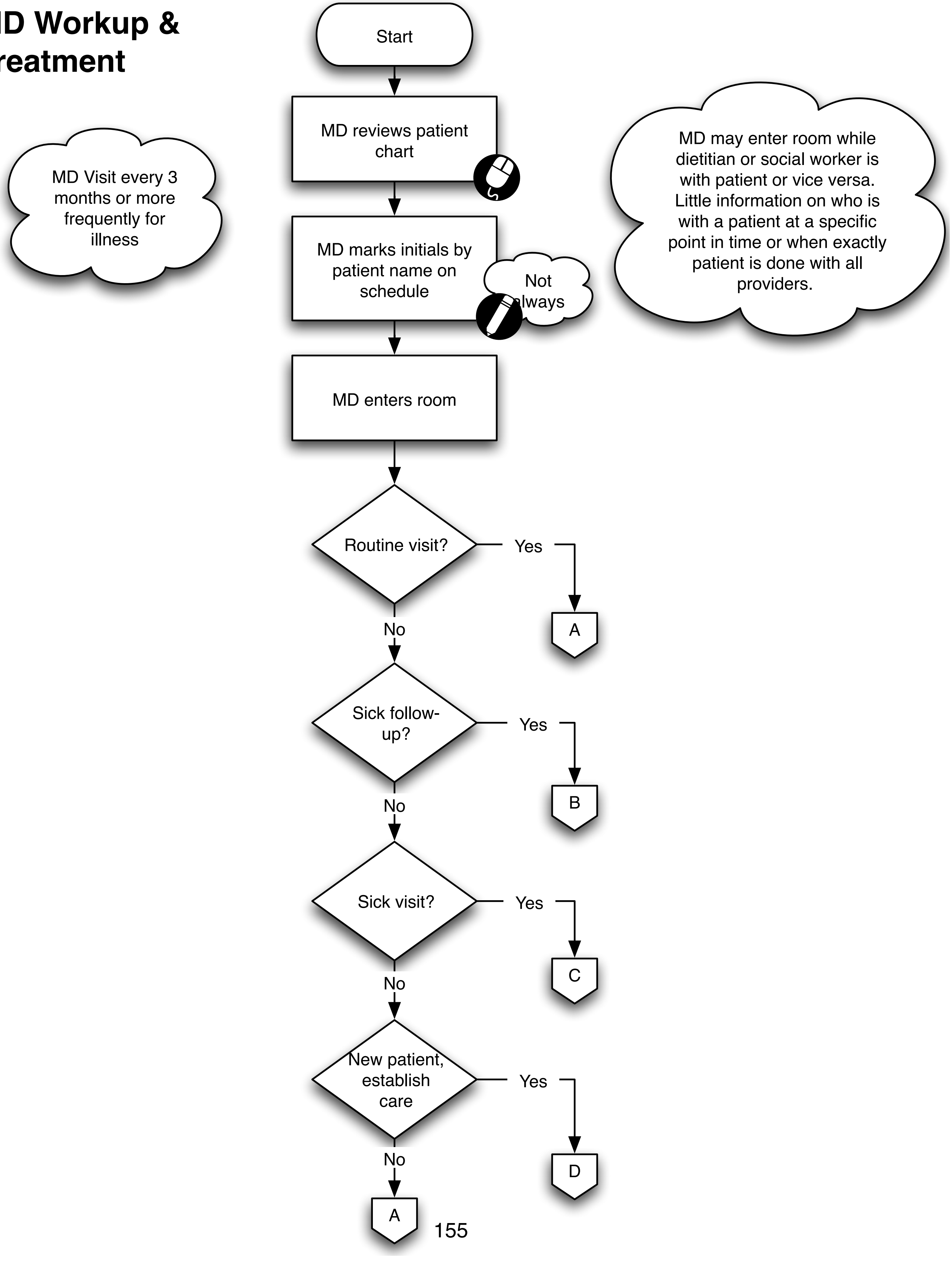

A
Patient brought list of medications
No
Yes
Patient gives list to RN
No
Yes
Verbal interaction re: medications
RN recording information in StarPanel right away
Yes
No
RN records information in StarPanel
RN takes information and enters it later
Delay, time passes, information not available
Go to Hand-off from RN

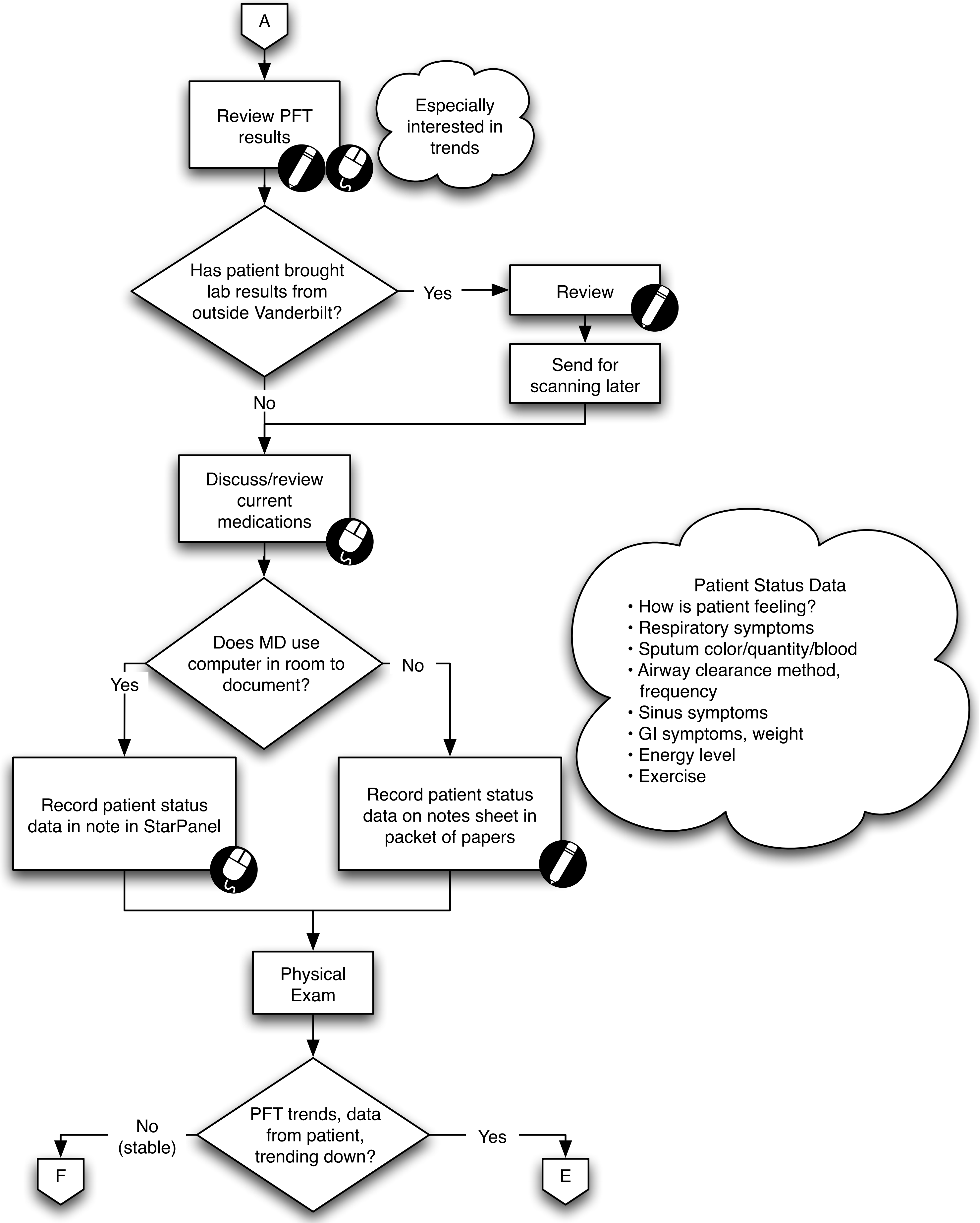
Hand-off from RN

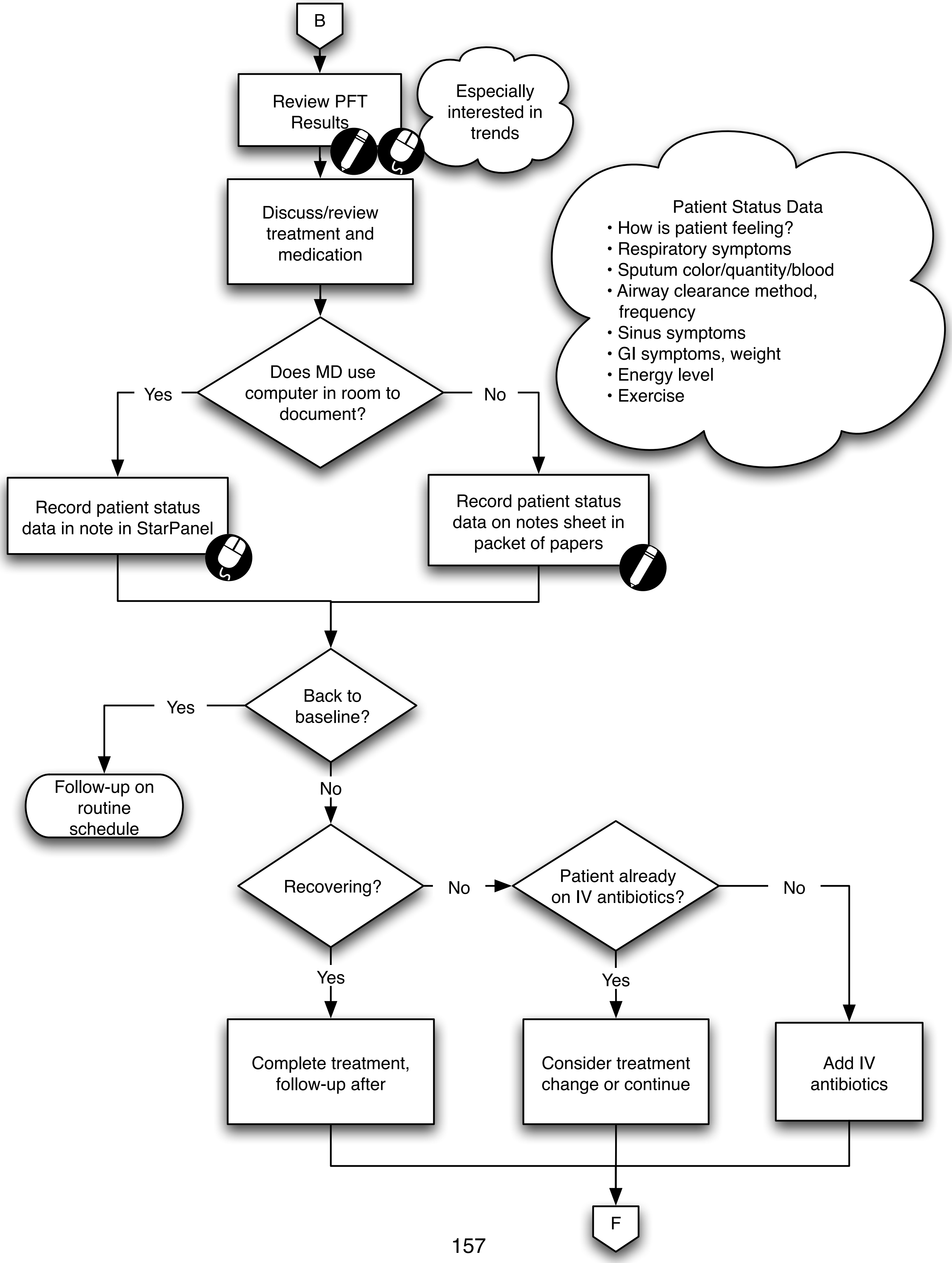


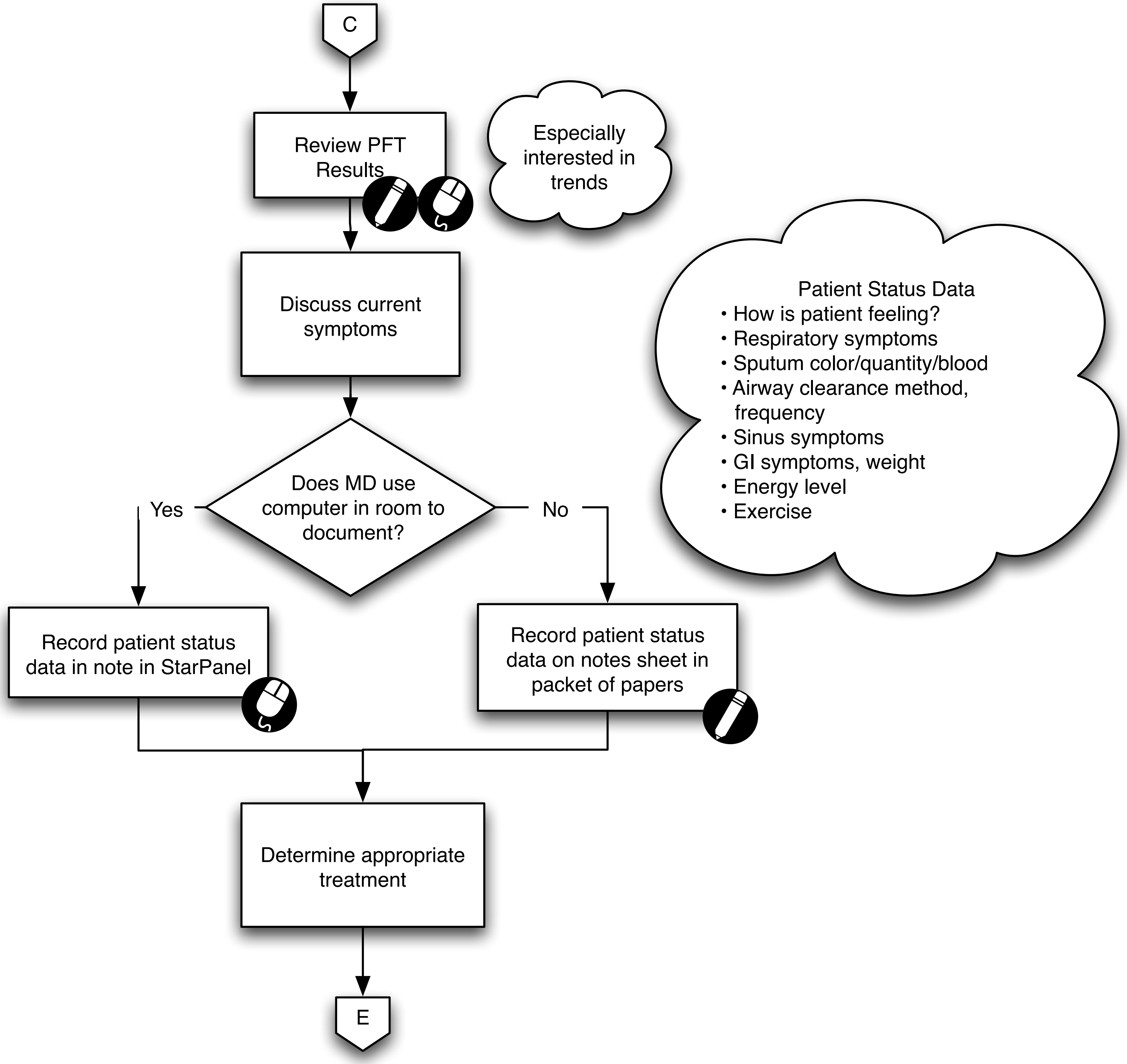
NOTE: This handoff takes little notice of actual appointment time, it is based on when patients are finished with nurse intake and when providers become aware they are available. Providers are not seen in any particular order.

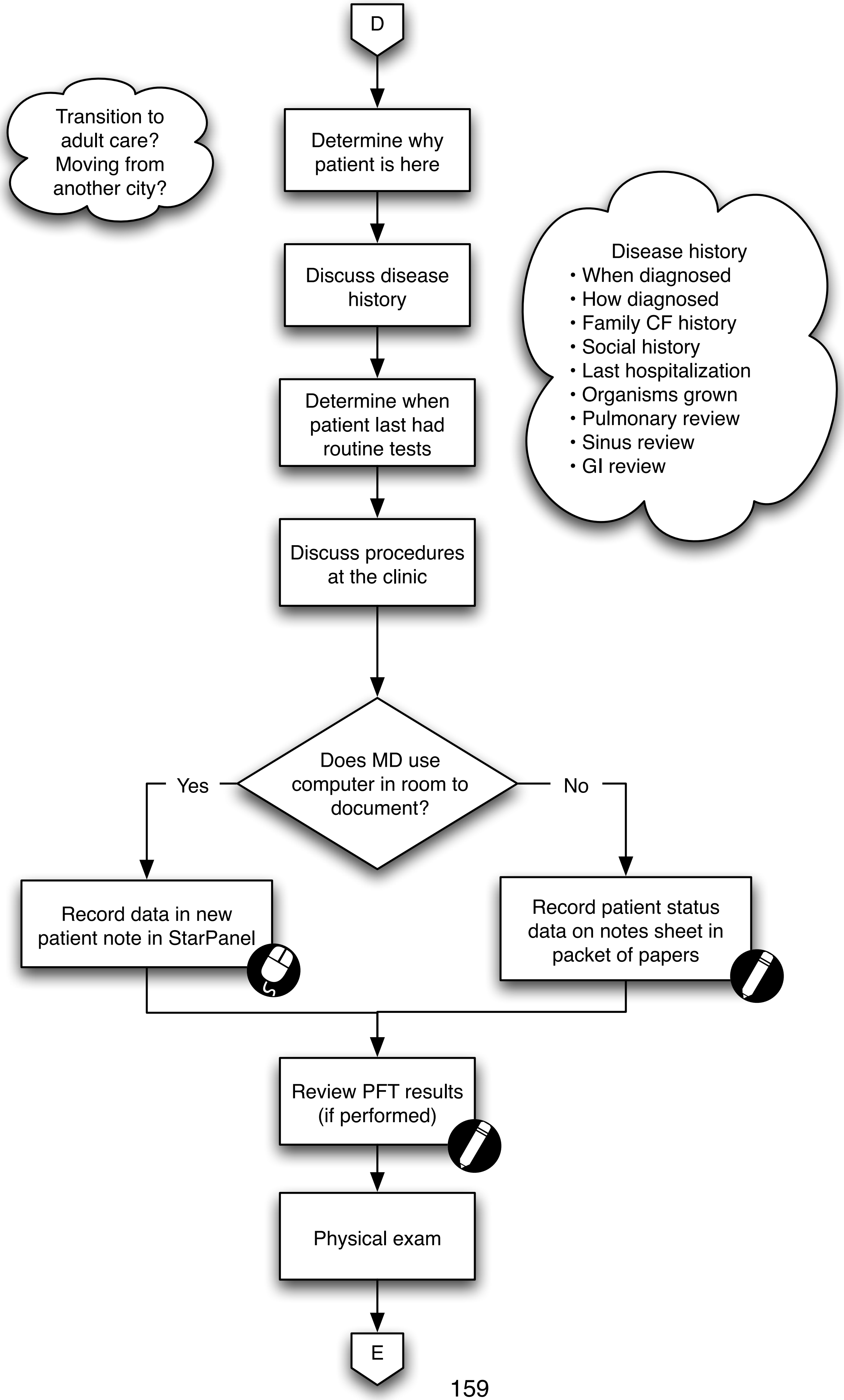
MD Workup & Treatment

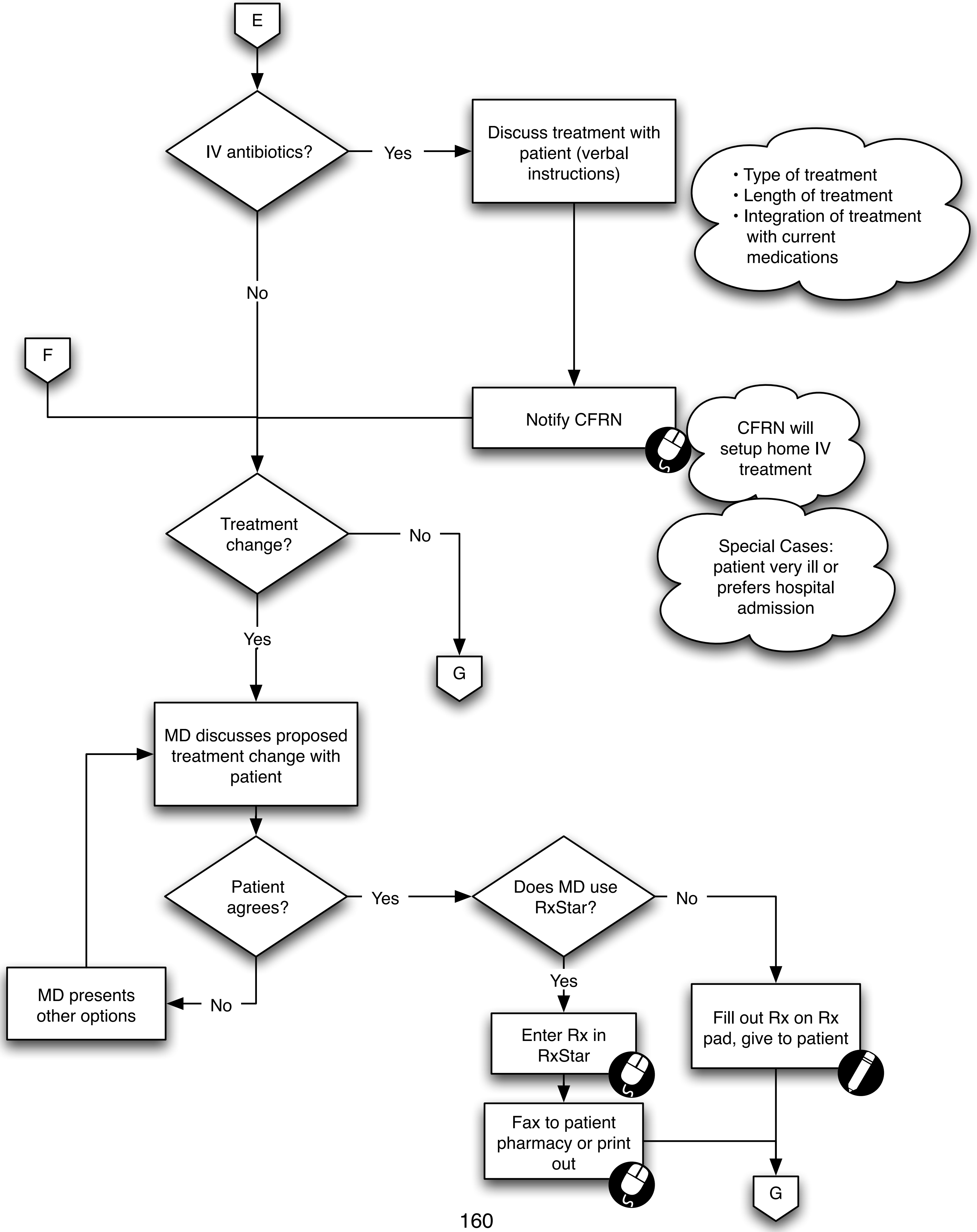


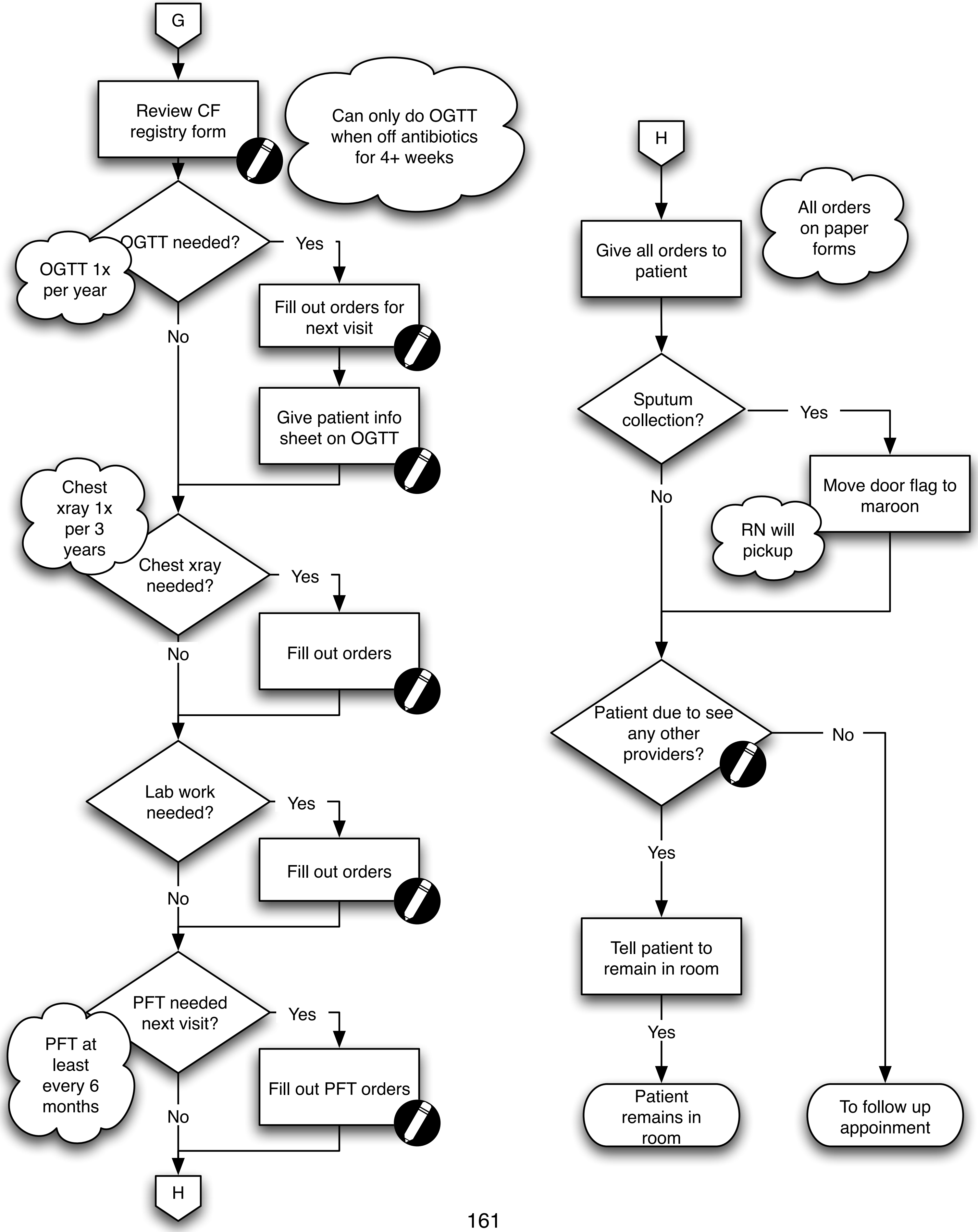

A
Review PFT results
Especially interested in trends
Has patient brought lab results from outside Vanderbilt?
Yes
Review
Send for scanning later
No
Discuss/review current medications
Does MD use computer in room to document?
Yes
No
Record patient status data in note in StarPanel
Record patient status data on notes sheet in packet of papers
Patient Status Data
• How is patient feeling?
• Respiratory symptoms
• Sputum color/quantity/blood
• Airway clearance method, frequency
• Sinus symptoms
• GI symptoms, weight
• Energy level
• Exercise
Physical Exam
PFT trends, data from patient, trending down?
No (stable)
Yes
F
E

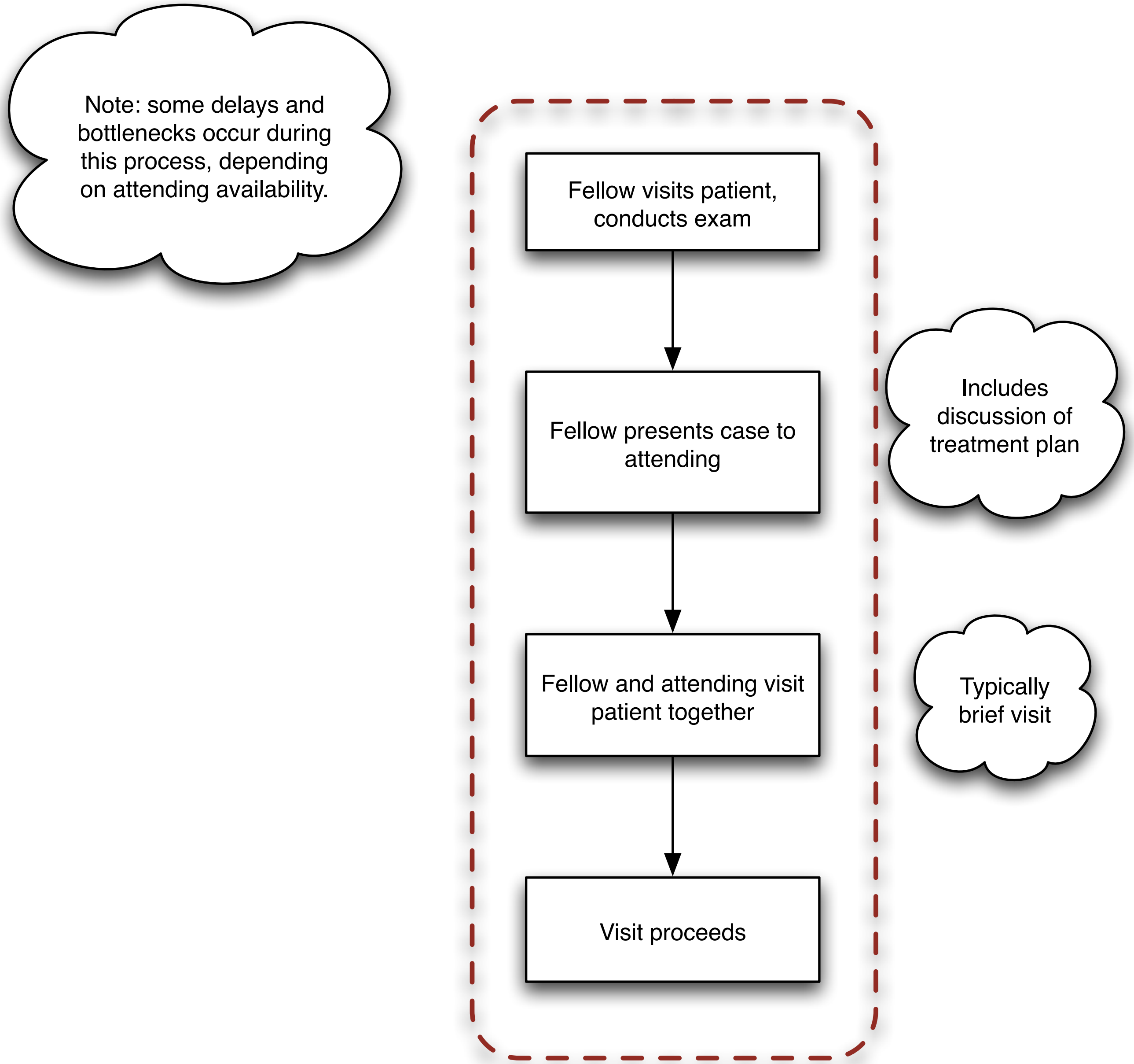

B
Review PFT Results
Especially interested in trends
Discuss/review treatment and medication
Patient Status Data
• How is patient feeling?
• Respiratory symptoms
• Sputum color/quantity/blood
• Airway clearance method, frequency
• Sinus symptoms
• GI symptoms, weight
• Energy level
• Exercise
Does MD use computer in room to document?
Yes
No
Record patient status data in note in StarPanel
Record patient status data on notes sheet in packet of papers
Back to baseline?
Yes
Follow-up on routine schedule
No
Recovering?
No
Patient already on IV antibiotics?
No
Yes
Yes
Complete treatment, follow-up after
Consider treatment change or continue
Add IV antibiotics
F


C
Review PFT Results
Especially interested in trends
Discuss current symptoms
Patient Status Data
• How is patient feeling?
• Respiratory symptoms
• Sputum color/quantity/blood
• Airway clearance method, frequency
• Sinus symptoms
• GI symptoms, weight
• Energy level
• Exercise
Does MD use computer in room to document?
Yes
No
Record patient status data in note in StarPanel
Record patient status data on notes sheet in packet of papers
Determine appropriate treatment
E

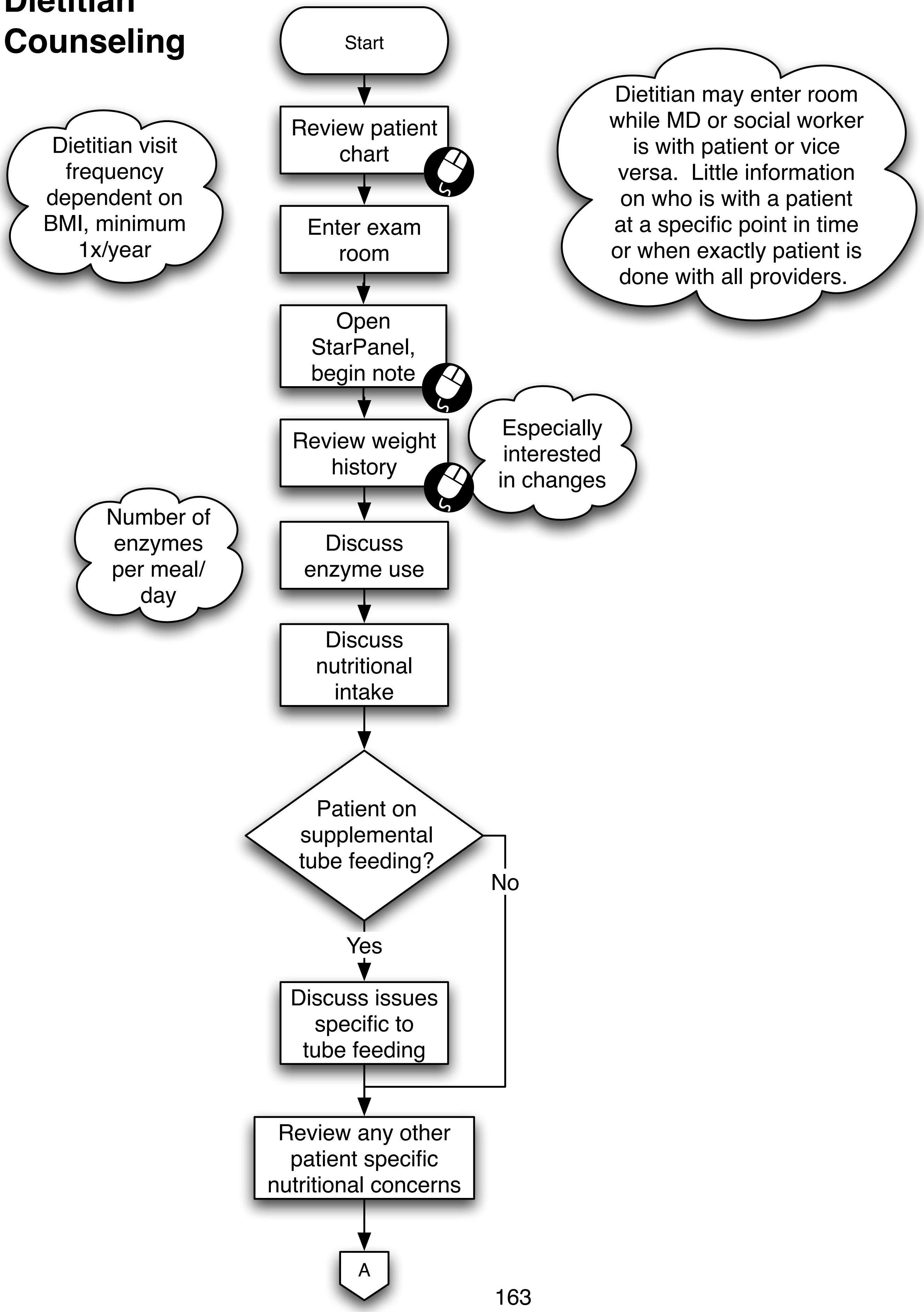

D
Transition to adult care? Moving from another city?
Determine why patient is here
Discuss disease history
Disease history
• When diagnosed
• How diagnosed
• Family CF history
• Social history
• Last hospitalization
• Organisms grown
• Pulmonary review
• Sinus review
• GI review
Determine when patient last had routine tests
Discuss procedures at the clinic
Does MD use computer in room to document?
Yes
No
Record data in new patient note in StarPanel
Record patient status data on notes sheet in packet of papers
Review PFT results (if performed)
Physical exam
E

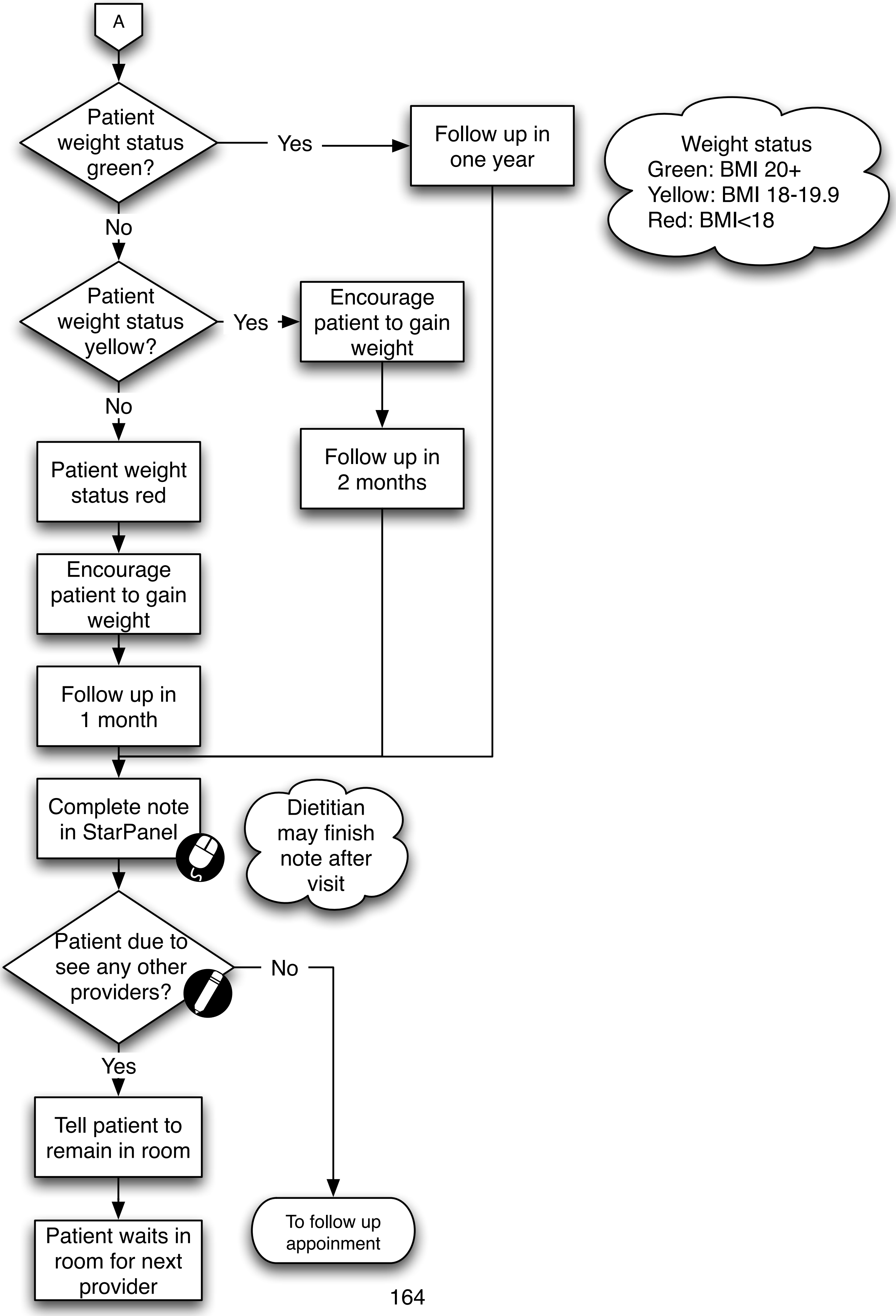

E
IV antibiotics?
Yes
Discuss treatment with patient (verbal instructions)
• Type of treatment
• Length of treatment
• Integration of treatment with current medications
No
F
Notify CFRN
CFRN will setup home IV treatment
Special Cases: patient very ill or prefers hospital admission
Treatment change?
No
G
Yes
MD discusses proposed treatment change with patient
Patient agrees?
Yes
Does MD use RxStar?
No
MD presents other options
No
Yes
Enter Rx in RxStar
Fill out Rx on Rx pad, give to patient
Fax to patient pharmacy or print out
G


G
Review CF registry form
Can only do OGTT when off antibiotics for 4+ weeks
OGTT needed?
OGTT 1x per year
Yes
Fill out orders for next visit
Give patient info sheet on OGTT
No
Chest xray 1x per 3 years
Chest xray needed?
Yes
Fill out orders
No
Lab work needed?
Yes
Fill out orders
No
PFT needed next visit?
PFT at least every 6 months
Yes
Fill out PFT orders
No
H
H
Give all orders to patient
All orders on paper forms
Sputum collection?
Yes
Move door flag to maroon
RN will pickup
No
Patient due to see any other providers?
No
Yes
Tell patient to remain in room
Yes
Patient remains in room
To follow up appoinment

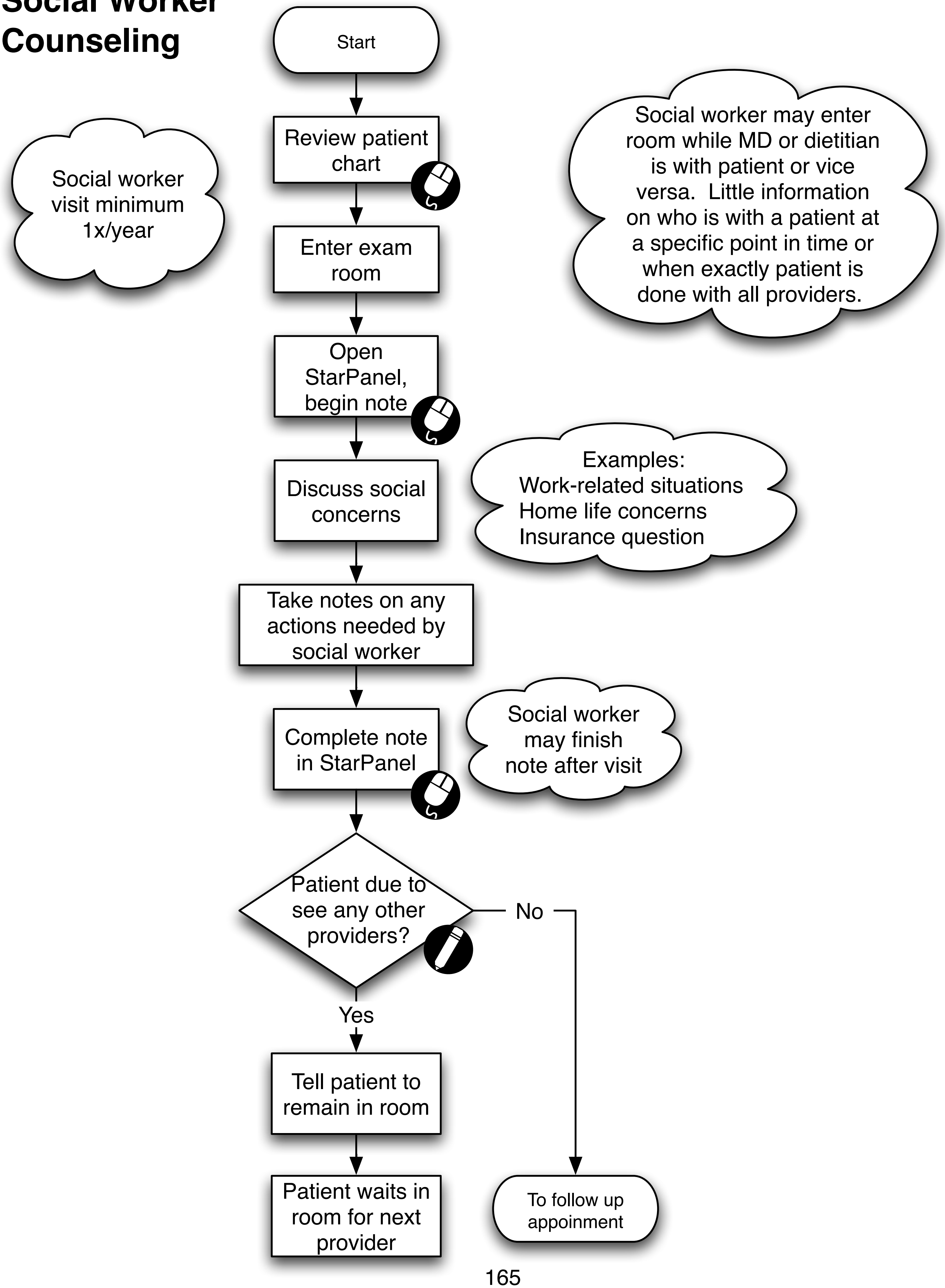

Note: some delays and bottlenecks occur during this process, depending on attending availability.
Fellow visits patient, conducts exam
Fellow presents case to attending
Includes discussion of treatment plan
Fellow and attending visit patient together
Typically brief visit
Visit proceeds

Dietitian Counseling

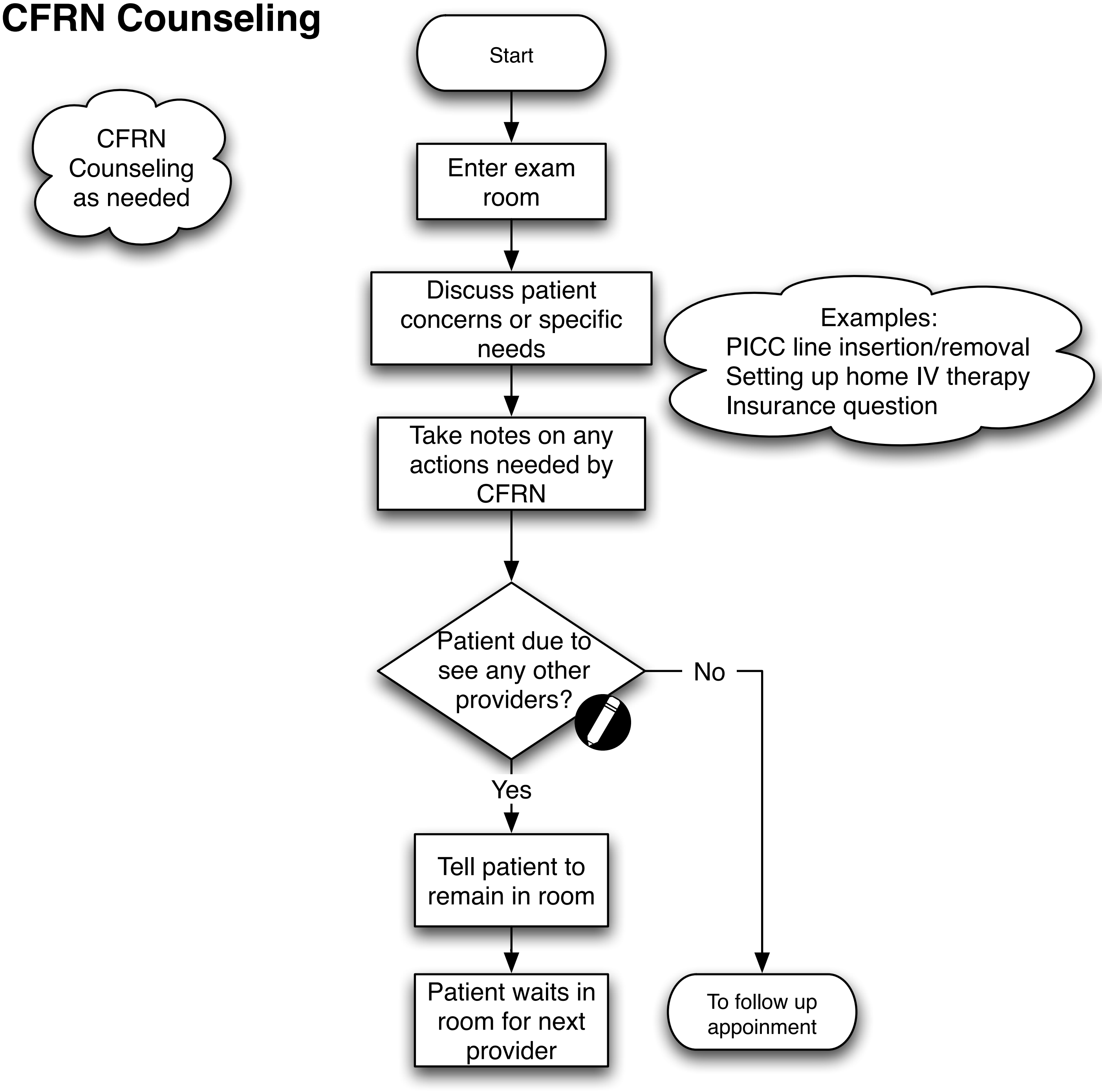



A
Patient weight status green?
Yes
Follow up in one year
Weight status
Green: BMI 20+
Yellow: BMI 18-19.9
Red: BMI<18
No
Patient weight status yellow?
Yes
Encourage patient to gain weight
Follow up in 2 months
No
Patient weight status red
Encourage patient to gain weight
Follow up in 1 month
Complete note in StarPanel
Dietitian may finish note after visit
Patient due to see any other providers?
No
Yes
Tell patient to remain in room
Patient waits in room for next provider
To follow up appoinment

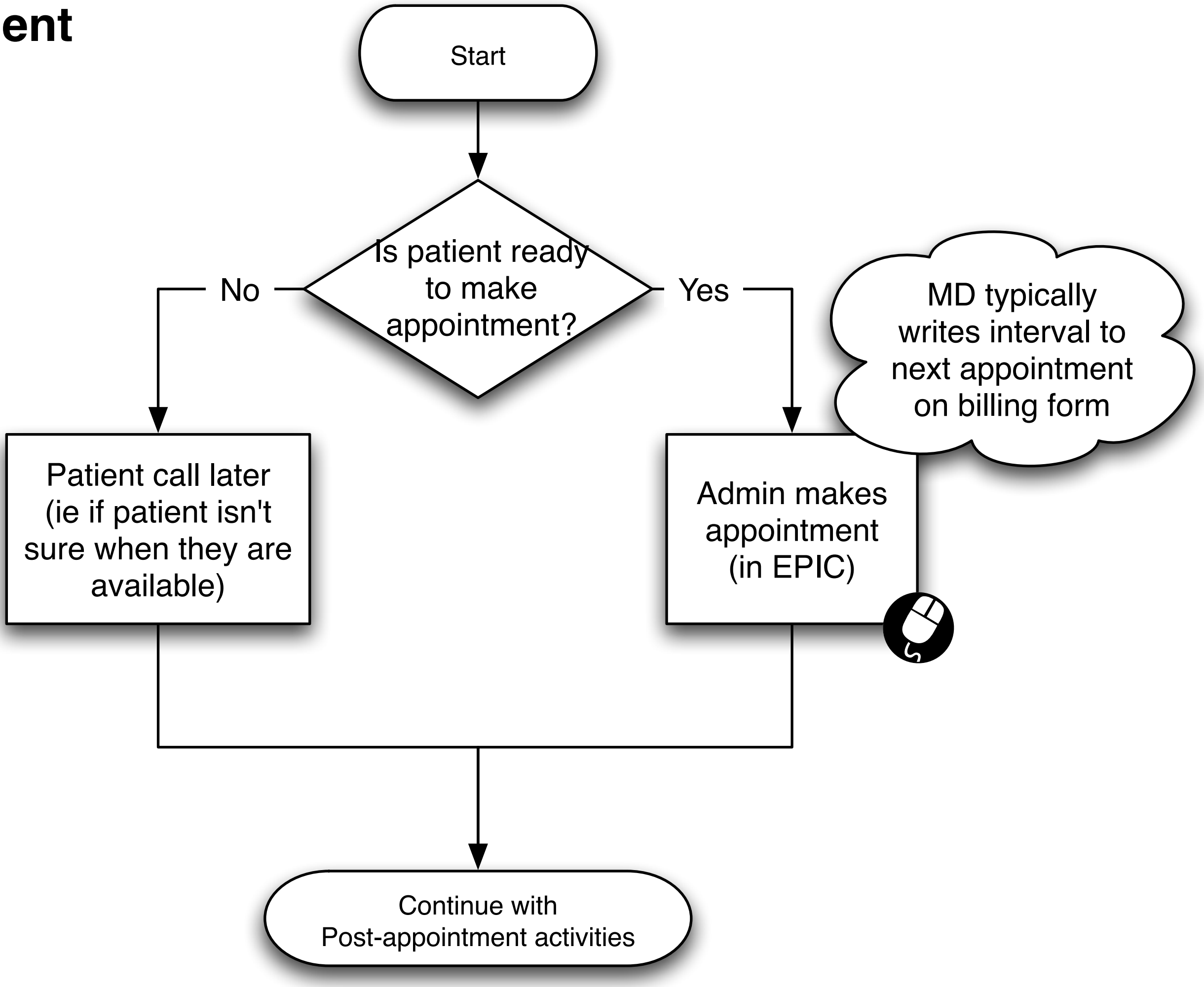
Social Worker Counseling



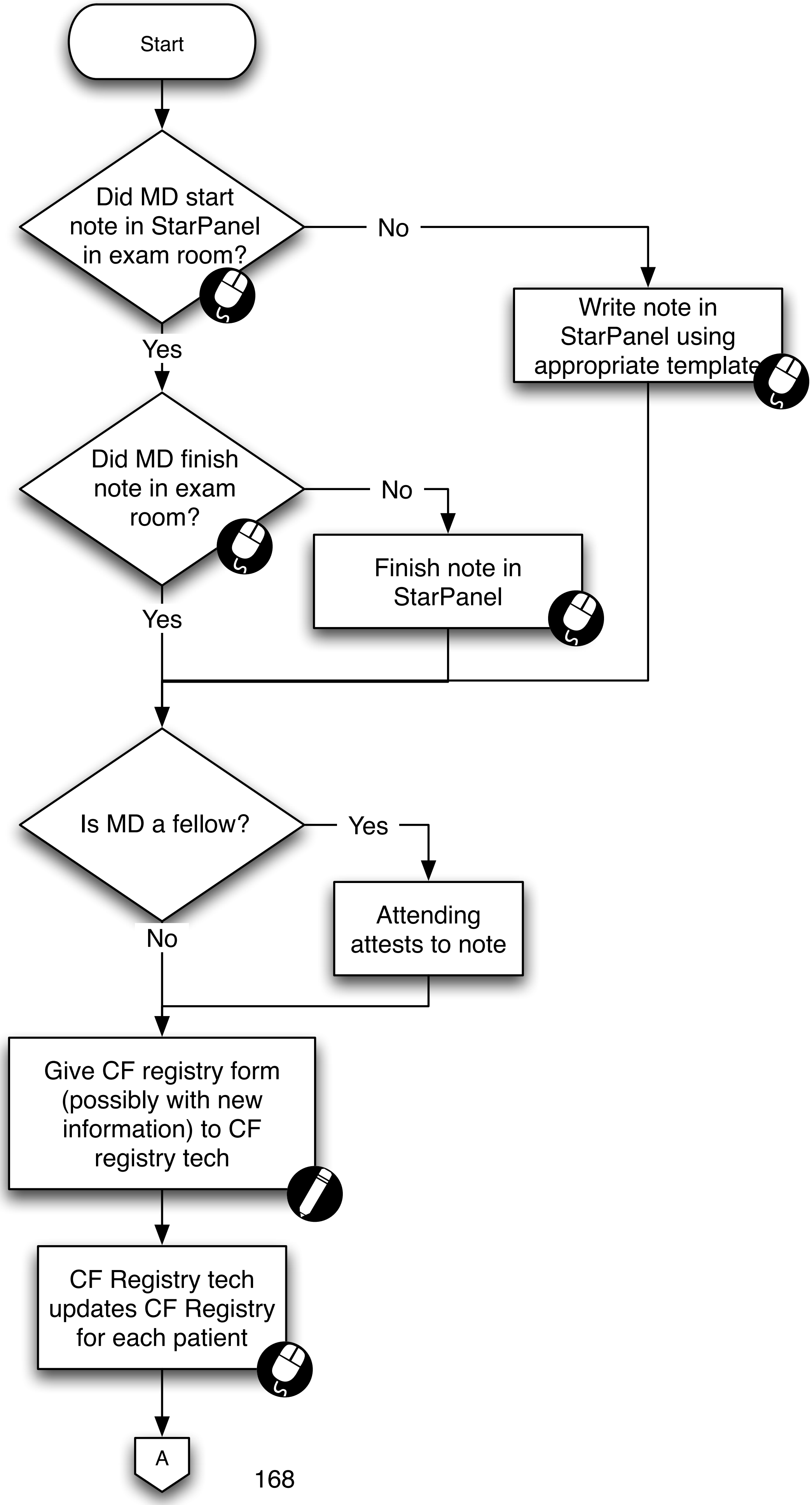
CFRN Counseling

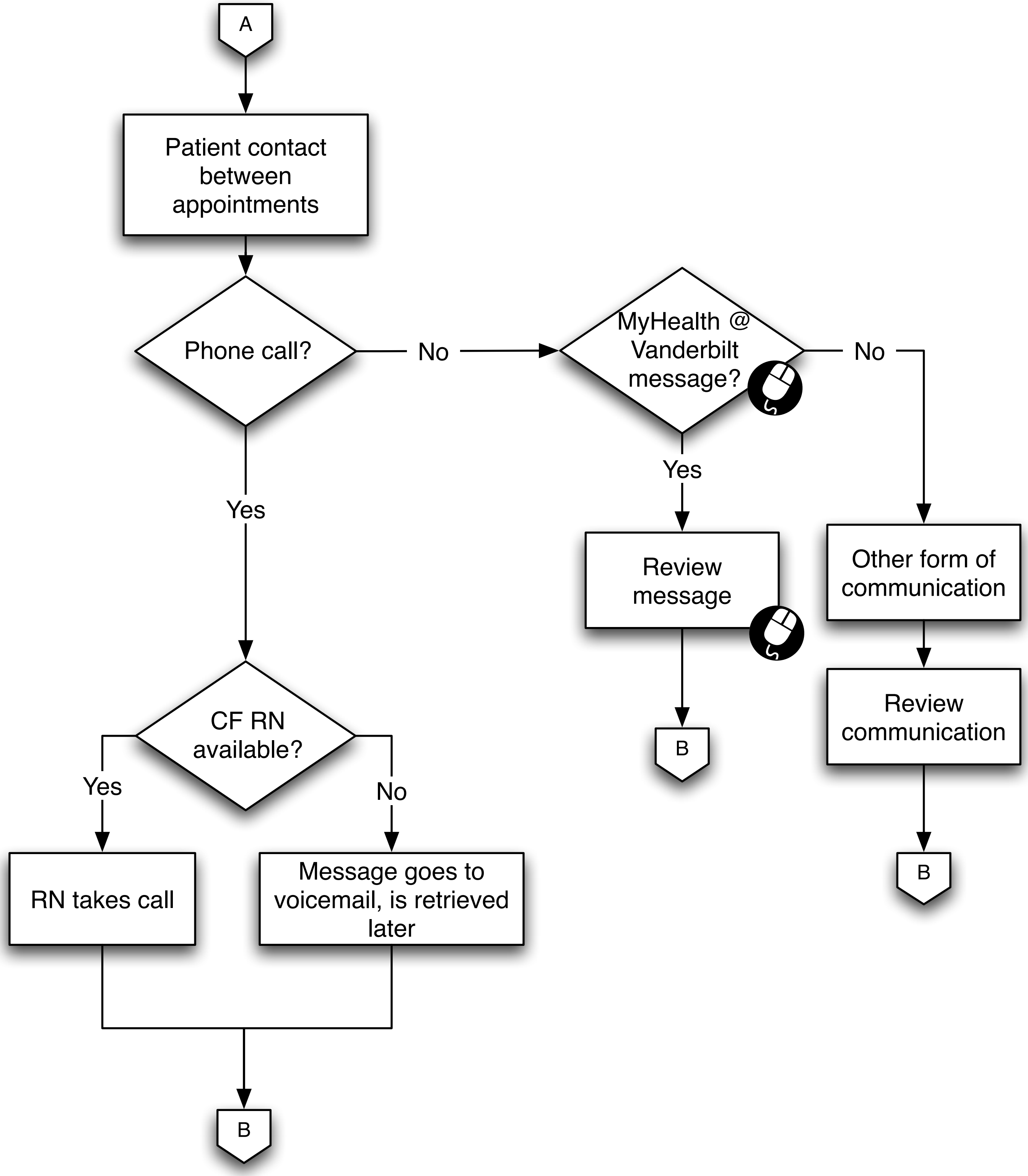


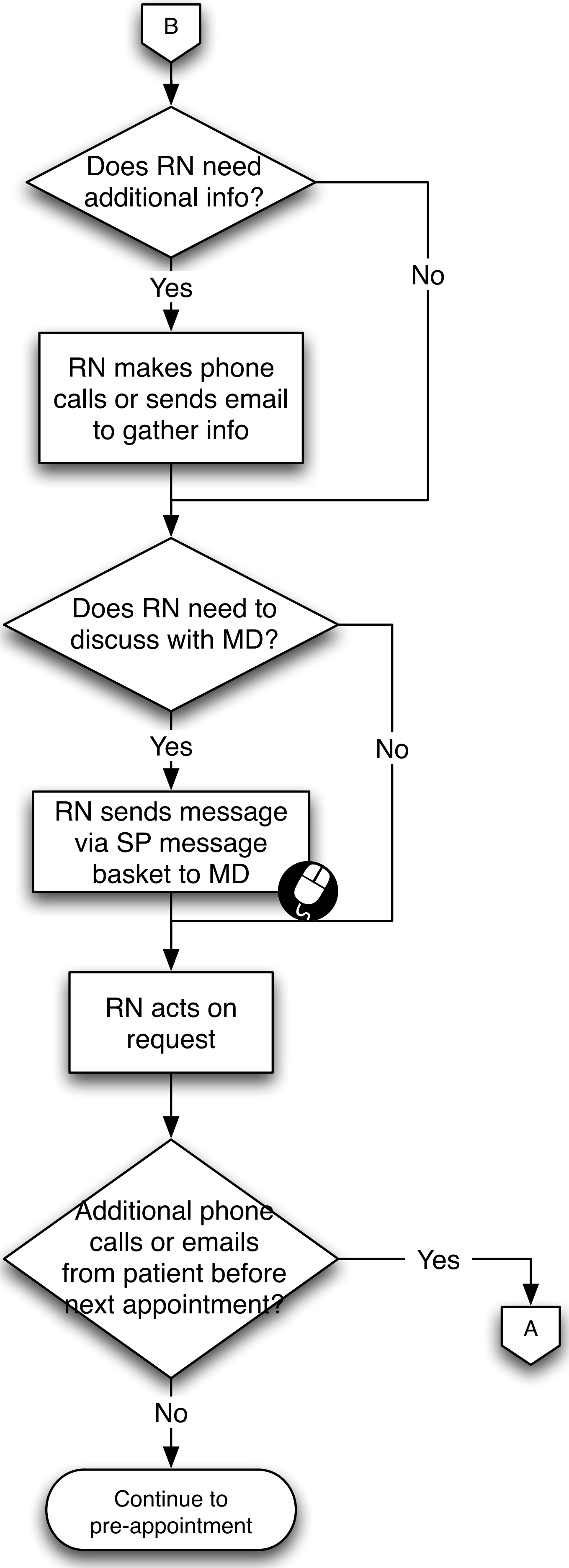
Follow-up Appointment



Post-Appointment



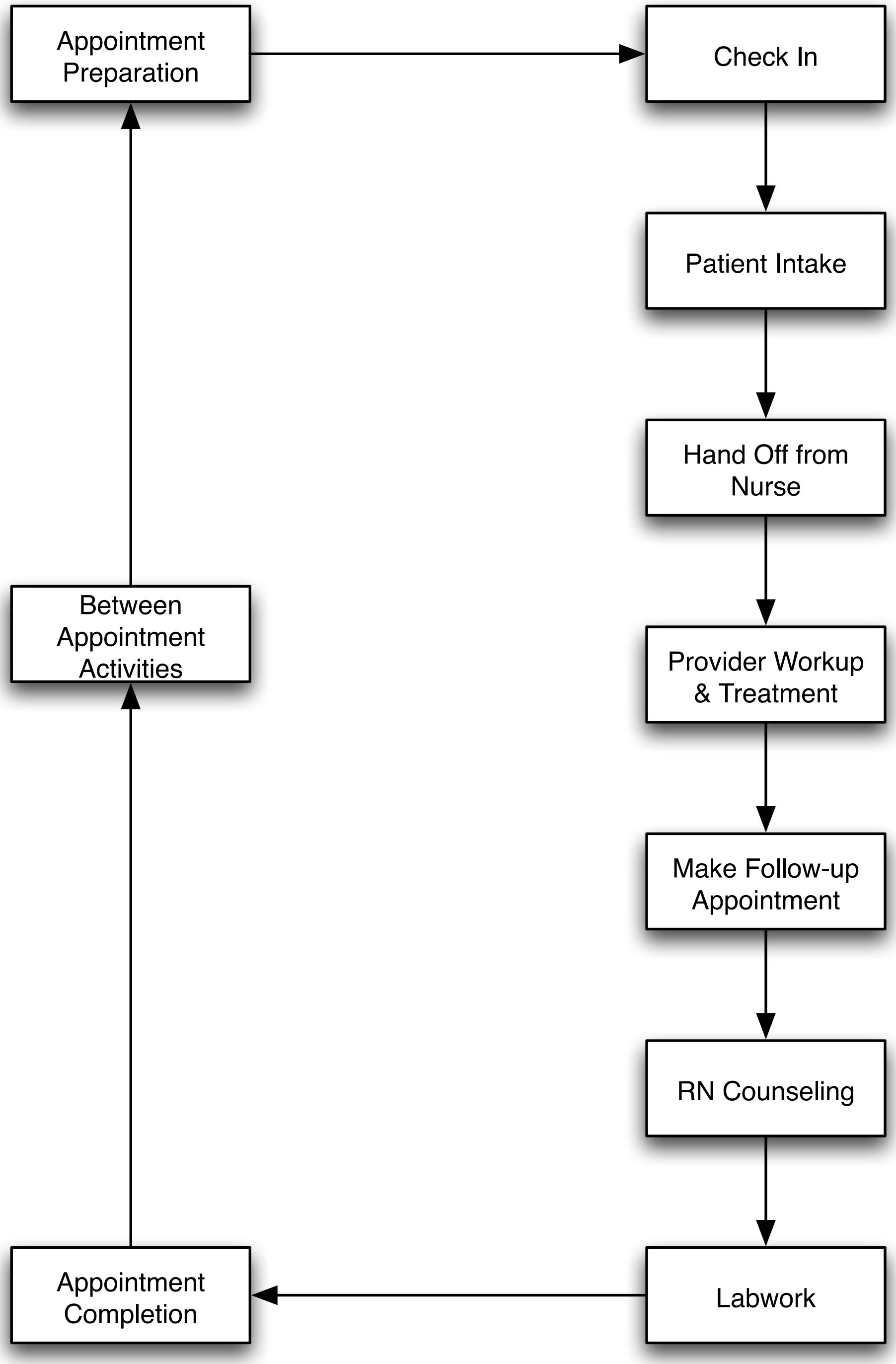

A
Patient contact between appointments
Phone call?
No
MyHealth @ Vanderbilt message?
No
Yes
Yes
Review message
Other form of communication
Review communication
B
B
CF RN available?
Yes
No
RN takes call
Message goes to voicemail, is retrieved later
B


B
Does RN need additional info?
No
Yes
RN makes phone calls or sends email to gather info
Does RN need to discuss with MD?
Yes
No
RN sends message via SP message basket to MD
RN acts on request
Additional phone calls or emails from patient before next appointment?
Yes
A
No
Continue to pre-appointment

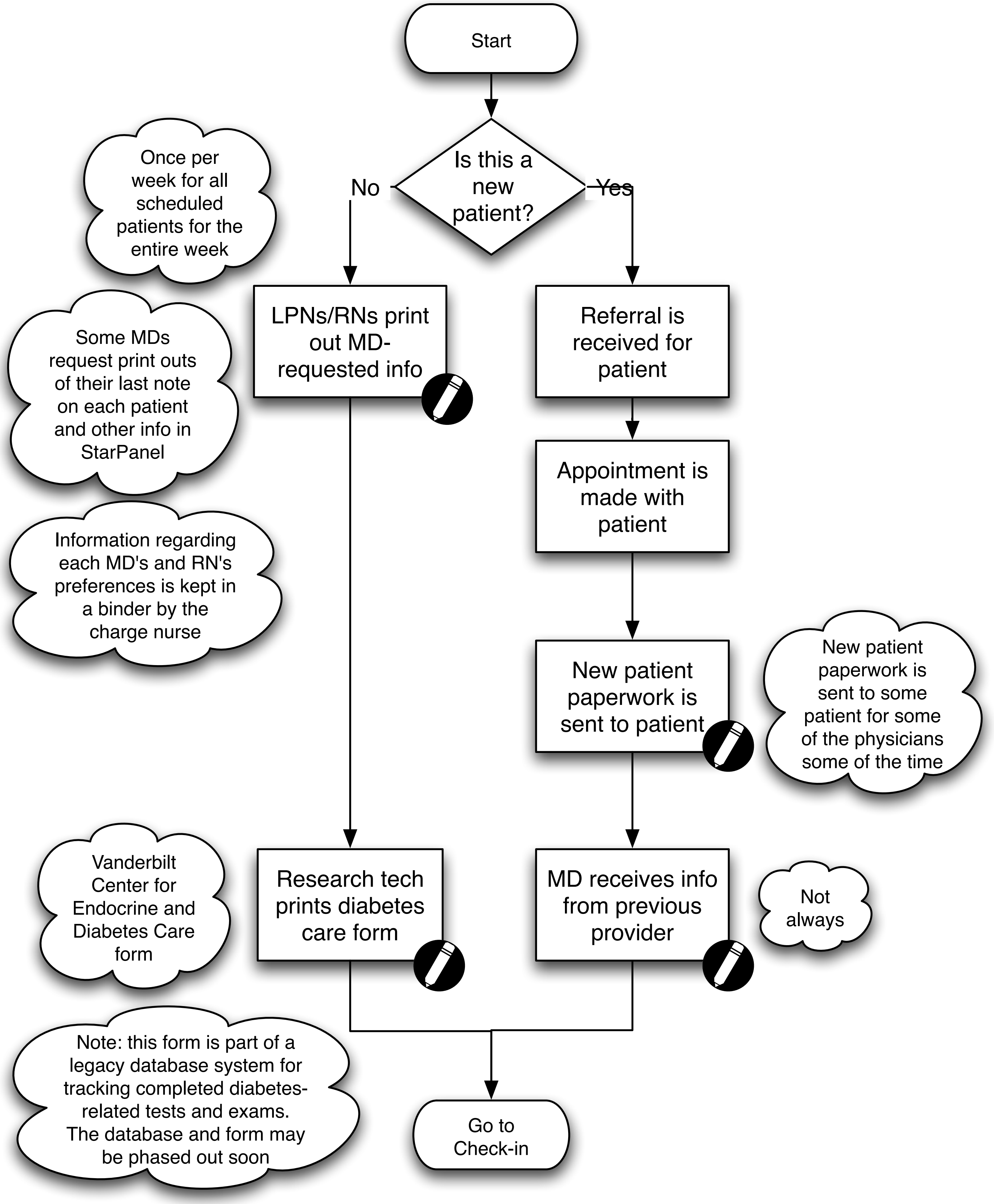
APPENDIX D

WORKFLOW IN DIABETES CLINIC

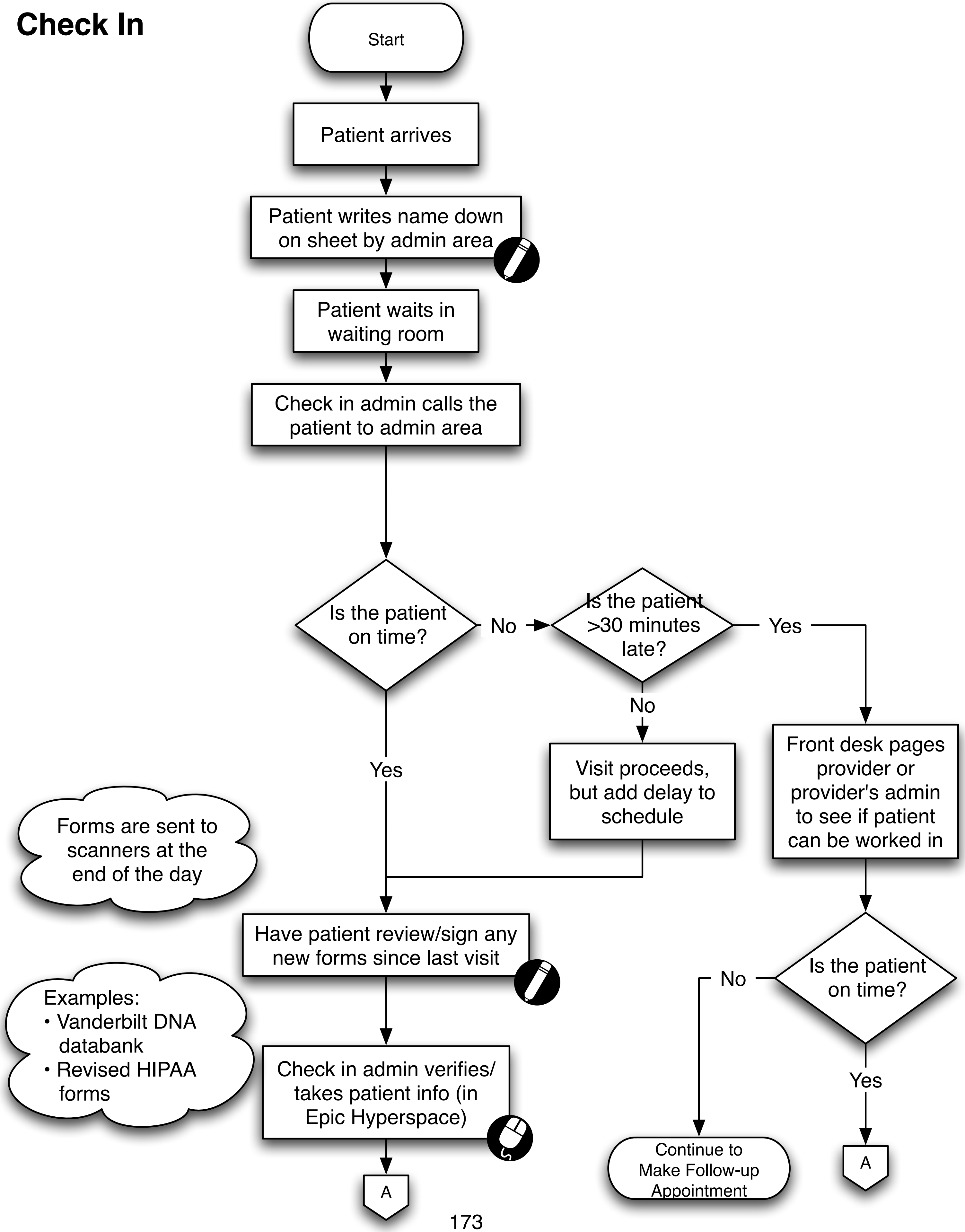
Overview



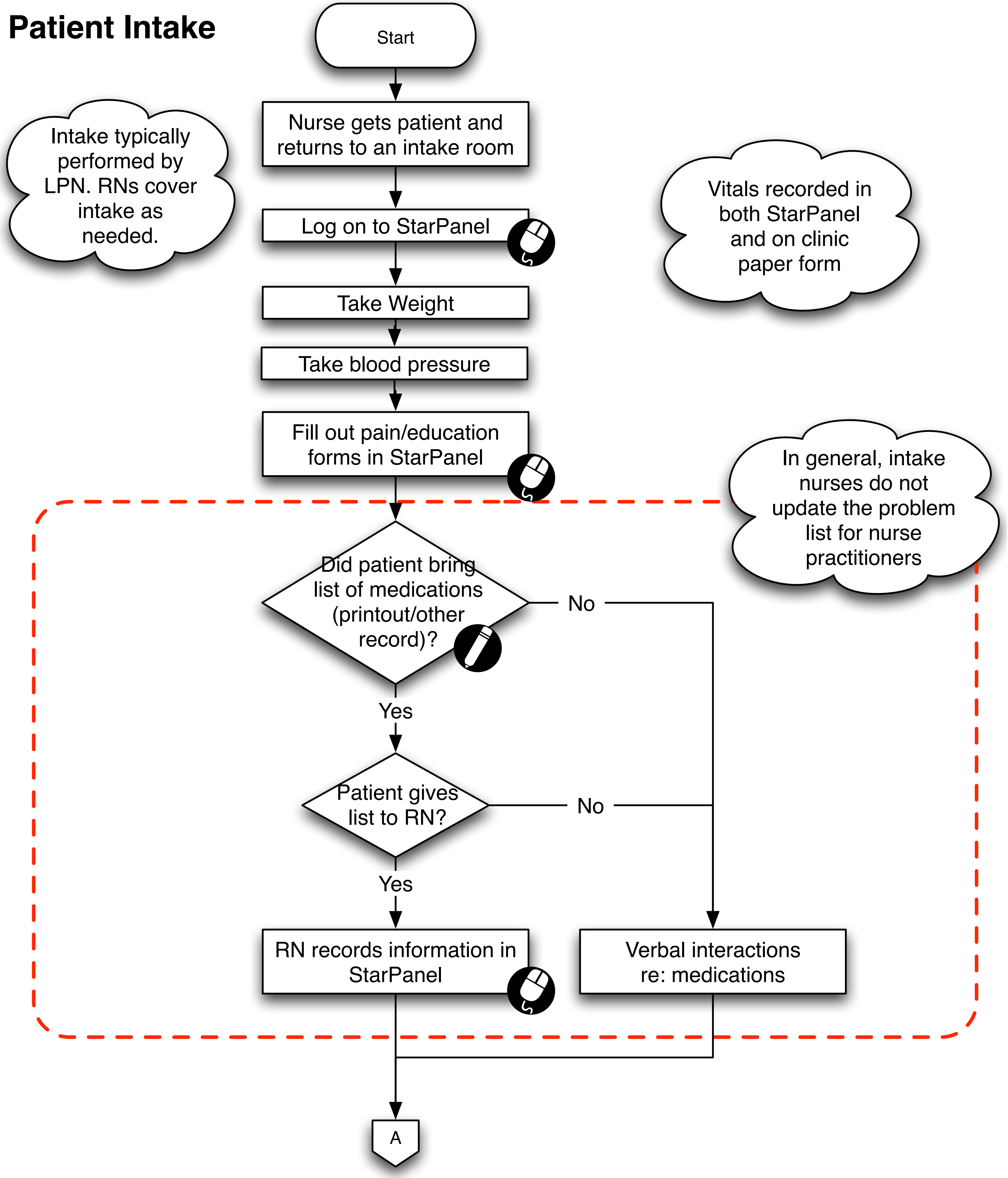
Appointment Preparation

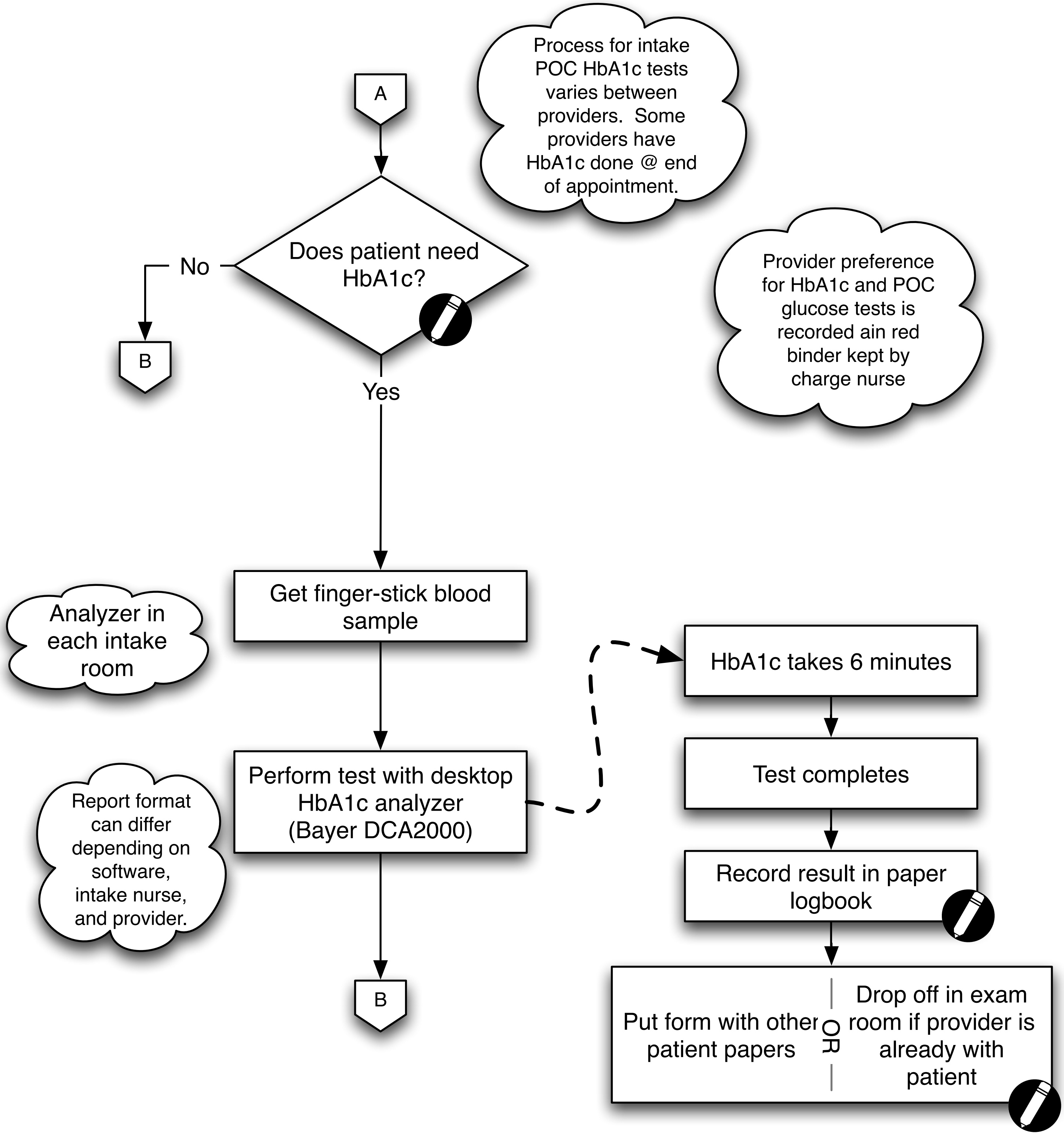


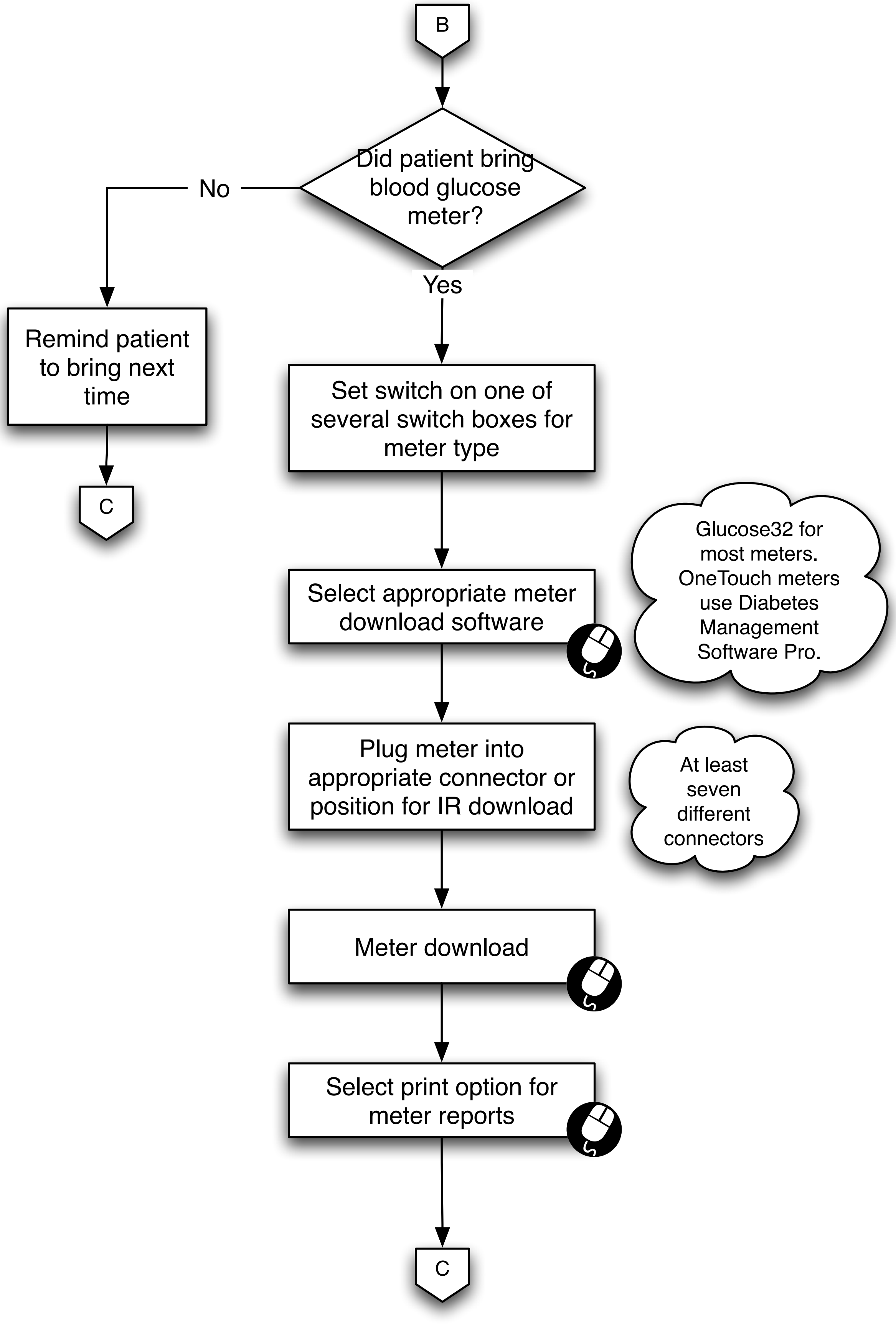
Check In

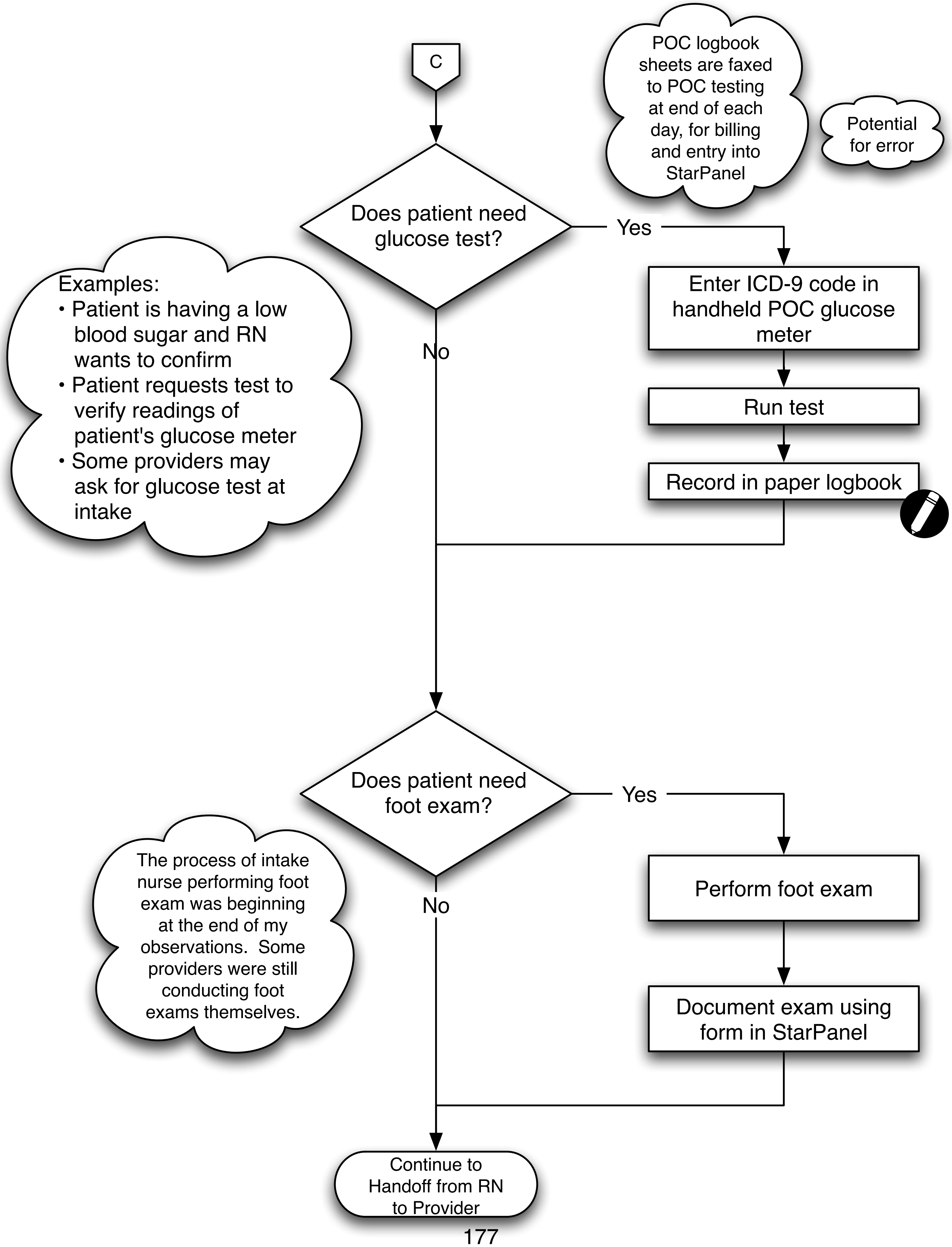

Start
Patient arrives
Patient writes name down on sheet by admin area
Patient waits in waiting room
Check in admin calls the patient to admin area
Is the patient on time?
No
Is the patient >30 minutes late?
Yes
No
Visit proceeds, but add delay to schedule
Front desk pages provider or provider's admin to see if patient can be worked in
Yes
Forms are sent to scanners at the end of the day
Have patient review/sign any new forms since last visit
Examples:
• Vanderbilt DNA databank
• Revised HIPAA forms
Check in admin verifies/ takes patient info (in Epic Hyperspace)
A
Is the patient on time?
No
Yes
Continue to Make Follow-up Appointment
A

Patient Intake

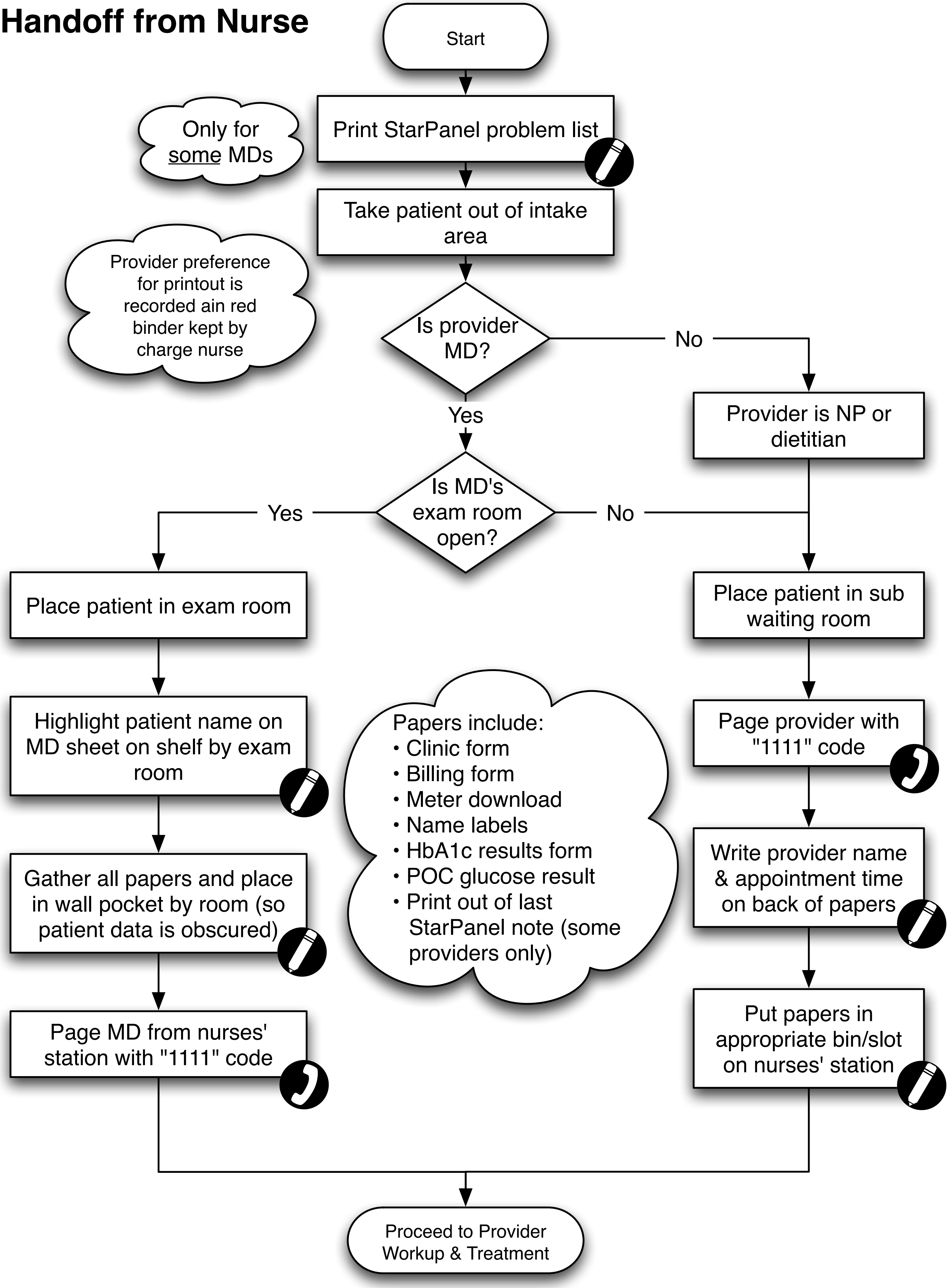



A
Does patient need HbA1c?
No
B
Yes
Process for intake POC HbA1c tests varies between providers. Some providers have HbA1c done @ end of appointment.
Provider preference for HbA1c and POC glucose tests is recorded ain red binder kept by charge nurse
Get finger-stick blood sample
Analyzer in each intake room
Perform test with desktop HbA1c analyzer (Bayer DCA2000)
Report format can differ depending on software, intake nurse, and provider.
B
HbA1c takes 6 minutes
Test completes
Record result in paper logbook
Put form with other patient papers
OR
Drop off in exam room if provider is already with patient

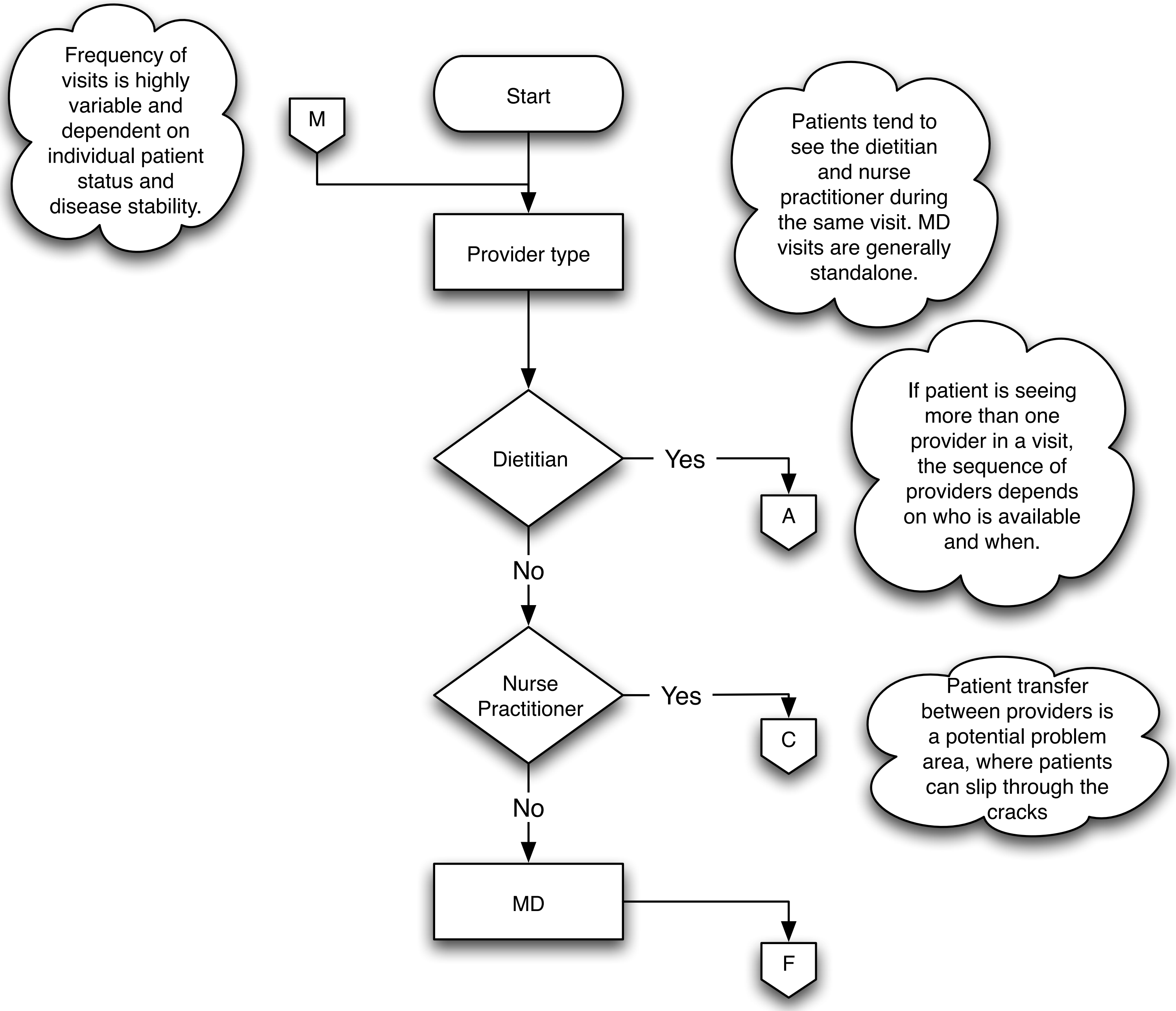

B
Did patient bring blood glucose meter?
No
Yes
Remind patient to bring next time
C
Set switch on one of several switch boxes for meter type
Select appropriate meter download software
Glucose32 for most meters. OneTouch meters use Diabetes Management Software Pro.
Plug meter into appropriate connector or position for IR download
At least seven different connectors
Meter download
Select print option for meter reports
C


C
POC logbook sheets are faxed to POC testing at end of each day, for billing and entry into StarPanel
Potential for error
Does patient need glucose test?
Yes
Enter ICD-9 code in handheld POC glucose meter
Run test
Record in paper logbook
No
Examples:
• Patient is having a low blood sugar and RN wants to confirm
• Patient requests test to verify readings of patient's glucose meter
• Some providers may ask for glucose test at intake
Does patient need foot exam?
Yes
Perform foot exam
Document exam using form in StarPanel
No
The process of intake nurse performing foot exam was beginning at the end of my observations. Some providers were still conducting foot exams themselves.
Continue to Handoff from RN to Provider

Handoff from Nurse



Provider Workup & Treatment



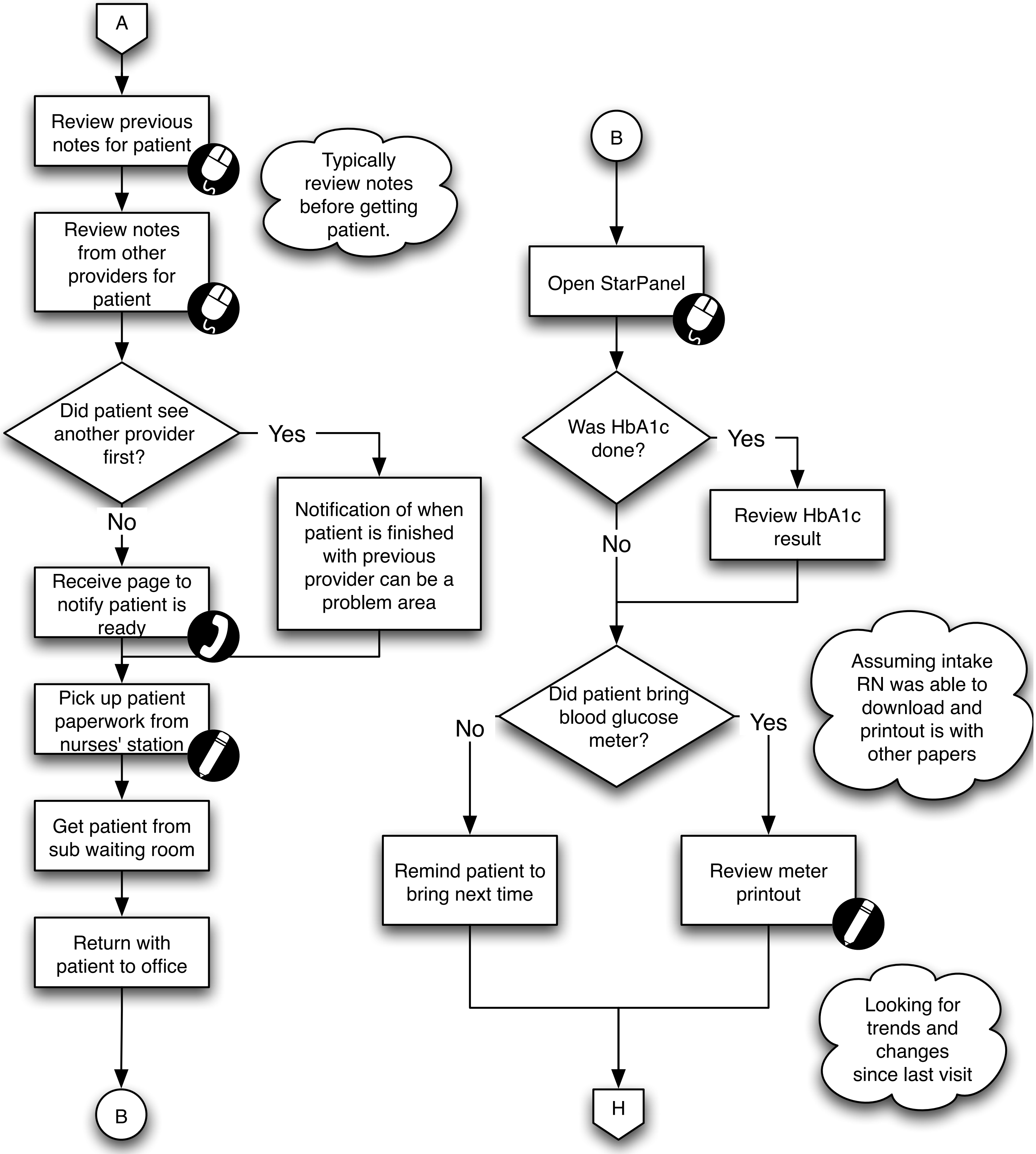
Frequency of visits is highly variable and dependent on individual patient status and disease stability.

Patients tend to see the dietitian and nurse practitioner during the same visit. MD visits are generally standalone.

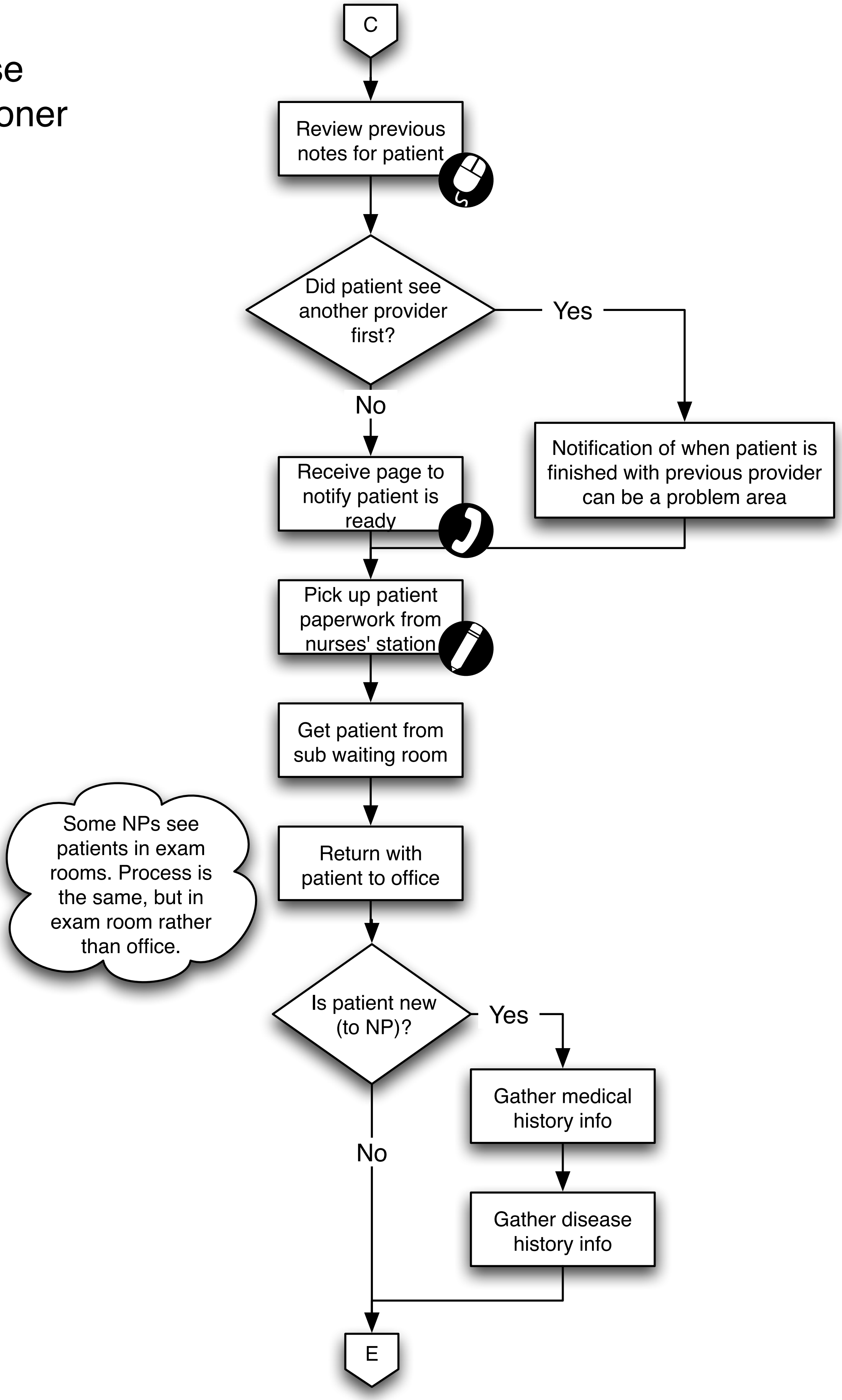
If patient is seeing more than one provider in a visit, the sequence of providers depends on who is available and when.

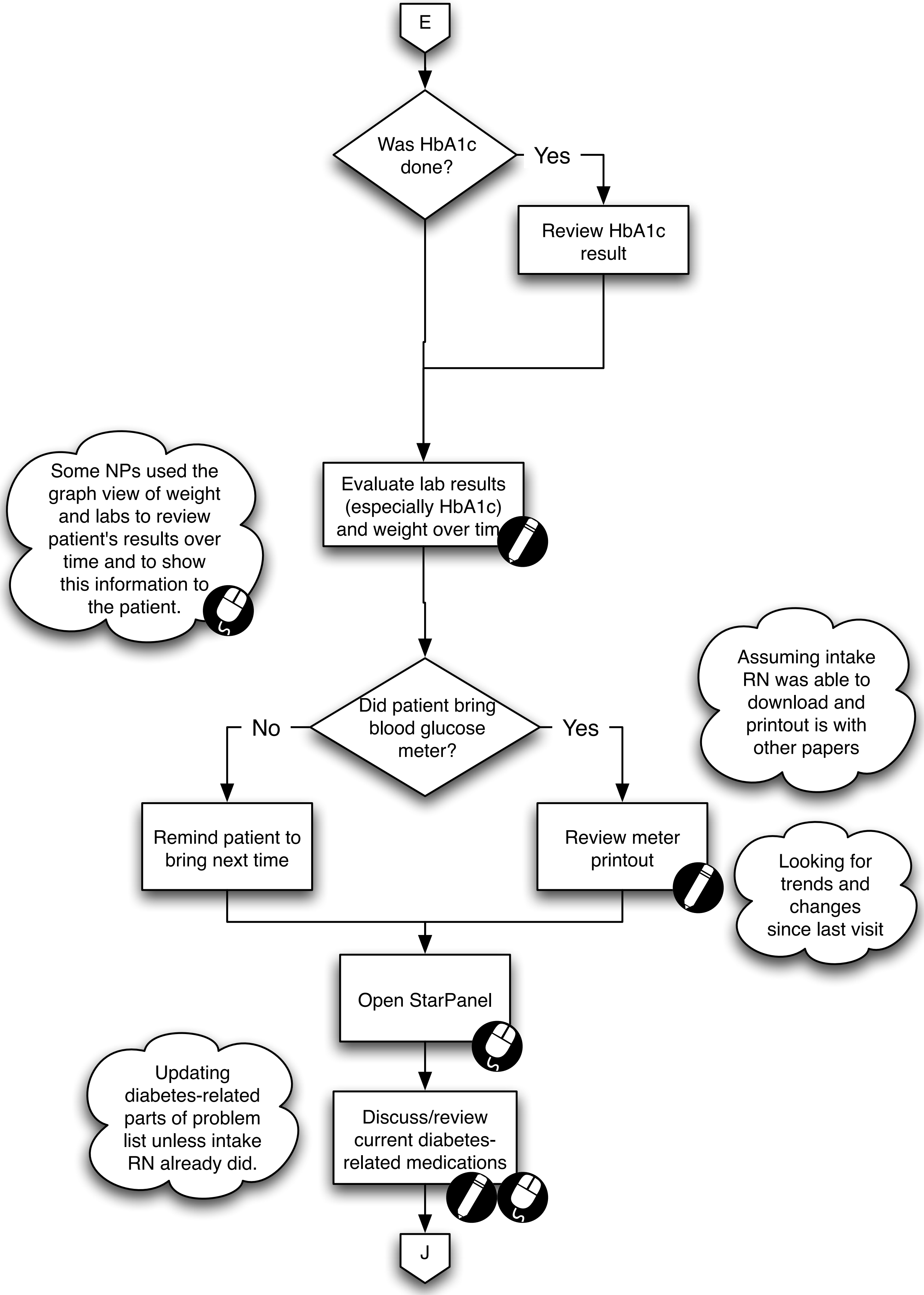
Patient transfer between providers is a potential problem area, where patients can slip through the cracks

Dietitian

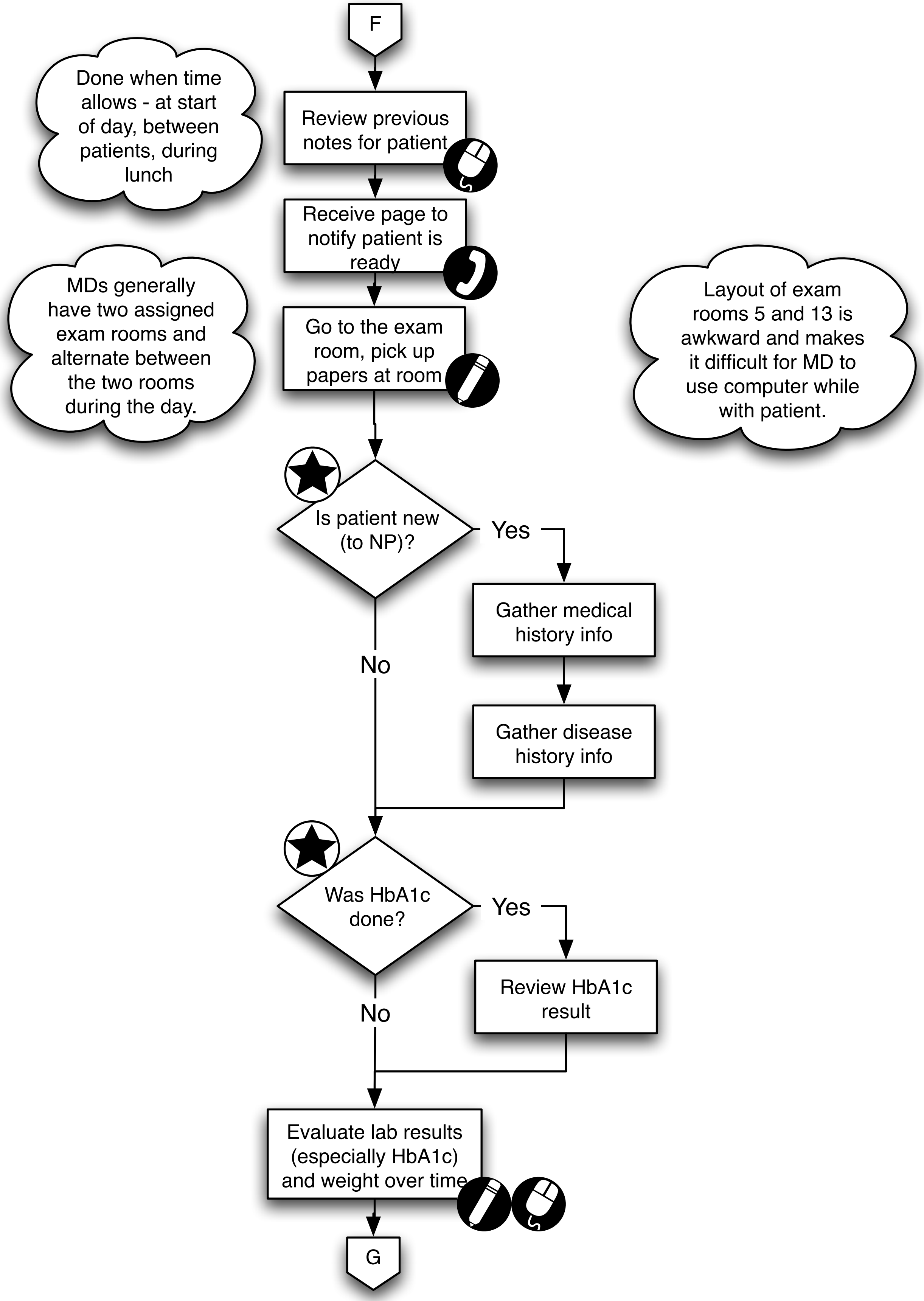

A
Review previous notes for patient
Typically review notes before getting patient.
Review notes from other providers for patient
Did patient see another provider first?
Yes
Notification of when patient is finished with previous provider can be a problem area
No
Receive page to notify patient is ready
Pick up patient paperwork from nurses' station
Get patient from sub waiting room
Return with patient to office
B
B
Open StarPanel
Was HbA1c done?
Yes
Review HbA1c result
No
Did patient bring blood glucose meter?
No
Yes
Assuming intake RN was able to download and printout is with other papers
Remind patient to bring next time
Review meter printout
Looking for trends and changes since last visit
H

Nurse Practitioner

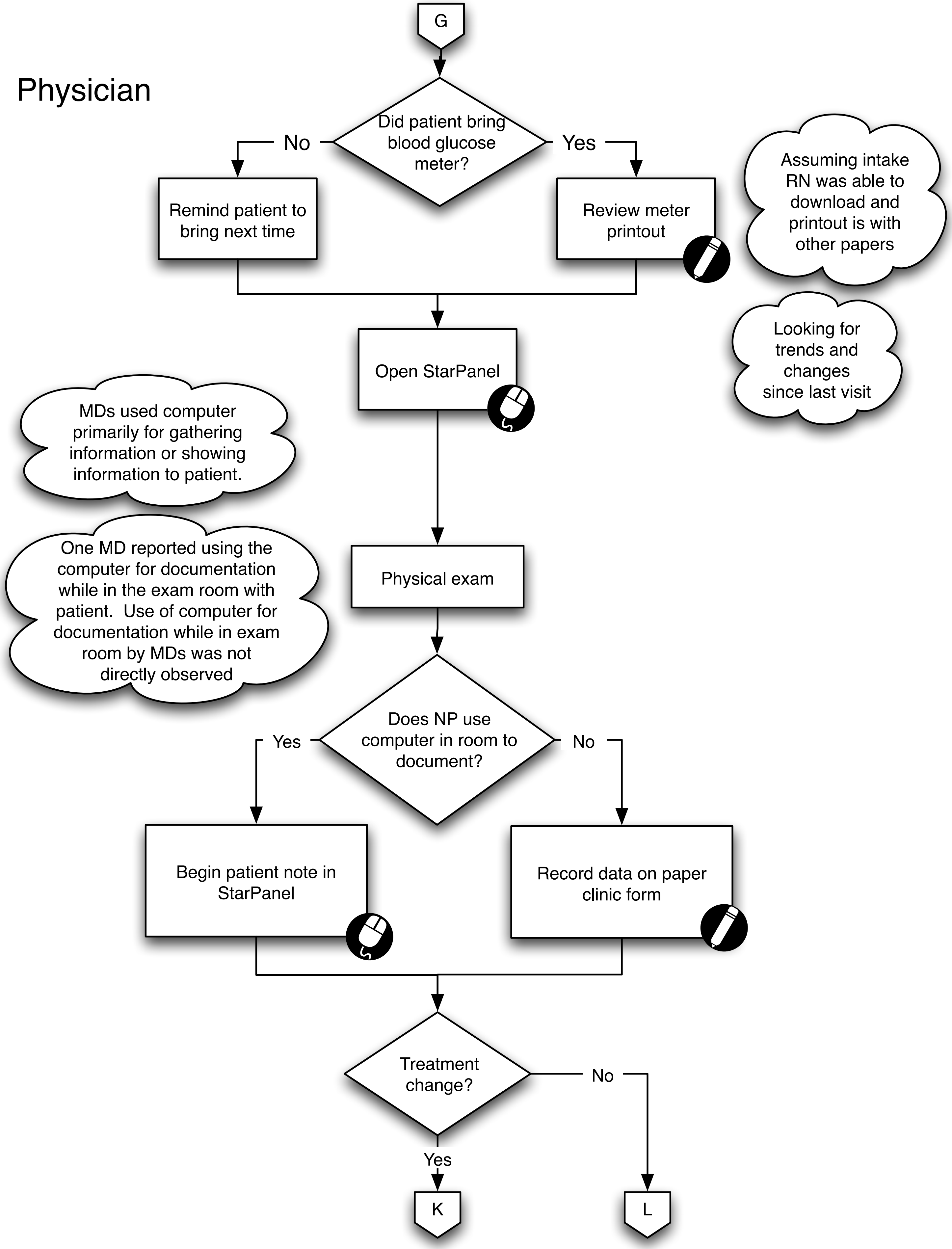


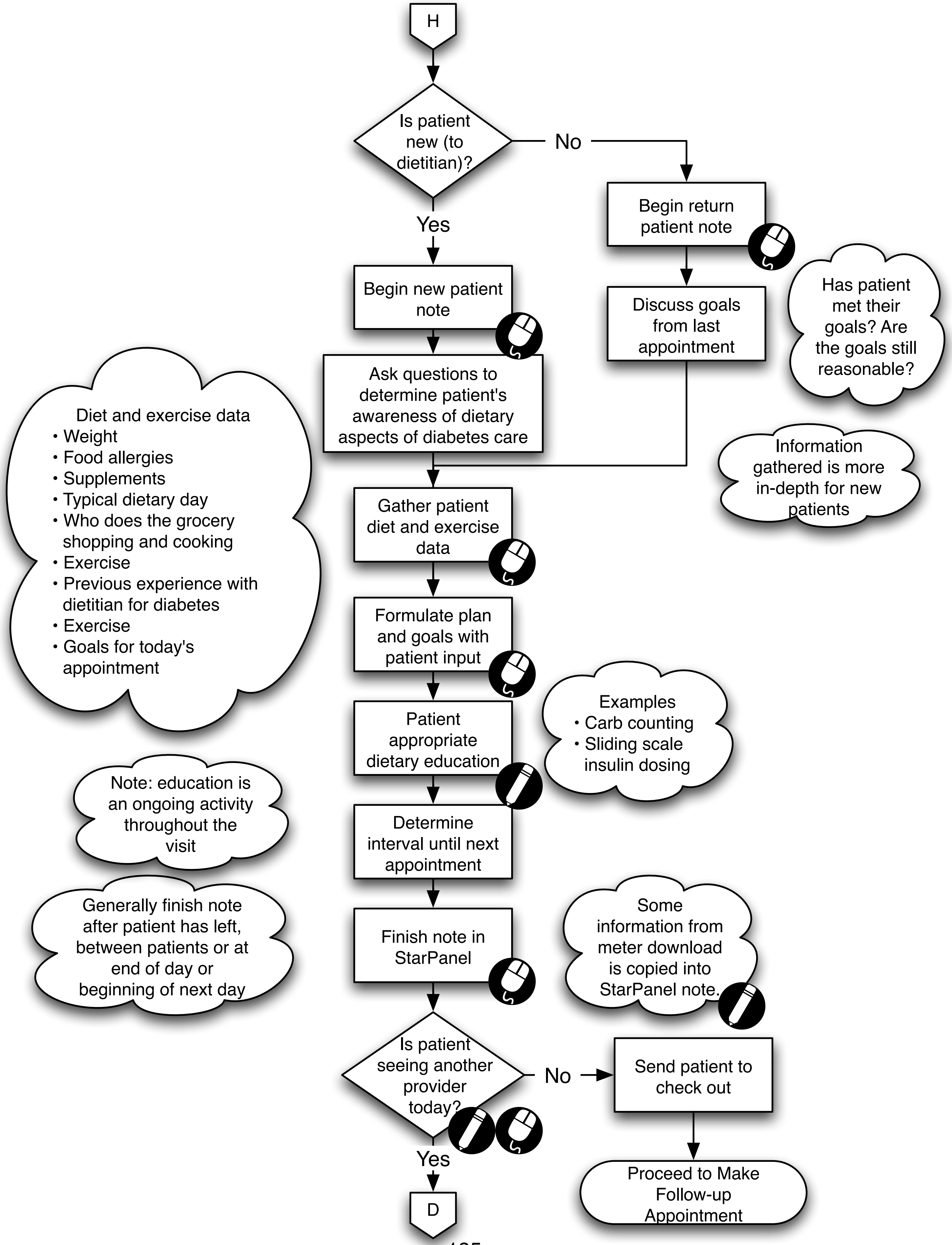

E
Was HbA1c done?
Yes
Review HbA1c result
Evaluate lab results (especially HbA1c) and weight over tim
Some NPs used the graph view of weight and labs to review patient's results over time and to show this information to the patient.
Did patient bring blood glucose meter?
No
Yes
Assuming intake RN was able to download and printout is with other papers
Remind patient to bring next time
Review meter printout
Looking for trends and changes since last visit
Open StarPanel
Updating diabetes-related parts of problem list unless intake RN already did.
Discuss/review current diabetes-related medications
J

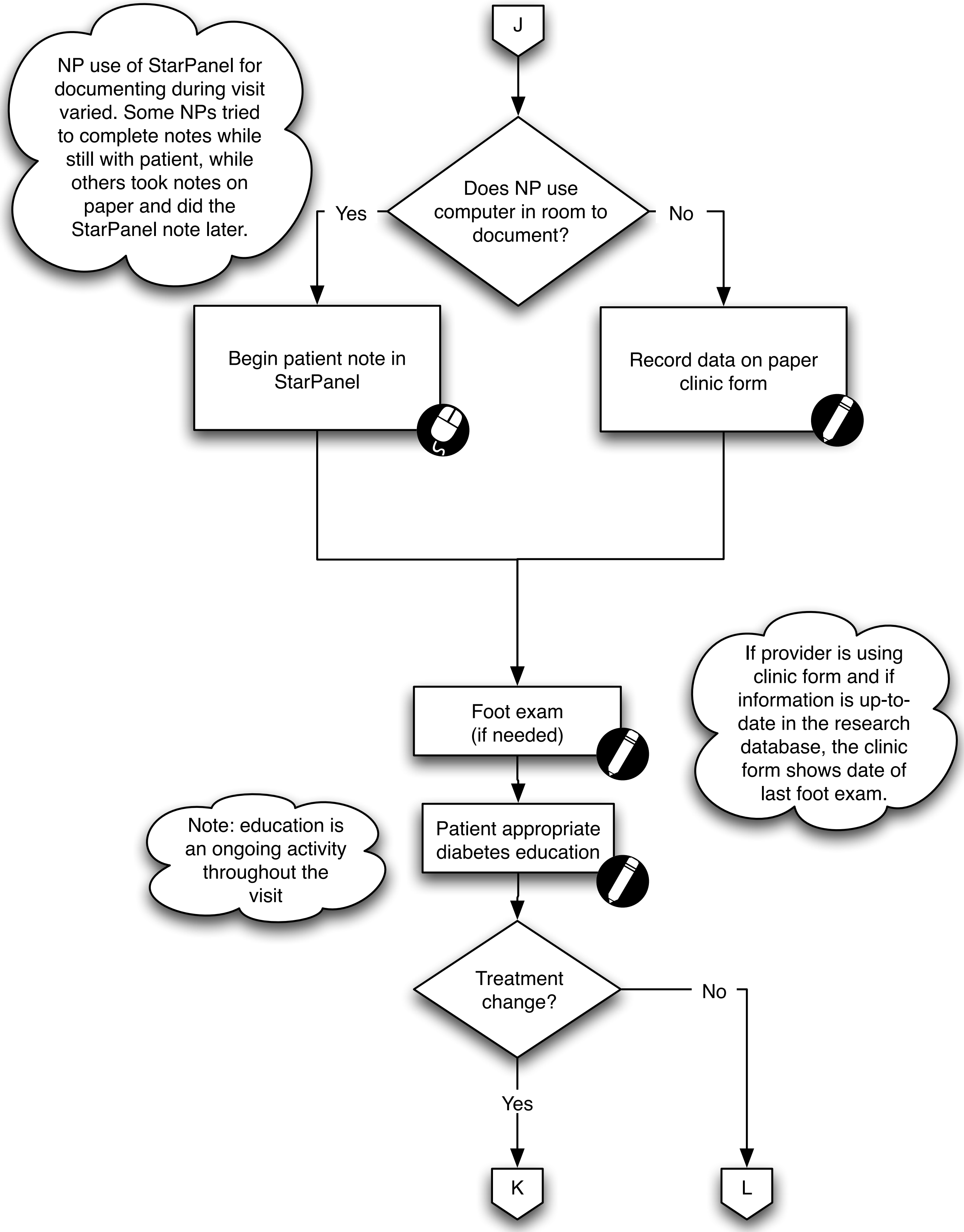
Physician

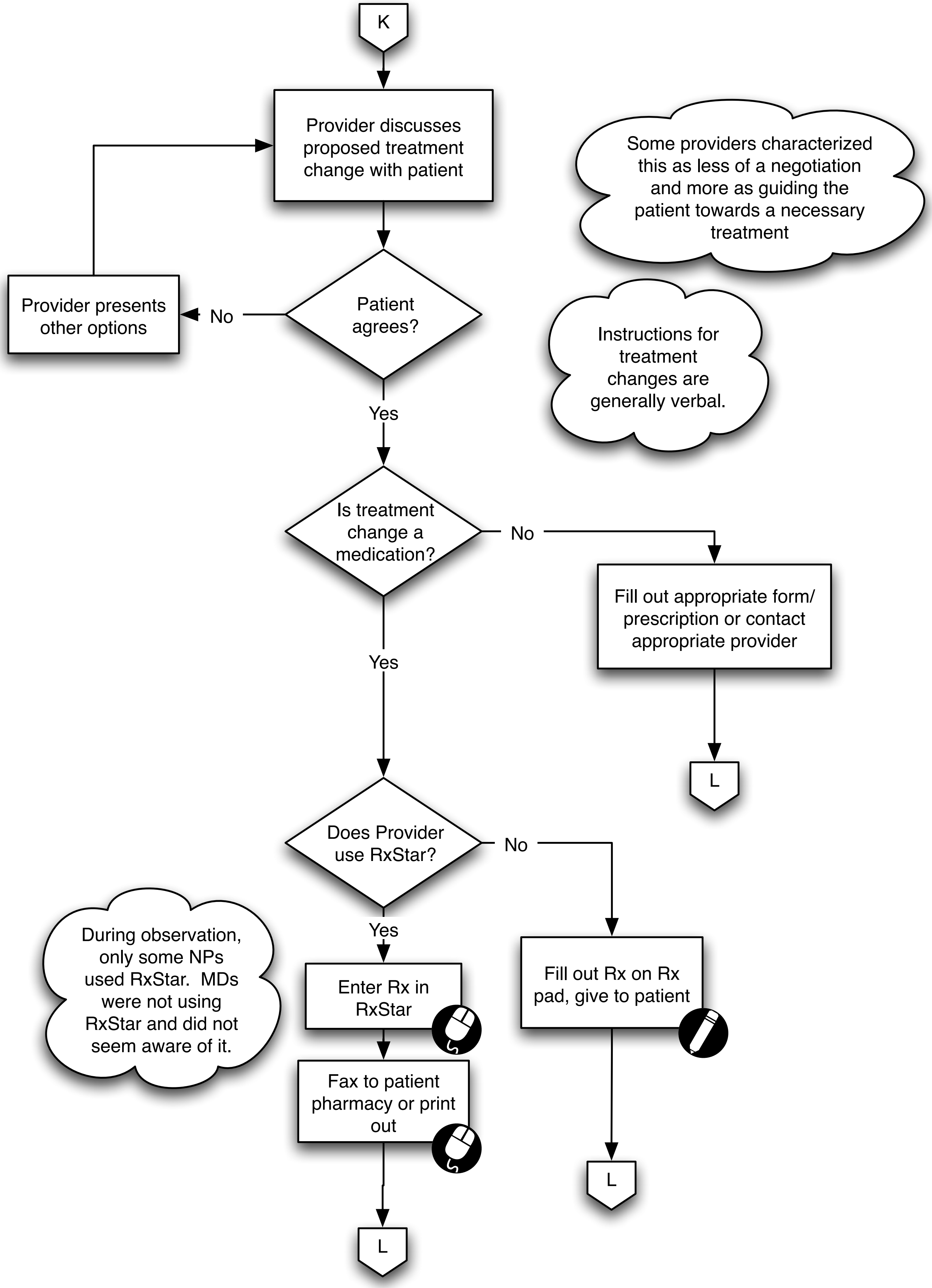

F
Done when time allows - at start of day, between patients, during lunch
Review previous notes for patient
Receive page to notify patient is ready
MDs generally have two assigned exam rooms and alternate between the two rooms during the day.
Go to the exam room, pick up papers at room
Layout of exam rooms 5 and 13 is awkward and makes it difficult for MD to use computer while with patient.
Is patient new (to NP)?
Yes
Gather medical history info
Gather disease history info
No
Was HbA1c done?
Yes
Review HbA1c result
No
Evaluate lab results (especially HbA1c) and weight over time
G

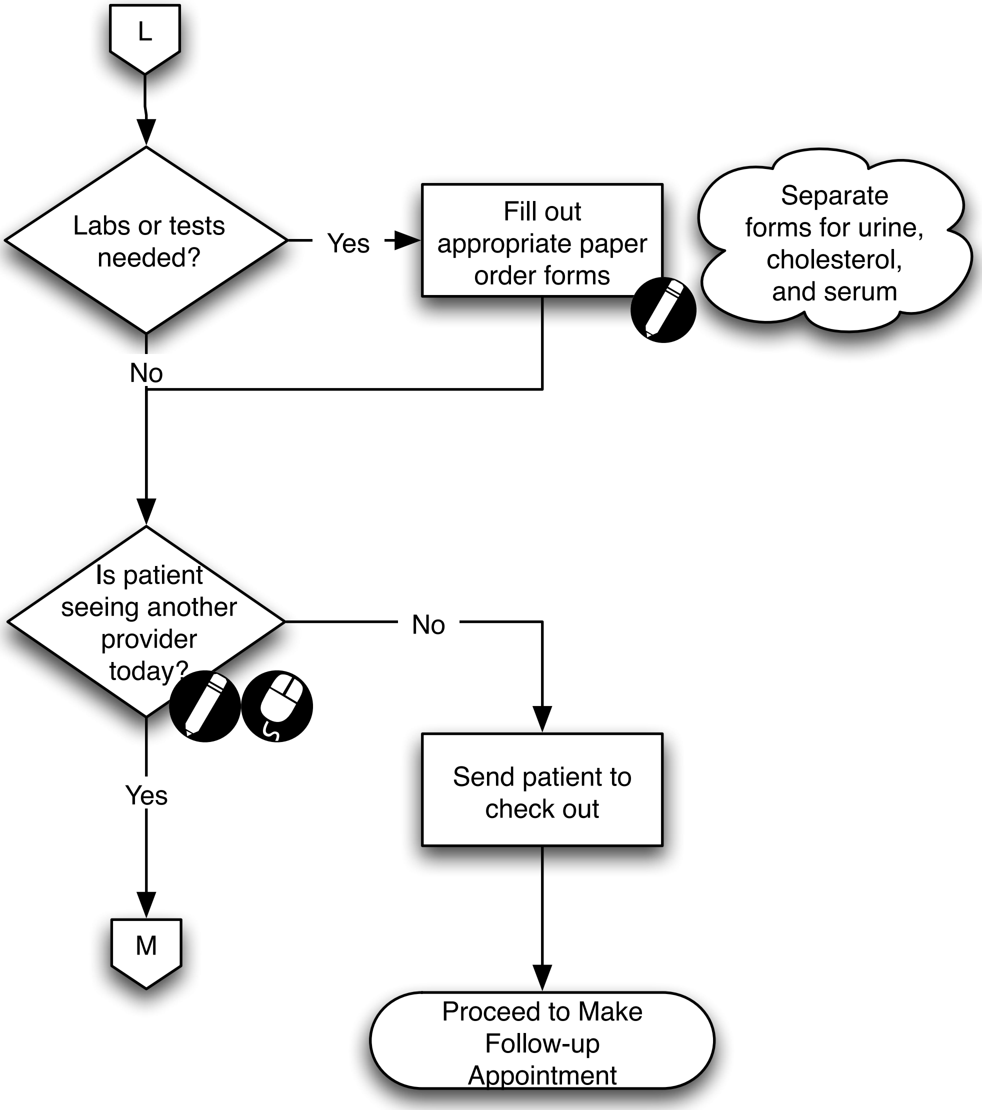
Physician


G
Did patient bring blood glucose meter?
No
Yes
Remind patient to bring next time
Review meter printout
Assuming intake RN was able to download and printout is with other papers
Looking for trends and changes since last visit
Open StarPanel
MDs used computer primarily for gathering information or showing information to patient.
One MD reported using the computer for documentation while in the exam room with patient. Use of computer for documentation while in exam room by MDs was not directly observed
Physical exam
Does NP use computer in room to document?
Yes
No
Begin patient note in StarPanel
Record data on paper clinic form
Treatment change?
No
Yes
K
L

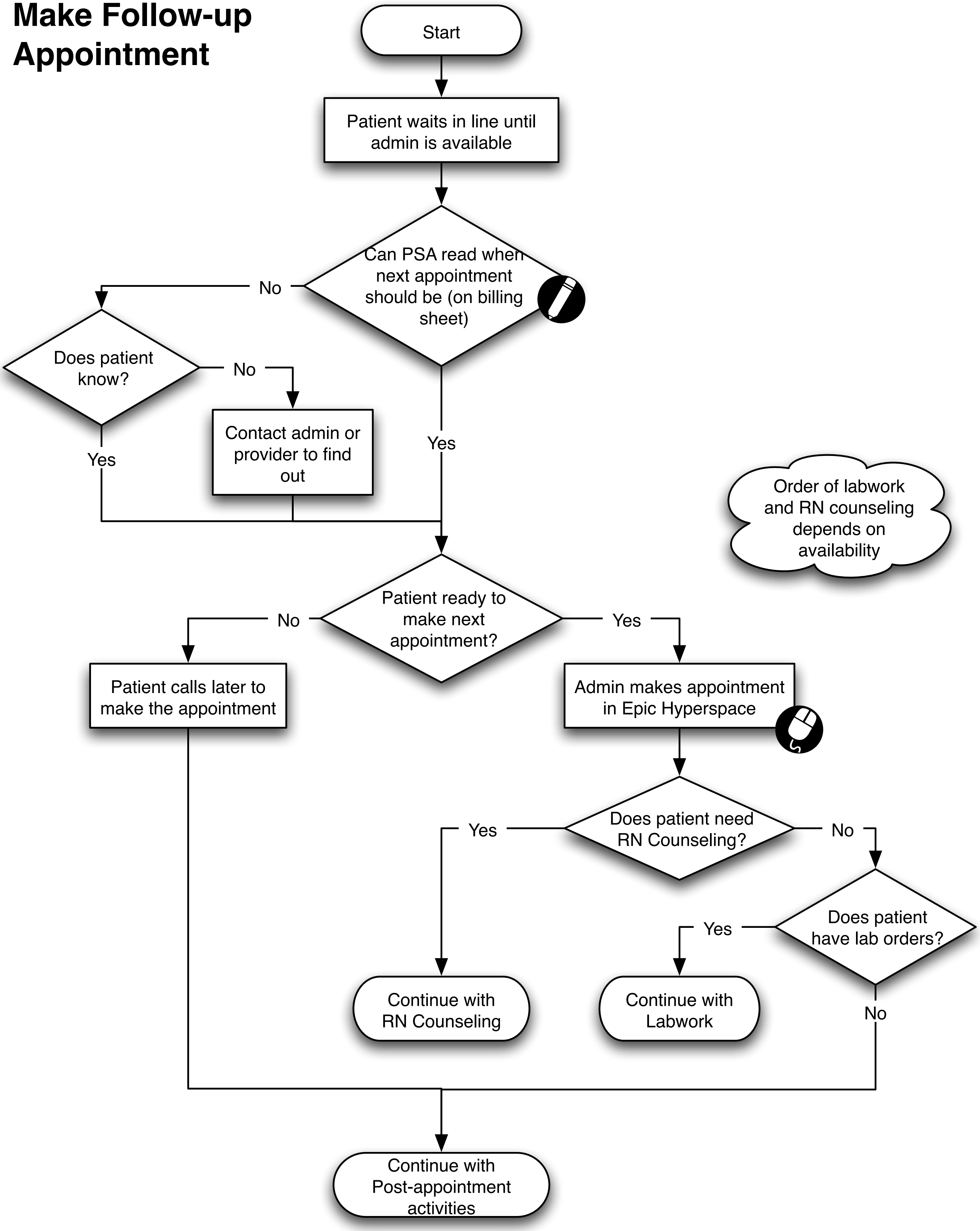

H
Is patient new (to dietitian)?
No
Yes
Begin return patient note
Discuss goals from last appointment
Has patient met their goals? Are the goals still reasonable?
Information gathered is more in-depth for new patients
Begin new patient note
Ask questions to determine patient's awareness of dietary aspects of diabetes care
Diet and exercise data
• Weight
• Food allergies
• Supplements
• Typical dietary day
• Who does the grocery shopping and cooking
• Exercise
• Previous experience with dietitian for diabetes
• Exercise
• Goals for today's appointment
Gather patient diet and exercise data
Formulate plan and goals with patient input
Patient appropriate dietary education
Examples
• Carb counting
• Sliding scale insulin dosing
Note: education is an ongoing activity throughout the visit
Determine interval until next appointment
Generally finish note after patient has left, between patients or at end of day or beginning of next day
Finish note in StarPanel
Some information from meter download is copied into StarPanel note.
Is patient seeing another provider today?
No
Send patient to check out
Proceed to Make Follow-up Appointment
Yes
D


J
NP use of StarPanel for documenting during visit varied. Some NPs tried to complete notes while still with patient, while others took notes on paper and did the StarPanel note later.
Does NP use computer in room to document?
Yes
No
Begin patient note in StarPanel
Record data on paper clinic form
Foot exam (if needed)
If provider is using clinic form and if information is up-to-date in the research database, the clinic form shows date of last foot exam.
Note: education is an ongoing activity throughout the visit
Patient appropriate diabetes education
Treatment change?
No
Yes
K
L

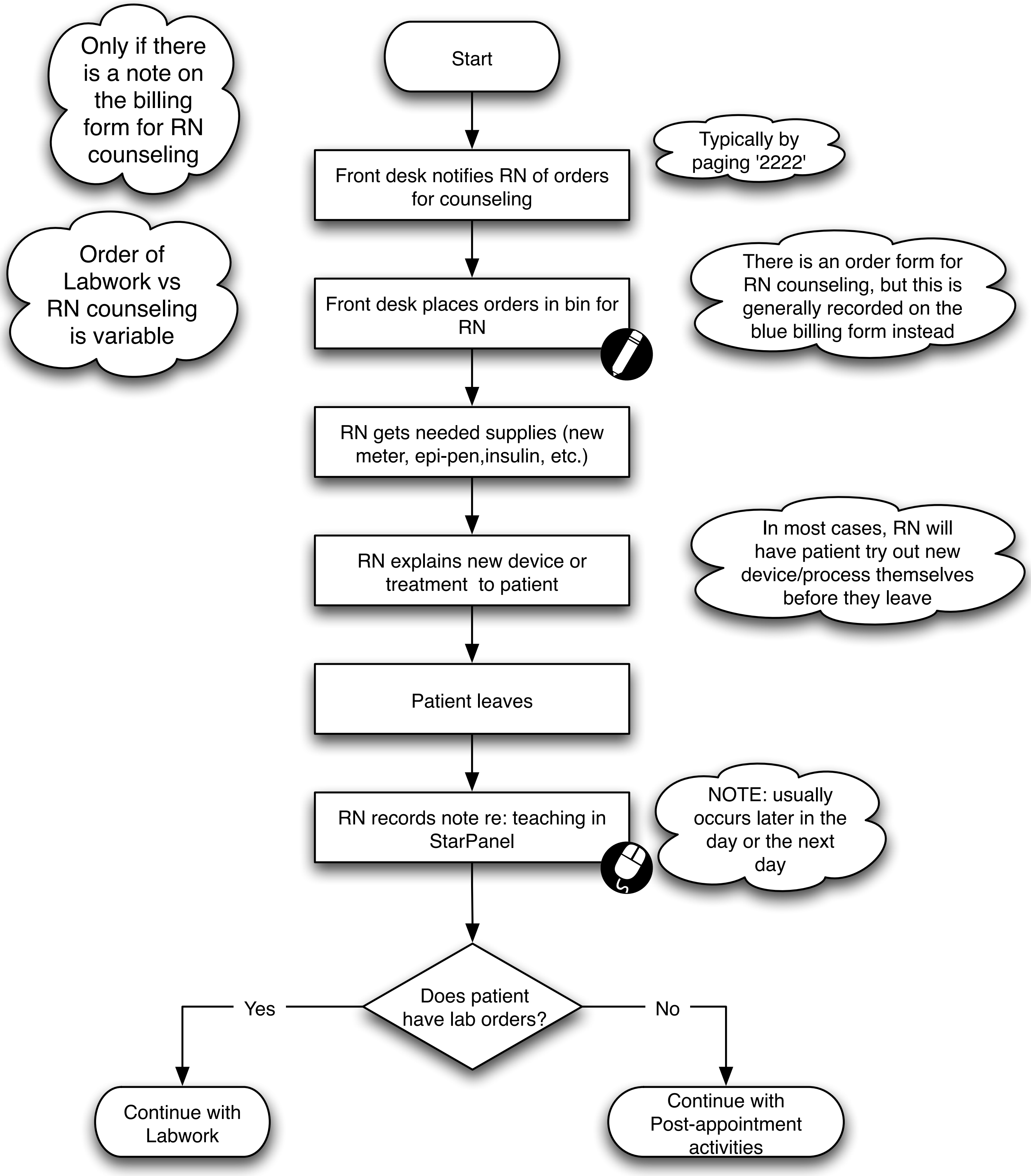

K
Provider discusses proposed treatment change with patient
Some providers characterized this as less of a negotiation and more as guiding the patient towards a necessary treatment
Patient agrees?
No
Provider presents other options
Instructions for treatment changes are generally verbal.
Yes
Is treatment change a medication?
No
Fill out appropriate form/ prescription or contact appropriate provider
L
Yes
Does Provider use RxStar?
No
Yes
During observation, only some NPs used RxStar. MDs were not using RxStar and did not seem aware of it.
Enter Rx in RxStar
Fill out Rx on Rx pad, give to patient
Fax to patient pharmacy or print out
L
L


L
Labs or tests needed?
Yes
Fill out appropriate paper order forms
Separate forms for urine, cholesterol, and serum
No
Is patient seeing another provider today?
No
Yes
Send patient to check out
M
Proceed to Make Follow-up Appointment

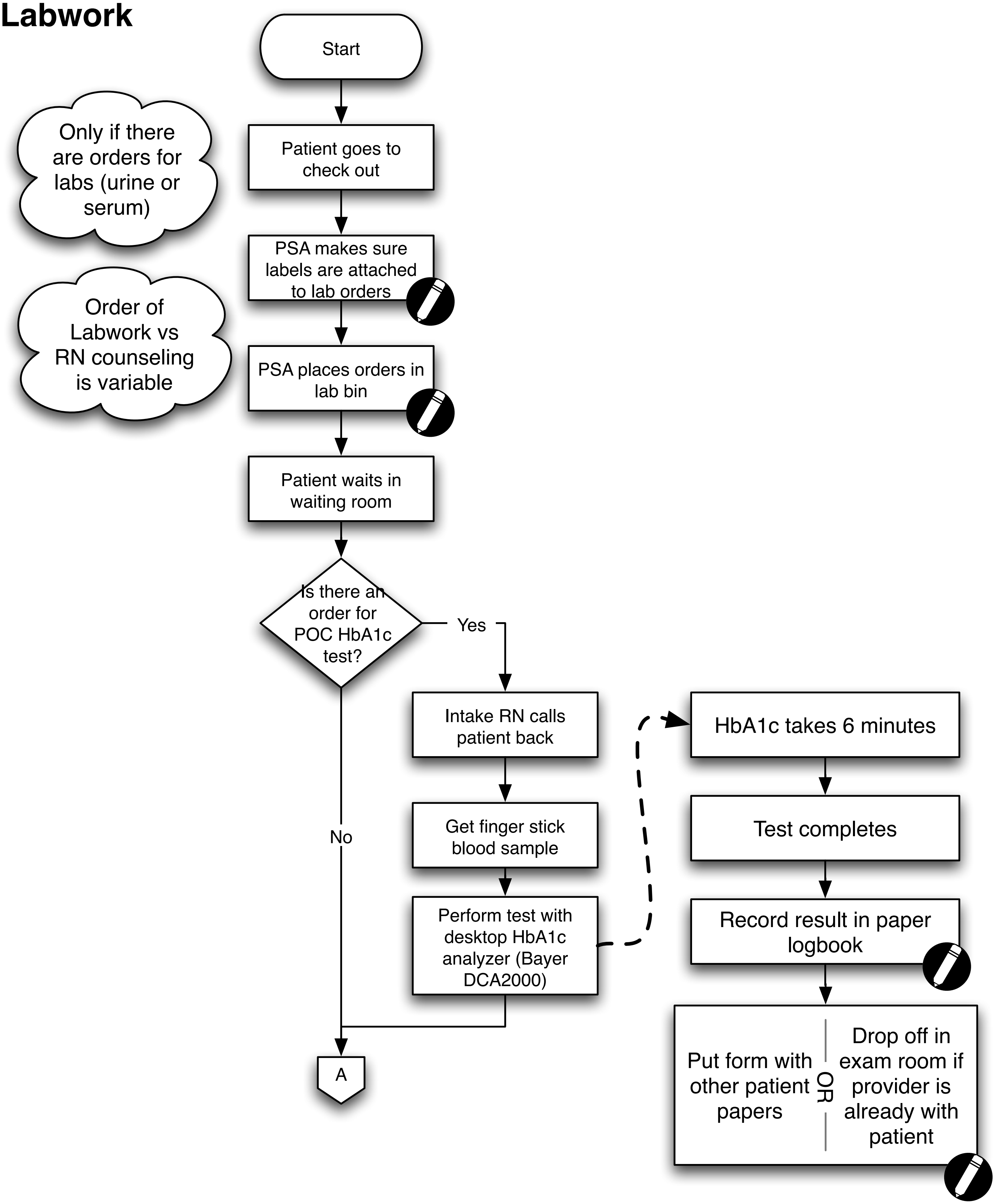
Make Follow-up Appointment

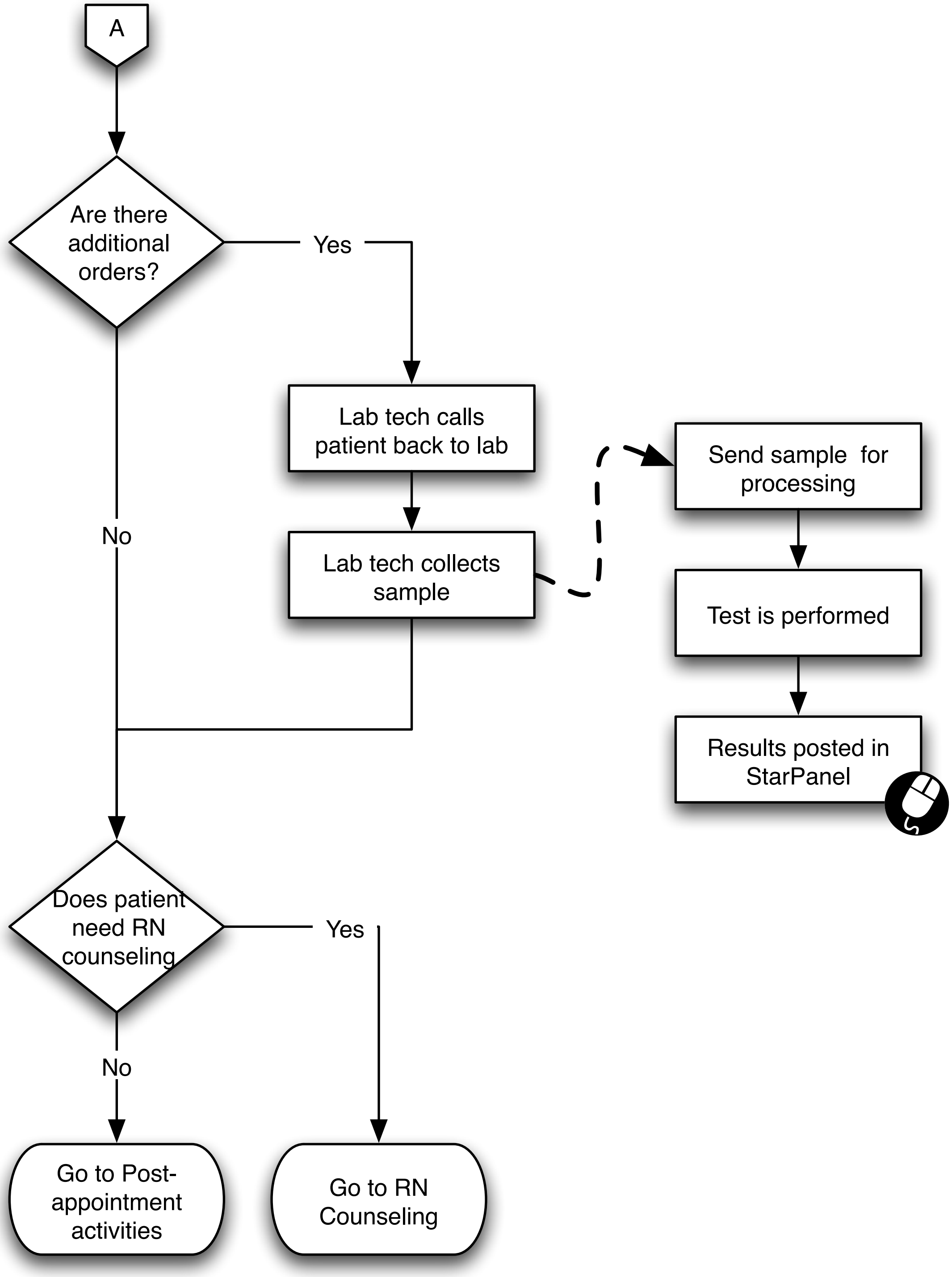


RN Counseling

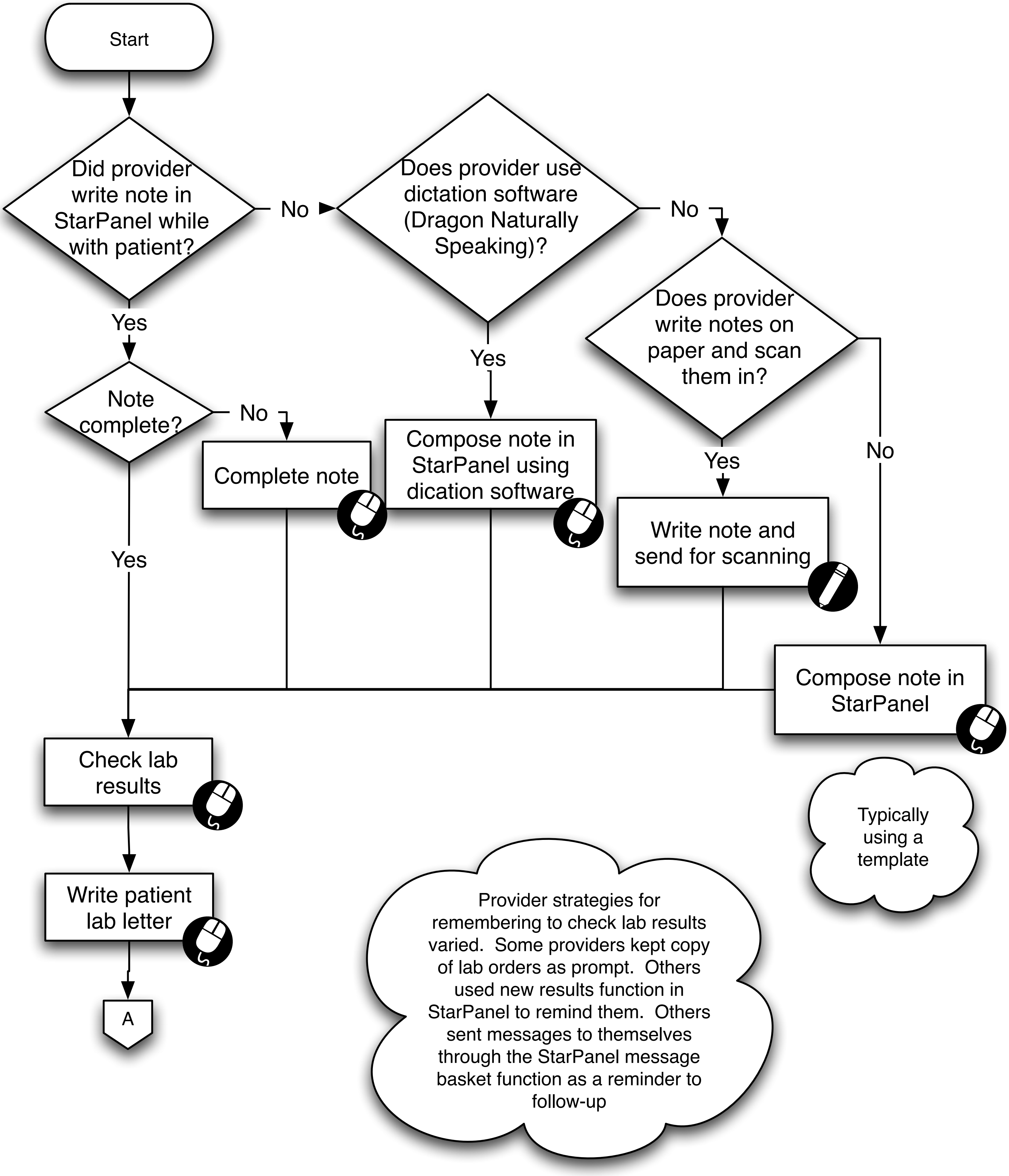


Labwork


Start
Only if there are orders for labs (urine or serum)
Patient goes to check out
PSA makes sure labels are attached to lab orders
Order of Labwork vs RN counseling is variable
PSA places orders in lab bin
Patient waits in waiting room
Is there an order for POC HbA1c test?
Yes
No
Intake RN calls patient back
Get finger stick blood sample
Perform test with desktop HbA1c analyzer (Bayer DCA2000)
HbA1c takes 6 minutes
Test completes
Record result in paper logbook
Put form with other patient papers
OR
Drop off in exam room if provider is already with patient
A


A
Are there additional orders?
Yes
No
Lab tech calls patient back to lab
Lab tech collects sample
Send sample for processing
Test is performed
Results posted in StarPanel
Does patient need RN counseling
Yes
No
Go to Post-appointment activities
Go to RN Counseling

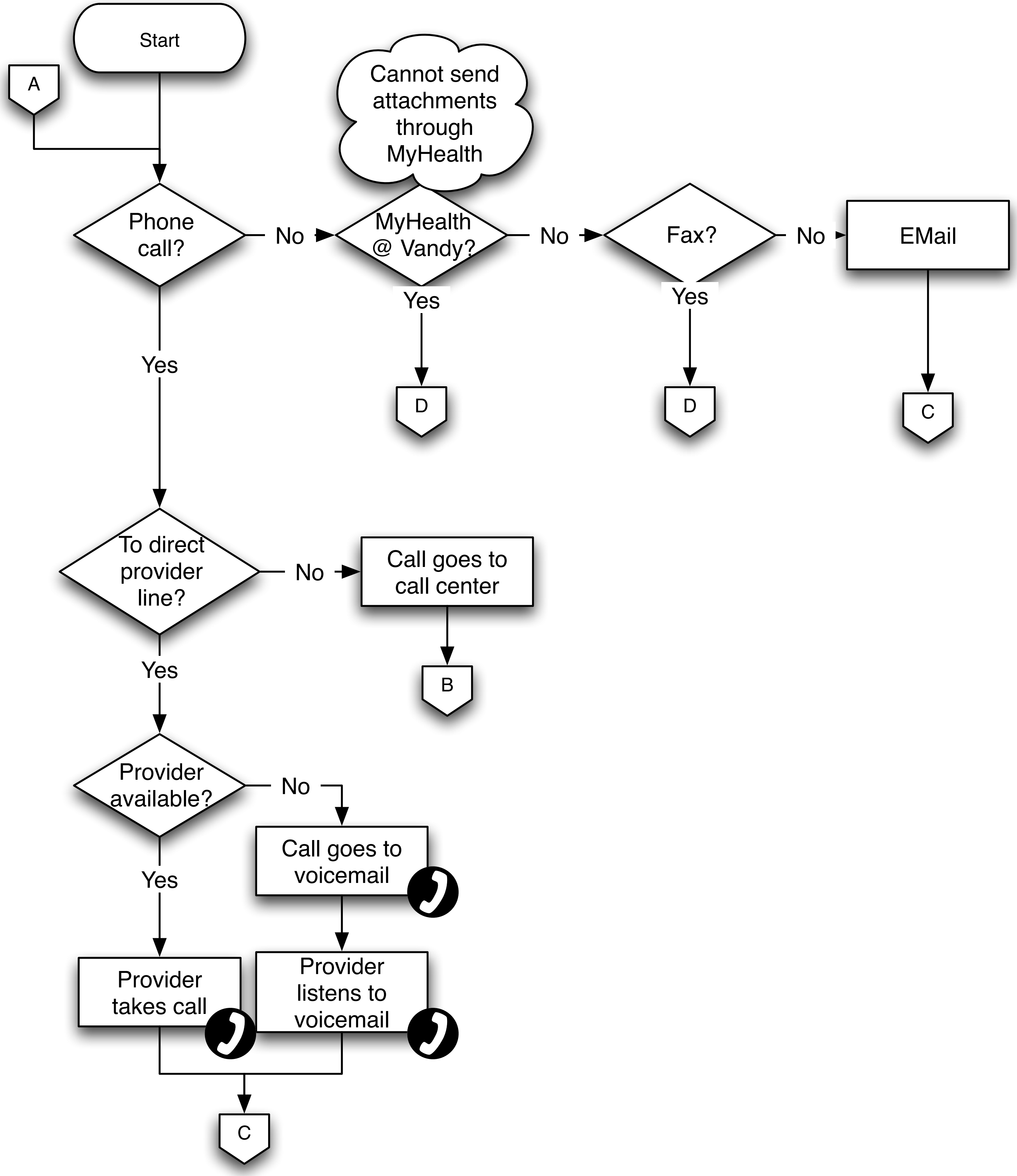
Appointment Completion

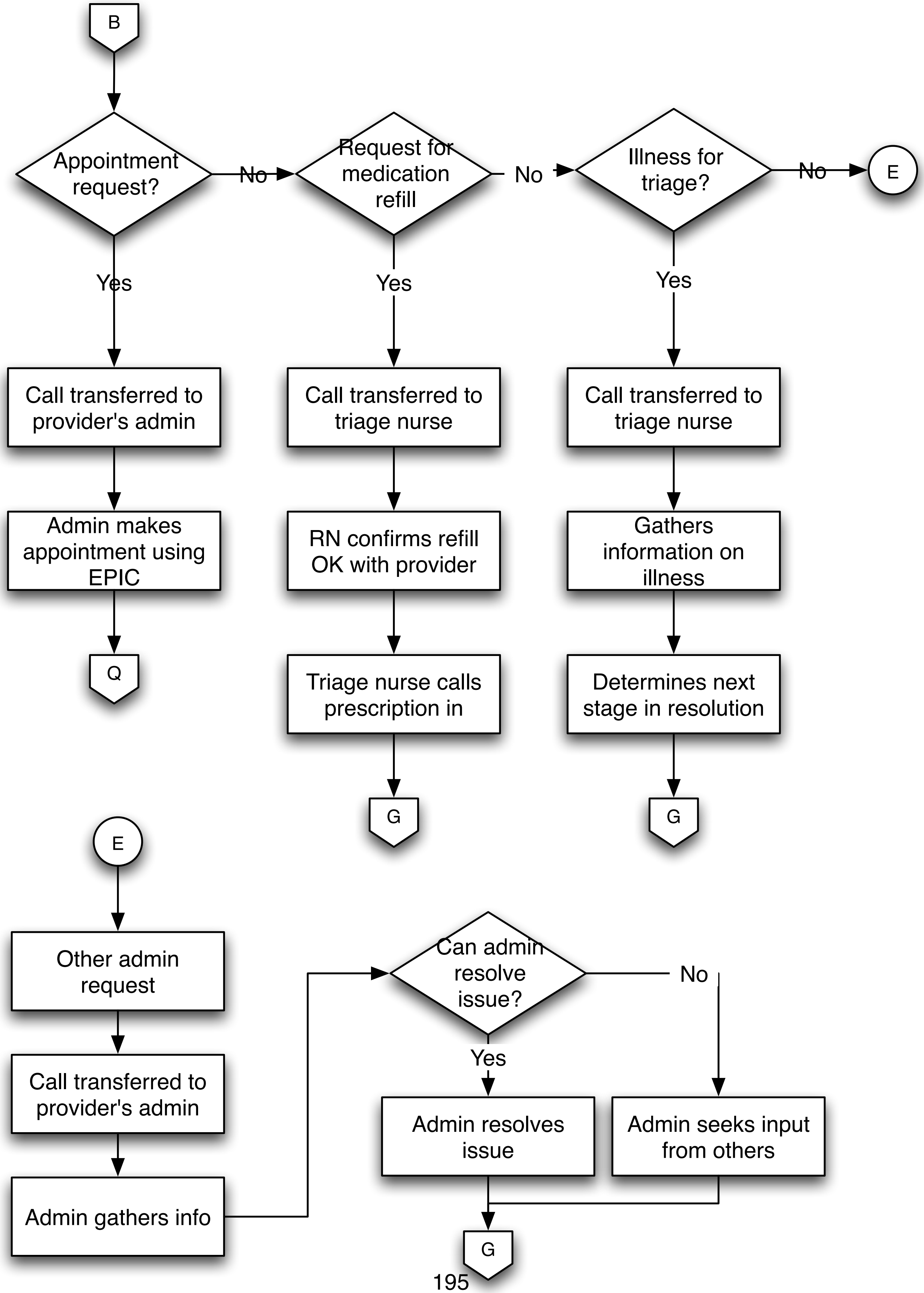


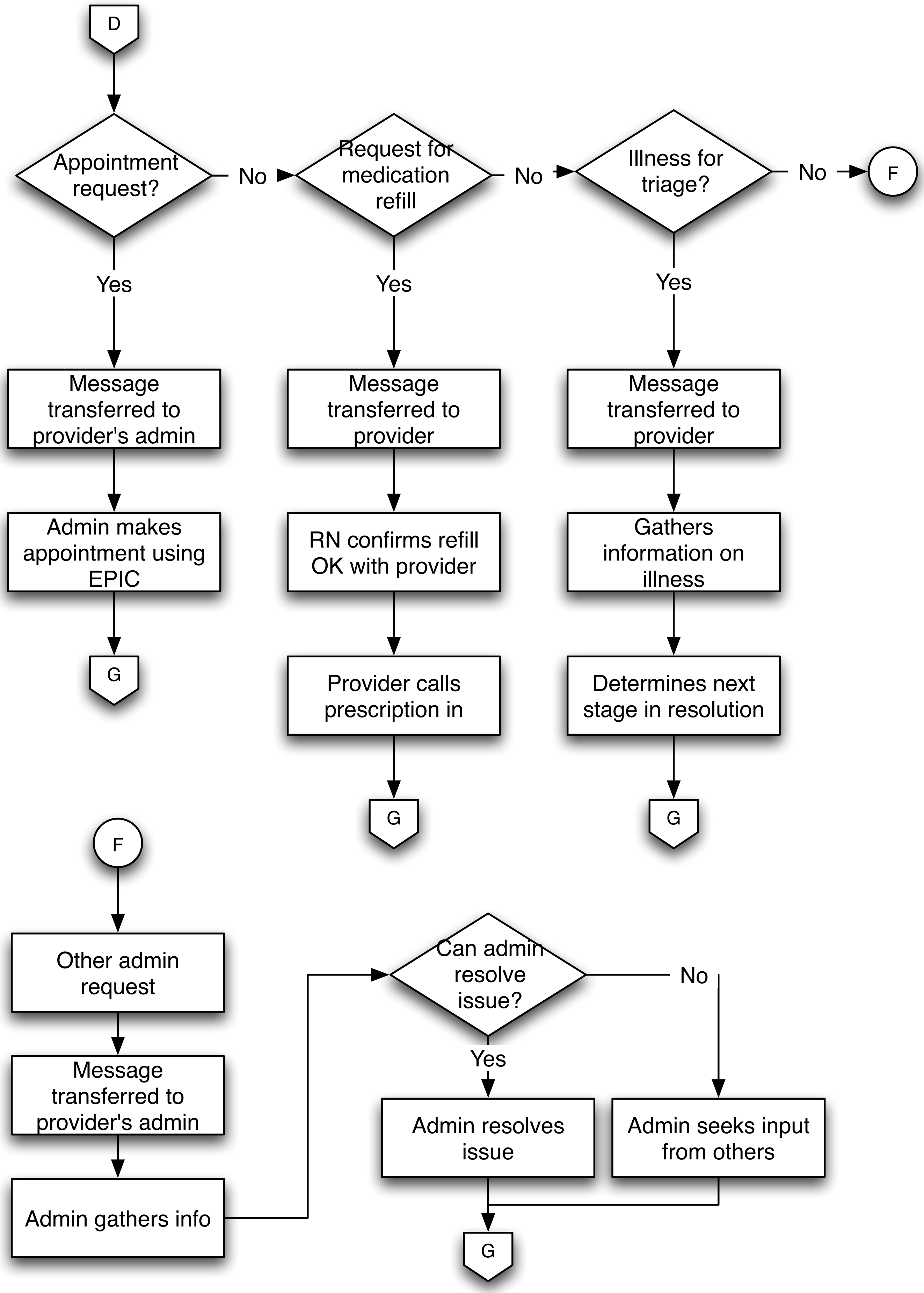
Typically using a template

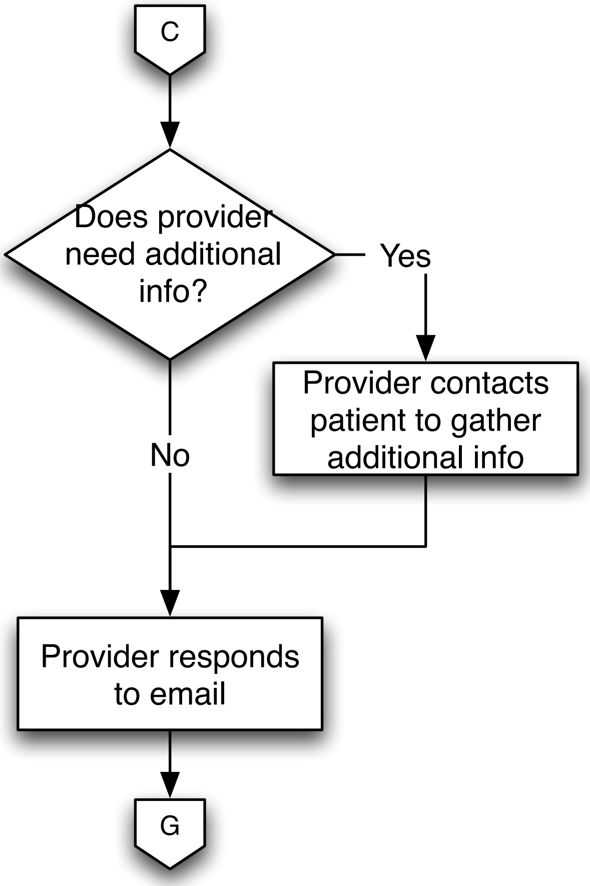
Provider strategies for remembering to check lab results varied. Some providers kept copy of lab orders as prompt. Others used new results function in StarPanel to remind them. Others sent messages to themselves through the StarPanel message basket function as a reminder to follow-up

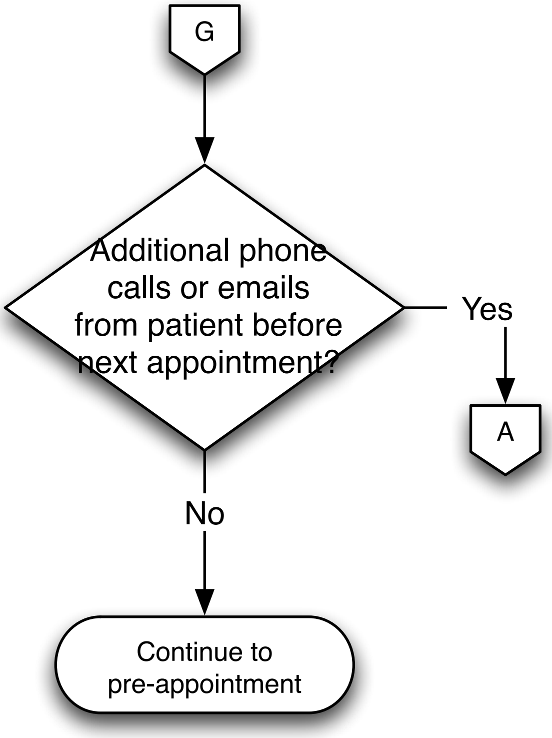
Between appointment activities




B
Appointment request?
No
Request for medication refill
No
Illness for triage?
No
E
Yes
Yes
Yes
Call transferred to provider's admin
Call transferred to triage nurse
Call transferred to triage nurse
Admin makes appointment using EPIC
RN confirms refill OK with provider
Gathers information on illness
Q
Triage nurse calls prescription in
Determines next stage in resolution
G
G
E
Other admin request
Call transferred to provider's admin
Admin gathers info
Can admin resolve issue?
No
Yes
Admin resolves issue
Admin seeks input from others
G


D
Appointment request?
No
Request for medication refill
No
Illness for triage?
No
F
Yes
Yes
Yes
Message transferred to provider's admin
Message transferred to provider
Message transferred to provider
Admin makes appointment using EPIC
RN confirms refill OK with provider
Gathers information on illness
G
Provider calls prescription in
Determines next stage in resolution
G
G
F
Other admin request
Message transferred to provider's admin
Admin gathers info
Can admin resolve issue?
No
Yes
Admin resolves issue
Admin seeks input from others
G

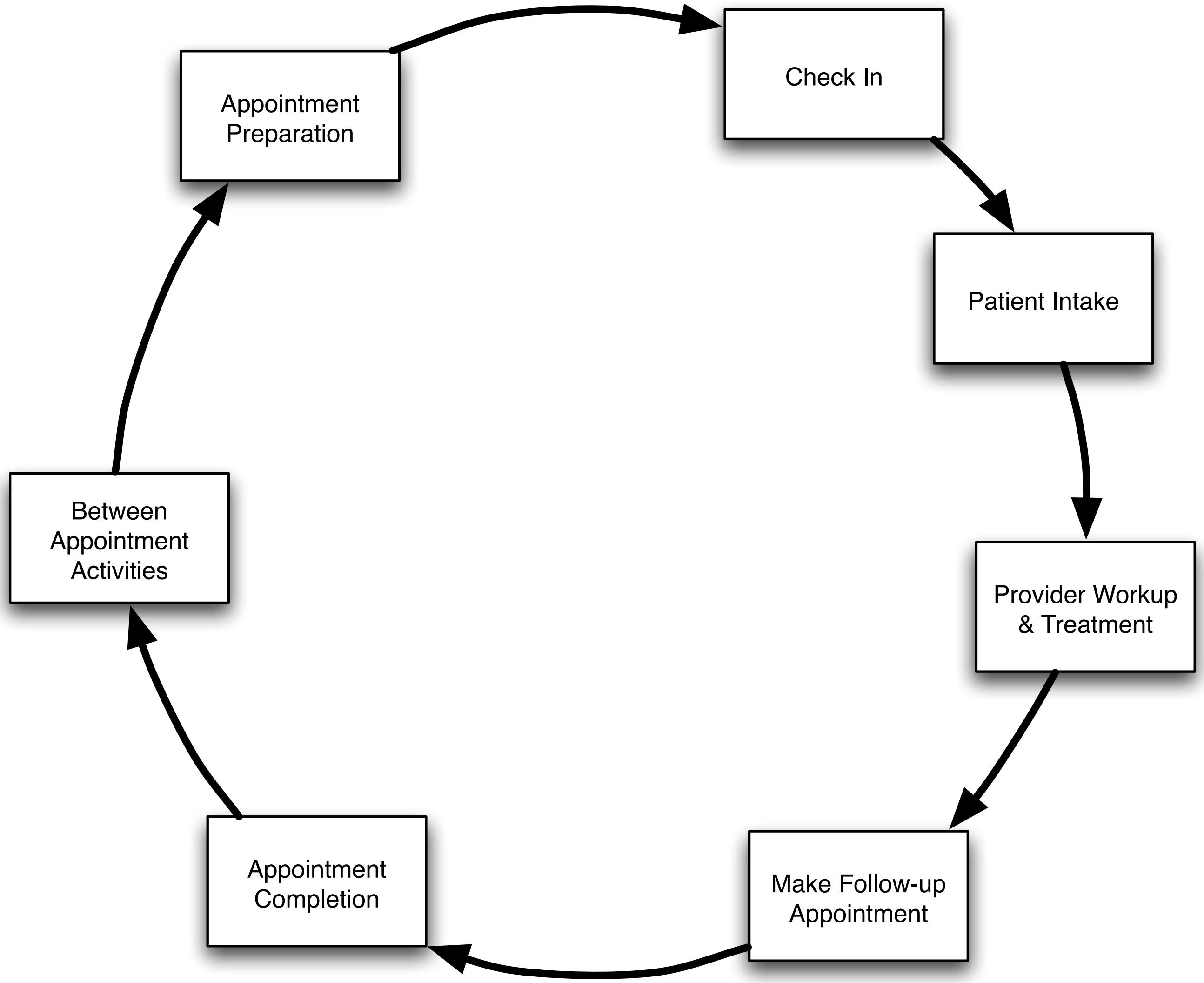

C
Does provider need additional info?
Yes
Provider contacts patient to gather additional info
No
Provider responds to email
G


G
Additional phone calls or emails from patient before next appointment?
Yes
A
No
Continue to pre-appointment

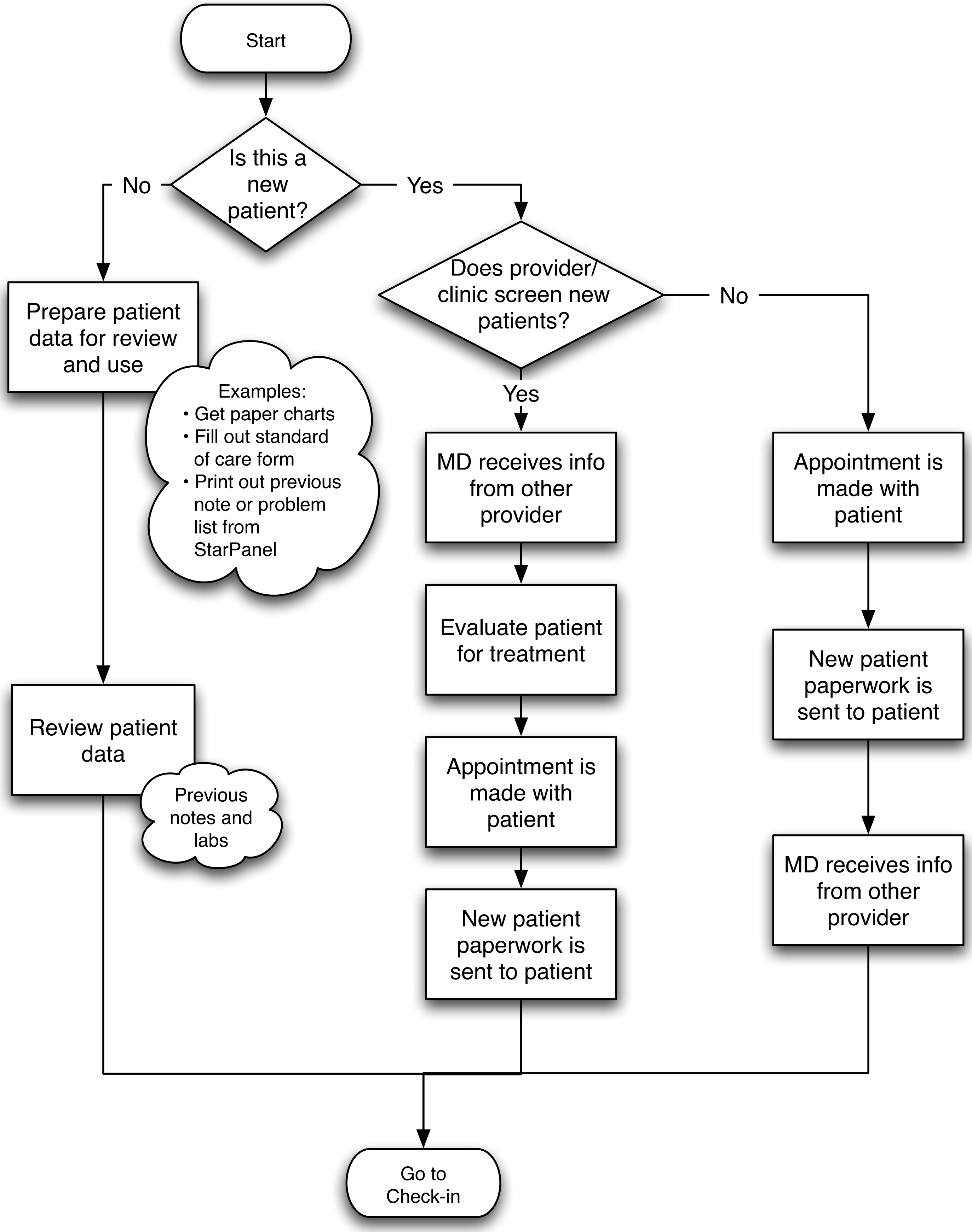
APPENDIX E

Generalized Chronic Disease Workflow

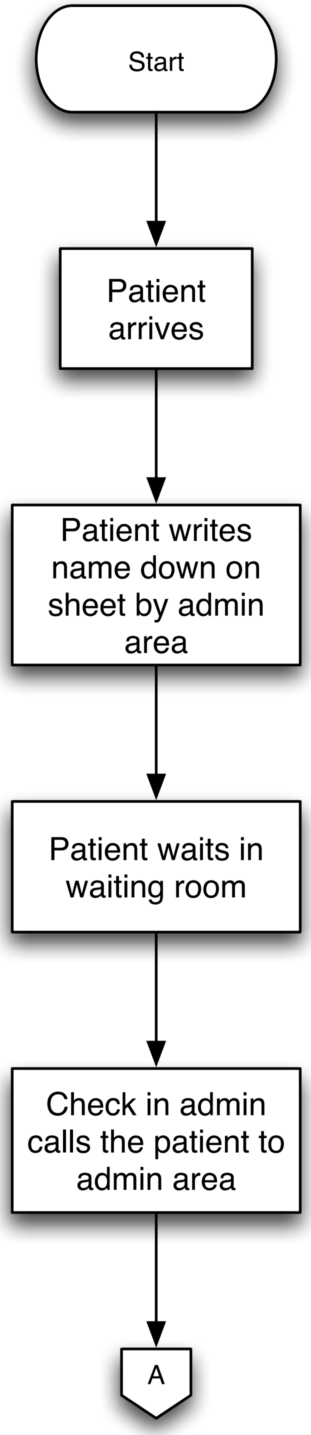
Overview

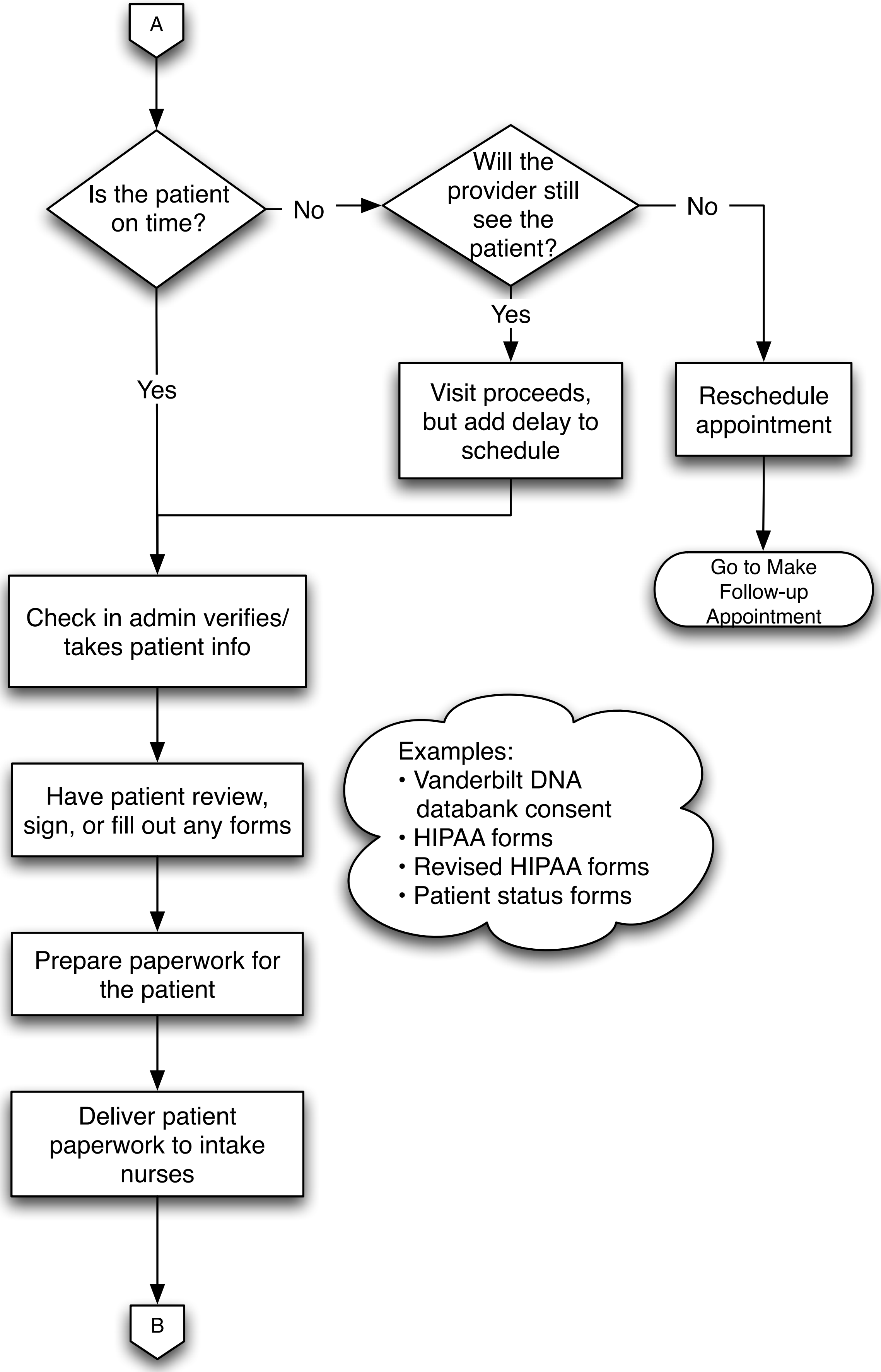


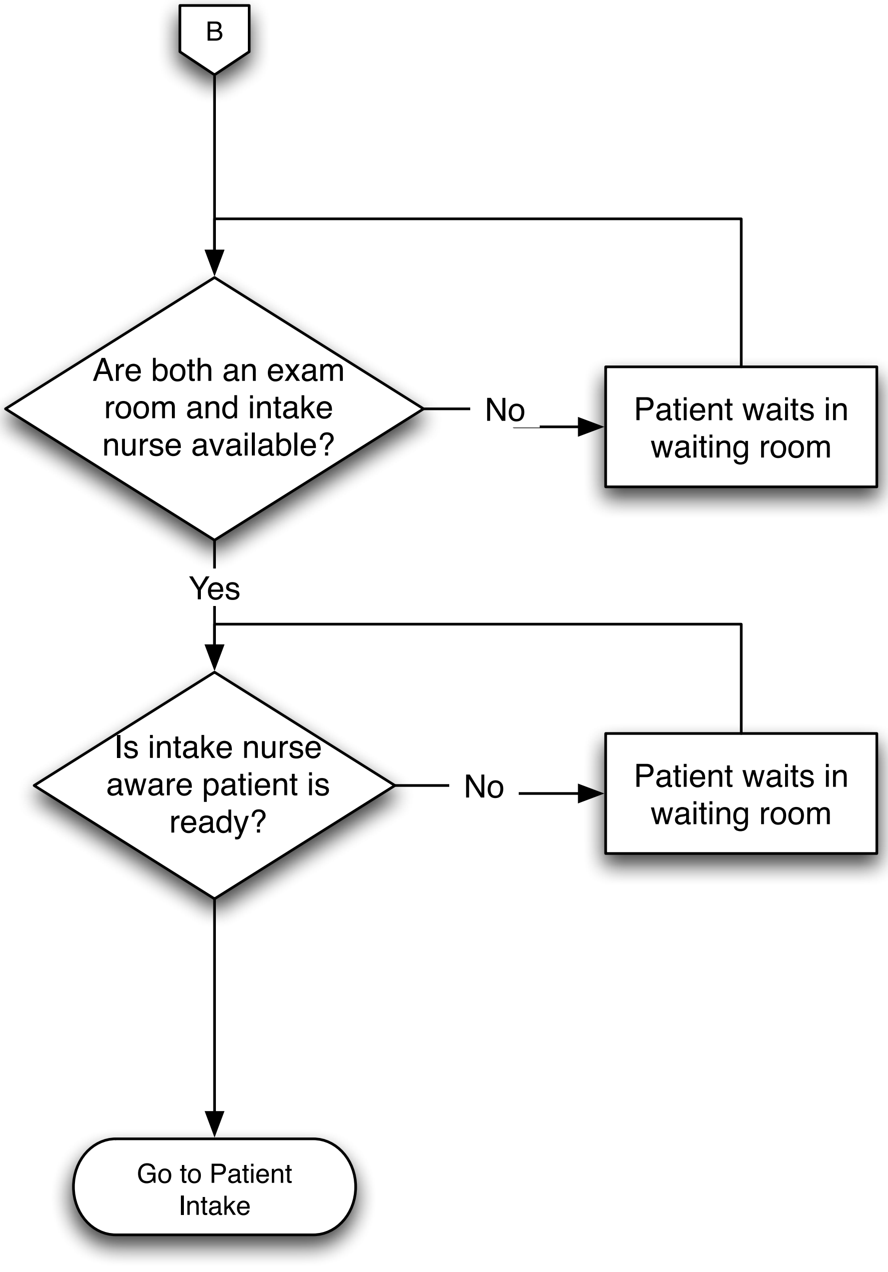
Appointment Preparation



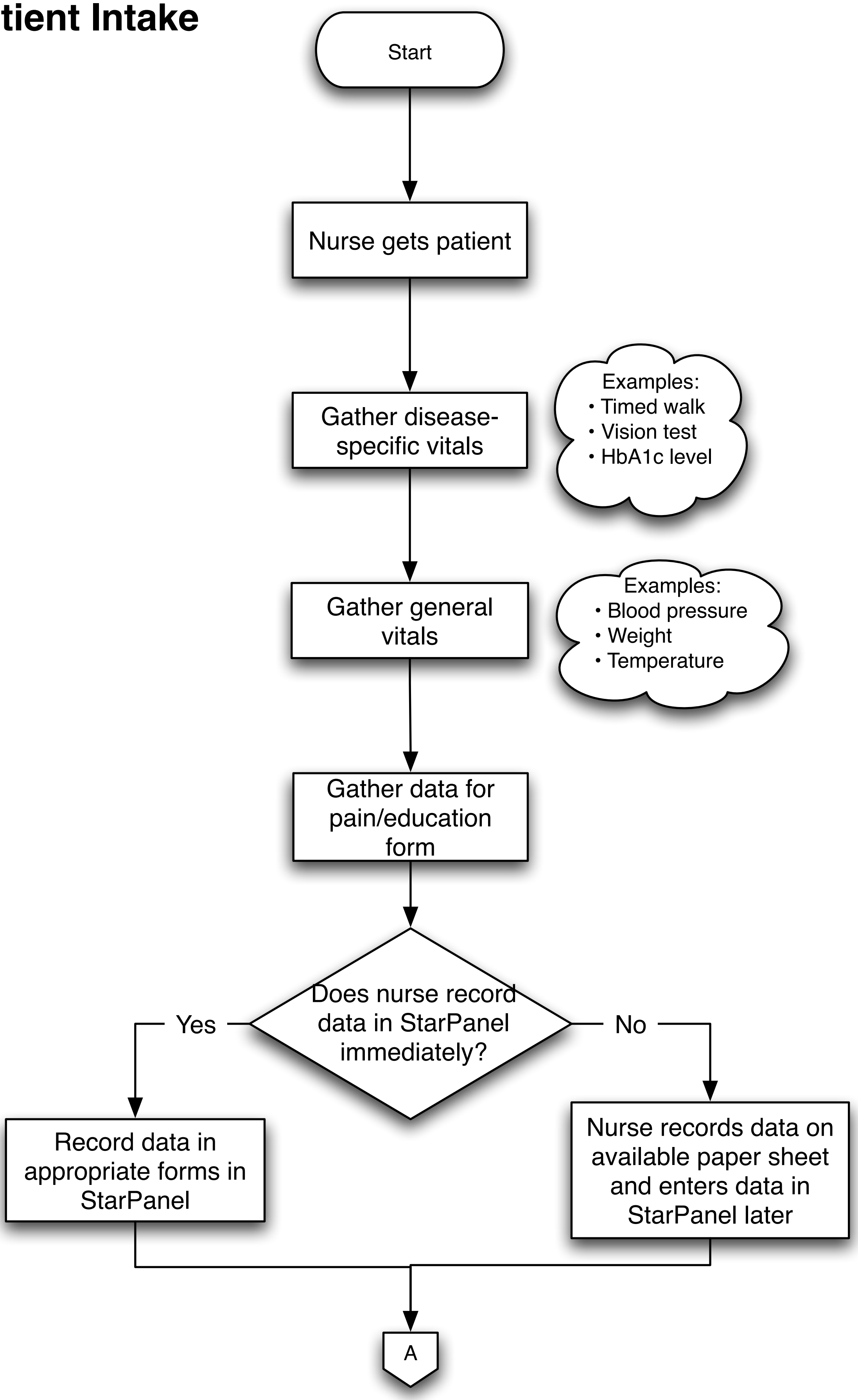
Check In

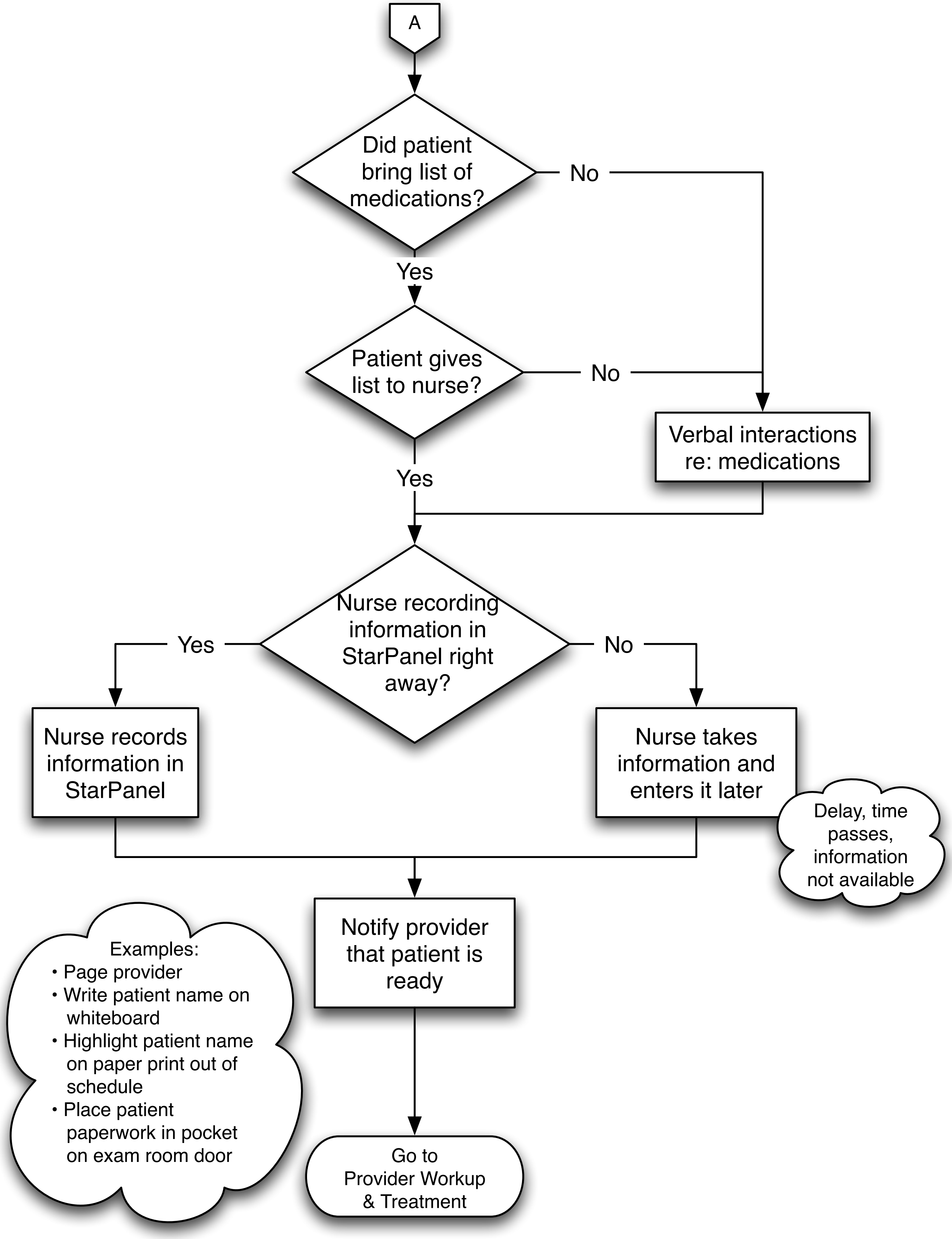

Start
Patient arrives
Patient writes name down on sheet by admin area
Patient waits in waiting room
Check in admin calls the patient to admin area
A


A
Is the patient on time?
No
Will the provider still see the patient?
No
Yes
Yes
Visit proceeds, but add delay to schedule
Reschedule appointment
Go to Make Follow-up Appointment
Check in admin verifies/ takes patient info
Have patient review, sign, or fill out any forms
Examples:
• Vanderbilt DNA databank consent
• HIPAA forms
• Revised HIPAA forms
• Patient status forms
Prepare paperwork for the patient
Deliver patient paperwork to intake nurses
B

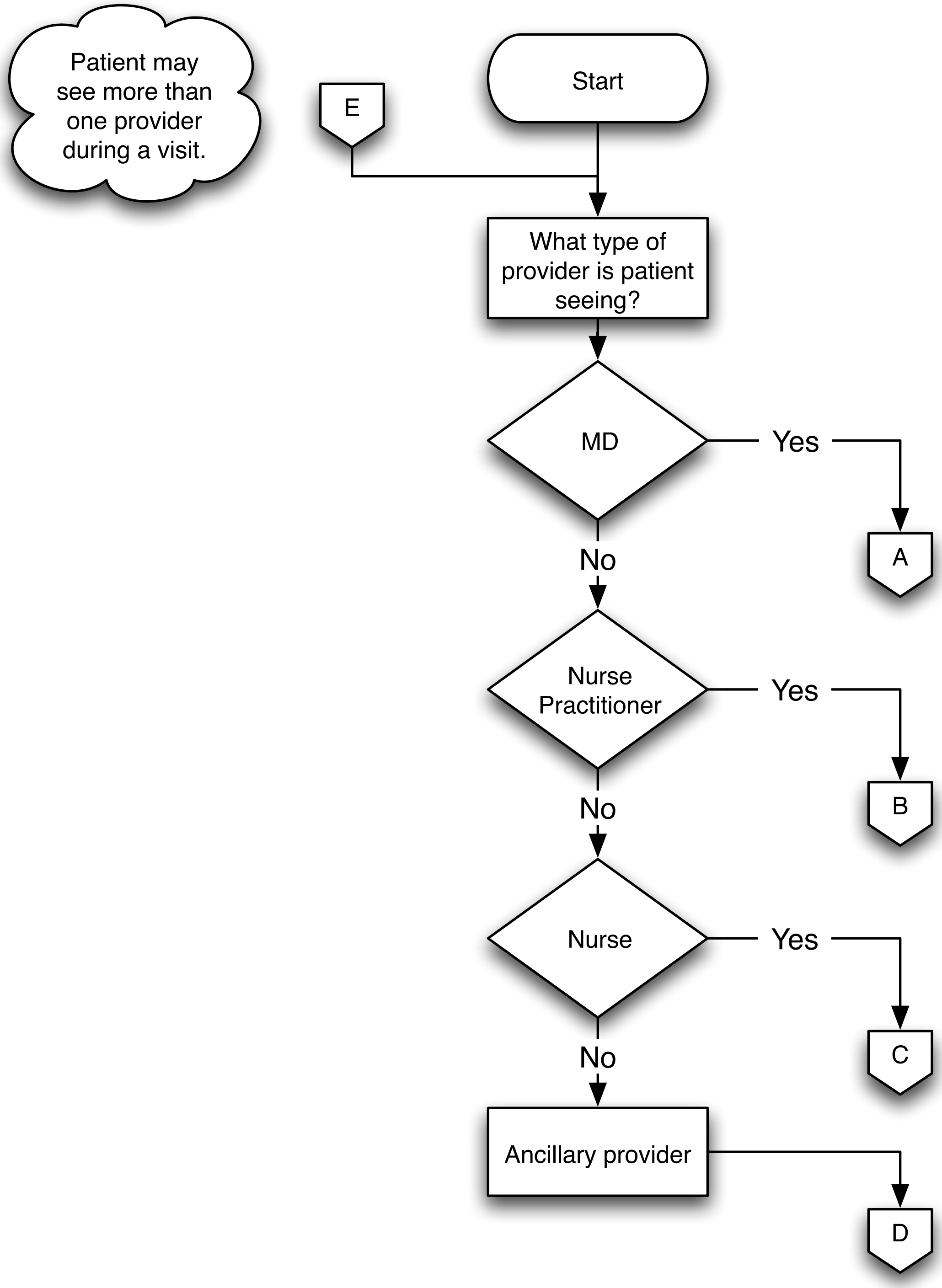

B
Are both an exam room and intake nurse available?
No
Patient waits in waiting room
Yes
Is intake nurse aware patient is ready?
No
Patient waits in waiting room
Go to Patient Intake

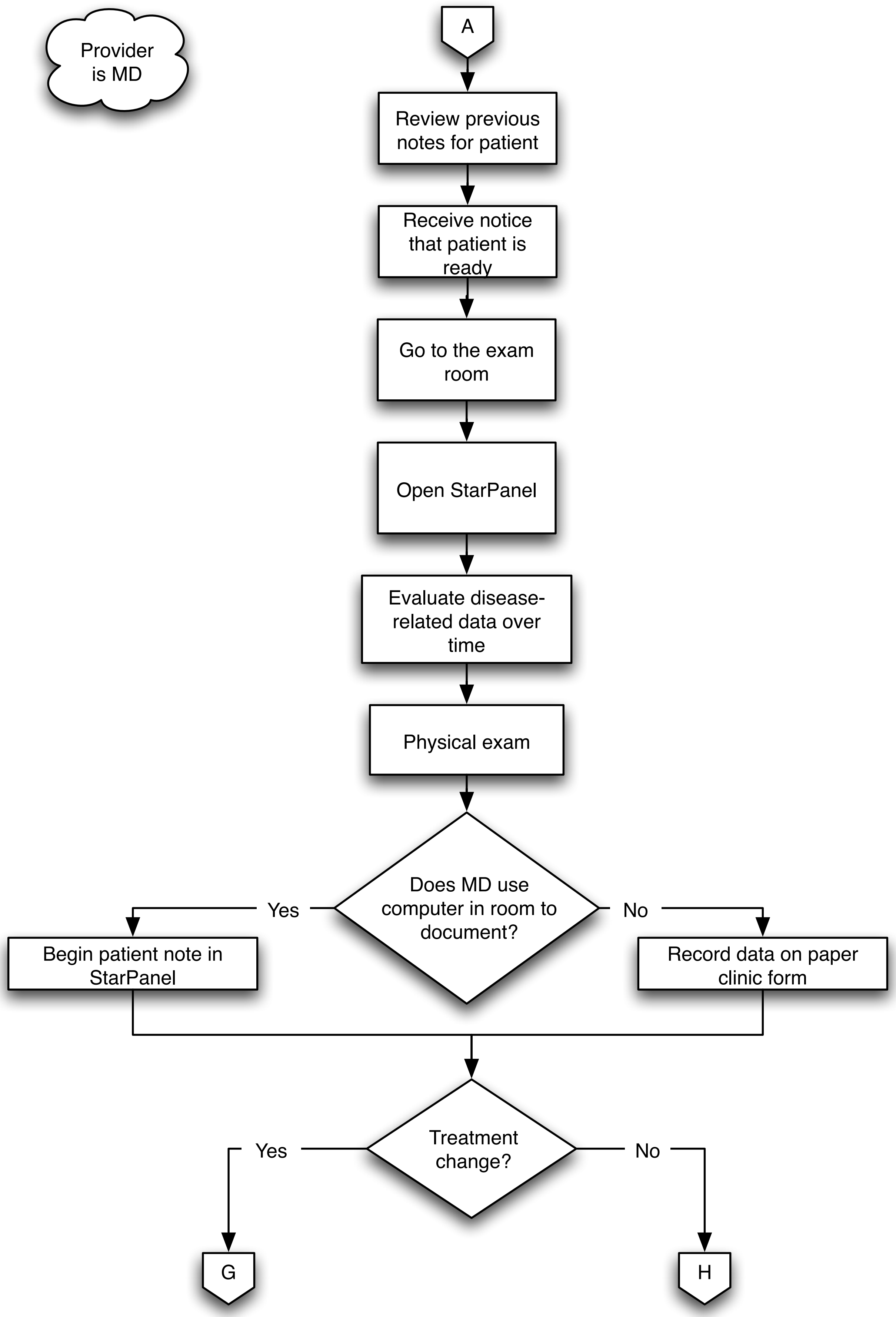
Patient Intake

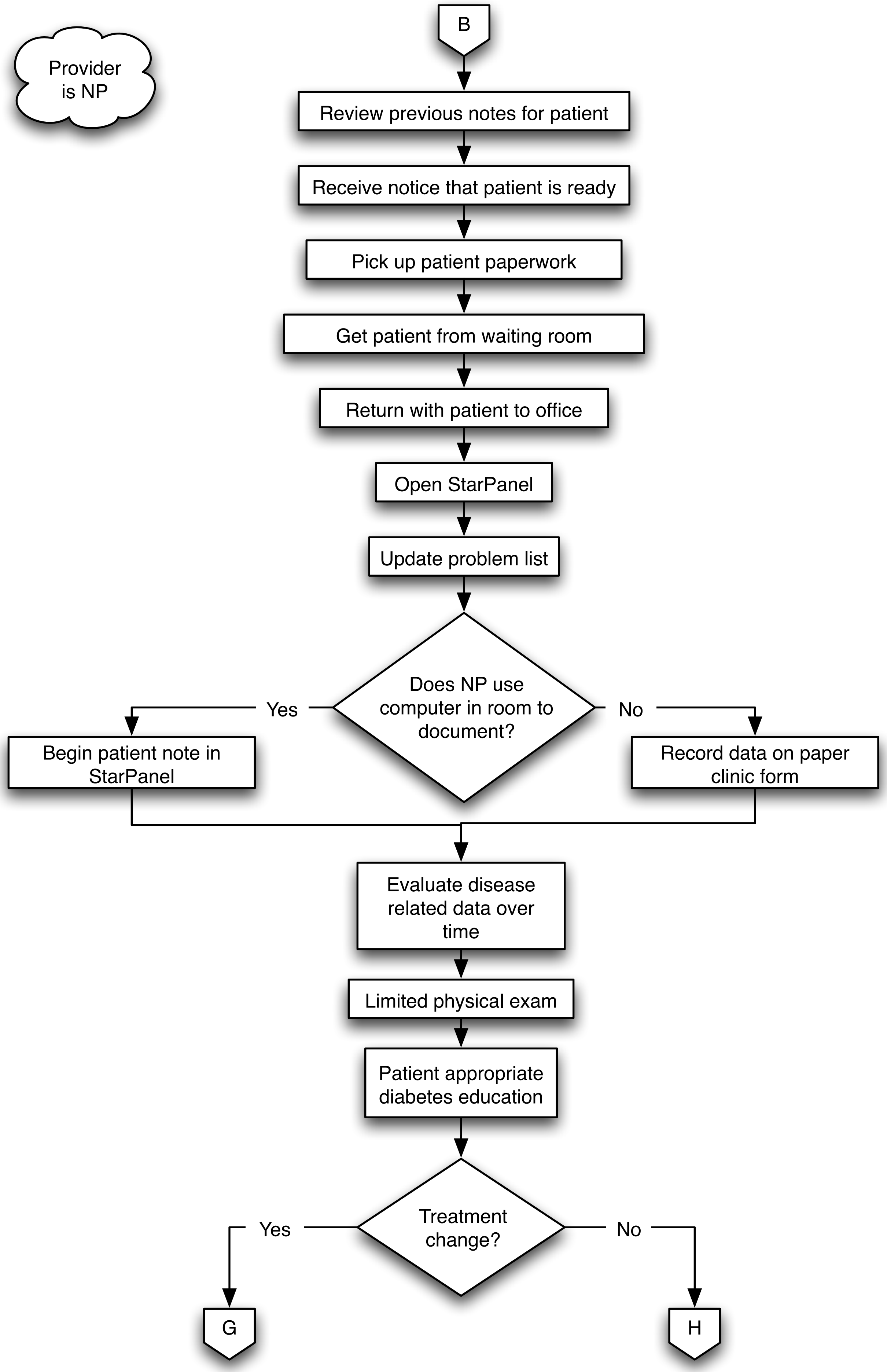


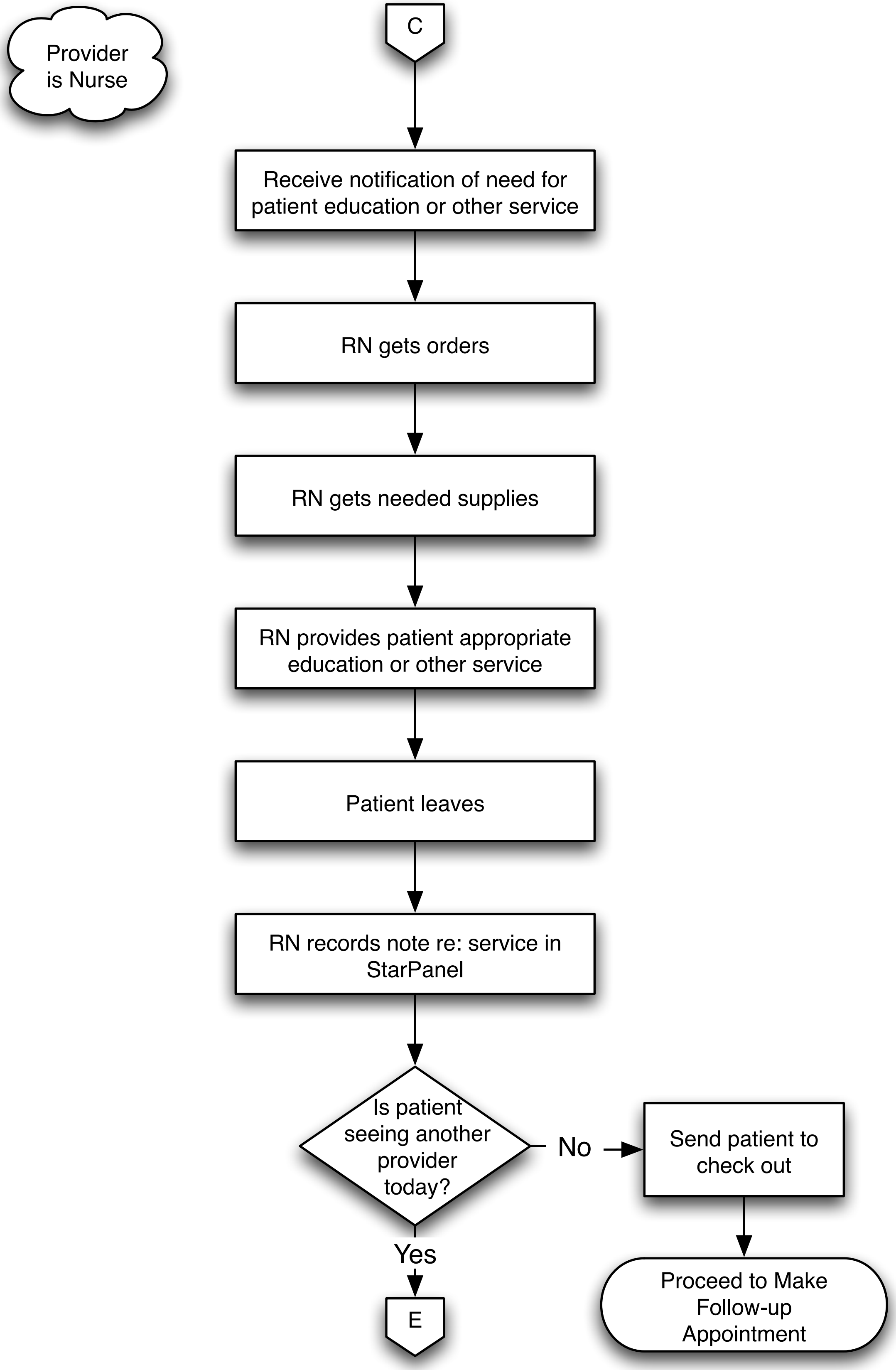

A
Did patient bring list of medications?
No
Yes
Patient gives list to nurse?
No
Verbal interactions re: medications
Yes
Nurse recording information in StarPanel right away?
Yes
No
Nurse records information in StarPanel
Nurse takes information and enters it later
Delay, time passes, information not available
Notify provider that patient is ready
Examples:
• Page provider
• Write patient name on whiteboard
• Highlight patient name on paper print out of schedule
• Place patient paperwork in pocket on exam room door
Go to Provider Workup & Treatment

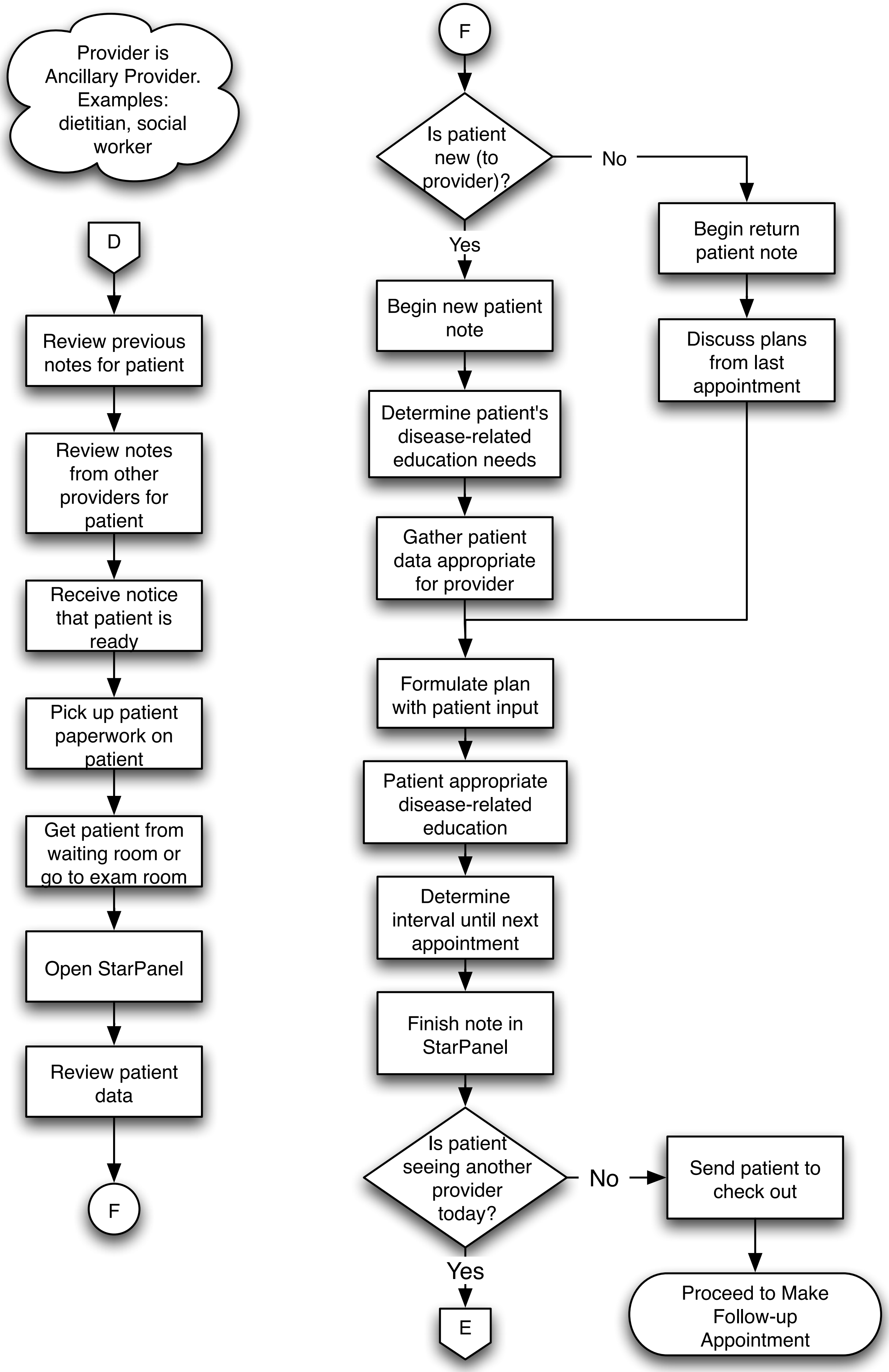
Provider Workup & Treatment

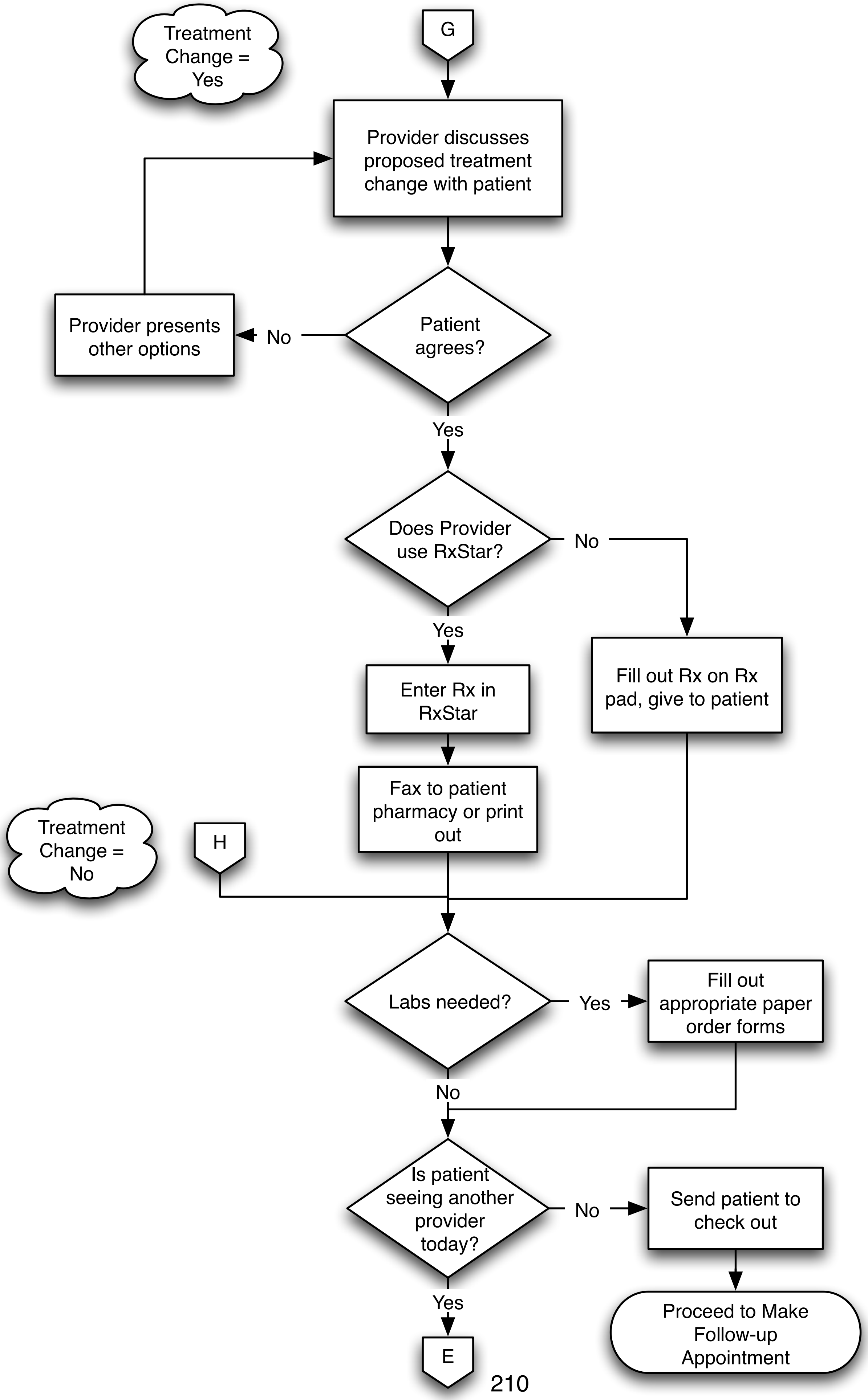



Provider is MD
A
Review previous notes for patient
Receive notice that patient is ready
Go to the exam room
Open StarPanel
Evaluate disease-related data over time
Physical exam
Does MD use computer in room to document?
Yes
No
Begin patient note in StarPanel
Record data on paper clinic form
Treatment change?
Yes
No
G
H

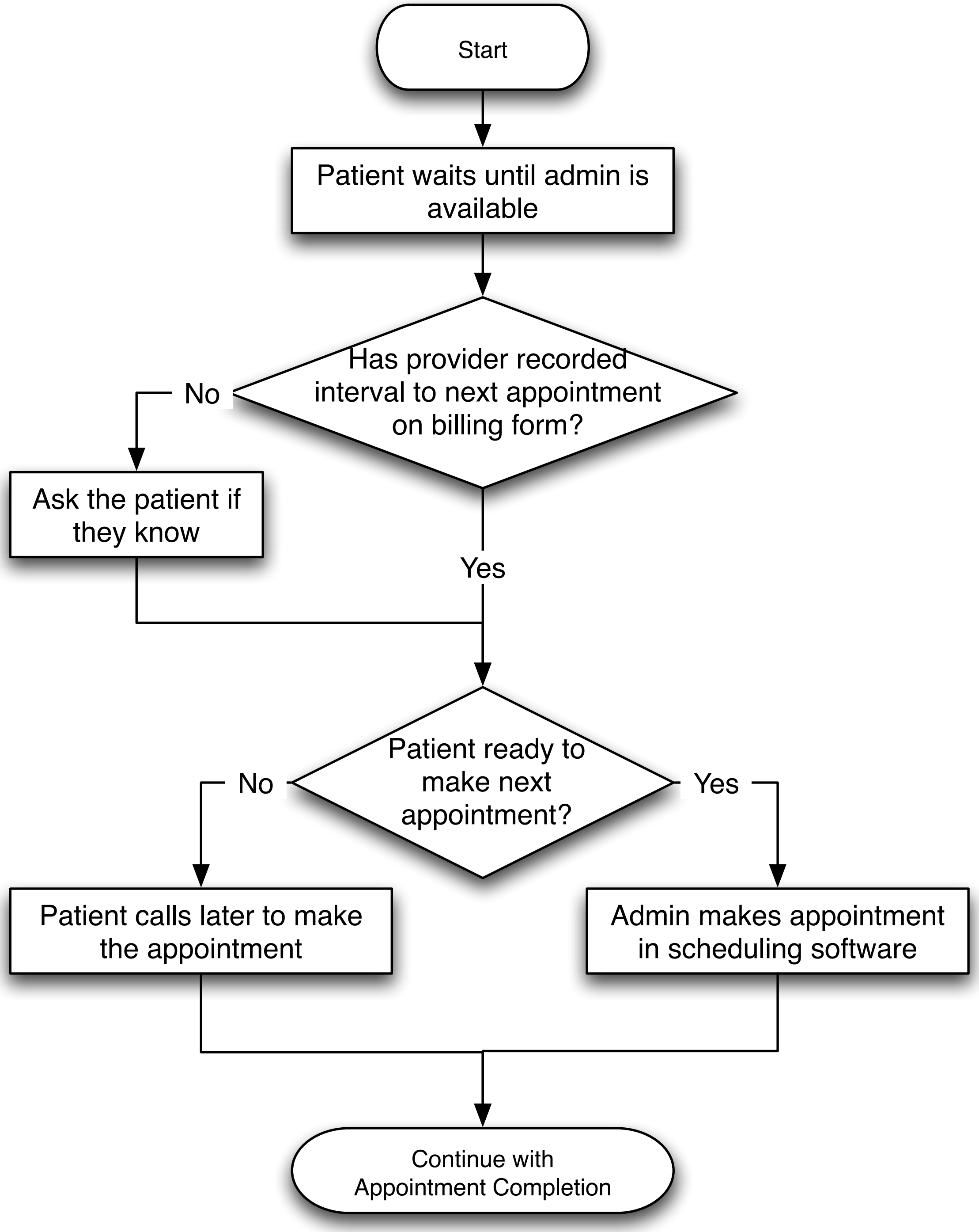

Provider is NP
B
Review previous notes for patient
Receive notice that patient is ready
Pick up patient paperwork
Get patient from waiting room
Return with patient to office
Open StarPanel
Update problem list
Does NP use computer in room to document?
Yes
Begin patient note in StarPanel
No
Record data on paper clinic form
Evaluate disease related data over time
Limited physical exam
Patient appropriate diabetes education
Treatment change?
Yes
G
No
H


Provider is Nurse
C
Receive notification of need for patient education or other service
RN gets orders
RN gets needed supplies
RN provides patient appropriate education or other service
Patient leaves
RN records note re: service in StarPanel
Is patient seeing another provider today?
No
Send patient to check out
Proceed to Make Follow-up Appointment
Yes
E

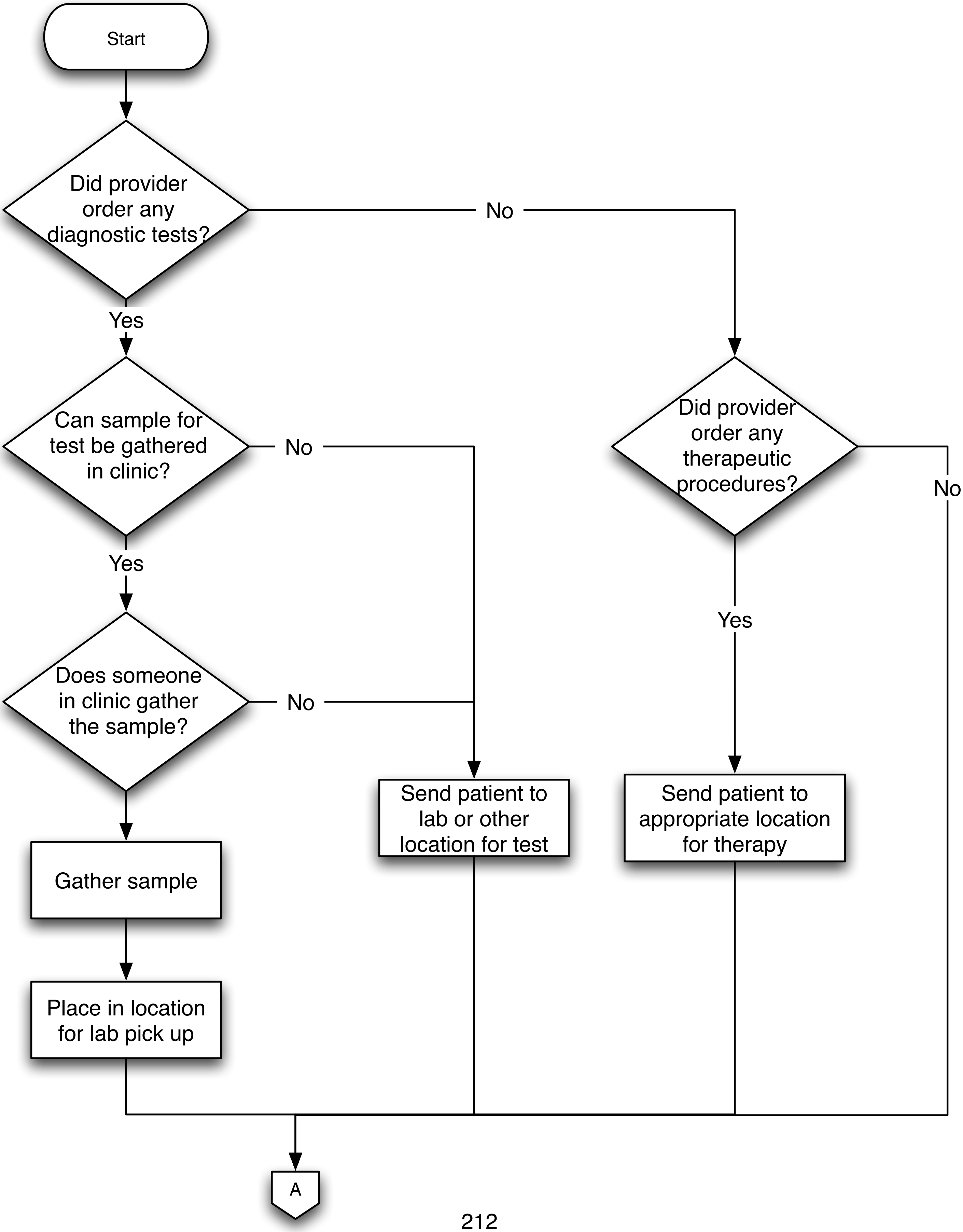

Provider is Ancillary Provider. Examples: dietitian, social worker
D
Review previous notes for patient
Review notes from other providers for patient
Receive notice that patient is ready
Pick up patient paperwork on patient
Get patient from waiting room or go to exam room
Open StarPanel
Review patient data
F
F
Is patient new (to provider)?
No
Begin return patient note
Discuss plans from last appointment
Yes
Begin new patient note
Determine patient's disease-related education needs
Gather patient data appropriate for provider
Formulate plan with patient input
Patient appropriate disease-related education
Determine interval until next appointment
Finish note in StarPanel
Is patient seeing another provider today?
No
Send patient to check out
Proceed to Make Follow-up Appointment
Yes
E

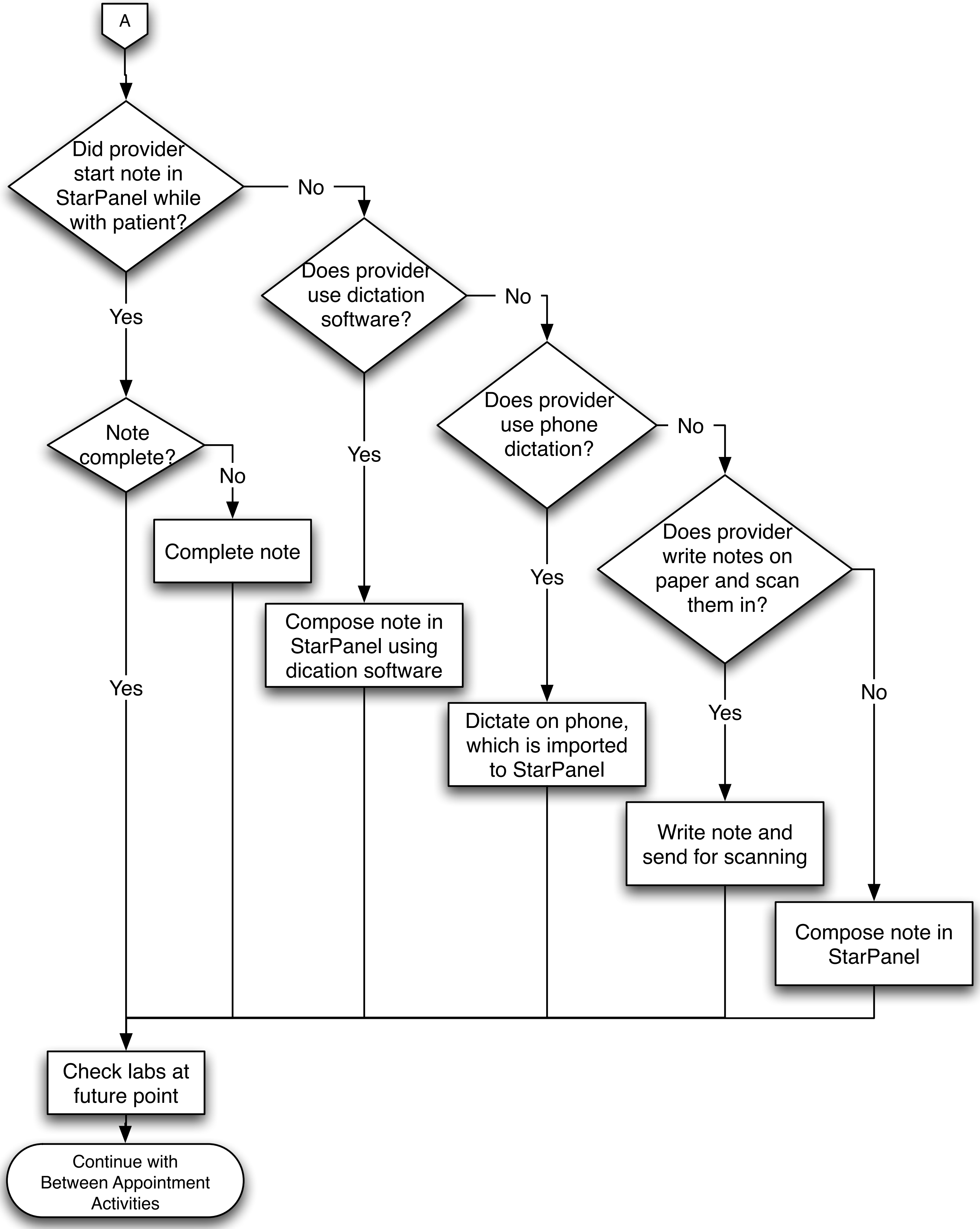

Treatment Change = Yes
G
Provider discusses proposed treatment change with patient
Patient agrees?
No
Provider presents other options
Yes
Does Provider use RxStar?
No
Yes
Enter Rx in RxStar
Fill out Rx on Rx pad, give to patient
Fax to patient pharmacy or print out
Treatment Change = No
H
Labs needed?
Yes
Fill out appropriate paper order forms
No
Is patient seeing another provider today?
No
Send patient to check out
Proceed to Make Follow-up Appointment
Yes
E

Make Follow-up Appointment

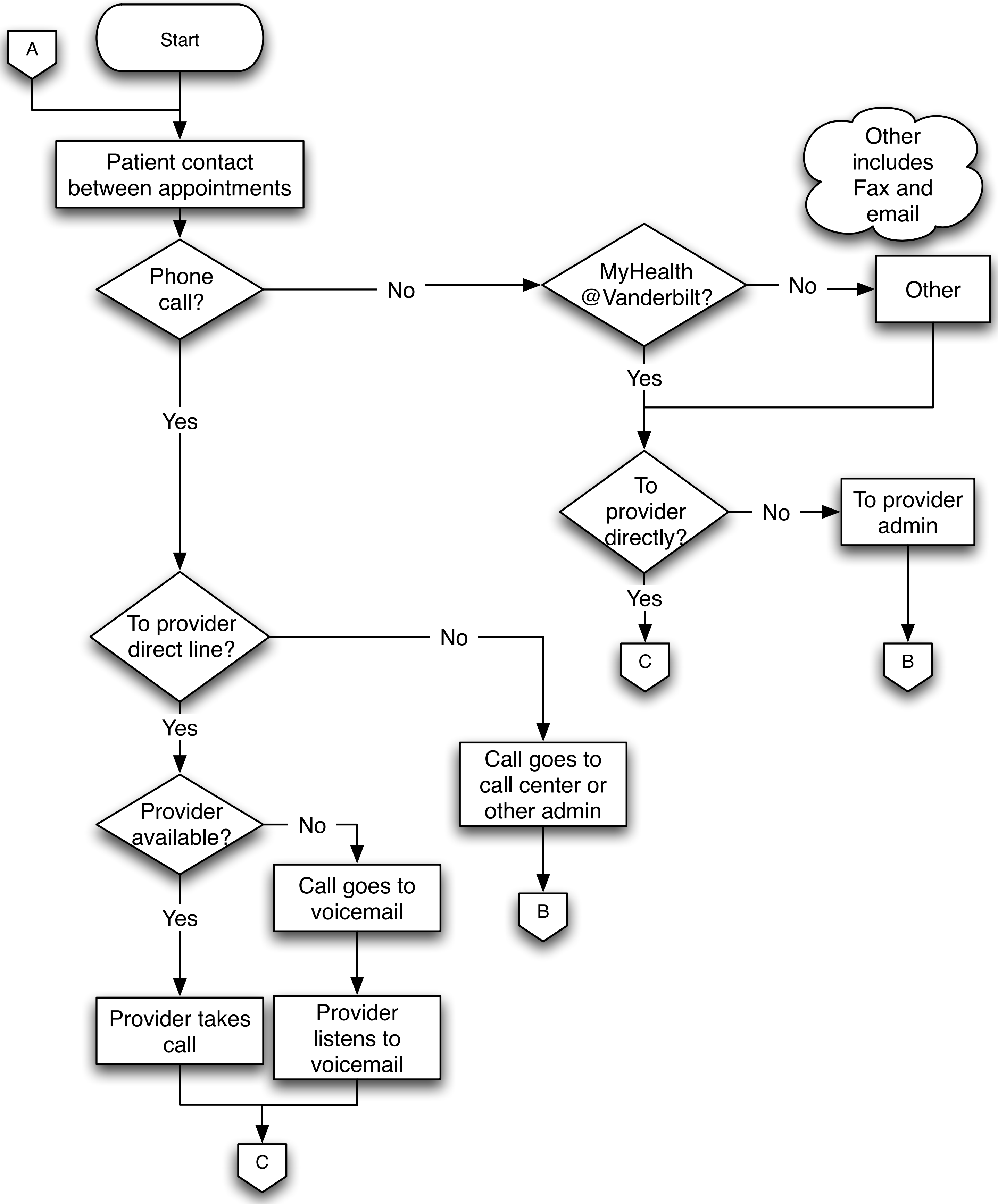


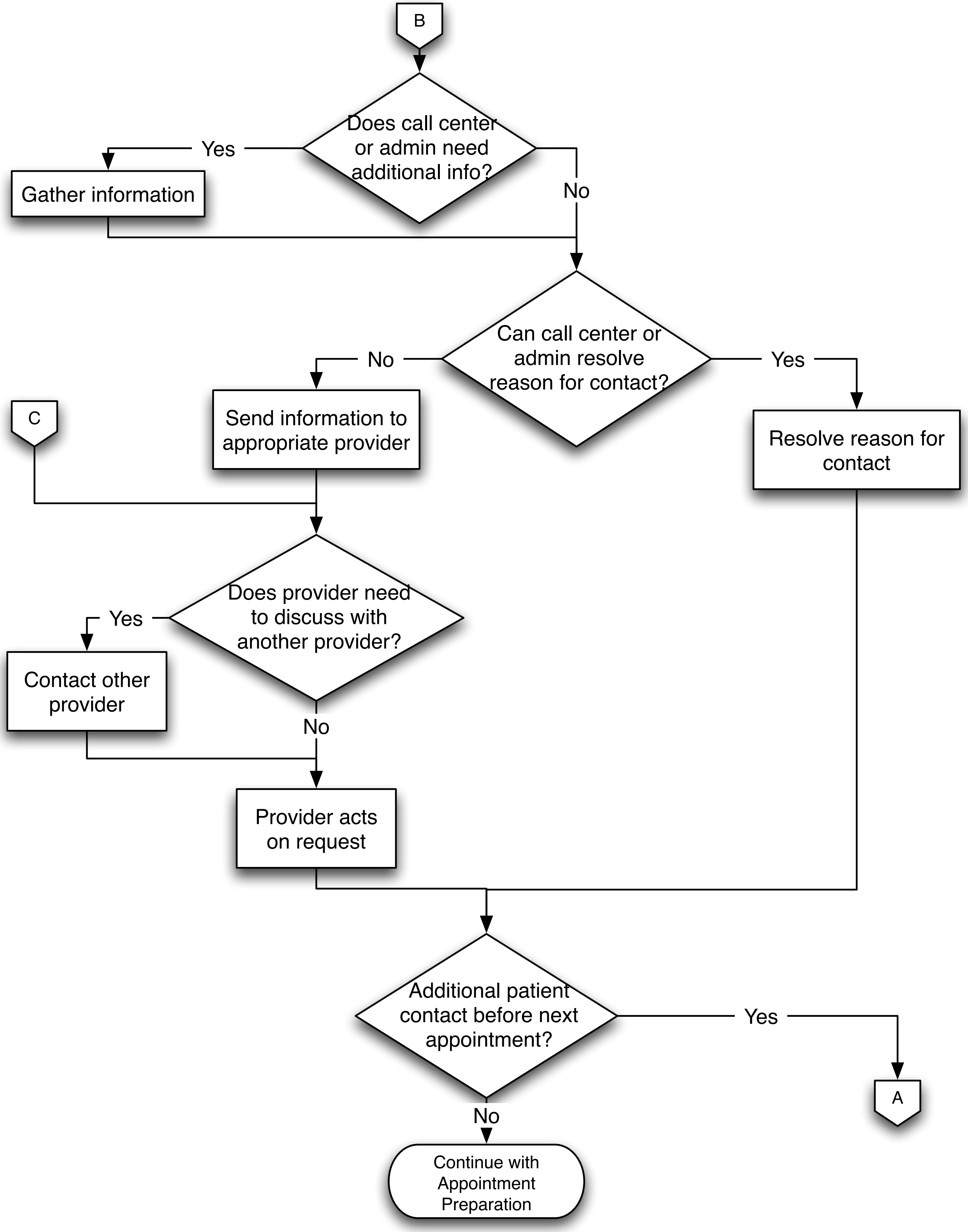
Appointment Completion




A
Did provider start note in StarPanel while with patient?
No
Does provider use dictation software?
No
Does provider use phone dictation?
No
Does provider write notes on paper and scan them in?
Yes
Note complete?
No
Complete note
Yes
Compose note in StarPanel using dication software
Yes
Dictate on phone, which is imported to StarPanel
Yes
Write note and send for scanning
No
Compose note in StarPanel
Yes
Check labs at future point
Continue with Between Appointment Activities

Between Appointment Activities




B
Does call center or admin need additional info?
Yes
Gather information
No
Can call center or admin resolve reason for contact?
No
Send information to appropriate provider
Yes
Resolve reason for contact
C
Does provider need to discuss with another provider?
Yes
Contact other provider
No
Provider acts on request
Additional patient contact before next appointment?
Yes
A
No
Continue with Appointment Preparation

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