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Development of an Evidence-Based Implementation Plan for a System-Wide Anticoagulation Management Service

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Development of an Evidence-Based Implementation Plan for a System-Wide Anticoagulation Management Service

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Capstone requirement for the Master of Science in Health Policy and Management

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Background

Anticoagulation is a prescribed therapy that thins a patient's blood in order to treat certain diagnoses or prevent the occurrence of certain events. The most common indications for anticoagulation therapy are to treat or prevent clotting disorders such as pulmonary emboli (PE) or deep vein thrombosis (DVT) and embolic stroke from irregular heart rhythms such as atrial fibrillation. Points of entry and methods for managing this treatment may vary within a single healthcare system, and without a systematic approach and standardized protocols, patients may not receive optimal treatment. Anticoagulation is unique to many treatment therapies because the most commonly used medication in treatment, warfarin (or Coumadin/Jantoven), has a relatively narrow therapeutic range and requires frequent dose adjustments based on the close monitoring of blood draws. The lab value used for monitoring the therapeutic effect of treatment is the prothrombin time/international normalized ration (PT/INR) which indicates serum clotting time. Potential risks associated with poor dosage control include hemorrhagic and thromboembolic events such as stroke and pulmonary emboli (PE). Transitions in care, medical procedures, surgeries, antibiotics, and changes in diet can further complicate treatment efforts and require more frequent monitoring and dosage changes. Coordination of care through integrated delivery systems is essential to the management of these patients.

National Awareness:

Over the past decade there has been an increased focus on the safety and management of patients receiving anticoagulation therapy. In 2008, The Joint Commission added an additional safety requirement to the National Patient Safety Goals specifically addressing the use of anticoagulation therapy (NPSG 3.05.01). This new standard focuses on the need for patient education and the use of approved protocols and policies. The National Quality Forum Safe Practice 29 also focuses specifically on the safety of anticoagulation therapy and performance measures surrounding quality improvement efforts. (NQF, 2010) Further efforts by the Institute for Safe Medicine Practices (ISMP) have created

additional resources for hospitals that are available as an online toolkit and includes items such as a self-assessment tool and sample failure modes and effects analysis (FMEA) for hospitals to assess their ability to provide high quality anticoagulation therapy in a safe and effective manner (ISMP, 2014).

Problem

The Mercy Health System of Maine (MHSM) is a large healthcare system located in Southern Maine. It consists of three inpatient campuses, one level II Emergency Department, four Express Care centers, seven Primary Care locations and an array of specialist practices. The organization has identified a need for improved management of anticoagulation therapy within the system as a large number of patients are receiving anticoagulation therapy throughout all of the various healthcare access sites. In order to address this need, MHSM seeks to implement a system-wide, standardized approach for managing patients receiving anticoagulation therapy.

In April of 2014, MHSM approved a plan to implement an anticoagulation management service (AMS) based in the cardiology practice. This service will initially see patients at the cardiology practice site and then begin to serve patients at selected outlying practice sites on certain scheduled days as well. The AMS will first consist of any existing anticoagulated cardiology patients as well as any inpatients being discharged from the hospital with a new prescription for anticoagulation therapy. Once the program is established, further enrollment will aim to provide services to additional patients in the Mercy System from the primary care sites via a referral approach. The organization is in the process of developing the clinical policies and protocols and obtaining necessary resources to establish and mobilize a system-wide approach. There is a need for a strategic plan for implementation to identify current processes, key players, and necessary human and technological resources. Additionally, determining structural and operational practices will allow clinicians to deliver patients with optimal anticoagulation therapy. Incorporating these practices into the development plan will ensure that the organization best serves the needs of the population receiving care at MHSM.

Methods

The approach for the study is a qualitative review of the evidence in relation to current practices throughout the system and identification of future considerations for implementation. In order to adequately assess the scope of the project and the areas for development, a close look at what currently exists in the system in relation to what evidence recommends as best practice has been performed based on the chronic care model with a specific focus on the following four core elements of this model: 1) *delivery system design, 2) clinical information systems, 3) a prepared and proactive team, and 4) informed activated patients* (Wagner et al., 2001). With these four elements in mind, a review of the literature was conducted and questions were developed to interview staff at each of the nine outpatient sites currently managing patients on chronic anticoagulation therapy. The interviews were performed in conjunction with a field experience opportunity in which practice sites were visited and staff provided information on how current anticoagulation therapy is currently being managed. Interviewees included physicians, RNs/LPNs, MAs and practice managers from eight of the nine sites (one practice sites was unable to be scheduled in time for inclusion in results). Through an analysis of the interviews and information from the site visits, and in collaboration with the project's business and clinical teams (which consists of the physician champion, cardiology practice manager, and pharmacy director among others), the following tools construct the framework for the project: 1) a thorough literature review for evidence based practice, 2) a logic model identifying project resources, inputs and outputs, and outcomes, 3) process maps of both current and future work flows, 4) an evidence-based gap analysis, 5) an organizational readiness assessment, 6) a patient-centered care model, and 7) additional recommendations pertaining to education, documentation, patient engagement, and operational considerations. These tools will assist and guide the organization in designing a system-wide, evidence-based strategic plan for implementing an anticoagulation management service (AMS) that will meet program goals during all phases of implementation.

Literature Review

In order to identify best practice recommendations and existing operational considerations for implementing an anticoagulant management service, a review of the literature has been conducted to address the following points:

1. Standards for best practice and the identification of factors known to contribute to health outcomes for patients receiving anticoagulation therapy.
2. Staffing considerations, resources and the necessary key players for success.
3. Operational and organizational recommendations for providing high quality anticoagulation management.

The findings from the literature review provide the foundation for the gap analysis and are the basis for the recommendations of a strategic plan that will aim to reach all MHSM patients on anticoagulation therapy.

As the literature review focuses primarily on areas of research pertaining to the implementation of an anticoagulation management therapy program, a search of PUBMED, CINAHL and Google Scholar databases was conducted using the key terms: *anticoagulation therapy, anticoagulation management, outpatient anticoagulation management, anticoagulation clinic,* and *operational anticoagulation*. Articles were then reviewed to look specifically for evidence-based guidelines for managing anticoagulation services. Relevant citations were also reviewed for further information and the following recommendations were identified.

Review of Evidence Based Guidelines:

Systematic approach: Possibly the most widely recognized method for increasing safety and efficiency in anticoagulation therapy is the creation of a system-wide, evidence-based approach for managing care. And as described by Garcia et al. (2008), this is often implemented through a dedicated

anticoagulation management service (AMS). However, these authors also note that this is not how the majority of patients in North America are currently receiving this care (Garcia et al., 2008). The positive impact on quality metrics for patients receiving therapy through a centralized service as compared to usual care has been well studied and published for over twenty years (Chiquette, Amato, & Busey, 1998), (Witt, Sadler, Shanahan, Mazzoli, & Tillman, 2008), (Baker, Cios, Sander, & Coleman, 2009), (Wilson et al., 2003).

Qualifications and Supervision of Staff: Another recommendation for ensuring high quality anticoagulation therapy is the training and supervision of staff involved in the care of patients receiving therapy. Specifically it has been suggested that patient assessment and therapy management should be administered only by licensed healthcare professionals who have received formal education and training on anticoagulation therapy management (Garcia et al., 2008). For practitioners or organizations that may be working with a referring provider to manage patient care it is encouraged that a collaborative practice agreement be established in order to clearly define the roles and responsibilities of the healthcare team (Garcia, et al., 2008).

Care Coordination: In order to best identify, track and manage patients a great deal of focus should be placed on the specific care coordination efforts within any management service. This includes the development of policies and procedures and documentation and tracking systems that facilitate access to information and monitoring of quality data. Specific items that may be addressed by policies and procedures include: risks and benefits of therapy, patient's understanding, indications, target INR values, planned duration of therapy, managing initiation of therapy, management of non-therapeutic INR values, monitoring intervals, definition and documentation of adverse events, method for follow-up of missed appointments, timely reporting of lab results, managing transitions or interruptions in care, managing non-adherence, developing criteria for discharge, reimbursement, quality measures, management during pregnancy, and eligibility criteria for patient self-testing (PST) (Garcia et al., 2008).

A tracking system that promotes documentation of desired elements and facilitates quality measurements should include patient demographics, treatments, and communication with the patient including education (Garcia et al., 2008).

Patient Assessment and Education/Communication: As described above, policies and procedures and documentation/tracking systems should help guide clinicians in the assessment and education of patients. The initial patient assessment should include a comprehensive medical history, social, employment and lifestyle profiles, as well as the patient's beliefs, attitudes, level of understanding, health literacy, resources, and motivation (Garcia et al., 2008). Knowledge assessment tools specific to anticoagulation have already been utilized and proven to be of value and may be helpful for providers in establishing education needs for individual patients (Garcia et al., 2008), (Briggs, Jackson, Bruce & Shapiro, 2005). Documentation of patient communication and the management of missed appointments or changes to plans of care are also recommended (Garcia et al., 2008)

Quality Metrics: Time in therapeutic range (TTR) is the most widely reported and recognized quality metric for evaluating patient management. Significant research has been conducted on the impact TTR has on patient outcomes and rate of mortality. It is well documented in the evidence that time spent out of therapeutic range is strongly correlated with increased incidences of hemorrhagic and thrombotic complications associated with anticoagulation therapy and an increase in TTR has been associated with decreased mortality, myocardial infarction, and stroke (Witt et al., 2008) (Phillips & Ansell, 2008). Current recommendations for the proportion of patients INR time spent in therapeutic range should be around 60-70% (Phillips & Ansell, 2008). The frequency of INR testing is recommended as every four weeks once stable and at least every two weeks for unstable patients, with no more than one week elapsing after an out of range INR (Phillips & Ansell, 2008). Once dosing has been established and the INR has been therapeutic for greater than three months the INR can be monitored every eight to twelve weeks thereafter (Holbrook et al, 2012). The other well accepted and reported quality metric

is the rate of adverse events including hemorrhage and thromboembolism, which can also be tracked and evaluated in comparison to recommended benchmarks. As suggested by Phillips and Ansell (2008) overall rates of hemorrhagic and thromboembolic events in established patients should be no higher than 1-2% per patient year. Most importantly, continuous tracking of quality metrics assessed by a consistent method is recommended within any setting where anticoagulation therapy is being managed.

Initiation/Maintenance of Therapy: Another prominent practice recommendation in the literature is the establishment of system-wide evidence-based protocols that clearly define the actions to be taken during the initiation phase of therapy and subsequent treatment changes throughout the course of therapy. Clinical practice guidelines are well established and frequently reviewed and published and are already widely in use. Identification and standardization of a protocol for system-wide use improves coordination across transitions of care and ensures that all providers within a system are working from the same tool. The American College of Chest Physicians published evidence-based practice guidelines on managing Vitamin K Antagonists in 2008 and in 2012 released evidence-based clinical practice guidelines on antithrombotic therapy and prevention of thrombosis which both outline in detail the clinical practice recommendations for managing anticoagulated patients.

New Areas of Research:

Process Measures and Operational Indicators of Quality: In addition to quality metrics ensuring the effectiveness of clinical management services, there is newer research that aims to assess the operational aspects of anticoagulation management services by focusing on structural and process measures. This research points out that while there are ample examinations of the clinical and patient care aspects of anticoagulation therapy, little attention has been paid to what managerial and operational practices impact patient outcomes. In 2009 The Joint Commission (Rose et al., 2009) released a performance improvement article describing methods for assessing the quality of operational functions of systems providing anticoagulation management services to patients. This article describes

indicators addressing both the structure of the service where the care is provided, how INR results are collected, and tracking software, as mentioned above as well as process measures such as time to initiation of therapy, maximum time for INR testing after initiation, and timeliness of follow up patient notification when an INR falls outside an acceptable range. The article also identified the need for further research to correlate structural and process indicators with clinical quality data to evaluate the impact that different operational variants may have on patient outcomes.

Following the release of the Joint Commission article, two additional studies have been conducted both within the Veterans Health Administration (VA) facilities. The first published in 2011 (Rose et al, 2011) sought to identify specifically which organizational and management features could be associated with better clinical outcomes. The authors surprisingly found no statistical significance for any of the current clinical guidelines that have been recommended to date in the literature. However, the results of this study then spurred on a second qualitative study by Rose et al., (2012) that compared three of the highest performing anticoagulation clinics (ACCs) with three of the lowest performing ACCs in the VA. From this information alternative domains of organization associated with level of performance were identified and described. The six domains that were found to be significant include: 1) sufficient staffing to handle workload, 2) innovation to encourage EBP, 3) presence of a quality champion, 4) residency-trained pharmacists, 5) creating a climate of group learning, and 6) internal performance measurement.

Additional Areas of Research:

While not reviewed in depth at this time the following areas of research were identified as frequently recurring themes and may be of interest to key players in the project:

Calculation of Quality Metrics for Clinical Outcomes: Three methods for calculating time in therapeutic ration (TTR) were tested in a study by Schmitt et al. (2003). The results found that all three methods of calculating TTR possessed inherent limitations, and the authors identified that while this makes large scale comparisons of clinical outcomes across studies difficult it is important that investigators select one method and remain consistent in their techniques.

Design Methods Impacting Quality: Studies have indicated that the method for INR monitoring can influence metrics including the TTR, and specifically that the utilization of POC devices, which can be done at locations where laboratory access is an issue, may improve clinical outcomes due to the ability to provide patients with more frequent and easier access to testing (Franke, Dickerson, & Carek, 2008). Other studies have focused on the accuracy of POC devices and provide recommendations for periodic equipment testing (Sunderji et al., 2005) and the need for an established range for validation of out-of-range INR results (Dorfman et al., 2005).

Models of Care: Since at this time the decision has been made to initially implement a facility based anticoagulation management service, the location specific models of care including usual medical care (UC), Anticoagulation Clinic (AC), Patient Self-Testing (PST), and Patient Self-Monitoring (PSM) were not explored in depth. It is important to note however that the model of care has been found to impact factors including but not limited to: frequency of testing, patient satisfaction, cost, and quality metrics including TTR.

Peri-operative Management: While not discussed in depth for the development of an anticoagulation management service, there is a great deal of research concerning the topic of peri-operative anticoagulation which is often used as a prophylaxis for prevention of thrombotic adverse events related to surgical procedures.

Future Considerations: New medications for anticoagulation therapy have emerged over the past several years, and this has implications for clinic models and recommendations for clinical

management for all providers. The new oral anticoagulants work using a different mechanism of action than warfarin by effecting a different segment of the clotting cascade, because of this, they do not require INR monitoring. A recent article by Burnett and Trujilo (2013) outlines how these new therapies might impact practice and what can be expected in the coming years.

Logic Model

MHSM will be implementing the anticoagulation management program in a phased method, beginning first with existing cardiology patients and any patients discharged from the hospital with a new prescription for an anticoagulant. As the project advances through the phases of implementation it is vital that there is an assessment of progress based on the initial goals and outcomes. To aid with this evaluation and to begin the identification of inputs and outputs, strategies, and outcomes a logic model was created (see Appendix A).

Process Flows

Process mapping of the current flow of anticoagulated patients throughout the system enables the organization to analyze existing processes, strategies currently being utilized, variations in practice, and opportunities to streamline workflow for consideration in future planning. Process mapping the future work flows allows the project team to begin identifying and addressing any points in the process that could potentially be problematic. This will define current access points for patients, identify barriers, and help clinicians understand the flow of patients through the care continuum. For instance, current management of anticoagulation therapy is provided either by the prescribing provider or the PCP, in an AMS model, steps for referral and the transfer of patient care would need to be discussed and worked out prior to opening. See Appendix B for process maps of current work flow and Appendix C for process maps of potential future work flows.

Gap Analysis

Utilizing the Agency for Healthcare Research and Quality (AHRQ) Gap Analysis Tool (Toolkit, 2012) each area of evidence-based practice, along with new considerations for operational and organizational areas of performance related to high quality anticoagulation care as studied by Rose et al. (2012) were evaluated in contrast to current practices within the MHSM outpatient areas. The key areas for consideration resulting from the gap analysis include: the need for standardized clinical protocols, policies and procedures, patient assessment and education needs, documentation and tracking capabilities, safety practices and quality measurement, and resources to encourage innovation and evidence-based practice. Please see Appendix D for complete results and recommendations.

Organizational Readiness

Based on interviews and information gathered during the field experience, an assessment of the organizational state of readiness was performed (see Appendix E). This information allows the organization to identify which key actions need to be performed prior to moving forward with the project implementation and whether or not implementation is feasible at this time. The readiness assessment yielded a recommendation is to move forward. The key actions items include:

- the hiring and training of staff
- the purchase of necessary equipment
- distribution of a patient letter/survey to engage patients in the process change (see Appendix F)
- creation of an Anticoagulation Council to support the project on an ongoing basis
- development of policies and procedures
- collaboration with key stakeholders (specifically the Director of Primary Care to establish location of services)

- supplying the primary care providers with education in regards to referral process.

A care model has been created in order to identify the many individuals and teams who would play a role in managing the care for an anticoagulated patient. The Chronic Care Model (Wagner, 1998) provides a useful framework to display visually the key players and the points at which they interact. Included in the model are the recommended actions for maximizing the roles and connections between the key players and the areas of the model they correspond to (see Appendix G).

Documentation and Quality Design

Recommendations for documentation and assessment of quality metrics have been developed based on evidence obtained from the literature review and will serve to help inform the decisions of the organization when addressing aspects of the system design. At MHSM the outpatient physician practices utilize an electronic documentation system (or electronic health record-EHR) and the functionalities of this system were investigated during the interview process. The following areas were discussed for feedback from MHSM clinicians: patient identification and assessment information, process flows for the input and tracking of clinical data (including labs and dosage changes), patient education practices, procedures during transitions of care, and the process for patient follow up communications.

Through a review of the information gathered during the interviews, current documentation elements being recorded in the EHR, and those that are being recorded elsewhere (either on paper or in supplemental documentation tools) are outlined in table 1. Recommendations for the necessary components that incorporate evidence-based practice elements into patient assessment and documentation are listed in table 2. The area of concern most frequently expressed during the interviews is the inability of the EHR to provide system-generated data to assist in the tracking and monitoring of patient INRs, missed appointments, and overdue labs. Currently there is no report or reminder that allows clinicians to review which patients may have missed having an INR. Several

different strategies have emerged to address this need including paper charting, manually updated excel tracking spreadsheet, manually created reminder tasks, and paper tracking tools.

In regard to quality monitoring, there is also no system-generated quality measurement data, and the process for obtaining the data is manual and cannot be accessed through the EHR for all anticoagulated patients because some documentation of INR values is still on paper. Manual tracking of quality measures is not being performed at this time. Quality metrics will need to be assessed in order to further evaluate current practices. Once this is done, the organization will be able to compare the quality of current anticoagulation therapy to any future efforts throughout the implementation phases of the project. Recommended baseline quality metrics for tracking progress includes the two widely accepted clinical quality metrics of time in therapeutic range (TTR) for patients' INR values and the rate of adverse events such as hemorrhage/bleeding and stroke. In addition to these important benchmarking measures, it is strongly recommended that operational metrics for measuring internal performance measures of practice are considered and built into any future assessment fields. This could include measures such as time taken to contact patients, time from referral to first appointment, number of patients discharged, and percent of scheduled tests completed.

Table 1. Examination of Documentation Elements

Documentation Items Currently Captured in the Existing Electronic Health Record Anticoagulation Flowsheet:
• INR • Current dose • New dose • Recheck • Pt notified • Comments
Documentation Items not captured in Electronic Health Record:
• Provider managing INR • INR goal • Indication • Method of testing • Tablet Strength • Patient Instructions • Education • Physician signature • Necessity for anticoagulant bridging • Outstanding labs/Coumadin agreement • Patient letters

Table 2. Recommendations for Assessments (Ansell, Oertel, & Wittkowsky, 2009)

Recommended Assessment Fields	
New Patient Education:	**Initial Intake Assessment:**
• Reason/indication for anticoagulation • How anticoagulants work • Importance of adherence with dosing and appointments • Dosing and administration • Tablet strength-with visual recognition • What to do for a missed dose • Different names of anticoagulant • Potential drug interactions • Avoidance of NSAIDS and Aspirin • Activities/Fall precautions • Dietary and alcohol considerations • Importance of laboratory/clinic monitoring • Signs of bleeding • Signs of disease recurrence • What to do in case of bleeding • Plan for length of therapy • Interruptions in therapy for surgical/invasive or dental procedures • Travel considerations • Informing other healthcare professionals • Anticoagulant card or bracelet • Tracking INR and medication list • Emergency phone numbers • Preferred method for contact and timely follow up • Refills • Storage • Pregnancy	• Comprehensive Medical History • Social factors • Employment factors • Lifestyle factors • Beliefs • Attitudes • Level of understanding • Health literacy • Resources • Motivation • Care Contract
Education for established patients:	**Education to be covered at every visit:**
• Adherence • Actual dose taken • S&S of bleeding/bruising • S&S of disease recurrence • Diet changes • Alcohol use • Change in prescriptions/OTC/herbal medications • Recent illnesses • Surgical/invasive or dental procedures	• INR • Therapeutic or not • Dosage change • When to call office • What to do in case of bleeding • Date of next appointment • Reading ability • Written instructions/calendar • Teach back/patient understanding

Results

As a result of examining current practice and evidence-based practice, the gap analysis reveals many opportunities for improving the care of anticoagulated patients within the MHSM system. While it was evident during the interviews that providers are doing the best they can with the resources currently available to them, multiple barriers have been identified. The two primary barriers are a lack of system-wide policies and procedures to help guide clinician in clinical decision making and management of care, and information systems that don't allow for tracking of patient data or quality monitoring.

Currently, patients in the system are managed by providers across multiple settings with varying methods for communication regarding the management and coordination of the patient's INR. While providers report utilizing dosing standards consistent with clinical guidelines there is no written protocol to guide clinical decision making including determining which patients may need bridging for invasive procedures. The term 'bridging' refers to the need to place a patient on an alternate anticoagulant with a shorter half-life than warfarin, such as enoxaparin subcutaneous injections, in order to safely perform invasive procedures. There are no reports or tracking tools available to clinicians that pull patient data from the anticoagulation flowsheet in the EHR where the majority of practices are documenting information. Some practices currently provide onsite laboratory services for patients which may help with compliance, especially in the more rural areas. However, because lab results come into the practices from a variety of settings including Mercy-owned labs, laboratory facilities outside of the Mercy system, the Visiting Nurses' Association point of care tests, and patient self-testing monitors, manual data entry is occurring in a variety of ways that makes tracking current data and therefore quality especially challenging. In an effort to overcome this some practices have established manual ways to create reminders and prompts for following up with patients with outstanding labs or who are non-compliant. Clinicians acknowledge that some patients may go longer than recommended between

INR draws and the procedure for then managing these patients also varies among sites of care. Based on these findings and research, the following recommendations have been created:

- Continue implementation of a system-wide Anticoagulation Management Service
    - Proceed in a phased approach starting with cardiology patients
- Form an anticoagulation council
    - To provide oversight during the development/implementation of policies and procedures (for both the AMS program as well as system-wide practice)
- Develop policies and procedures to guide anticoagulation practices
    - Address system-wide dosing standards, bridging therapy, and referral policies to the AMS program
- Engage patients during subsequent phases of implementation
    - Obtain patient consent for referral to the AMS program
    - Provide patients with additional options for location of care to encourage patient engagement
    - Consider utilizing a patient contract for anticoagulation care to inform and educate patients on the importance of follow up and the process for missed labs/appointments
- Involve patients in the program development process
    - Solicit feedback through a patient letter or survey
- Address educational needs at the system-wide level
    - Develop evidence-based tools to address educational assessment of anticoagulated patients
    - Create tools for ongoing education reassessment
- Explore EHR system capabilities

        - Create a report to be generated for tracking data and quality monitoring
        - Provide education on the use of these tools to practices for immediate enhancement of patient tracking
        - Use this information to begin reviewing and monitoring quality, provide this information to the practices
    - Consider ongoing needs for documentation and assessments
        - If assessment fields and quality monitoring cannot be captured in the current EHR the organization may want to explore software programs for purchase
    - Develop and utilize internal performance measures of quality
        - Timeliness of patient follow up
        - Time to first appointment (for the AMS)
        - Percentage of missed appointments
    - Implement point of care testing
        - Start with the AMS program
        - Enhance time spent with patients during appointments by taking results from point-of-care tests and incorporate into real time education on significance of results and dosing changes, use this opportunity to allow for patient questions and teach back

Discussion

The creation of a centralized program responsible for the identification and development of resources is the first key step to implementing a system-wide approach. From the organizational readiness assessment, it is clear that the MHSM organization is ready for this change. Based on the feedback gathered during the interview process, it is evident that clinicians are looking for the additional tools and resources to enhance care for anticoagulated patients. It is important that during the initial

implementation phases that patients themselves are also engaged in the process as any new developments, whether through system-wide policies or referrals to the AMS program will directly impact their current care. It is strongly recommended that the organization seek input regarding potential areas of improvement directly from the patients in order to ensure that the model will provide patient-centered care. The development of the program, including hiring and training of clinicians, the composition of policies, and the acquisition of necessary equipment will be a significant undertaking. And while this may consume the majority of available project resources, it is crucial that in the early stages of implementation the project team strive to identify short-term actions that can immediately improve patient care in all practice settings. These immediate changes will ensure that patients are receiving the necessary lab monitoring and therapy management prior to the implementation of subsequent phases of the project.

Establishing the capabilities of the EHR will also be essential in providing the outpatient areas with the tools to determine which patients may have outstanding labs and to help to establish baseline quality metrics. The investigation into the possible generation of reports for patient tracking should be a top priority for the improvement of anticoagulation care. Once these reports are available in the system, baseline quality metrics should be established in order to evaluate the quality of current practice. This will allow for the evaluation of subsequent phases of the project. If these reports cannot be run retrospectively it is highly recommended that resources be allocated to manually gather data in order to identify a starting point for quality enhancements.

Aside from clinical quality measures such as TTR, internal performance measurement of indicators such as missed appointments, patient discharges from the program, and timeliness of first appointment after initiation of therapy, should be considered as any new documentation capabilities are being created. It is also worth mentioning that due to the complexity of the clinical dosing guidelines, the depth of educational and patient assessment topics, and the importance of patient understanding, it

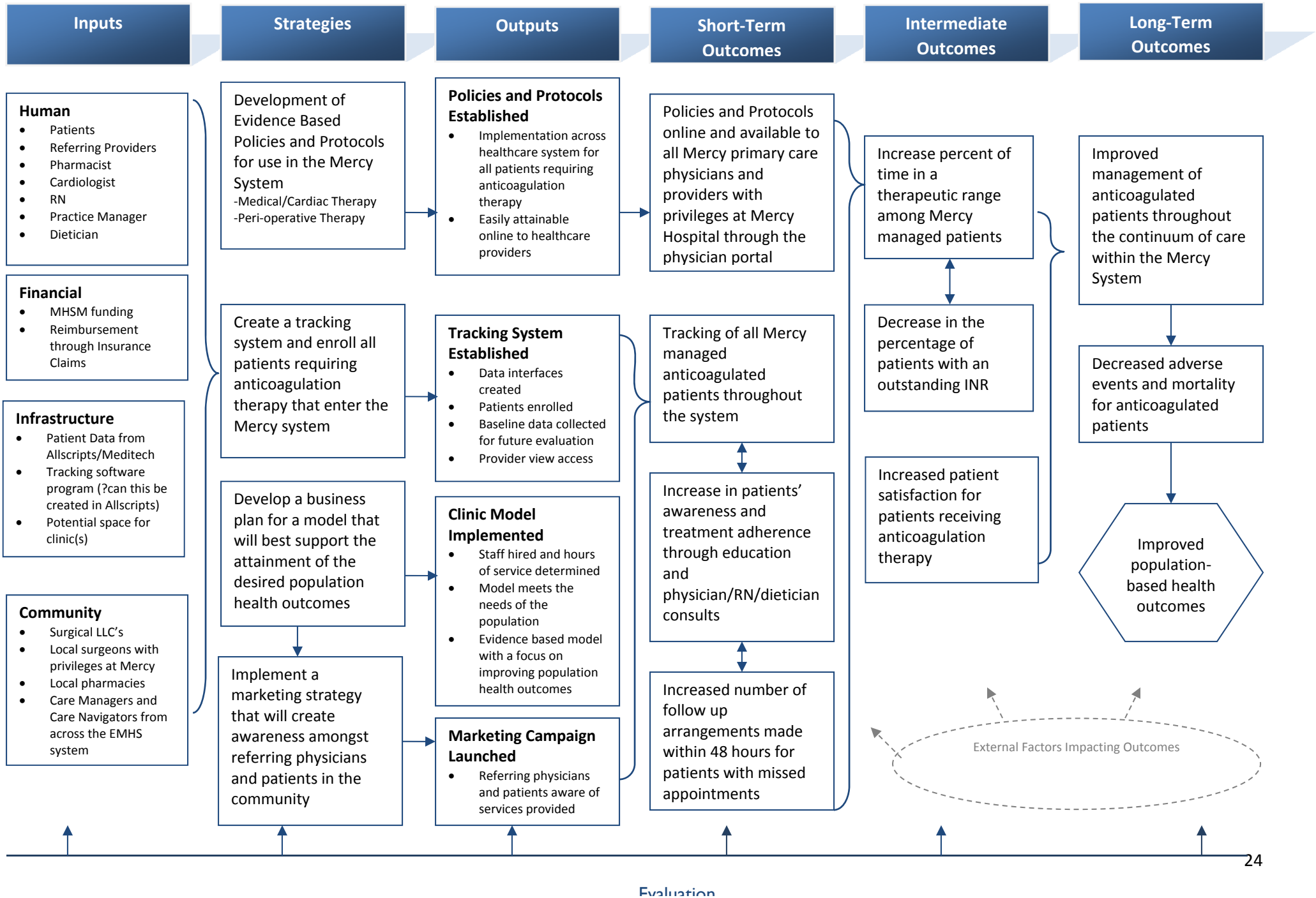
may not be possible to build the necessary documentation requirements into the current EHR. However, there are many resources and software programs available and investment in this type of software should be a consideration.

One strength of this project is the wide availability of clinical guidelines and additional resources. There are web-based clinical decision tools for calculating dosage changes that are free and have been endorsed by well-established, high-performing anticoagulation clinics. The Anticoagulation Forum is an organization that focuses on anticoagulation therapy and their website has many links and resources to sample policies, guidelines, and current research. There is also an Anticoagulation Center of Excellence that offers certification that can be found through the Anticoagulation Forum website. The Anticoagulation Center of Excellence provides clinics with an assessment tool to apply for recognition as well as feedback on areas for improvement to obtain recognition as a center of excellence. Membership to the anticoagulation forum is free and all of these resources are easily accessible.

It is clear that there is a desire amongst clinicians to improve the management of anticoagulated patients throughout the system, and based on regulatory standards, it is imperative that steps are taken toward improving the safety of administering anticoagulation therapy. The range of services, the methods for implementation, and the extent to which the project executes processes to ensure optimal quality still need to be established, but the recommendations and action items discussed above may be used to help guide and inform these decisions as the organization moves forward. Given the complexity of the anticoagulated patient, and the importance of the patient's educational needs and level of understanding, it is essential that care be coordinated in such a way that the very serious risks of poor management are minimized. The potential impact of this program on patient care and health outcomes is promising. The success of the program can be accomplished through the incorporation of patient-centered services, additional educational and technological resources, and a goal-oriented team focused on anticoagulation.

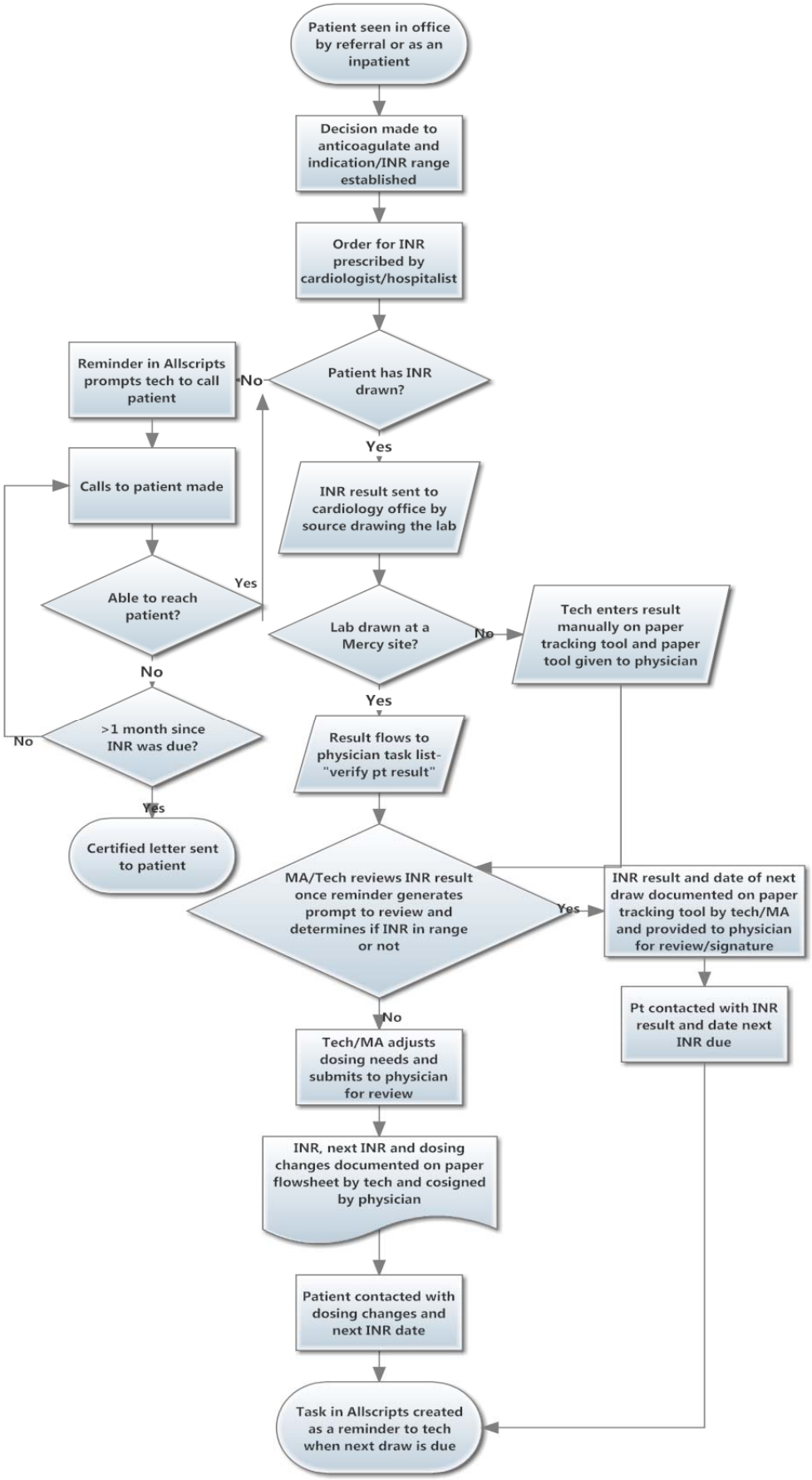
Appendix A

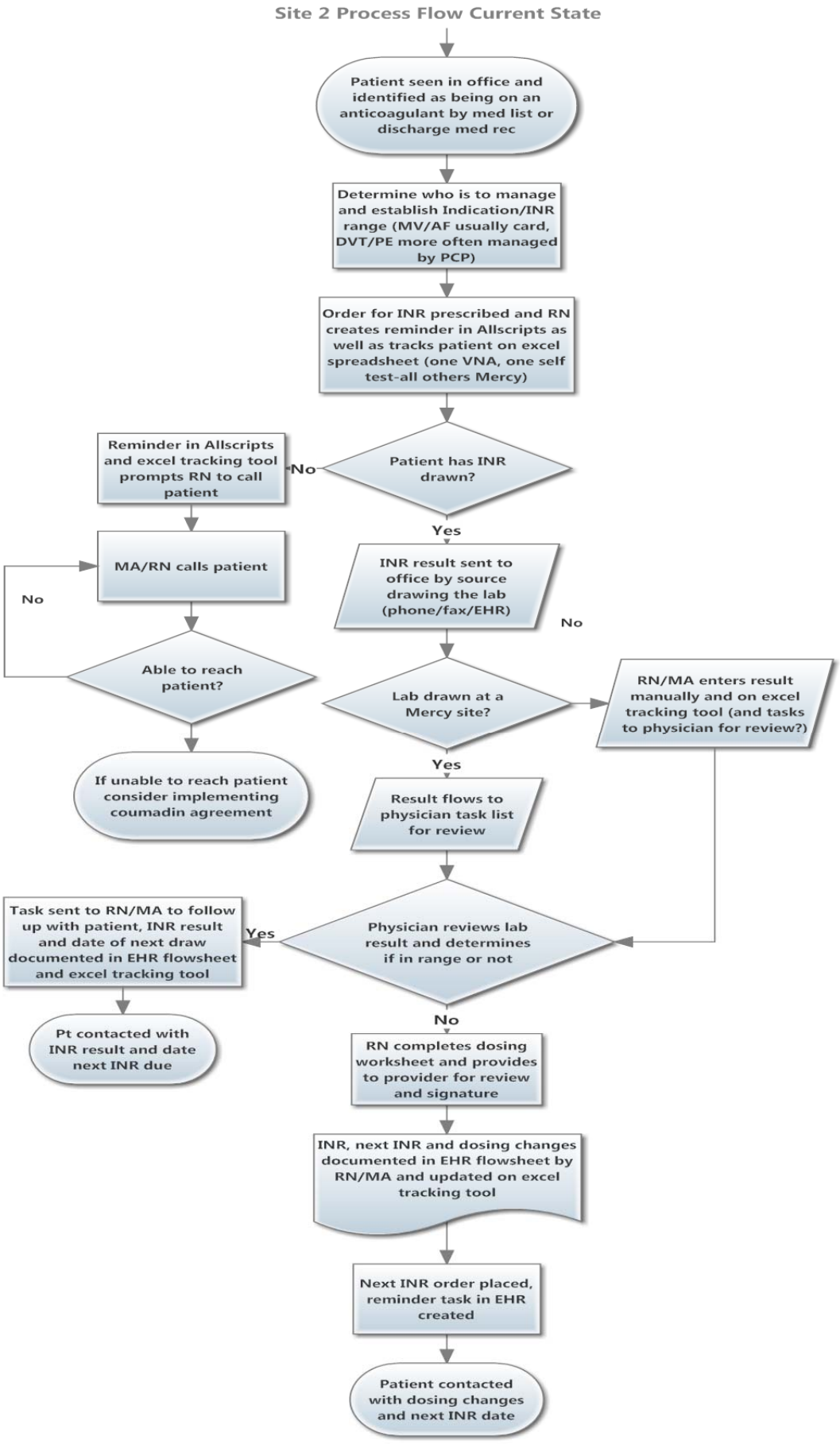
Improving Health Outcomes through a System-Wide Approach to Anticoagulation Therapy

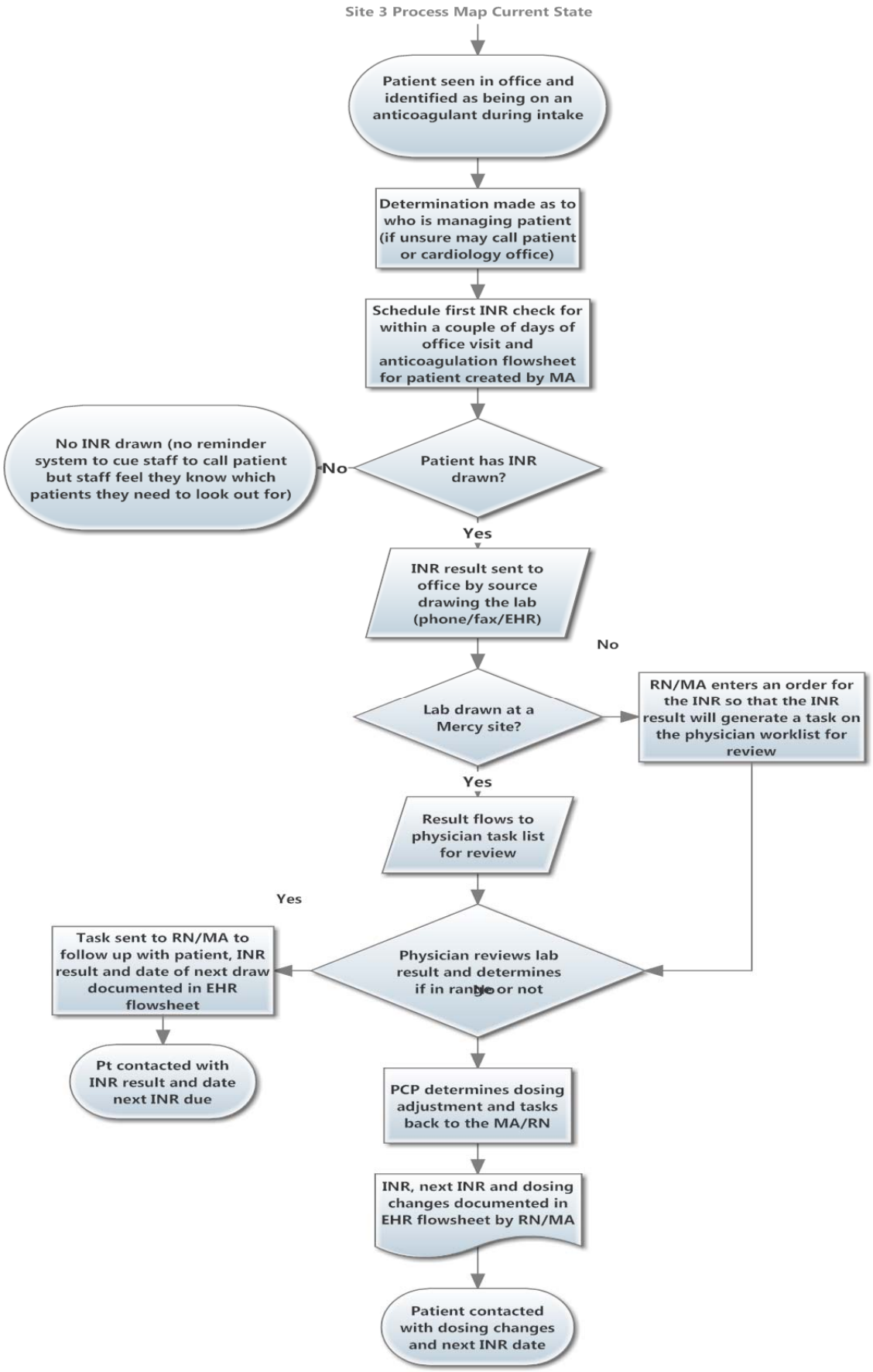


Appendix B

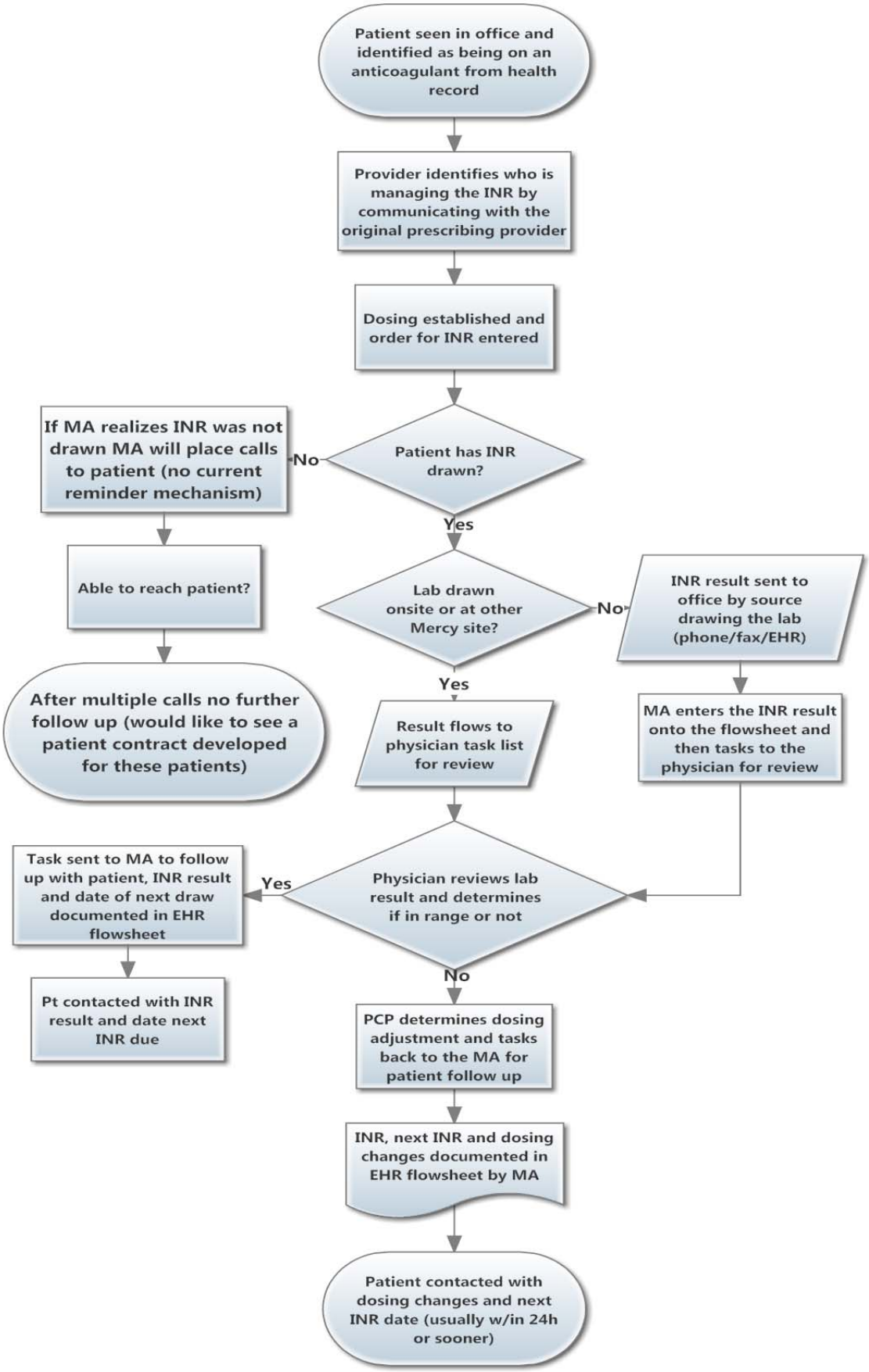
Site 1 Process Map Current State



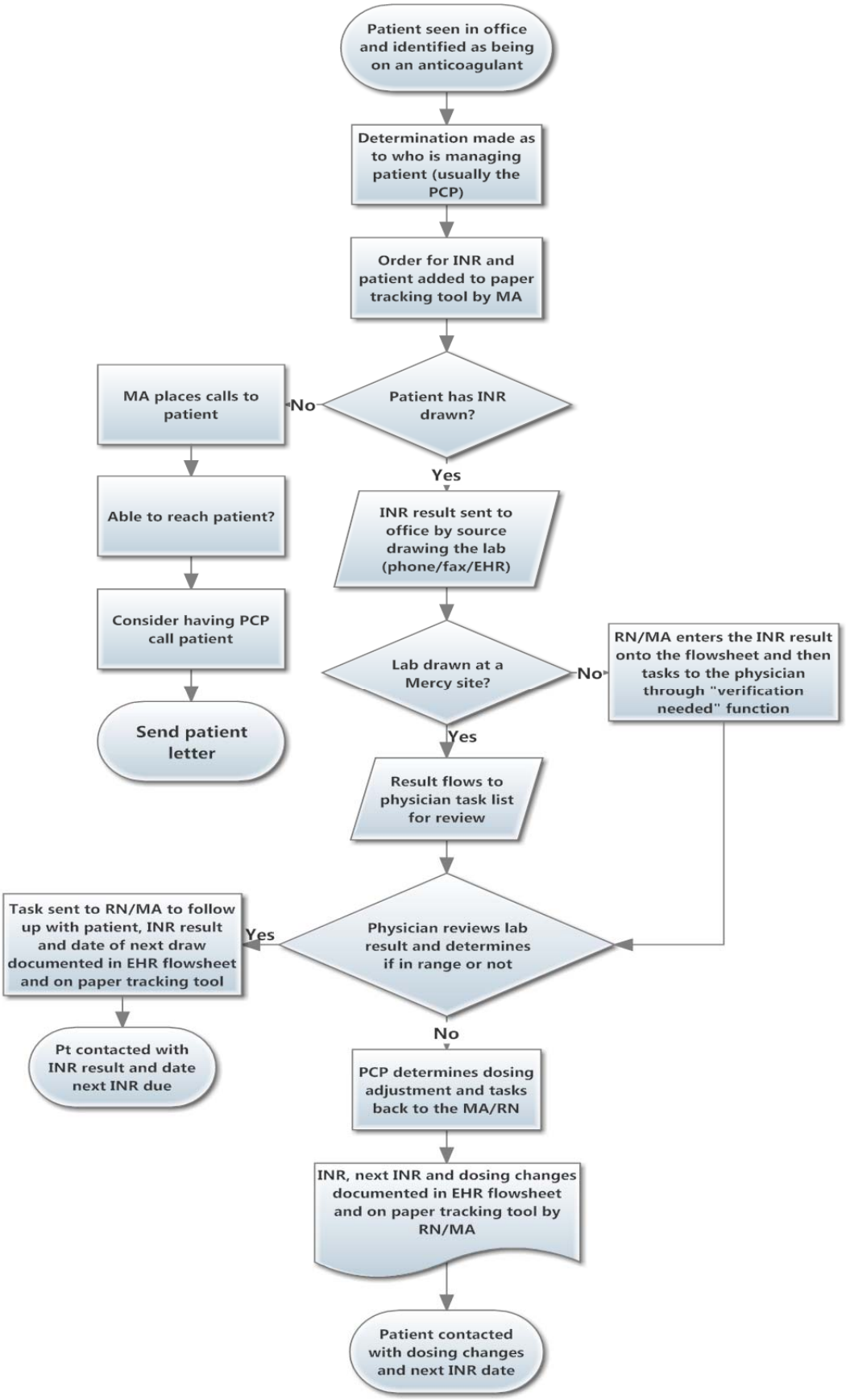

Site 2 Process Flow Current State
Patient seen in office and identified as being on an anticoagulant by med list or discharge med rec
Determine who is to manage and establish Indication/INR range (MV/AF usually card, DVT/PE more often managed by PCP)
Order for INR prescribed and RN creates reminder in Allscripts as well as tracks patient on excel spreadsheet (one VNA, one self test-all others Mercy)
Patient has INR drawn?
No
Reminder in Allscripts and excel tracking tool prompts RN to call patient
MA/RN calls patient
No
Able to reach patient?
If unable to reach patient consider implementing coumadin agreement
Yes
INR result sent to office by source drawing the lab (phone/fax/EHR)
No
Lab drawn at a Mercy site?
RN/MA enters result manually and on excel tracking tool (and tasks to physician for review?)
Yes
Result flows to physician task list for review
Physician reviews lab result and determines if in range or not
Yes
Task sent to RN/MA to follow up with patient, INR result and date of next draw documented in EHR flowsheet and excel tracking tool
Pt contacted with INR result and date next INR due
No
RN completes dosing worksheet and provides to provider for review and signature
INR, next INR and dosing changes documented in EHR flowsheet by RN/MA and updated on excel tracking tool
Next INR order placed, reminder task in EHR created
Patient contacted with dosing changes and next INR date


Site 3 Process Map Current State
Patient seen in office and identified as being on an anticoagulant during intake
Determination made as to who is managing patient (if unsure may call patient or cardiology office)
Schedule first INR check for within a couple of days of office visit and anticoagulation flowsheet for patient created by MA
Patient has INR drawn?
No
No INR drawn (no reminder system to cue staff to call patient but staff feel they know which patients they need to look out for)
Yes
INR result sent to office by source drawing the lab (phone/fax/EHR)
Lab drawn at a Mercy site?
No
RN/MA enters an order for the INR so that the INR result will generate a task on the physician worklist for review
Yes
Result flows to physician task list for review
Physician reviews lab result and determines if in range or not
Yes
Task sent to RN/MA to follow up with patient, INR result and date of next draw documented in EHR flowsheet
Pt contacted with INR result and date next INR due
PCP determines dosing adjustment and tasks back to the MA/RN
INR, next INR and dosing changes documented in EHR flowsheet by RN/MA
Patient contacted with dosing changes and next INR date

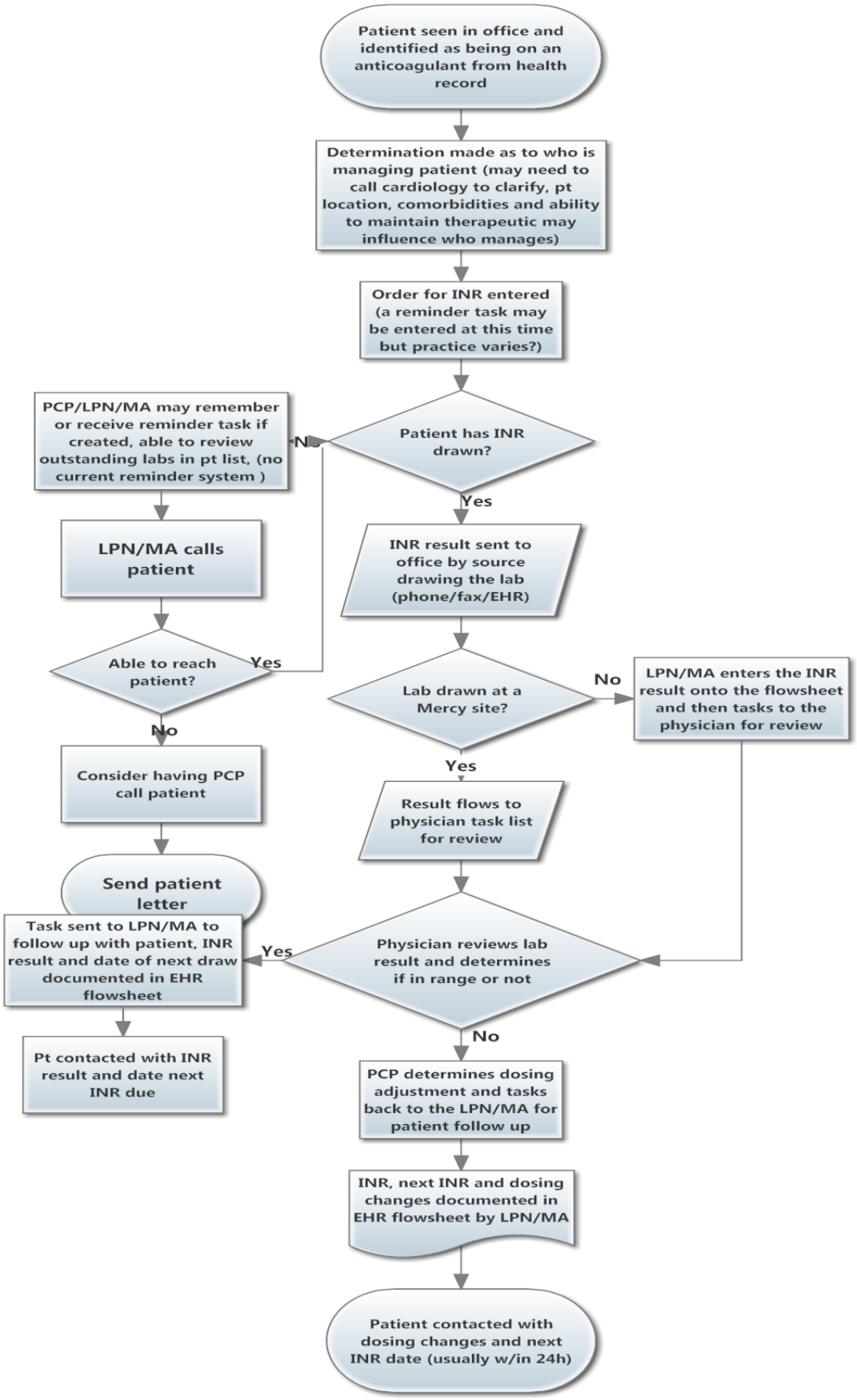
Site 4 Process Map Current State



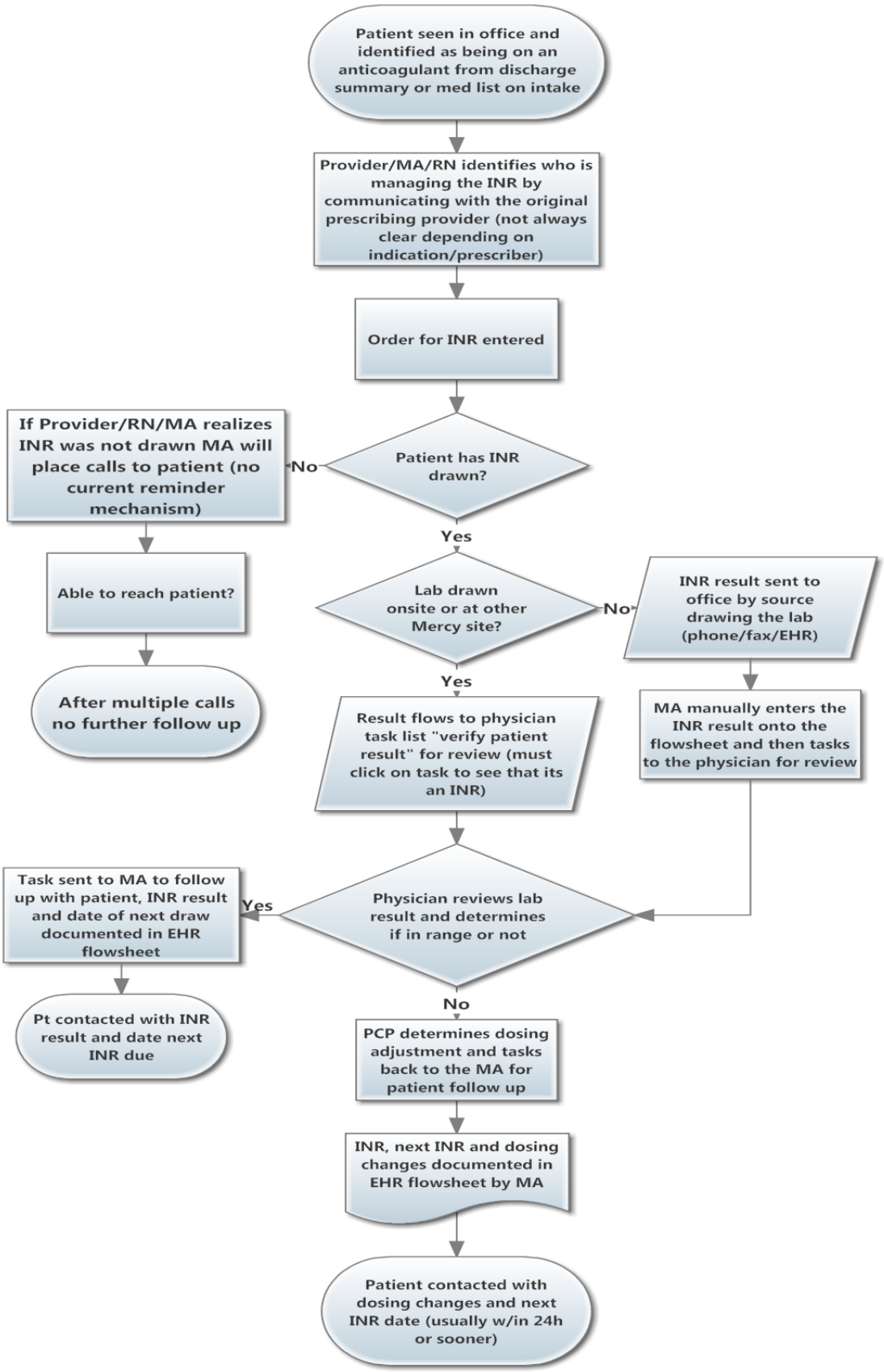
Site 5 Process Map Current State



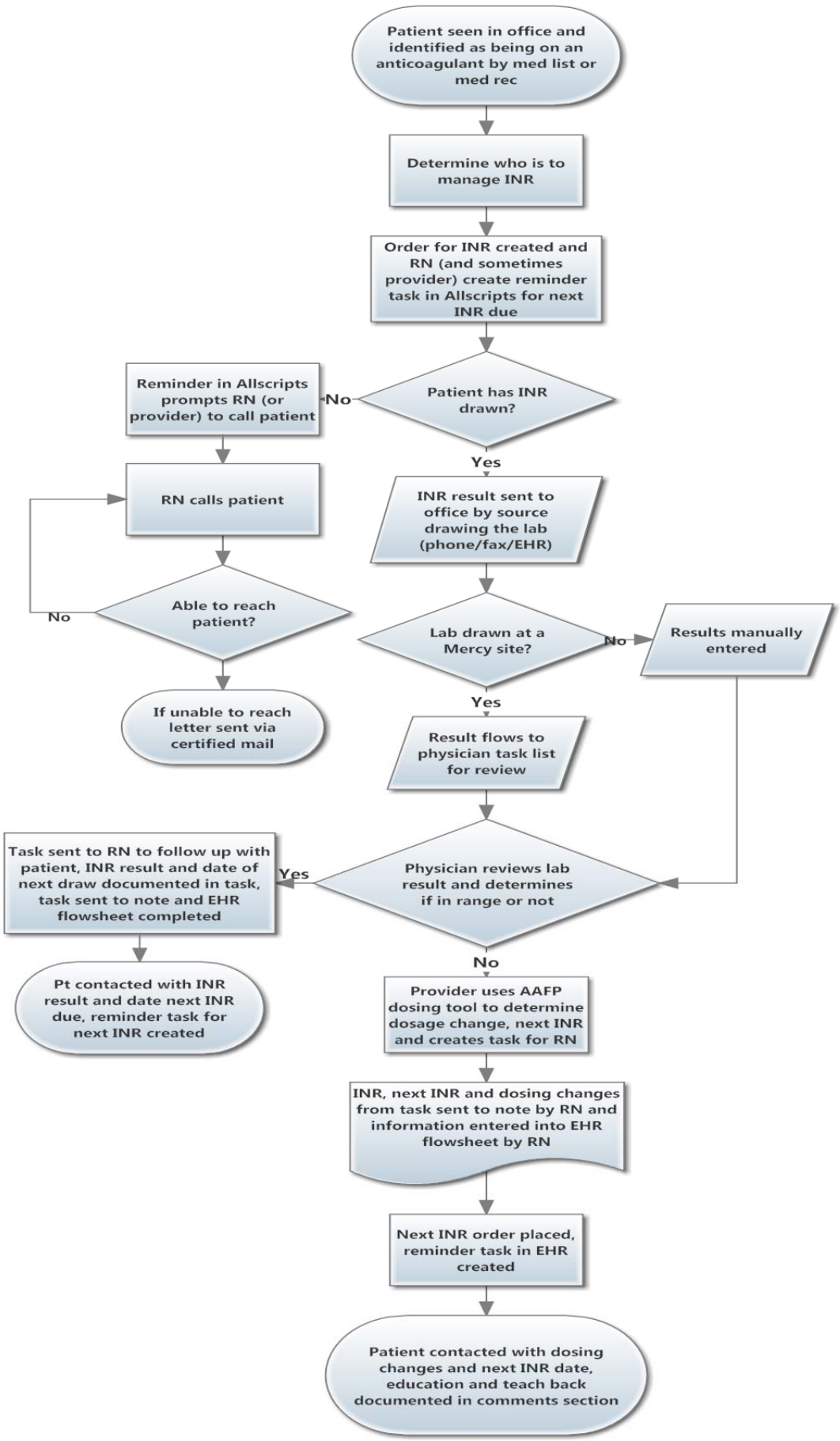
Site 6 Process Map Current State



Site 7 Process Map Current State

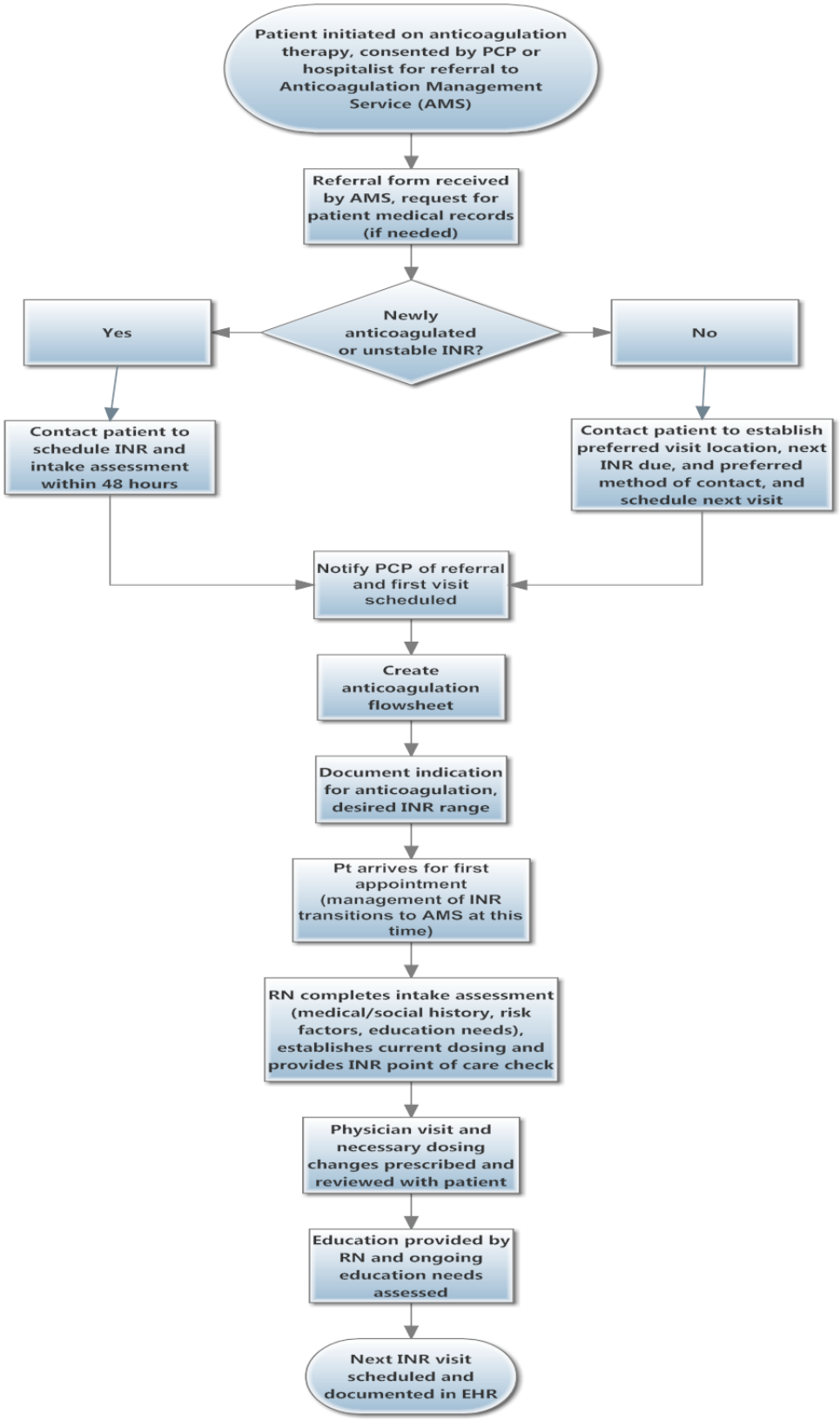


Site 8 Process Flow Current State

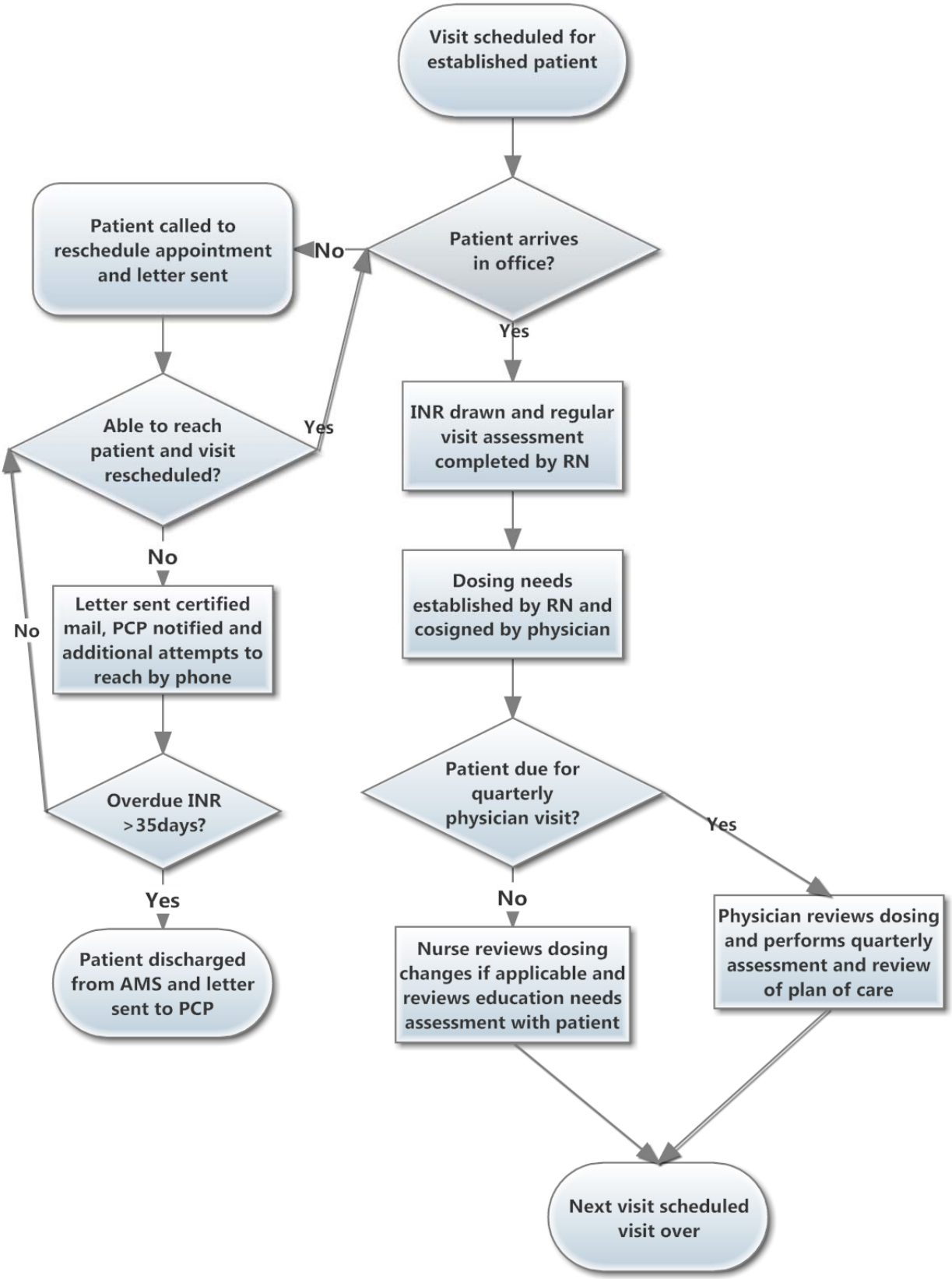


Appendix C

Process Map Future State New Patient



Established Patient Visit Future Flow



Appendix D

Gap Analysis

Project: Implementation of an Evidence-Based System-Wide Anticoagulation Management Service at Mercy Health System of Maine

Prepared by: Sarah Varney, RN, BSN

Best Practice: As Mercy has received approval to begin the development of a system-wide anticoagulation management service it is crucial to establish what best practice strategies currently exist, how these differ from current practices, what barriers exist to implementation of these best practices, and how the implementation of this program would address these areas of practice. Best practice recommendations were identified through a review of regulatory and expert, evidence based publications from sources including The Joint Commission, the Board of Directors of the Anticoagulation Forum, expert reviews, and current original research.

Best Practice	Best Practice Strategies	How Your Practices Differ From Best Practices	Barriers to Best Practice Implementation	Will Implement Best Practice? (Yes/No Why not?)
Ensure that anticoagulation therapy is effective and safe (NQF, Safe Practice 29)	The use of approved protocols for the initiation and maintenance of anticoagulant therapy.	No standard protocol selected for use in the outpatient setting at this time.	Compliance across multiple settings may be difficult unless centralized management service developed.	Yes
Reduce the likelihood of patient harm associated with the use of anticoagulant therapy (NPSG 3.05.01)	Before starting a patient on warfarin, assess baseline coagulation status and document in the patient record.	The baseline INR is currently being captured in the patient record. However, there is no consistent method for documenting indication, INR goal, tablet strength, whether or not anticoagulant bridging would be required for procedures, and who is managing the anticoagulation therapy. This information is typically flagged or documented in notes but finding this information can be difficult and it is not consistently documented clearly.	Barriers include the ability to document these aspects of coagulation status in the electronic health record (EHR).	Yes

	Use authoritative resources to manage potential food and drug reactions for patients on warfarin.	Education resources and protocols for outpatient setting vary and are inconsistent.	Identification and dissemination of resources.	Yes
	A written policy addresses baseline and ongoing lab tests required for anticoagulants.	No current outpatient policy.	Creating policy and educating providers will take time.	Yes
	Provide education to prescribers, staff, patients and families. Patient/family education includes the following: the importance of follow-up monitoring, compliance, drug-food interactions, the potential for adverse drug reactions and interactions.	Educational resources vary throughout practice settings. The educational material for patients is inconsistent across the organization.	Education is currently being provided primarily by the physicians and some RN/MAs. Educational materials will need to be created and disseminated to all potential areas of care and to all providers and staff.	Yes
	Evaluate anticoagulation safety practices, take action to improve practices and measure the effectiveness of those actions in a time frame determined by the organization.	There is no current structure in place to look specifically at anticoagulation safety and there is difficulty extracting data from the current EHR to evaluate effectiveness of improvement initiatives.	The EHR will need to be altered or a report will need to be created in order to track and evaluate effectiveness of anticoagulation safety practices.	Yes
Qualifications and Supervision of Staff (Garcia et al., 2008)	Patient assessment and therapy management provided by licensed healthcare professionals who have received formalized training.	Currently assessment and therapy is managed by either the specialist prescribing or the primary care provider, while all are licensed healthcare providers trained in patient assessment and care there is no formalized process across the system for additional training on anticoagulant therapy.	The primary barrier at this point in time is that anticoagulation therapy is being managed by a multitude of different providers across many different care settings which make formalized training difficult to administer. The creation of a dedicated AMS would alleviate this barrier.	Yes

	Collaborative practice agreement when working with referring providers.	As there is not currently a dedicated AMS no such collaborative agreement exists at this time as it is not necessary since there are no referrals specifically for anticoagulation management.	As an AMS is developed this should be a consideration, barriers would be limited to time and resources to work on putting an agreement in place.	Yes
Care Management and Coordination/Documentation (Garcia et al., 2008)	Organization should have established policies and procedures that address the following areas: risks and benefits of therapy, patient's understanding, indications, target INR values, planned duration, managing initiation of therapy, management of non-therapeutic INR values, monitoring intervals, definition and documentation of adverse events, method for follow-up of missed appointments, timely reporting of lab results, managing transitions or interruptions in care, managing non-adherence, criteria for discharge, reimbursement, quality measures, management during pregnancy, eligibility criteria for patient self-testing (PST).	These policies have not yet been approved for the outpatient setting at the system level.	Barriers include staff and resources available to work on the development of these policies and approval from authoritative councils (Pharmacy and Therapeutics, Medical Executives).	Yes
	Utilization of a tracking system to promote documentation of desired elements and facilitate quality measurements including information such as patient demographics, treatments, communication and education.	While this data is entered into the system at this time there is no mechanism for tracking or generating reports from this information in order to track patients or monitor quality data.	Barriers include IT resources and analysts to develop the capability of the system to generate a report or reminder function to aid in the tracking of patient information such as next	Yes

			INR due and overdue INRs.	
Patient Assessment and Education/Communication (Garcia et al., 2008)	Initial patient assessment consisting of a comprehensive medical history, social, employment and lifestyle profiles, as well as the patient's beliefs, attitudes, level of understanding, health literacy, resources, and motivation.	While providers may cover these areas in their patient visits there is not a formal assessment for the anticoagulation patient.	One existing barrier would be that any patient assessment tools would need to be incorporated and built into the EHR.	Yes
	Knowledge assessment tools specific to anticoagulation that establishes education needs for individual patients.	There is no consistent tool identified for use at the system level at this time in the outpatient setting.	Minimal barriers identified as this could be performed using a paper tool and the results documented in the EHR.	Yes
	Documentation of patient communication and the management of missed appointments or changes to plans of care.	Documentation of patient communications and missed appointments is currently recorded in the EHR, some sites have created processes for managing patients who miss appointments but there is no standardized system-wide process in place and many sites identify this as a needed resource.	Minimal barriers as the ability to document this information exists currently however a system-wide policy for addressing missed appointments should be developed and would require time for development and approval from appropriate decision making councils.	Yes
	Periodic review of treatment plan for appropriateness throughout course of therapy.	While this may be occurring there is no formal documentation or established policy to support this.	There would need to be some method for documenting this review or a policy outlining how this review would be conducted in order to ensure this occurred.	Yes
Laboratory Monitoring/ Initiation &	Proportion of patient INRs time in therapeutic range measured using consistent methodology (Phillips &	This is not currently being measured in the outpatient setting at this time.	Will need IT resources to create the ability for the EHR to generate this	Yes

Maintenance of Therapy (Phillips & Ansell, 2008) (Garcia et al, 2008)	Ansell, 2008).		information so that it can be more easily tracked.	
	Tracking of rates of hemorrhagic and thromboembolic events in patients on anticoagulant therapy (Phillips & Ansell, 2008).	This is not currently being measured in the outpatient setting at this time.	Will need to create a method for recording and tracking this in the EHR.	Yes
	Regular laboratory monitoring of INR for anticoagulation effect (Garcia et al., 2008).	Currently there is no tracking system to establish compliance of laboratory monitoring with established clinical recommendations.	Will need to create a method for obtaining this information from the EHR.	Yes
	Use of a system-wide evidenced based protocols that clearly define the actions to be taken during the initiation phase of therapy and subsequent treatment changes throughout the course of therapy (Garcia et al., 2008).	No current system-wide policies or protocols in place at this time.	Resources and information to inform policies and support from approving committees.	Yes
Process Measures for Quality (Rose et al., 2012)	Sufficient staffing to handle workload-staff are able to work in an organized, comfortably paced environment with adequate support staff, time dedicated to anticoagulation duties.	Currently providers across the system are managing the workload in a multitude of settings. Some providers and staff identify that managing this population is time consuming and labor intensive.	Will need to identify roles and hire and train staff to support providing care for this population. Will also need to ensure as the patient population expands that staffing is revaluated on an ongoing basis.	Yes
	Innovation to encourage EBP such as note templates to assist in clinical reasoning and documentation as well as software that enhances workflow and reduces loss to follow-up.	Current organizational culture encourages innovation and this would be a strength to the project going forward, however specific IT structures to enhance innovation around anticoagulant care need to be further developed.	Ensuring that newly hired staff for the AMS program are supported/encouraged and allowed the time and resources needed to foster innovation and involvement in EBP education and	Yes

			conferences/training. Support the development of functionalities in the EHR to enhance workflow and encourage EBP.	
	Presence of a quality champion.	There has been a cardiologist identified as the project champion who in the beginning stages of the project at least would serve as the quality champion.	No identified barriers at this time, sufficient interest and hiring should support this.	Yes
	Staff Qualifications, pharmacists should be residency-trained.	There is no involvement from pharmacists in the outpatient anticoagulation management.	The current plan is to have an RN led model as opposed to pharmacist led model, with UNE pharmacy student involvement this is a result of resources. Note that the study making this recommendation looked only at pharmacist led models.	No-the new program will not be a pharmacist led model of care.
	Creation of a group learning climate that allows the discussion of difficult cases with colleagues on a frequent basis.	Currently primary care providers are able to discuss cases amongst their colleagues; however, with the management of this population being described as time consuming and difficult there may not presently be ample opportunities for these discussions to take place in some cases.	With the proposed team members consisting of dedicated formally trained RN and MA as well as a cardiologist and UNE pharmacy students there should be plenty of opportunity and few barriers to a group learning environment.	Yes
	Internal performance measurement either through manual data extraction or software generated data.	Currently there is no information on the internal performance of the outpatient setting being measured.	Software currently does not support the collection of this data and the addition of this	Yes

			functionality will need to be explored. Manual data in the meantime will be labor intensive but is recommended to gather baseline data for current performance prior to the project go live.	

Gap Analysis Tool adapted from AHRQ Quality Indicators Toolkit: tool D.5. Accessed on 4/16/14 at www.ahrq.gov/professionals/systems/hospital/qitoolkit/d5-gapanalysis.pdf

Appendix E

Assessment of Organizational Readiness

Step One: Identify the Anticipated or Desired Change

Program Description: Implement a system-wide anticoagulation management program at Mercy Health System of Maine to improve patient outcomes.

Step Two: Determine the Current State of the Organization in Relation to the Desired Change

1. *Does the proposed project align with the organization's current vision, mission, and strategic plan?*
    - Does the project support the organization's vision of its desired future?
    - Does the project align itself with the organization's belief of who it is, what it does, and how it serves?
    - Does the project support the organization's approach to achieving its goals and objectives?

	Major Barrier	Substantial Barrier	Significant Changes Needed	Minimal Changes Needed	Full Support
Alignment with Organizational Vision/Mission					X
Alignment with Strategic Plan					X

Actions Required to Become Fully Ready/ Comments:
The project is well aligned with Mercy's vision for the future and specifically seeks to address the quality of care it provides to the population to which it serves. Also, it aligns with regulatory requirements that aid in achieving goals and objectives.

2. *Is the proposed project consistent with the organization's values and culture?*
    - Is the consistent with the organization's guiding principles?
    - Does the project align with the organization's existing beliefs, assumptions, and expectations?
    - Does the organization's culture support innovation and clinical technology applications?

	Major Barrier	Substantial Barrier	Significant Changes Needed	Minimal Changes Needed	Full Support
Alignment with Organizational Values/Culture					X

Actions Required to Become Fully Ready/ Comments:
The project is very well aligned with the Mercy values, specifically the values of community and excellence.

3. *Are resources available to begin development of the proposed project?*
    - Is funding available for the initial planning activities?
    - Is there staff available to work on the project?
    - Are there initiatives competing against the project?

	Major Barrier	Substantial Barrier	Significant Changes Needed	Minimal Changes Needed	Full Support
Resource Availability				X	

Actions Required to Become Fully Ready/ Comments:

Funding for the project has been secured, staff needs have been identified in the business plan and recruitment will need to occur for the RN and MA positions. Current support is being provided by the Manager of Cardiovascular Services, the Lead Cardiologist, and a student internship. Project team members also include the Pharmacy Director, Director of Primary Care, Director of Ancillary Services, Allscripts analysts, and an Inpatient Nurse Manager. Competing initiatives include conversions to the EMHS IT programs.

4. *Does the proposed program have a champion?*
    - Is there a clinical champion for the project?
    - Is there an administrative champion for the project?
    - Are there leadership groups in place to foster support?

	Major Barrier	Substantial Barrier	Significant Changes Needed	Minimal Changes Needed	Full Support
Identified Champion					X
Decision Maker Interest					X
Support for Initiative				X	

Actions Required to Become Fully Ready/ Comments:

A cardiologist has been identified as a clinical champion for the project. The administrative champion is the Manager of Cardiovascular services. There are leadership groups in place who are supportive of the project, however a specific council focused on anticoagulation will need to be created to support ongoing efforts and initiatives.

5. *Do stakeholders support the program?*
    - What perceptions do stakeholders have about the proposed program?
    - Are stakeholders educated about the proposed program?

	Major Barrier	Substantial Barrier	Significant Changes Needed	Minimal Changes Needed	Full Support
Stakeholder program perceptions				X	
Stakeholder program education			X		

Actions Required to Become Fully Ready/ Comments:

Perceptions about the program are that revenue generated from this project will be modest but that to provide clinically excellent care and meet regulatory requirements it is an area that needs to be addressed. Education to the stakeholders is in the process of occurring currently, education will need to be provided to primary care providers and leaders.

6. *Who has authority over the proposed program?*
    - Who has to approve the project?
    - Are they supportive of the project?

	Major Barrier	Substantial Barrier	Significant Changes Needed	Minimal Changes Needed	Full Support
Program Authority					X

Actions Required to Become Fully Ready/ Comments:
The business plan for the program has been approved by the Systems Integration Team and the Mercy Board of Directors will be informed of the initiative.

7. *What does a SWOT analysis reveal about organizational successes and potential barriers?*
    - What are the organization's strengths?
    - What are the organization's challenges or weaknesses?
    - Where are the organization's business opportunities?
    - Are there any barriers to the organization's success?

	Major Barrier	Substantial Barrier	Significant Changes Needed	Minimal Changes Needed	Full Support
Internal Factors (skill sets, strengths, weaknesses)				X	
External Factors (opportunities, challenges)				X	

Actions Required to Become Fully Ready/ Comments:
Strengths for the project include a supportive cardiology practice with physician capacity to expand care provided to additional patients and primary care physicians who identify the need for improvements in the way care is provided. The Electronic Health Record is currently a barrier to the process in terms of tracking patients but in terms of documenting patient activity it is widely used and seen as a strength in most regards. The capabilities of the EHR to perform in a way that enhances care through a tracking mechanism is something that needs to be explored and most likely minimal changes will need to be made to create this functionality. Transitioning patients from phlebotomy draws for INR results to point of care testing as is reflected in the business plan would be a strength. The greatest potential barriers the organization faces at this time is for the competition of available resources for all projects and specifically IT resources as the organization is in the process of transitioning to a new parent company.

Assessing Organizational Readiness Summary

Date: 4/11/14	Organization: Mercy Health System of Maine
Brief Description of Desired Initiative: Implement a System-Wide Anticoagulation Management Program at Mercy Health System of Maine to improve patient outcomes.	

Record all of your answers to the previous questions in the appropriate boxes below.

Rate Readiness Factors	Not Ready←----------→Ready				
	Major Barrier	Substantial Barrier	Significant Changes Needed	Minimal Changes Needed	Full Support
Alignment with Organizational Vision/ Mission					X
Alignment with Strategic Plan					X
Alignment with Organizational Values/ Culture					X
Resource Availability: Funding					X
Resource Availability: Human Resources				X	
Resource Availability: IT				X	
Skill Sets					X
Internal Factors				X	
External Factors				X	
Program Authority					X
Identified Champion					X
Decision Maker Interest					X
Support for Initiative					X
Other Priorities				X	
Overall Rating					X

List of Actions Require to Become Fully Ready:

- □ Hire and train staff
- □ Purchase Point of Care Equipment
- □ Patient letter/survey to engage patient in the process change
- □ Create an Anticoagulation Council
- □ Finalize policies and procedures
- □ Collaborate with the Director of Primary Care to establish location of services provided
- □ Provide PCP/FNP with education in regards to referral process

RECOMMENDATION:

□ Move Forward Now

□ Make Necessary Changes and Reassess in _____months

□ Not Appropriate

Assessment of Organizational Readiness adapted from:

California Telemedicine and eHealth Center Discovery Series Assessing Organizational Readiness (2009). www.CTEConline.org. Accessed from http://www.hrsa.gov/quality/toolbox/methodology/readinessassessment/part4.html

Appendix F

Date

Mercy Hospital

144 State Street

Portland, ME 04101

Dear Valued Customer,

Here at Mercy we take your healthcare seriously. In an effort to improve the care and services we provide you with we are reviewing the way in which we deliver care specifically to our patients who are receiving anticoagulant therapy, or blood thinners.

You have been identified as either currently receiving or having received a prescription for a blood thinner and we would like to hear from you as to how we are doing providing the care you received while on a blood thinner.

We truly value your input as we strive to provide with you with clinically excellent, compassionate care. If you could take a moment to share your experiences and ideas by completing and returning the enclosed form or sending us an email at mercyfeedback@emhs.org this will help us assess our service to you.

Thank you,

[Name, Title]

Please take a moment and think about your most recent experience(s) with blood thinners as a Mercy customer and answer the following questions:

1. I have a good understanding of the reason I am on a blood thinner
   □ Yes □ No
   Comments:_____
   _____
   _____

2. Someone has explained to me how the effectiveness of my blood thinner is measured
   □ Yes □ No
   Comments:_____
   _____
   _____

3. I have received all the information I need including foods to avoid, signs and symptoms of bleeding, and when to call my doctor
   □ Yes □ No
   Comments:_____
   _____
   _____

4. I understand the importance and frequency of lab tests while on a blood thinner
   □ Yes □ No
   Comments:_____
   _____
   _____

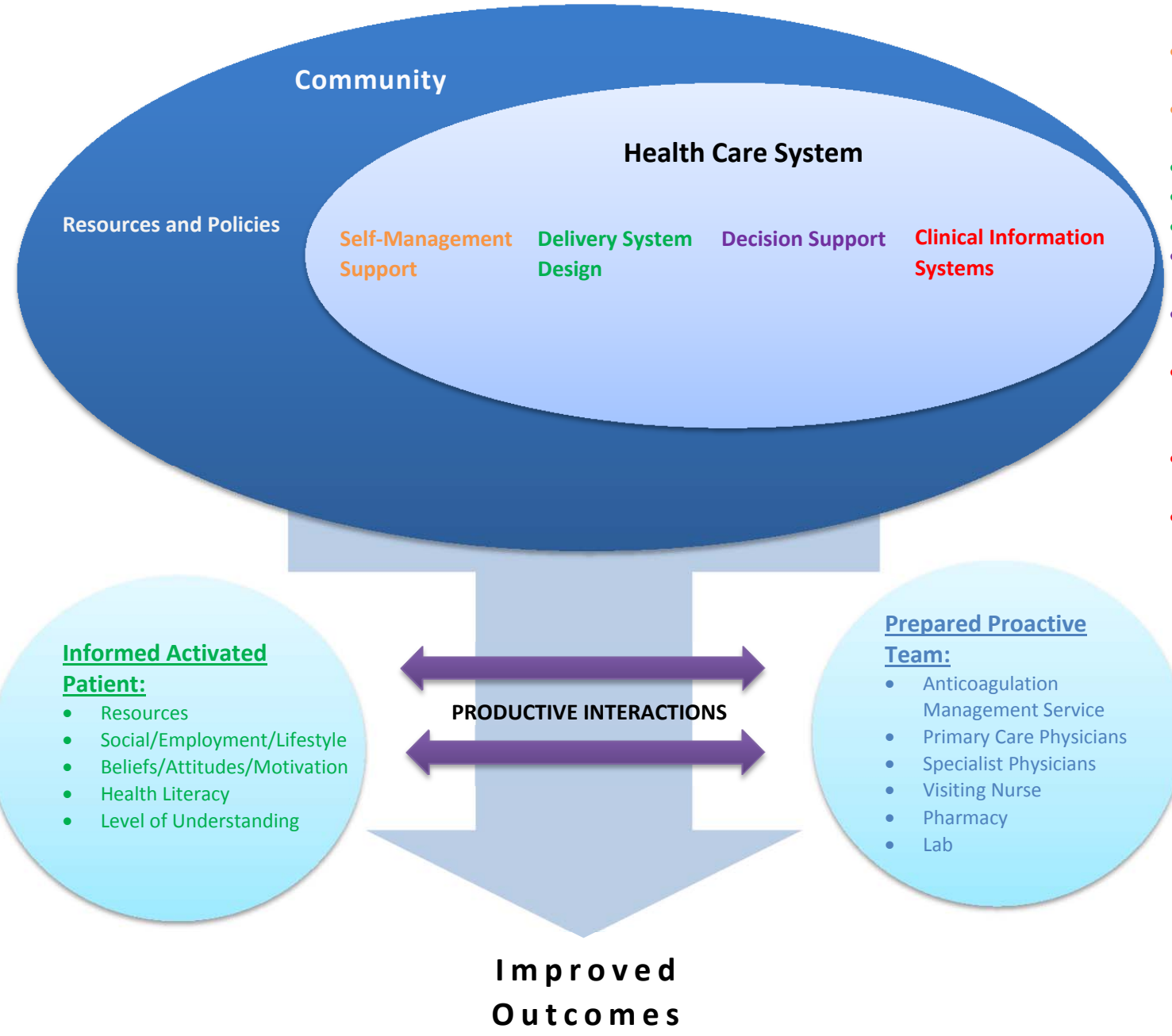
5. I receive the results of lab tests and any changes in dosing in a timely manner
   □ Yes □ No
   Comments:_____
   _____
   _____

6. I would be interested in having the care of my blood thinner managed by a clinic focused solely on blood thinner medications
   □ Yes □ No
   Comments:_____
   _____
   _____

Please feel free to provide any additional feedback or comments below and thank you for your time:

_____
_____
_____

Appendix G



Actions:

- Guidelines for patient-self testing
- Education assessments
- Location
- Point-of-Care Testing
- Policies and Protocols
- Pharmacy Collaboration
- Primary Care Providers
- Electronic Health Record (or external tracking system)
- Assessment/Education Documentation
- Flowsheet/Tracking tool

Actions:

- Patient Letter/Survey
- Referral Consent
- Anticoagulation Care Contract
- Ongoing educational assessments
- Periodic review of plan of care

Actions:

- Formal Training
- Anticoagulation Council
- Communication with PCP and specialty care
- Internal policies for provision and management of care
- Tracking and internal performance measures

(Wagner, 1998)

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