GUIDEBOOK

for implementation of a

CLINICAL WORK PROCESS-BASED ORGANIZATIONAL STRUCTURE

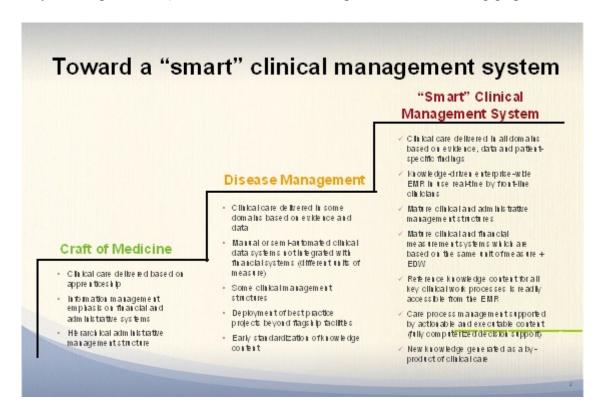
INTRODUCTION

Purpose

The purpose of this *Guidebook* is to help you as a healthcare organization to implement an organizational structure based on the key clinical work processes which make up the care you deliver to patients. As you will see in the sections that follow, you will need such a clinical management structure to develop and test improvement hypotheses in order to implement best practice consistently across your organization.

Toward a "Smart" Clinical Management System

In the past we delivered healthcare based on the "Craft of Medicine" – based on apprenticeship training. More recently we have begun a transition into "Disease Management," with more and more care delivered based more on scientific evidence and data. The challenge that lies ahead of us is to expand Disease Management to all clinical domains and improve the clinical and electronic infrastructure that support it so that we evolve a "smart" clinical management system (i.e., a system of production) with the characteristics depicted in the following graphic:



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The Information Technology Delusion

Many healthcare organizations labor under the delusion that if they implement an electronic medical record (EMR) and/or an enterprise data warehouse (EDW), clinicians will automatically change their behavior. You must view these important electronic infrastructure elements not as solutions but as "enablers" which provide important support to clinicians as they develop and implement best practice — view these elements as necessary, but not sufficient. The healthcare industry is littered with examples of organizations who saw no return on their investment in electronic infrastructure because they failed to involve clinicians in the "take off" not just the "crash landing."

Anatomy of Healthcare Delivery

Healthcare delivery can be categorized into four major clinical management domains, including:

- Diagnostic work-up and triage for clinical management
- Ambulatory management
- Intensive medical management
- Invasive management

There are sub-domains within each of these four major clinical management domains. They are discussed in Chapter One.

Clinical Work Processes

One of the fundamental ideas of quality improvement theory is to identify key work processes, then organize around them. Healthcare is a complex business consisting of thousands of work processes. A limited number of these processes make up the vast majority of services you provide to patients. Each of the clinical management domains and their sub-domains consists of a finite number of these clinical work processes. For example, the management of Diabetes mellitus is one of the clinical work processes in the ambulatory management domain.

Pareto Analysis of Clinical Work Processes

Various data sources (e.g., case mix, claims) and commercially available "groupers" (e.g., 3M's APR-DRG grouper, Symmetry's Episode Treatment Grouper) can be used to identify and define the relative size (e.g., based on cost dollars, allowed amounts) of the clinical work processes. Pareto analyses can then be conducted on various views of the clinical work processes. Details concerning how to identify and conduct a quantitative analysis of clinical work processes are discussed in Chapter Two.

Aggregation of Clinical Work Processes into Clinical Programs/Clinical Service Lines

Once you have a working draft of what your clinical work processes are, your next step is to develop an organizational structure that brings together clinicians (e.g., physicians, nurses, therapists, technologists) who share one or more clinical work process. The sharing may occur as clinicians work together on a given clinical work process as, for example, when obstetricians and obstetrical nurses provide care to patients within the labor and delivery clinical work process. Sharing may also take the form of the output of one set of clinicians being the input to another set of physicians. For example, the output of obstetrical specialists in the labor and delivery work process becomes the input to the clinical work processes of the neonatologists.

Once you identify the clinicians who share clinical work processes, the next step is to develop a draft schema which brings them together into a Clinical Program/Clinical Service Line ("Clinical Programs") organizational structure which can facilitate their efforts to generate and test improvement hypotheses. Clinical Programs are discussed in Chapter Three.

Timing of Involvement of Key Stakeholders

It is important that you give early attention to clinical management structure in your quest to implement best practice. You will reap substantial dividends in outcomes if you involve key clinician and administrator stakeholders in decisions which pertain to their work. This includes decisions such as selection and configuration of electronic infrastructure (e.g., EMR, EDW). Involving key stakeholders in the journey allows them to get their fingerprints on the decisions.

Strategic Prioritization

You will not be able to organize all Clinical Programs at once, nor will you be able to work on all the clinical work processes in any given Clinical Program at once. You will need to prioritize and plan your investment of time and resource. The Pareto analysis of clinical work processes will provide you with one dimension; however, you will want to consider other important factors such as budget, leadership availability (e.g., physician, nurse), availability of data, and priorities of strategic partners (e.g., managed care plans, major employers, business health coalitions). You will reap substantial downstream benefits if you involve your key physician (e.g., CMO/VP of medical affairs), nursing (e.g., CNO) and administrator (e.g., main/hub facility administrators) in your prioritization process.

CHAPTER ONE ANATOMY OF HEALTHCARE DELIVERY

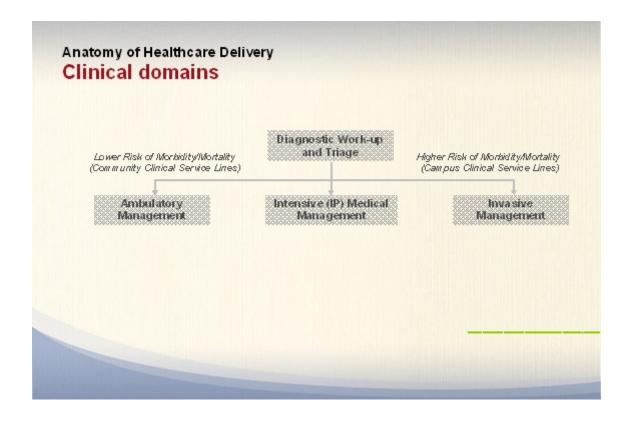
Simplifying Construct

Even though healthcare delivery is very complex, we have dissected it into a construct which consists of a small number of domains and sub-domains which can help you understand how it all fits together, "The Anatomy of Healthcare Delivery."

Healthcare Delivery Domains and Sub-Domains

There are four major functional domains in healthcare delivery:

- Diagnostic Work-up and Triage Domain
- Ambulatory Management Domain
- Intensive Medical Management Domain
- Invasive Management Domain



Anatomy of Healthcare Delivery - Clinical Domains

Anatomy of Healthcare Delivery Clinical domains and sub-domains Diagnostic Work-up and Triage History & Diagnostic Physical Testing Lower Risk of Morbidity/Mortality Higher Risk of Morbidity/Mortality (Community Clinical Service Lines) (Campus Clinical Service Lines) Ambulatory Intensive (IP) Medical Invasive Management Management Management Preventive Acute Chronic In valid ve Investive Health 1CU Med-Surg Self-Limited Recurrent Medical Surgical Maintenance Substance preparation Intervention and post-procedure care Bedside care

The four major domains can be further classified into sub-domains as follows:

Anatomy of Healthcare Delivery - Domains and Sub-Domains

Each of the domains and/or sub-domains consists of a finite number of clinical work processes, For example, the Chronic Recurrent Sub-Domain consists of clinical work processes such as degenerative joint disease, diabetes mellitus, depression and ischemic heart disease.

There is a common template for each domain which describes the steps in the process by which a patient flows through the domain or sub-domain. For example, in the Diagnostic Work-up and Triage Domain, the steps in the common template include:

- Chief complaint
- History and physical examination
- Differential diagnosis
- Diagnostic testing (e.g., lab, imaging)
- Triage for clinical management

These common templates are important because the general process of care is the same for all clinical work processes within a Domain or Sub-domain. This means that one subsystem can be used for multiple clinical work processes (e.g., data capture module in the EMR, visualization technique or report format in the EDW).

The templates are also important because the types and underlying structure of *clinical knowledge assets* which clinicians use to implement best practice are the same within each domain and sub-domain.

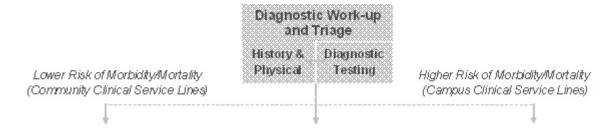
Clinical knowledge assets are the building blocks of care process models ("CPMs"). CPMs are evidence-based models which define the standardized steps in the diagnosis and management of a clinical work process (e.g., community acquired pneumonia CPM). Some examples of clinical knowledge assets include:

- <u>Diagnostic Algorithms</u> which include identification of a chief complaint, taking a history, performing a physical exam, formulating a differential diagnosis, obtaining appropriate diagnostic tests (e.g., lab, imaging) and triaging the patient for clinical management based on risk of morbidity/mortality.
- Ambulatory Management Algorithms which include protocols and treatment cascades for administration of immunizations, provision of education, administration of one-time or ongoing treatments based on a CPM treatment cascade and appropriate follow-up and monitoring of key indicators.
- <u>Indications for Referral</u> which are criteria which define when a patient has failed to respond adequately to traditional primary care acute or chronic ambulatory treatment and requires more specialized ambulatory, intensive medical or invasive management.
- <u>Indications for Intervention</u> which are findings in a patient which meet scientifically valid and/or professionally recognized criteria for performing a major therapeutic procedure.
- <u>Invasive Management</u> which includes written protocols and/or standardized procedures for patient preparation, patient/procedure control (e.g., "time out" to ensure correct patient, correct site), infection control, glucose control, venous thromboembolism prevention, pain control, bleeding control and foreign body prevention.
- <u>Post-Procedure Management</u> which includes written protocols and/or procedures for Phase 1 recovery, triage (e.g., admission to Intensive Medical Management versus discharge to specialty office follow-up), specialty office follow-up and return to primary ambulatory management.
- <u>Intensive Medical Management</u> which includes order sets and treatment protocols, substance preparation protocols and/or procedures, initial bedside care management processes, subsequent bedside care management processes, discharge planning process, patient and family education.

In the sections which follow, we will examine each of the domains and sub-domains in greater detail. The general format of each section is the same and consists of a definition of the following elements:

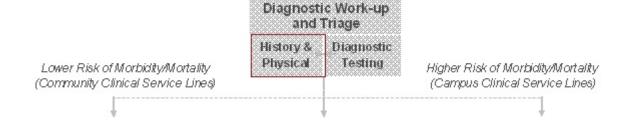
- 1. Participants: Defines the clinicians involved
- 2. Common Work Flow/Common Work Process: Documents the high-level clinician (MD, bedside care, lab, imaging) work flow/work process that is common to all the clinical work processes in the domain
- **3. Clinical Work Processes**: Define the specific clinical work processes which belong to the Domain
- **4. Knowledge Assets**: Define the types of clinical knowledge assets which belong to each common template.

Diagnostic Work-up and Triage Domain



Because the domains are functional, the participants may employ the tools of the domain in a variety of physical locations. For example, the common template process for this domain may be employed in an emergency care unit, urgent care location, a primary care or referral care office.

Diagnostic Work-up and Triage Domain - History and Physical Sub-Domain



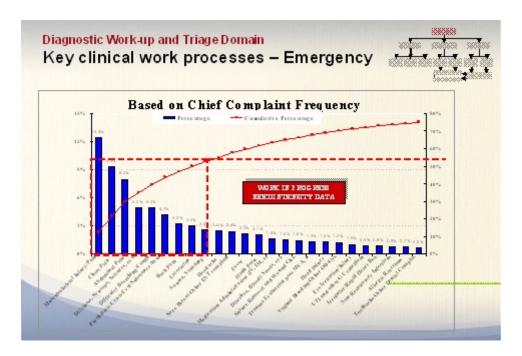
1. Participants:

- Primary care physicians and advance practice clinicians (APCs)
- Referral care physicians
- Urgent care centers
- Emergency care units

2. Common Work Flow/Common Work Process

- Chief complaint: Patient presents with a chief complaint (description of the problem in the patient's own words)
- History and physical: MD/APC takes a medical history and performs a physical exam on the patient with specific focus on body systems relevant to the chief complaint
- Differential diagnosis: MD/APC weighs the probability of one disease versus that of other diseases accounting for the patient's symptoms and signs
- Diagnostic studies: MD/APC obtains diagnostic studies (e.g., lab, imaging) based on symptoms, signs and differential diagnosis.
- Triage: MD/APC triages the patient to one of the three clinical management domains based on risk of morbidity/mortality

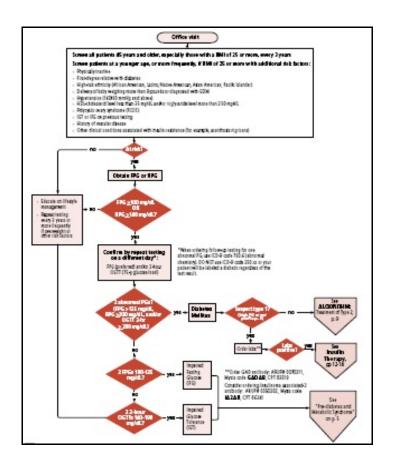
3. Clinical Work Processes



History and Physical Sub-Domain Clinical Work Processes - Emergency Care Unit

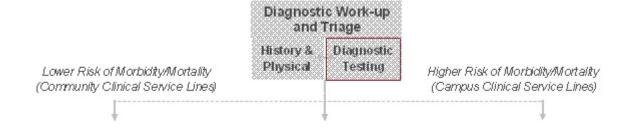
4. Sample Clinical Knowledge Assets

The main form of clinical knowledge asset in the History and Physical Sub-Domain is the diagnostic algorithm, which defines the standardized steps in the diagnosis of a given condition (e.g., diabetes)



Diagnostic Algorithm
Diabetes Mellitus

Diagnostic Work-up and Triage Domain - Diagnostic Testing Sub-Domain



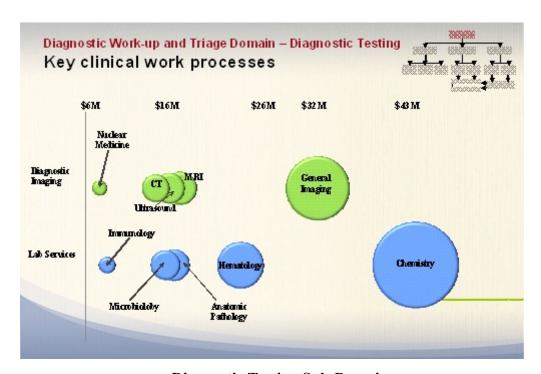
1. Participants:

- Diagnostic radiology
- Obstetrical ultrasound
- Clinical pathology
- Bacteriology
- Anatomic pathology (e.g., dermatopathology)
- Cytology

2. Common Work Flow/Common Work Process

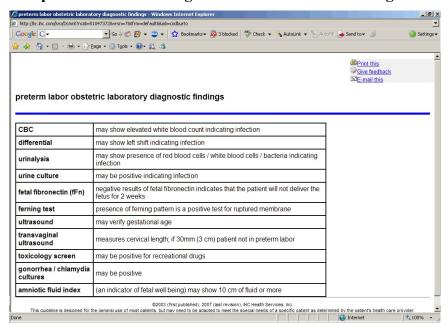
- Order placement: Attending MD places the order for a diagnostic test
- Acquisition queuing: Clerk schedules study
- Acquisition: Technician or nurse obtains image or specimen
- Evaluation queuing: Clerk queues specimen or image for evaluation by physician
- Interpretation: Physician, technician or machine interprets the image or specimen
- Reporting: Physician reports critical findings by phone or physician, technician or machine dictates or records routine findings
- Distribution: Computer system distributes reports to Attending MD/nursing unit

3. Clinical Work Processes



Diagnostic Testing Sub-Domain Clinical Work Processes

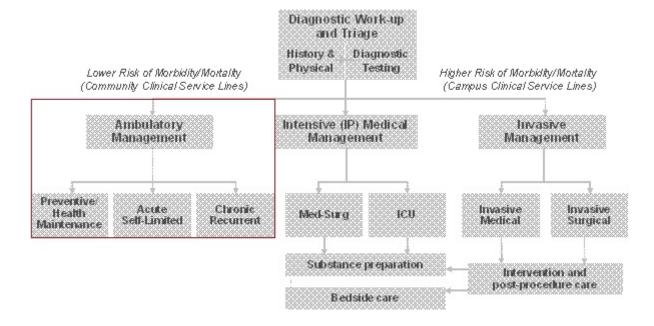
4. Sample Clinical Knowledge Assets - Pre-Term Lab Diagnostic Findings



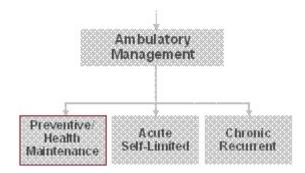
Ambulatory Management Domain

The Ambulatory Management Domain includes three sub-domains:

- Preventive and health maintenance
- Acute self-limited
- Chronic recurrent



Ambulatory Management Domain - Preventive and Health Maintenance Sub-Domain



1. Participants

- Primary Care Physicians and Advance Practice Clinicians
- Referral Care Physicians
- Patient/Family

2. Common Work Flow/Common Work Process

- Appointment: Patient schedules a well-person visit
- History: MD/APC takes a medical history by interviewing patient regarding family history, social history and review of systems
- Physical Exam: MD/APC performs physical exam on patient with specific focus on body systems relevant to positive findings from history
- Screening Diagnostic Studies: MD/APC orders screening diagnostic studies based on applicable preventive care guidelines (e.g., pediatric, adolescent, adult)
- Preventive Management: MD/APC orders immunizations, provides preventive and health promotion education and schedules follow-up appointments/testing at appropriate intervals

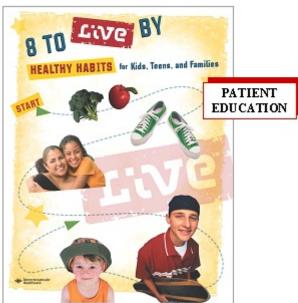
3. Clinical Work Processes

- Preventive Care
- Immunizations (childhood, adolescent, adult)
- Nutrition and activity counseling (preventive)
- Obesity (treatment)
- Smoking cessation

4. Sample Clinical Knowledge Assets

The main form of clinical knowledge asset in the Preventive and Health Maintenance Sub-Domain is educational material such as:





Provider and Patient Educational Material Weight Management for Children and Adolescents

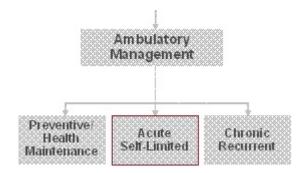






Preventive Care Recommendations Pediatric, Adolescent and Adult

Ambulatory Management Domain - Acute Self-Limited Sub-Domain



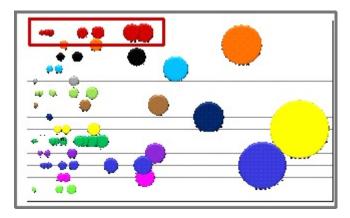
1. Participants

- Primary care physicians/advance practice clinicians (APCs)
- Referral care physicians
- Urgent care centers
- Emergency care units

2. Common Work Flow/Common Work Process

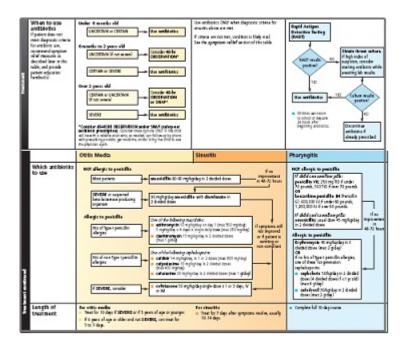
- Chief complaint: Patient presents with a chief complaint (description of the problem in the patient's own words)
- History and physical: MD/APC takes a medical history and performs a physical exam on the patient with specific focus on body systems relevant to the chief complaint
- Differential diagnosis: MD/APC weighs the probability of one disease versus that of other diseases accounting for the patient's symptoms and signs
- Diagnostic studies: MD/APC obtains diagnostic studies (e.g., lab, imaging) based on symptoms, signs and differential diagnosis.
- Triage: MD/APC triages the patient to one of the three clinical management domains based on risk of morbidity/mortality (usually ambulatory)
- Management: MD/APC prescribes treatment, provides education and schedules follow-up appointment/testing if indicated (follow-up in this sub-domain is often "as needed")

3. Key Clinical Work Processes



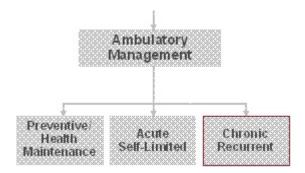
- Tonsillitis, adenoiditis, or pharyngitis
- Sinusitis
- Otitis media
- Lung infections (e.g., community acquired pneumonia)
- Acute bronchitis
- Other infectious diseases

4. Sample Knowledge Assets



Care Process Model
Diagnosis and Treatment of Otitis Media

Ambulatory Management Domain - Chronic Recurrent Sub-Domain



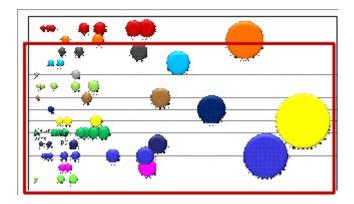
1. Participants

- Primary care physicians/advance practice clinicians
- Referral care physicians
- Urgent care centers
- Emergency care units

2. Common Work Flow/Common Work Process

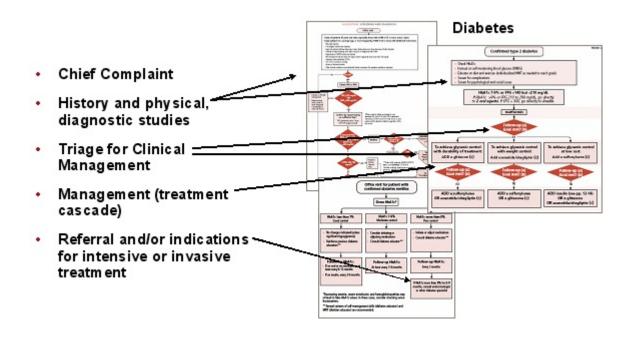
- Chief complaint: Patient presents with a chief complaint (description of the problem in the patient's own words)
- History and physical: MD/APC takes a medical history and performs a physical exam on the patient with specific focus on body systems relevant to the chief complaint
- Differential diagnosis: MD/APC weighs the probability of one disease versus that of other diseases accounting for the patient's symptoms and signs
- Diagnostic studies: MD/APC obtains diagnostic studies (e.g., lab, imaging) based on symptoms, signs and differential diagnosis.
- Triage: MD/APC triages the patient to one of the three clinical management domains based on risk of morbidity/mortality (usually ambulatory)
- Management: MD/APC:
 - Prescribes treatment based on treatment cascade, provides education, and schedules follow-up appointments and testing
 - Pursues treatment cascade until control is achieved or refers patient for consultation and/or intensive management (ambulatory or inpatient)

3. Key Clinical Work Processes



- Degenerative joint diseases
- Diabetes
- Depression
- Ischemic cardiovascular disease
- . . .

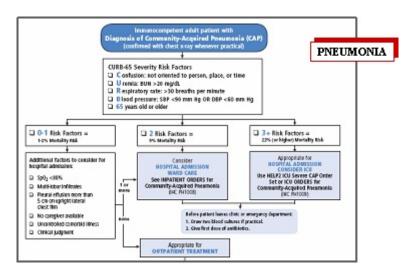
4. Sample Knowledge Assets



Chronic Recurrent Care Process Model
Diabetes Mellitus

Ambulatory Domain - Indications for Referral - Acute Self-Limited Sub-Domain

- 1. Failure to Respond to Ambulatory Treatment Referral for Intensive Medical Management: Some patients with acute, self-limited medical conditions (e.g., community acquired pneumonia) may be initially triaged for ambulatory management, but then fail to respond adequately and require hospitalization for treatment.
- 2. Sample Clinical Knowledge Asset Admission Criteria

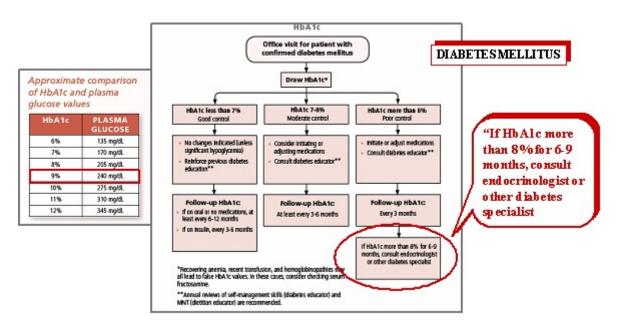


Admission Criteria
Community Acquired Pneumonia

- 3. Failure to Respond to Ambulatory Treatment Referral for Evaluation by Invasive Surgical Specialist: Some patients with acute self-limited conditions (e.g., otitis media) who experience frequent recurrences, resistance to medical therapy and/or complications (e.g., chronic effusion) may require referral for evaluation for possible invasive treatment.
- 4. Sample Clinical Knowledge Assets Indications for Referral Evaluation Otitis Media with Effusion ("OME")
 - Sensory, physical, cognitive and/or behavioral factors that place children with OME at increased risk for development difficulties (e.g., Down syndrome)
 - Effusion which has been documented by penumatic otoscopy and has not cleared with watchful waiting for at least three months from the onset of the effusion
 - Significant hearing loss
 - Suspected structural abnormalities of the eardrum or middle ear

Ambulatory Domain - Indications for Referral - Chronic Recurrent Sub-Domain

- 1. Failure to Respond to Ambulatory Treatment Referral for Intensive Management in Chronic Disease Referral Clinic: Some patients with chronic recurrent medical conditions (e.g., Diabetes) fail to respond to the primary ambulatory management treatment cascade or respond initially and later become resistant to basic therapy. These patients may require more intensive medical management by a specialty team in a chronic disease clinic (e.g., diabetes referral center)
- 2. Sample Clinical Knowledge Assets Indications for Referral to Chronic Disease Specialty Clinic Diabetes



Indications for Referral to Specialty Clinic - Diabetes

3. Coordinated Management of Chronic Medical Conditions by Primary Care Clinics and Chronic Disease Medical Sub-specialty Clinics

Primary Care Physicians, medical assistants and generalist ambulatory care managers are capable of managing the vast majority of patients with chronic medical conditions (e.g., diabetes, heart failure) if they have ready access to and are supported by:

- Care Process Models including supporting provider and patient educational materials
- Chronic disease sub-specialty clinic teams with whom they can consult and to whom they can refer patients for consultation

This coordinated (Primary Care - Chronic Disease Medical Sub-specialty Clinic) management model may be represented conceptually as follows:

Total Population with Chronic Disease (e.g. Diabetes)			
~ 2/3	~ 1/6	~ 1/6	
Primary Care Physician General Internist or Pediatrician Family Practitioner		Adult or Peds Medical/Psych Specialist	
Medical Assistant	Generalist Care Manager & Mental Health Clinician	Specialist Care Manager and Other Support Staff	

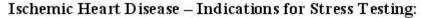
Primary Care Physician + **Medical Assistant:** As can be seen in the graphic above, a Primary Care Physician and a medical assistant can manage about two-thirds of diabetics, i.e., those who respond to the basic treatment cascade of oral agents and/or basic insulin therapy.

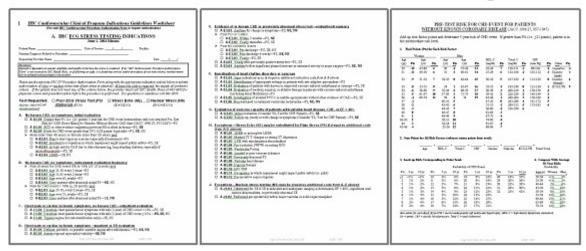
Primary Care Physician + Generalist Care Management Team: The Primary Care Physician is qualified and capable of managing roughly half of the remaining one-third of patients with diabetes (i.e., one-sixth of the total population) with the assistance of a generalist care management dyad consisting of a general care manager and mental health clinician. This care management dyad spans multiple primary care clinics and has patients with a variety of chronic medical conditions in the populations it manages (e.g., diabetics, heart failure patients, hypertensives, asthmatics)

Medical Sub-specialist + Condition-Specific Care Management Team: The remaining one-sixth of the total population of diabetics require more intensive management by a team of physician and care management specialists organized as a chronic disease medical sub-specialty clinic. For example, in the case of diabetes, the physician expert is either an endocrinologist or general internist whose practice is focused primarily on diabetes. However, the non-physician resources of the sub-specialty clinic are at least as important as the physician resources. They may include professionals such as Advance Practice Clinicians (e.g., nurse practitioners), certified diabetic educators, dietitians and behavioral health clinicians specialized in diabetes. The sub-specialty physician provides telephone consultation as well as in-person consultation to Primary Care Physicians with a goal to help Primary Care Physicians succeed in managing as many diabetic patients as possible. The sub-specialty clinic provides primary medical management for that subset of patients that is: 1) brittle or refractory to the basic treatment cascade; and/or 2) requires specialized care management support (medical and/or behavioral)

Ambulatory Domain - Indications for Referral for Evaluation by Invasive Specialists - Chronic Recurrent Sub-Domain

- 1. Failure to Respond to Ambulatory Treatment Referral for Evaluation by Invasive Medical or Surgical Specialist: Some patients with chronic recurrent medical conditions (e.g., ischemic cardiovascular disease, degenerative joint disease) experience acute or chronic deterioration and require referral for intensive medical and/or possible invasive management.
- 2. Sample Clinical Knowledge Assets Indications for Diagnostic Testing Ischemic Heart Disease

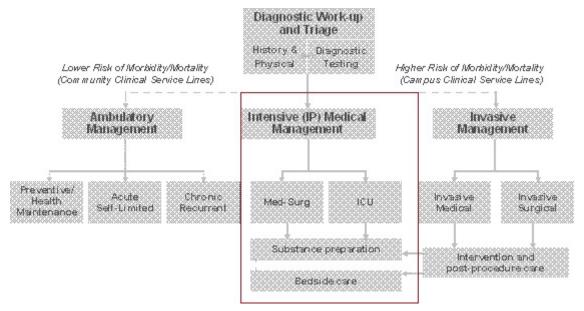




Indications for Specialty Diagnostic Testing Ischemic Heart Disease - Stress Testing

Intensive (IP) Medical Management Domain

The Intensive (IP) Medical Management Domain includes two sub-domains - Med-surg and ICU



Intensive (IP) Medical Management Domain

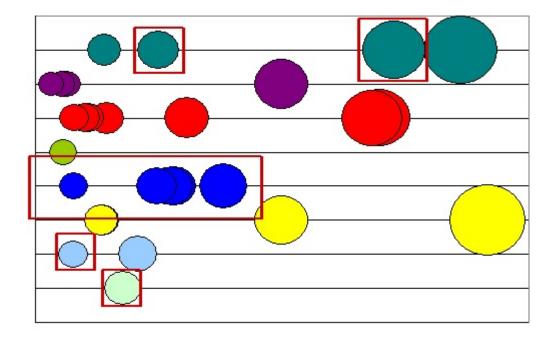
1. Participants

- Hospitalists
- Critical care physicians
- Referral care physicians

2. Common Work Flow/Common Work Process

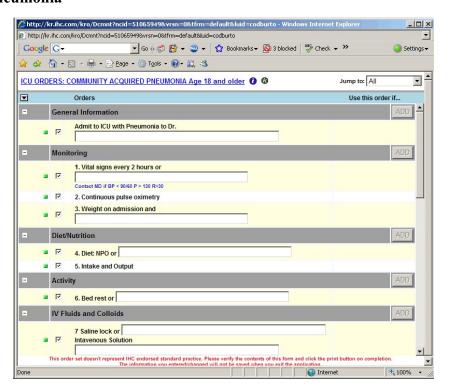
- Admission: MD admits patient to med-surg or ICU (through emergency care unit or directly)
- History: MD/APC takes a medical history by interviewing patient regarding family history, social history, review of systems and present illness
- Physical Exam: MD/APC performs physical exam on patient with specific focus on body system(s) relevant to positive findings in history
- Diagnostic Studies: MD/APC orders diagnostic studies based on CPM if not obtained prior to admission
- Initial Management MD/APC implements standing orders based on primary problem and co-morbid condtions

3. Clinical Work Processes



Intensive Medial Management Domain Clinical Work Processes

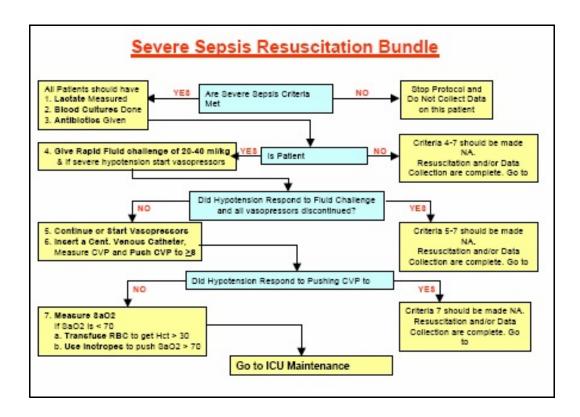
4. Sample Clinical Knowledge Assets - ICU Order Set - Community Acquired Pneumonia



- 5. ICU MD Management: Because of the higher level of intensity of illness treated in the ICU, various protocols and "bundles" have been developed to: 1) support failing body systems; 2) to prevent body system failure and patient injury; and 3) to standardize unit procedures. Examples of such protocols include:
 - Insulin protocol
 - Ventilator bundle or protocol
 - Long-term sedation protocol
 - Enteral feeding protocol
 - Heparin protocol

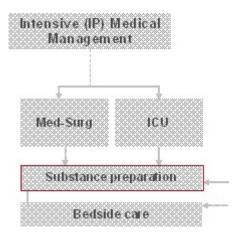
- Electrolyte replacement protocols (e.g., K+, Mg++)
- Incisional wound care unit routines
- Arterial and venous catheter unit standards

6. Sample Clinical Knowledge Asset - Severe Sepsis Resuscitation Bundle



Intensive Medical Management Domain
ICU Sub-Domain - Severe Sepsis Resuscitation Protocol (Bundle)

Intensive Medical Management Domain - Substance Preparation Sub-Domain



1. Participants

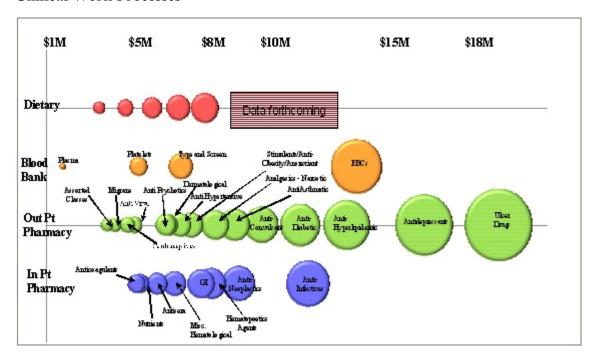
- Pharmacy personnel
- Blood bank technologists
- Dietary personnel

2. Common Work Flow/Common Work Process

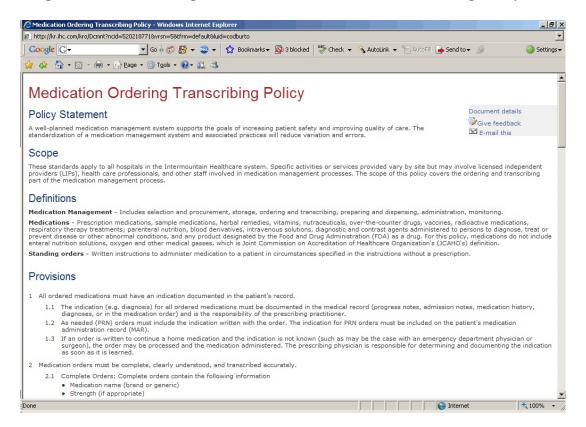
Normally the blood bank would be categorized as one of the laboratory services rather than being included in a consideration of the pharmacy and dietary departments. However, when the work flow of these three areas is considered, it becomes apparent that all three areas are engaged in a generic work process of substance preparation, which includes:

- **Order Placement:** MD/APC writes order (which creates a department worklist item)
- **Order Transmission:** Unit clerk transmits order to department (e.g., via fax, tube or courier)
- Order Entry: Departmental personnel enter order into computer
- Patient Safety Search: Computer searches for triggers/alerts (e.g., allergies, drug or blood factor interactions)
- **Dispensing:** Substance is dispensed (e.g., by robot, automated cabinet, manually)
- **Transport:** Substance is transported to care unit (e.g., via manual courier, tube, automated cabinet)

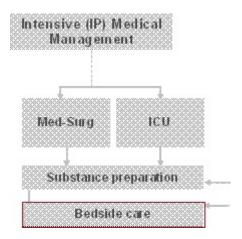
3. Clinical Work Processes



4. Sample Clinical Knowledge Asset - Medication Order Transcribing Policy:



Intensive Medical Management Domain - Bedside Care Sub-Domain



1. Participants

- Nurses (RN, LPN) and aides
- Clinical pharmacists
- Respiratory therapists
- Physical, occupational and speech therapists
- Dietitians
- Social services personnel

2. Common Work Flow/Common Work Processes - Initial Care Plan and Work List Development

- **General Assessment:** Initial assessment based on demographics and general nursing practice (e.g., Basic Cares Collaborative Practice Guideline ["CPG"])
- **Specific Independent Actions:** Nursing practice guidelines (e.g., CPGs) specific to patient problem/findings
- **Specific Dependent Actions:** Work list items based on MD/APC orders
 - Substance administration (e.g., meds, fluids/lytes, blood, enteral/TPN)
 - Respiratory, physical/rehab and metabolic support
 - Interventions (e.g., ET tube, IV, urinary catheter)
- Education: Patient/family education
- **Discharge:** Discharge planning process

3. Common Work Flow/Common Work Processes - Care Plans for Subsequent Shifts/ Day(s) and Work List Development

Planned Reassessments:

- Planned reassessments based on MD orders (e.g., VS, I & O) and those generated from Initial Assessment of patient injury risks (e.g., "Risk For" Problems)
- Planned reassessments based on nursing practice guidelines (e.g., CPGs) specific to patient problems/findings
- **Unplanned Reassessments:** Unplanned reassessments based on unanticipated events/changes in status (e.g., adverse trend in extended vital signs monitoring)
- Time-Driven Work List Items
 - Measurement and observations (e.g., daily weight)
 - Substance administration (e.g., medication administration)

 Maintenance and monitoring (e.g., ET tube, IV, urinary catheter, dressing)
- Education: Patient and family
- **Discharge:** Discharge planning process

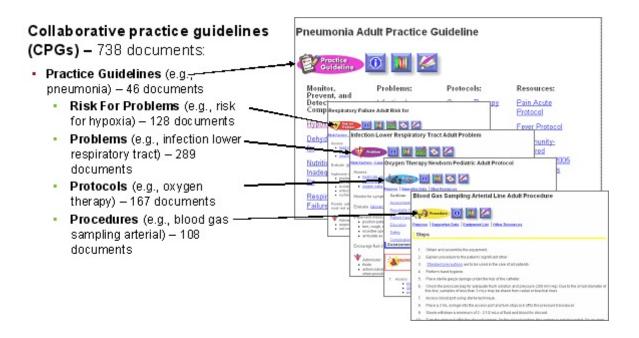
4. Clinical Work Processes - Bedside Care

Caring and Concern

- Critical thinking and care plan development including Level 1 care management
- Assessment (initial, planned reassessment, unplanned reassessment, transfer, discharge)
- Basic Cares (inpatient complication prevention)
 - Medication reconciliation (ADE prevention)
 - Maintenance of skin integrity (pressure injury prevention)
 - Strength, agility, mobility and cognition (fall prevention)
 - VTE prophylaxis (VTE prevention)
 - Extended vital signs monitoring and evaluation (rapid response teams)
 - Deconditining (atrophy and flexion contracture prevention)
- Patient and family education (initial, daily, transfer discharge)

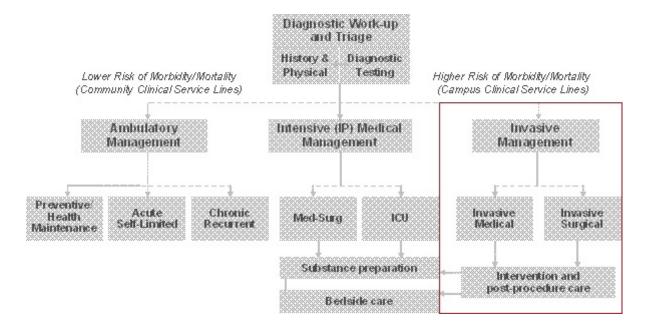
- Substance administration: medications, blood products, fluids/electrolytes, TPN
- Respiratory support: oxygen administration, aerosolized bronchodilators, chest PT, incentive spirometry, ventilator management
- Physical/rehab support: physical, occupational, speech therapy
- Metabolic/nutritional support: glucose management, enteral/parenteral feeding
- Interventions: ET tube, IV, urinary catheter
- Maintenance and monitoring: IV, urinary catheter, chest tube, wound dressing
- Administrative ("hunting and gathering" [contact M D, lab, imaging, pharmacy] and charting/ documentation)
- Discharge process (agencies, meds, equipment)

5. Sample Clinical Knowledge Assets - Collaborative Practice Guidelines



Invasive Management Domain

The Invasive Management Domain includes two sub-domains - Invasive medical and invasive surgical

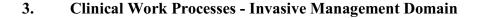


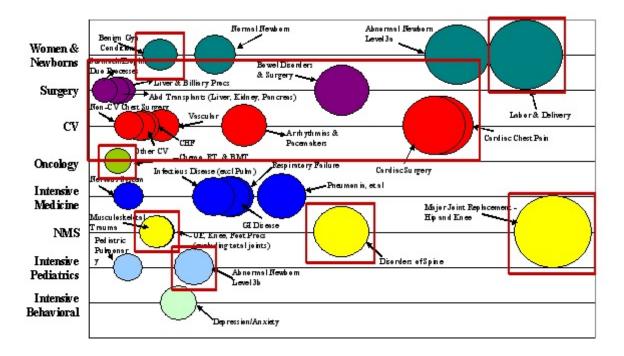
1. Participants

- a. Invasive Medical Specialists
 - Cardiologists (cath and EP)
 - Interventional radiologists
 - OB forceps/vacuum
 - MFM ablations
 - Interventional pain management
 - Interventional gastroenterology
- b. Invasive Surgical Specialists
 - General Surgeons
 - Neurosurgeons
 - Thoracic surgeons
 - Orthopedic surgeons
 - Urologists
 - Ophthalmologists
 - ENTs
 - Plastic surgeons
 - OB-Gyns (C-Section, gyn surgeons)

2. Common Work Flow/Common Work Process

- **Referral:** Patient is referred to invasive specialists by ambulatory, urgent care or emergency care MD/APC
- **History and Physical Exam:** MD takes a specialized history and performs physical exam with specific focus on the body system in question
- Specialized Additional Diagnostic Studies: MD orders or performs additional specialized diagnostic studies needed to determine whether intervention indications are present (e.g., stress echocardiogram, diagnostic endoscopy, surgical biopsy, MFM ultrasound)
- **Indications for Intervention:** MD triages patient:
 - To intervention if indications are present and intervention risk is acceptable
 - To medical management (e.g., back to ambulatory care domain) if findings are not present and/or intervention risk is not acceptable





4. Sample Clinical Knowledge Assets - Indications for Intervention

An invasive medical or surgical specialist uses the history, physical exam and specialized additional diagnostic tests to determine whether the findings in a patient meet scientifically valid and/or professional recognized criteria for performing a major therapeutic intervention/procedure.

The following graphics illustrate the diagnosis and management of patients with chest pain, including:

- Assignment of patients to an Acute Coronary Syndrome ("ACS") probability category (1-4) based on signs and symptoms
- Admission and treatment of patients based on ACS-probability category (1-4)

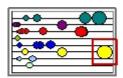
	O STEMI stelluzion M	2 High-peolethery ACS Non-SE-South #1 (#3550) DR definite vestable angles (##)	Moderate- probability ACS	O Low- protectility ACS
Symptoms?	Typical of ischemic/inferction	Strongly suggestive of ischemic/inforction	Strongly suggestive of ischemia	Suggestive—but atypical—for ischemia
ENGP	Ischemic ST elevation in 2 or more configuous leads OR Hypercoute Twores OR Signs of soute posterior MTOR B88 obscuring ST segment enalysis—with MI history	ST depression >1 mm or Deep T-wave inversion	Normal or non-specific, with or without pain	Normal or non-specific, with ar without pain
Cardiac blomarkers? (CK, CK-MB, trepenin)	May or may not be elevated at 0 hours, typically elevated at 6 hours	If normal: Dofinito UAP If planeted (with or without DVG changes): NSTEM!	Normal at 0, 6, 12, and 24 hours	Normal at 0 and 6 hours
High risk Indicators for adverse CV overt? Presence of risk indicators may warrant moving patient to a higher ACS-probability category.	Anterceptal MI Hypotension, cardiogenic shock ST changes of inferoposterolateral MI RV inferction New significant arrhythmia or heart block Heart failure Age >75	Elevated troponin Hyposanston Dynamic EKG changes with pain Prolonged lachemic pain or recurrent pain after initial relief New significent or heart block > 2 enginal events within the prior 24 hours Heart failure Age > 75	≥3 traditional risk factors for CAD Prior coronary stenosis >50% Use of ASA within past 7 days Recurrence of pain after initial reliaf >2 anginal events within the prior 24 hours Heart failure Age >75	≥3 traditional rick fectors for CAD Prior coronary stancesis >50% Use of ASA within past 7 days Recurrence of pain after initial reliaf >2 anginal events within the prior 24 hours Heart failure Age >75

MANAGEMENT Admit and trest patient based on ACS-probability estagory (1.4).

	O STEMI STBackto M	2 High-probability ACS Rea ST-Excelor M (ASTERS) CR definite crestable angles (LPF)	Moderate probability ACS	Dow- protestity ACS
Admit status	Cath Lab/CCU	CCU	Inpatient Telemetry	ER/Observation
Diagnostic/ therapeutic care	Urgent Reportusion Primary PCI (PPCI) in ≤00 minutes done in-ballon nitine Fibrinalytic ≤90 minutes if PPCI not available in ≤00 minutes EKB and cardiac biomarkers at 0, 6, 12, and 24 hours	EKG and cardiac biamarkors at 0, 6, 12, and 24 hours Lipids and heGRP Carb with LV function within 4B his [preferably <12 house-immediately if ongoing pain]	EKG and cardiac blomarters at 0, 6, 12, and 24 hours Upide and BHP Hilos- nod erate risk, imaging stress test or cardiac Ci Hilgher risk, cardy-CI within 48 hours (prefixely-42 hous)-immediately if ongoing pain.	BIG and cardisc blomaties at 0 and 6 lieus (12 hours finitially indicated) Upids and ENP
Initial medications/ treatment (unless contraindicated)	ASA Beta blocker NTS Q ₂ Heparin (ADS dosage) Epithadda only if PPCI (Abctamab If large dot burden) Morphise, prin	ASA Bota blocker NTG Og Hoparin (ACS domage) Eptitlestide (start in ED) Morphine, pre	ASA Beta blocker NTG O ₂ Emoxapath 1 mg/kg subcut Bi D Morphise, pm	Medications as indicated
Adjunct care (unless contraincleated)	Struit ACB (or ARB) when BP stable, especially IFEF <40% Aldosterane blocker IFEF <40%	Statin ACE (or ARB) when BP stable Addistrions blocker FEF <40%	Scrip ACEI (or ARB) when BP stable Aldosteione blocker if EF <40%	As indicated
Subsequent care	Clopidogrei for ≥9-6 months actor PCL/CABG (≥12 months FDES) If throutholycic, cach <24 hours Fagoing pain, immediate hoccus PCI F pain-free, cath 24-48 hours	Clopidagrel for ≥3-6 menths after PC yCAB6 (≥12 menths if DE6) If activation is negative for ischemia, consider primmary amballam, porteatiffe, sortic dissection, and GI	Chapidogel for ≥9-6 months after PCI/CABG (≥1.2 months if DES) He evaluation is negative for ischania, consider pulmonary embolism, particulate, acris dissection, and GI	If low-modesite (a)k and stable with signs, condider dischauge and inflaging since size or cardiac CT within 72 hours If higher risk, imaging stress test before release or within 48 hours If evaluation is regality for lachemia, consider pulmonary ambol lan, portrandits, acritic dissection, and GI

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Lest updated Nevember 2008, replaces September 2008



OSTEOARTHRITIS Indications for Total Joint Replacement Surgery

Pain at hip

- Increased with initiation of activity
- Increased with weight bearing
- Interferes with ADLs

Findings at hip

- Pain with passive ROM
- Limited ROM
- Antalgic gait

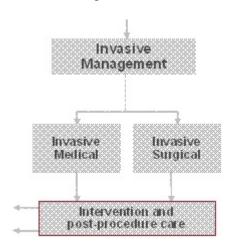
Arthritis at hip by X-ray

- Subchondral cysts
- Subchondral sclerosis
- Periarticular osteophytes
- Joint subluxation
- Joint space narrowing

Continued Sx/findings after Rx

- NSAID > 4 wks
- PT > 12 wks
- External joint support > 12 wks

Invasive Management Domain - Intervention Sub-Domain



1. Participants

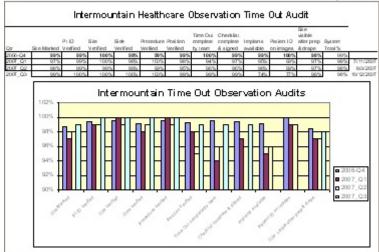
- Invasive medical specialists
- Invasive surgical specialists
- Analgesia/anesthesia specialists
- Nurses, technicians, et al

2. Common Work Flow/Common Work Processes

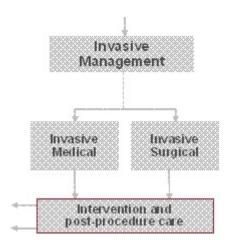
- **Preparation:** Patient and site prepared for surgery
 - **Patient/Procedure Control:** Observation "time-out" process to ensure right patient and right site
 - **Infection Control**: Prophylactic antibiotics administered within appropriate time window
 - Glucose Control: Managing peri-operative glucose levels within a prescribed range
 - **VTE Prevention:** Initiation of preventive measures (e.g., compression boots, anticoagulation) intraoperatively to prevent venous thromboembolism
 - **Pain Control:** Administration of anesthetic and analgesic agents to ensure appropriate pain management without patient injury (e.g., respiratory depression)
 - **Bleeding Control:** Management of bleeding (e.g., through ligation, cauterization) to prevent hemorrhagic complications, including return to surgery
 - **Foreign Body Prevention:** Processes and procedures (e.g., sponge and instrument counts) to prevent retained foreign bodies

3. Sample Clinical Knowledge Assets





Invasive Management Domain - Post-Procedure Care Sub-Domain



1. Participants

- Invasive medical specialists and invasive surgical specialists
- Analgesia/anesthesia specialists
- Intensive medical specialists
- Bedside care team (multi-disciplinary RN, LPN, RT, PT, OT, dietitians)
- Invasive specialists office team

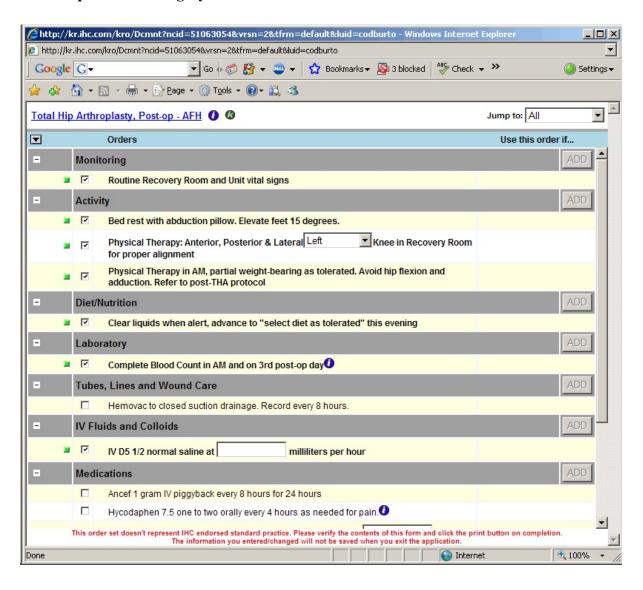
2. Common Work Flow/Common Work Processes

• **Initial Recovery:** Post-anesthesia care unit ("PACU")/rapid treatment unit ("RTU") Phase 1 recovery

• PACU/RTU Triage:

- Admit to ICU or general med-surg unit for intensive medical management
- Discharge from PACU/RTU to home and schedule for specialty office follow-up
- **Specialty Office Follow-up:** Post-procedure follow-up care by medical or surgical invasive specialist in specialist's office
- **Primary Ambulatory Management:** Discharge from post-procedure follow-up care in invasive specialist's office and return to primary ambulatory management

3. Sample Clinical Knowledge Asset - Post-op Standing Orders - Total Hip Replacement Surgery



CHAPTER TWO CLINICAL WORK PROCESS ANALYSIS

In our discussion in Chapter One of the anatomy of healthcare delivery, we introduced the clinical work processes which reside in each of the domains and sub-domains. We will now consider in detail how you can use raw data to identify and define the relative size of these clinical work processes

Data Sources

In order to conduct these analyses, you will need data from multiple sources. Some data will be available within your own organization (e.g., case mix data). Other data may require that you collaborate with external partners (e.g., ambulatory claims data). The following list is constructed around the domains and sub-domains discussed in Chapter One.

Anatomy of Healthcare Domain/Sub-Domain	Data Source
Diagnostic work-up and triage History and physical	Emergency care - case mix and departmental systems Primary care - clinic registration and billing system Urgent care - clinic registration and billing system
Diagnostic work-up and triage Diagnostic testing	Departmental systems
Ambulatory	Managed care claims Tumor registry linked to claims and case mix Pharmacy benefit management systems
Intensive medical management	Case mix and departmental systems
Substance preparation	Departmental systems
Bedside care	Medical records (automated data largely unavailable)
Invasive management	Case mix and departmental systems

"Groupers" - Grouping of Data Into Diagnostic and Procedural Clinical Work Processes

Two types of groupers are available to help you group much of the raw data listed in the table above into clinical work processes:

• **DRG Groupers:** Diagnosis-related groups (DRGs) are an inpatient classification system which organizes inpatient stays into one of approximately 500 groups. The DRG methodology was developed in the late 1970s at Yale University and subsequently adopted by HCFA (now CMS)in the early 1980s. The primary objective of the DRG

system was to identify and compare resource consumption in terms of gross charges. It was designed to minimize financial variation within a given DRG. Because the primary orientation of the HCFA DRGs was financial, diagnoses which consumed about the same amount of financial resource, but were not always relevant clinically were sometimes classified in the same DRG. HCFA DRGs are weak in areas relevant to populations not usually covered by Medicare (e.g., maternal, newborn)

3M later developed a diagnosis-related group patient classification system called All Patient Refined DRGs (APR-DRGs). The APR-DRG system meets the original objective (quantifying resource use, cost and payment) at a higher level of clinical and analytical sophistication and precision. APR-DRGs refine the description of DRG categories, offer greater clinical coherence, and include adjustments for severity of illness and risk of mortality.

• **Episode Groupers:** Episode groupers identify and classify an entire episode of care, including medical treatment a patient receives as an outpatient, an inpatient or both. Symmetry Health Data Systems developed a patient classification system called Episode Treatment Groups ("ETGs"), which as become the gold standard in the industry. The ETG classification system consists of about 700 statistically stable clinical groups. ETG software captures all clinically relevant services and prescriptions provided during a patient's treatment, and organizes the data into episodes of care.

Even though episode groupers such as Symmetry's ETGs capture inpatient information, the level of detail is not typically as robust as that available in a DRG grouper. This is because most hospitals provide only the minimum number of diagnostic and procedural ICDs (e.g., two) required to get paid by third-party payers.

You may need to form a collaborative working relationship with a managed care plan or business health coalition in order to gain access to ambulatory claims data if you do not own a managed care plan or have a relationship with a significant clinic network from which claims submissions may be obtained

You must pay a license fee to use the APR-DRG or ETG groupers.

Aggregation of Granular Information into Clinical Work Processes

Once you have used the groupers to identify and define the relative size of the APR-DRGs and ETGs you are ready to aggregate them into the next level of abstraction. It is important that you give attention at this point in the analysis to involve key clinical stakeholders in decisions pertaining to how clinical conditions and procedures are grouped into clinical work processes, which form the basis for development and implementation of best practice. These decisions and definitions will drive future decisions concerning electronic infrastructure (e.g., data marts in the EDW). Involving key stakeholders in the journey allows them to get their fingerprints on the decisions.

• Aggregation of APR-DRGs into Clinical Work Processes: With the aid of key clinical stakeholders, the 300+ APR-DRGs can be further grouped by aggregating APR-DRGs which are part of a common clinical process of care into a clinical work process. For example, your OB experts might choose to group the following APR-DRGs into a "Labor and Delivery" clinical work process:

APR-DRG#	APR-DRG Description
540	Cesarean Delivery
541	Vaginal Delivery W Sterilization &/or D&C
542	Vaginal Delivery W Complicating Procedure
560	Vaginal Delivery

Such aggregation will reduce the 300+ APR-DRGs into roughly 100 clinical work processes for inpatient care (intensive medical + inpatient invasive clinical work processes)

• Summary ETGs - Preliminary Clinical Work Processes: Many software programs which use the Symmetry ETG classification system will produce not only the 700+ atomic-level episode treatment groups, but also a higher level view which aggregates the 700+ into 200+ summary-level groups. For example, the summary level group "diabetes" includes the following granular ETGs:

ETG#	ETG Description
0028	Insulin dependent diabetes, with comorbidity
0029	Insulin dependent diabetes, w/o comorbidity
0030	Non-insulin dependent diabetes, with comorbidity
0031	Non-insulin dependent diabetes, w/o comorbidity

The summary-level view is a useful starting point for defining ambulatory clinical work processes. Involving key clinicians, such as primary care physicians, in refining this summary-level, clinical work process view will enhance your prospects of future success.

• Other Clinical Work Processes: Beyond these two major groupers, the approach to defining the clinical work processes which belong to each of the domains and subdomains described Chapter One will require more or less manual analytic effort depending on the data systems you have available in your organization.

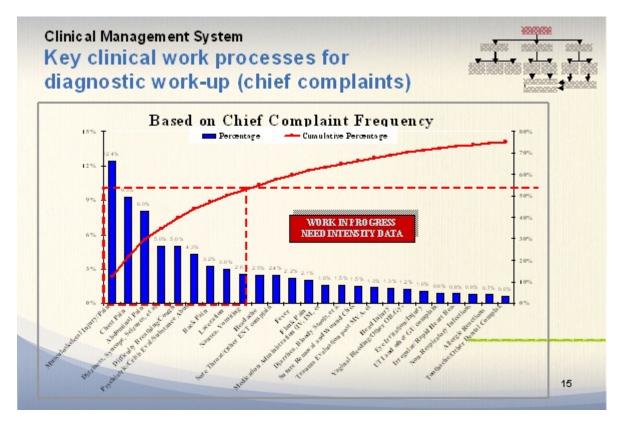
Pareto Analysis of Clinical Work Processes

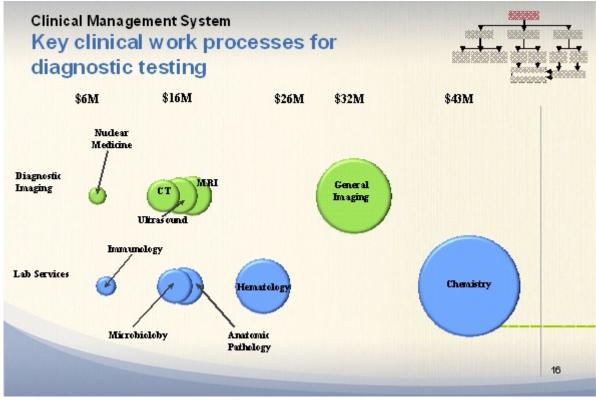
Once you have a preliminary definition of clinical work processes the next step is to conduct Pareto analyses on them.

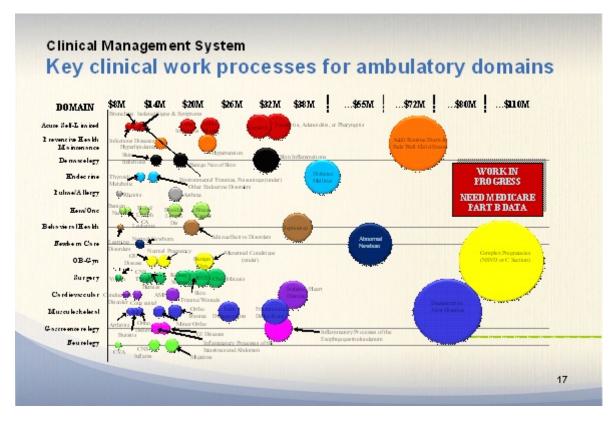
- APR-DRG Clinical Work Processes: In the ideal you will want to analyze frequency and cost dollars for each APR-DRG-based clinical work process. The cost dollars analysis tends to be more useful because it is a reasonably accurate reflection of clinical resource consumption (e.g., nursing time). First sort your data in descending order based on cost dollars. Next determine what % of the total cost dollars clinical work process line item represents. Then do a cumulative % analysis to see how many of the 100+ clinical work processes it takes to account for about 80% of the total cost dollars. Typically, 40 to 50 clinical work processes will account for 80%.
- ETG Clinical Work Processes: In the ideal you will want to analyze frequence and "allowed dollars" for each summary ETG clinical work process. Allowed dollars represents the sum of the amount paid to the provider by the managed care plan and the patient (e.g., in the form of copays, deductibles, coinsurance). Allowed amounts are a more reliable indicator of reality than are billed charges. The same sequence of analytic steps outlined above under "APR-DRG Clinical Work Processes" (i.e., descending sort, individual % and cumulative %) will reduce the 200+ line items to about 60+ episode-based clinical work processes which account for 80% of the allowed dollars.
- Other Clinical Work Processes: The APR-DRG and ETG analyses outlined above will cover large parts of the major domains and sub-domains discussed in Chapter One. You will need to employ some creative analytic approaches using departmental data (e.g., for pharmacy) and links between data bases (e.g., tumor registry and case mix for oncology) to define some of the work processes.

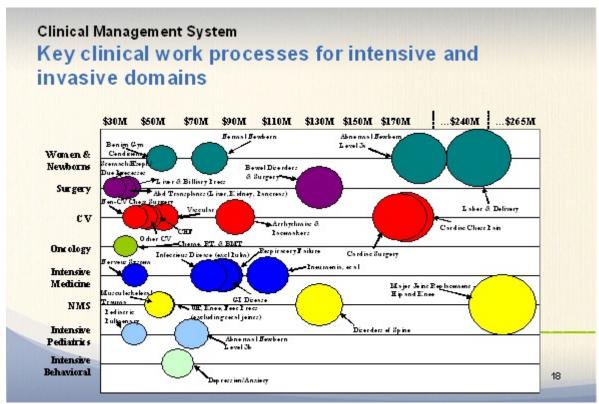
Graphical Displays

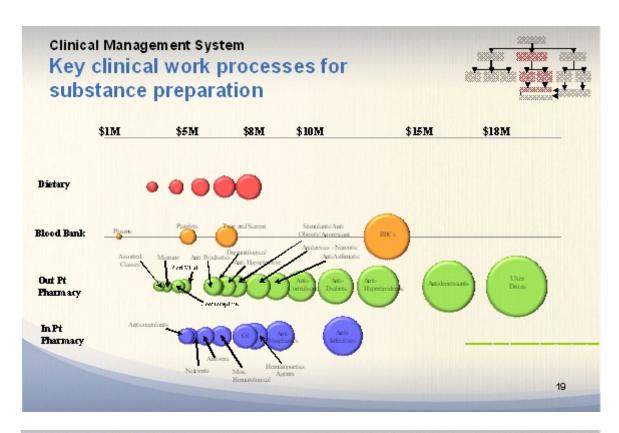
As you and your clinicians turn data into information using analytic tools and approaches such as those outlined above, your efforts to engage other key stakeholders (more key clinicians and administrative colleagues) will probably be enhanced by creating graphical displays of your information. You may find that displaying your information as bubble charts like the following is useful.



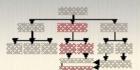








Clinical Management System Key clinical work processes for bedside care



Caring and Concern

- Critical thinking and care plan development including Level 1 care management
- Assessment (initial, planned reassessment, unplanned reassessment, transfer, discharge)
- Basic Cares (inpatient complication prevention)
 - Medication reconciliation (ADE prevention)
 - Maintenance of skin integrity (pressure injury prevention)
 - Strength, agility, mobility and cognition (fall prevention)
 - VTE prophylaxis (VTE prevention)
 - Extended vital signs monitoring and evaluation (rapid response teams)
 - Deconditining (atrophy and flexion contracture
- Patient and family education (initial, daily, transfer discharge)

- Substance administration: medications, blood products, fluids/electrolytes, TPN
- Respiratory support: oxygen administration, aerosolized bronchodilators, chest PT, incentive spirometry, ventilator management
- Physical/rehab support: physical, occupational, speech therapy
- Metabolic/nutritional support: glucose management, enteral/parenteral feeding
- Interventions: ET tube, IV, urinary catheter
- Maintenance and monitoring: IV, urinary catheter, chest tube, wound dressing
- Administrative ("hunting and gathering" [contact MD, lab, imaging, pharmacy] and charting/ documentation)
- Discharge process (agencies, meds, 20 equipment)

CHAPTER THREE INTERDISCIPLINARY ORGANIZATIONAL STRUCTURE

Aggregation of Clinical Work Processes into Clinical Programs/Clinical Service Lines

Once you have a working draft of what your clinical work processes are, your next step is to develop an organizational structure that brings together clinicians (e.g., physicians, nurses, therapists, technologists) who share one or more clinical work process. The sharing may occur as clinicians work together on a given clinical work process as, for example, when obstetricians and obstetrical nurses provide care to patients within the labor and delivery clinical work process. Sharing may also occur when the output of one set of clinicians becomes the input to another set. For example, the output of obstetrical specialists in the labor and delivery work process is the input to the clinical work processes of the neonatologists.

Once you identify the clinicians who share clinical work processes, the next step is to develop a draft schema which brings them together into a Clinical Program/Clinical Service Line (hereafter referred to generically as "Clinical Programs") organizational structure which can facilitate their efforts to generate and test improvement hypotheses.

Sample Outline of Clinical Programs Based on Clinical Work Processes

The following are sample Clinical Programs based on the process of aggregation of shared clinical work processes outlined above. Please understand that these configurations are for illustration, not to be taken as prescriptive. It is extremely important that the members of the Clinical Leadership Team (see below) have a major hand in and feel ownership of the definition of Clinical Programs and which specialties belong to which Clinical Program. Then as the Clinical Leadership Team sets priorities for organization of the first Clinical Program(s) the prospective physician and nurse-technologist leaders whom you intend to recruit, need to be allowed to provide endorsing and/or refining input to the definitions.

Clinical Program	Medical Specialties	Sample Clinical Work Processes		
Cardiovascular	Cardiologists, Cardiac surgeons Thoracic surgeons Vascular surgeons	ischemic, heart failure, electrophysiology, cardiac surgery, chest surgery, vascular surgery		
Women and Newborns	OB specialists (OB-Gyn, MFM, FP-OB, CNM) Newborn specialists (Neonatologists, Peds, FP- peds, NNP)	Pregnancy, labor and delivery, post-partum, benign gyn, normal newborn, abnormal newborn 3a (no 3b pediatric surgical subspecialty care)		

Intensive Medicine	Emergency medicine Critical care (including intensive neurologists) Hospitalists Transport specialists Traumatologists	Emergency care chief complaints (e.g., chest pain, abdominal pain, headache, et al) Critical care body system processes (e.g., respiratory support, infection management, hemodynamic support, nutritional support) Med-surg processes (e.g., pneumonia, stroke, respiratory failure, GI disease, non-pulmonary infections) Transport processes (e.g., dispatch, medical control, stabilization, transport) Trauma processes (e.g., musculoskeletal trauma, head injury)		
Neuromusculo- skeletal	Orthopedic surgeons Neurosurgeons Physiatrists Podiatrists	Joint replacement, spine, sports medicine (e.g., knee, shoulder), intracranial procedures, fractures		
Surgery	General surgeons Urologists Ophthalmologists Otolaryngologists Plastic surgeons	Cholecystectomy, appendectomy, bowel surg TURP Intraocular lens replacement Tubes and tymp, sinus procedures Skin grafting, cosmetic		
Pediatric Specialties	Peds intensivists Peds surgeons Peds neurosurgeons Peds cardiac surgeons	Peds critical care (see Intensive Medicine) Peds abdominal surgery Peds neurosurgery (congenital) Peds cardiac surgery (congenital)		
Primary Care (Community Medicine)	Pediatricians Med-peds specialists Family medicine Internal medicine Allergists Dermatologists Endocrinologists Amb Pulmonologists Amb Cardiology Medical Musculoskeletal Rheumatologists Gastroenterologists Neurologists	Well child, chronic peds (e.g., asthma) Well person, acute self-limited, chronic Well person, acute self-limited, chronic Well person, acute self-limited, chronic Allergic rhinitis, asthma Skin infections, benign neoplasms Diabetes, thyroid Asthma, COPD Heart failure, non-invasive testing Back pain, degenerative joint disease Arthritis GI inflammation Headache, seizures		
Behavioral	Intensive Ambulatory	Inpatient, residential, day treatment Depression, bipolar		

Oncology	Radiologists General surgeons Urologists Medical Oncologists Radiation Oncologists	Breast Cancer Prostate Cancer GI Cancer CNS Cancer
Radiology	Interventional Radiologists Diagnostic Radiologists	Biopsy, vascular interventions General imaging, MRI, US, CT, nuclear medicine, mammography
Pathology	Clinical Pathology Anatomic Pathology	Chemistry, hematology, microbiology, immunology, surgical pathology, gyn cytology
Anesthesiology	Anesthesiologists CRNAs Interventional physiatrists	Evaluation, induction, maintenance, Phase 1 recovery Acute and chronic pain management

Involvement of Key Stakeholders - Interdisciplinary Approach

It is important that you give early attention to clinical management structure in your quest to implement best practice. You will reap substantial dividends in outcomes if you involve key clinician and administrator stakeholders in decisions which pertain to their work. Involving key stakeholders in the journey allows them to get their fingerprints on the decisions.

As you design your organizational structure, you need to work from an interdisciplinary, shared leadership paradigm. Shared leadership means building around threesomes, including:

- <u>Physicians</u> who understand the scientific flow of best practice
- <u>Nurses, therapists and technologists</u> who have fundamental knowledge concerning the operations flow how to implement the scientific flow at the bedside or in the department
- <u>Administrators</u> who provide operations oversight and bring expertise in the management of capital and operating budgets, human resources and all the "hotel service" disciplines

If you fail to represent any of the three legs on this stool, you will either fail entirely or will fail to achieve all you could have achieved through involvement of all three dimensions of the management of clinical care.

Governance of Clinical Integration

Threesomes (physician, nurse or technologist and administrator) provide oversight and are accountable for governance at two levels in the organizational structure:

- Clinical Leadership Team ("CLT"): The Clinical Leadership Team acts as a "Board of Directors," which oversees all aspects of Clinical Integration, including, for example:
 - Prioritization of Clinical Programs organization. (It is not likely that you will want to or be able to organize all Clinical Programs at once which one(s) should be organized first?)
 - Prioritization of capital and operating budget funds to provide support to the Clinical Programs
 - Prioritization of resources to provide/enhance an electronic infrastructure to support the Clinical Programs (e.g., EMR, EDW)
 - Accountability for patient safety/patient injury prevention initiatives (i.e., the CLT serves as the "Guidance Team" for patient safety, since it spans multiple Clinical Programs)
 - Coordination and oversight of strategic sourcing/supply chain approaches and decisions which impact physicians and other clinicians
 - Approval of priorities and goals of individual Clinical Programs
 - Tracking of implementation and goal accomplishment
- Clinical Program Guidance Team ("GT"): The Guidance Team oversees all aspects of Clinical Integration within an individual Clinical Program, including, for example:
 - Prioritization of Development Team organization. (It is not likely that you will want to or be able to organize all Development Teams at once which one(s) should be organized first?)
 - Approval of Development Team clinical work process prioritization recommendations
 - Recruitment of key support staff dedicated to the Clinical Program (e.g., data manager, outcomes analyst, data architect)
 - Coordination with key support staff shared by the Clinical Program with other Clinical Programs (e.g., finance, IT liaison, clinical knowledge asset personnel)

- Guidance and approval of Clinical Program goals generated by Development Teams
- Oversight of recruitment of physician and clinical operations (e.g., nursing)
 clinical experts to provide clinical expertise to work groups and practice councils (see below)

Clinical Leadership Team

The organizational goal of the CLT is to identify and recruit a "threesome" (physician, nurse, administrator) to represent each major geographic cluster in the organization. For example, if your organization had four clusters which were geographically distinct areas and each of which included one or more major facility together with smaller facilities, you would want to include four threesomes in the CLT. If you try to represent every facility on the CLT, it will become an unwieldy body that will accomplish little.

It is important that you involve the right individuals the each of the cluster threesome roles. Here are some suggestions:

- Administrator: If your clusters are large enough that each facility has an administrator and there is another administrative person who is over all the other administrators (e.g., a region/cluster vice president), then the region or cluster vice president will probably be the logical choice. If there is no region/cluster vice president, the logical choice will likely be the administrator of the largest/hub facility in the cluster.
- **Physician:** If your cluster has a physician leader for the entire cluster (e.g., Chief Medical Officer or VP for medical affairs) that physician will probably be the logical choice. If no such position exists, the medical director of the largest/hub facility in the cluster may be the logical choice. Before jumping automatically to that conclusion, you will want to consider whether the medical director is more suited to quality improvement (strategic) activities or more included to quality control (tactical) activities (e.g., medical staff discipline, medical staff bylaws, credentialing details). The CLT physician role is strategic rather than tactical.
- **Nursing:** If your cluster has a nursing leader for the entire cluster (e.g., Chief Nursing Officer/CNO), that nurse will probably be the logical choice. If not such position exists, the nursing administrator of the largest/hub facility in the cluster may be the logical choice, but the same CAVEATs noted above under "physician" apply to nursing. Too much of a nursing operations focus may not serve you well.

The executive level of the CLT can be formed in either of the following ways or by using a combination of the two.

- **System wide executives model:** If you have in your system wide organizational structure physician, nursing and/or administrative leads (e.g., chief medical officer/VP for medical affairs, chief nursing officer/VP for nursing, chief administrative officer/VP for hospital operations) these individuals would be logical candidates to form the CLT executive team.
- "Chosen-from-among-the-number" executives model: One or more of the executive team can be chosen from one of the geographic clusters. The challenge with this approach is that the other cluster threesomes may feel that the cluster from which one of the executive team members is chosen is favored or has an advantage.

Any one of the executive team threesome can be the chair the CLT, with the other two members of the executive team threesome serving as vice-chairs. A good deal of time and effort will be required of whomever you select to be the chair if the CLT is to succeed in its role. You will also need to provide administrative assistant support for the chair and vice-chairs of the CLT.

The following organizational chart depicts a CLT with four geographic clusters:

Physician Chair Narse Adm instrate Vice-chair Vice-chair Geographic Cluster#1 Geographic Chrster #2 Geographic Cluster #8 Geographic Chaster #4 Mursing Physician Adm in ist rate Burne Thurs icion Ad m in istrate Hursing. Physician. Ad m in ist rate Nursing (eg. CHO) (eg, CAO) (eg. CA0) (eg. CHO) (eg, CM0) (eg, CA0) (eg, CMO) (eg, CAO) (eg. CMO)

CLINICAL LEADERSHIP TEAM

Once you organize the CLT, if it operates effectively, it will become a "lightning rod" for many issues. You will do well to restrict its standing members to the threesomes described above rather than expanding the membership to include all interested parties. Others can be involved by including their business as a standing agenda item or they can be included in the agenda on an *ad hoc* basis. This will keep the size of the team manageable.

You will probably find it useful to organize three councils or teams under the CLT:

- Chief administrative officer team
- Chief medical officer team
- Chief nursing officer team

These CLT Sub-teams can conserve the time of the CLT in order to ensure that the time of CLT members is put to its highest and best used. The sub-teams review detailed information pertaining to their area of expertise and develop recommendations for consideration, refinement and approval by the CLT. Sometimes two of the sub-teams will meet together (e.g., CMO and CNO sub-teams) in order to formulate a joint recommendation for the CLT.

You may want to convene the CLT on a monthly basis initially, but over time, an every-other-month meeting frequency should be adequate.

Clinical Program Guidance Team

The Clinical Program Guidance Team ("CPGT") is the next element of the organizational structure. Like the CLT it consists of threesomes from each geographic cluster. The members of the CLT from each cluster should play a primary role in identifying the CPGT members:

- Administrator: This member of the threesome should have administrative operations responsibility for the clinical services in the cluster which make up the Clinical Program. The nurse manager usually has a direct line reporting relationship to the administrator as does the physician, if he or she is employed. In the case of non-employed physician leaders, the administrator will often be responsible for management of the independent contractor relationship.
- **Physician:** This member of the threesome may be employed or may be an independent contractor. He or she is involved in the CPGT activities on a part-time basis (e.g., 1/4 to 1/2 time, depending on the size and maturity of the Clinical Program). Physician leaders lose credibility with their colleagues if they do not continue to practice in their specialty. Because CPGT activities place significant demands on their time, it is important that your organization provide compensation to them so that the "opportunity cost" does not work an undue hardship on them. Compensation philosophy is discussed in a later section in this chapter.
- **Nurse Manager:** This member of the threesome will usually be a full-time clinical manager. In the ideal the mangers of each of the departments which provide the services which make up the Clinical Program will have a direct-line reporting relationship to this nurse manager. Such an arrangement will facilitate changes which need to be made to processes within and across departments in order to improve clinical and financial outcomes. The bottom-line is that this nurse manager's portfolio should reflect the clinical work processes which make up the Clinical Program. For example, the CVCP nurse manager should be accountable for the EKG, echocardiography, nuclear, cath lab and EP services.

The executive level of the CPGT consists of a physician chair and a full-time nurse director. They are supported by a clinical-technical and technical staff.

- **Physician Chair:** The physician chair should be selected from among the cluster physician leaders. You may want to use a selection process something like the following. First develop a position description which outlines what you expect the physician chair to do and your best estimate of how much time will be required. Define how much you will pay and on what basis (e.g., per hour, monthly) A sample outline might include duties such as participation in the following:
 - Setting annual outcome and process goals (subject to approval of the CLT)
 - Working with Development Team leaders to set goals and priorities
 - Recommending infrastructure priorities for capital expenditures (e.g., facilities, equipment, IT infrastructure)
 - Monitoring progress in implementation and goal achievement
 - Chair the systemwide development team relevant to physician's specialty and provide overall guidance to their efforts to develop Care Process Models and their clinical knowledge assets
 - Coordination with managed care plans and hospitals in the management of medical expenses (e.g., managed care medical expense and cost per case)

You will next visit confidentially with each of the cluster physician leaders to ascertain which of them are interested in being considered. Any physician who belongs to one of the specialties you have included in the Clinical Program is a candidate. For example, the physician chair for the Women and Newborns Guidance Team could be a MFM, and OB-Gyn or a Neonatologist.

Next form an interview committee consisting of each cluster administrator and nurse manager plus any potential cluster physician leader not interested in being considered for the system wide physician leader position. Instruct the interview committee that they are to recommend to the CLT the two best qualified candidates. The CLT will make the final decision

• **Nurse Director:** The nurse director is the glue that holds the Clinical Program together. This is a full-time position for all of the large Clinical Programs. The nurse director manages all the day-to-day business of the Clinical Program. As soon as she/he is recruited, all the unsolved problems pertaining to the Clinical Program services will come out of the woodwork.

You will want a seasoned nurse with practice and management experience in one of the disciplines of the Clinical Program for this position (e.g., L&D or NICU nursing experience and nurse manager experience in one or both units for Women and

Newborns). If you have a system wide CNO position, the CP nurse directors should report to the CNO.

The nurse director works with the physician chairs to prepare the agendas and make arrangements with invited participants and staff for CP Guidance Team and Development Team meetings. She/he also participates with the physician lead in coordination efforts with managed care and hospital liaisons to develop strategies to manage managed care medical expense and hospital cost per case.

The data manager (see below) reports to the nurse director and offloads from her a significant amount of detail pertaining to the Clinical Program.

A sample position description for a **Nurse Director** is included in the Appendix.

• **Development Team Chairs:** In addition to the threesomes from the clusters and the full-time nurse director, the chairs of the Development Teams are also members of the Guidance Team. For example, if the Women and Newborns Guidance Team had OB-Gyn, Normal Newborn and Abnormal Newborn (NICU) Development Teams, the physician chairs of each of the three development teams would also attend the Guidance Team meetings.

If you decide to organize a Clinical Program, you should include in that decision an explicit commitment to provide the staff resources described below. Trying to take a "poor-boy" approach is extremely likely to be penny wise and pound foolish. Your will realize your worst nightmare if you engage physicians, nurse managers and administrators, have them generate exiting quality improvement hypotheses and fail to provide the staff to test and measure the hypotheses in a robust manner in order to hold their interest and capture their creative power. Physicians will stop attending the meetings and your attempts to "repent" will be met with cynicism. If you are "in for a dime," you must be "in for a dollar."

• **Data Manager:** The data manger is usually a nurse or technologist who has practice experience in one of the disciplines of the Clinical Program and also has training, experience and/or aptitude in data management and data quality assurance. For example a data manager may have worked in quality resources. The data manager is the boundary spanner between the clinical leaders of the Clinical Program and the rest of the data team. The data manager often assumes the role as "chair" of the data team.

The data manager takes the lead in designing data entry forms to capture the data elements required to generate reports, training front-line personnel in how to use the data entry forms and performing data quality assurance on the data captured to ensure that the data are timely, complete and accurate.

The data manager also leads the work groups (see below) in obtaining content expertise from physicians and bedside care clinical experts to develop strawperson work products

for review and refinement by Development Team members. She/he takes the lead in working with system wide clinical experts (see below) to develop Care Process Model flow charts as the beginning point for the data team to develop the measurement system.

A sample position description for a **Data Manager** is included in the Appendix.

• Outcomes Analyst: The outcomes analyst is a statistician, who usually does not have a clinical background. If you have someone with analytics experience to manage a mentor the outcomes analysts, bachelor-level preparation (e.g., BS in statistics) is usually adequate. He/she will usually report to whomever manages your analytics team (e.g., the manager of the EDW).

The outcomes analyst understands the various data systems, their strengths and limitations, and is the resourceful expert who develops the queries and manual extraction routines to produce reports from actual data, where the data are available or produce mock-ups of reports where the data are not available from an existing data source. He/she works with the data manager, the clinical experts and members of the relevant Development Team to iterate report format and content until it is useful for implementing best practice.

The outcomes analyst is a part of the analytics team responsible for mining the data in existing systems to discover relationships and build models (e.g., risk of morbidity and mortality) to assist clinicians in triaging patients to care management domains.

The outcomes analyst is also the key member of the data team who does drill down analyses to help clinicians understand and reduce assignable variation (i.e., quality waste).

A sample position description for an **Outcomes Analyst** is included in the Appendix.

• **Data Architect:** Once the extraction routines developed by the outcomes analyst are stable, the data architect designs data models, databases and data maps to automate the process of extracting, transforming and loading the data into data marts based on clinical work processes and their key indicators. He/she will usually report to whomever manages your analytics team (e.g., the manager of the EDW).

The data architect works with the data manager, outcomes analyst and clinical experts to define criteria for inclusion in a patient registry (e.g., criteria for including patients in a registry of diabetics).

The data architect also works with the data manager and outcomes analyst to design reports, processes and systems to report to external entities (e.g., CMS, JCAHO, national specialty societies) and to design custom reports to generate reports and prepare them for distribution (e.g., as hard copy, on the web). He/she also designs use monitoring routines to monitor utilization of reports and data sets (e.g., web hits, data set queries).

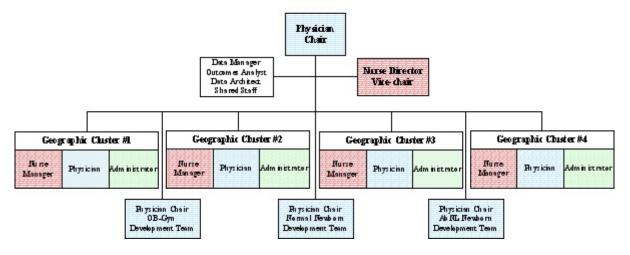
A sample position description for a **Data Architect** is included in the Appendix.

In addition to these "dedicated" resources assigned essentially full-time to an individual Clinical Program, there are shared resources which belong to non-clinical departments or who are shared across multiple or all Clinical Programs. These shared resources include:

- **Finance Liaison:** If you invest early in a partnership with your finance department, you will probably enjoy a substantial return. Most finance people are bright analysts who can help you see relationships and provide helpful suggestions on how to link changes in clinical processes to their impact on cost.
- IT Liaison: You will do well to establish a structured liaison with your IT department as well. You will need a link to your clinical information systems (e.g., EMR, departmental systems) so that improvements developed and tested by a Clinical Program can drive changes in configuration of software and/or enhancements.
- **EDW Personnel:** In addition to the dedicated data architect, you will need to provide shared EDW operations personnel(e.g., database administrators, ETL developers, report analysts/developers)
- Clinical Knowledge Asset Developers: You will need to decide whether you license clinical knowledge assets (e.g., provider and patient education materials, nursing guidelines) or whether you develop them internally. If you pursue the latter course you will need to provide a team to develop the knowledge assets (e.g., medical writers, graphics artists) and to make them electronically accessible (e.g., knowledge engineers)

The following organizational chart depicts a W&N Guidance Team with four geographic clusters:

WOMEN AND NEWBORNS CLINICAL PROGRAM GUIDANCE TEAM



Clinical Program Development Teams

In contrast to the Guidance Team which oversees both the clinical and business aspects of the Clinical Program, the primary focus of Development Teams is clinical, so while administrators are welcome to attend, it is not usually the highest and best use of their time.

Development Teams also differ from Guidance Teams in that they consist of physician specialist and nurse manager members from each facility or ambulatory geographic subdivision where the clinical work processes which belong to the Development Team are provided. For example you had in your system four geographic clusters with ten moderate to large facilities in your system which provide labor and delivery services there would be ten OB-Gyn physician specialist members of the OB-Gyn Development Team. Continuing the same example, if one nurse manager oversaw the L&D units in all facilities within each of the four clusters, there would be four nurse manager members of the Development Team.

By way of contrast, if in those same four clusters, there were only one facility in each cluster that provided NICU services, there would be only four neonatologist members of the AbNL Newborn or NICU Development Team.

Development Teams may also include additional members who represent other specialties on an at-large or geographic cluster basis. For example, an OB-Gyn development team might include one or more certified nurse midwife or family practice OB provider. The Development Team should also include the chair of each nursing, therapist or technologist practice council organized under the Development Team (e.g., chair of L&D practice council).

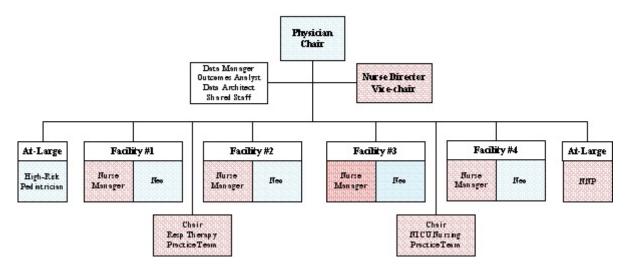
A Development Team member's responsibilities include:

- Acting as an assigned reviewer to evaluate and provide input in an iterative manner to the work group physician expert and work group staff concerning the draft work products they produced
- Solicit input from physician specialists and bedside care clinicians located at the facility and/or clinic(s) which the Development Team member represents regarding draft work group products
- Lead implementation of the clinical knowledge assets which are produced by the Development Team as a result of iterative refinement as outlined above, including providing feedback to facility and clinic physicians regarding their aggregate and individual performance

Development Teams are supported by the dedicated Clinical Program staff resource personnel (e.g., data manager, outcomes analyst and data architect) as well as the shared resource personnel outlined above in the Clinical Program Guidance Team Section.

The following organizational chart depicts a NICU (AbNL Newborn) Development Team with four geographic clusters:

ABNORMAL NEWBORN (NICU) CLINICAL PROGRAM DEVELOPMENT TEAM



Clinical Program Work Group

The Clinical Program Work Group is the fundamental unit of the clinical organizational structure. Its purpose is to conserve the time of Development Team members by researching and preparing draft work products to which Development Team members can react and critique. A work group consists of:

- Data Manager
- Clinical Experts (physician and front-line clinician)
- Outcomes Analyst
- Data Architect
- Education Expert (shared resource)
- Knowledge Engineer (shared resource)

The data manager acts a chair.

The physician clinical expert provides fundamental knowledge regarding the scientific aspect of the clinical work process.

The beside care clinical expert (who will usually be the chair of the nurse practice council which pertains to the clinical work process) provides fundamental knowledge regarding the operations aspect of the clinical work process.

The outcomes analyst and data architect provide expertise in producing sample reports.

The education expert provides expertise in developing provider and patient educational materials pertinent to the clinical work process.

The knowledge engineer assists the team in using knowledge authoring and review tools which facilitate production of clinical knowledge assets that are usable by the electronic infrastructure.

The charge of the Work Group is to produce and then update periodically a Care Process Model ("CPM") for the clinical work process, including the clinical knowledge asset elements which make up the CPM.

The initial Work Group activity is to develop a summary of available scientific knowledge concerning the clinical work process. This knowledge summary consists of:

- Regular review of the literature
- Clinical networking (identifying and consulting national experts)
- Presentations made a scientific society meetings
- Measures developed by regulatory and accreditation bodies (e.g., CMS, JCAHO, HEDIS)

The Work Group uses the knowledge summary to generate clinical knowledge asset work products such as the following:

- High-level conceptual flow diagram for the clinical work process (e.g., 4-5 PowerPoint slides which summarizes diagnosis and management of the condition)
- Key indicators and reports
- Diagnostic work-up and triage algorithm
- Treatment cascade, including indications for referral
- Indications for intervention
- Order sets and other protocols
- Guidelines, protocols and standards for bedside care

The draft work products of the Work Group are presented to Development Team members (assigned reviewers) for their review and critique. Development Team members also make work products available to other interested clinicians (volunteer reviewers) at the facility or clinic(s) they represent and actively solicit their input and critique. You can also develop other vehicles such as an on-line knowledge repository or listserve to facilitate access to and input from a broad base of clinicians.

Based on input from assigned and volunteer reviewers, the Work Group revises and refines the clinical knowledge asset work products and prepares them for implementation in alpha, beta and full production modes. The decision as to when clinical knowledge assets are ready for each phase of implementation rests with the Development Team. The Work Group provides clinical and technical support for implementation. The Work Group also is responsible to share new scientific findings and changes with clinical leaders and front-line colleagues (e.g., through CME sessions, learning days, academic detailing).

The typical profile of a physician clinical expert includes:

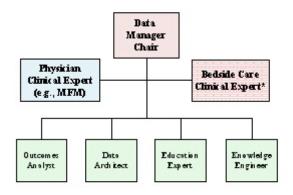
- **Active in providing clinical care** within the clinical work process domain ("hands-on" expertise)
- **Board certified** in the relevant specialty or subspecialty (with rare exception)
- **Recognized by peers** as an expert in the domain
- Formally trained in **clinical quality improvement**(ATP/mini-ATP grad)
- **Active participant** in one or more of the following:
 - Clinical research and publication in peer-reviewed journals
 - Authoring of scientific society bulletins, chapter(s) in textbook(s)
 - Graduate medical education

The typical profile of a bedside care clinical expert includes:

- Active in **providing clinical care** within the clinical work process domain (e.g., L&D) or having expertise in a generic domain (e.g., skin integrity/pressure injury)
- Masters prepared or technologist equivalent (rare exception)
- **Recognized by peers** as an expert in the domain
- Chair of the nurse, therapist or technologist practice team
- **Protected time** to perform knowledge expert duties and bedside care clinical research, as applicable

The following organizational diagram depicts a Labor and Delivery Work Group organized under the OB-Gyn Development Team:

LABOR AND DELIVERY WORK GROUP OB-GYN DEVELOPMENT TEAM



*Chair of L&D nurse practice council

Front-Line Care Teams

You will need to organize two additional teams which pertain to delivery of care at the front-line:

- Front-line practice teams, which are system wide teams consisting of clinicians (or technologists) representing each facility which provides services pertaining to the clinical work process. Front-line practice teams are organized to develop:
 - Interdisciplinary standards of clinical care
 - EMR formats
 - Protocols
 - Methods for implementing protocols and standing orders
- Standards/education teams, which are system wide teams consisting of nurse (or technologist) managers and clinical specialists/clinical educators representing each facility which provides services pertaining to the clinical work process. Standards/education teams are organized to standardize such things as:
 - Nursing unit structure
 - Staffing
 - Initial orientation
 - Evaluation of continuing competency
 - Equipment and supplies

The following table depicts a representative sample of front-line practice team and standards/education team representation for a Women and Newborns Clinical Program:

W&N Nursing Teams

77	W&N Nursing Practice Councils			W&N Nursing Standards/Education Teams					
Facility	L&D	Mom/Baby	NICU	Lactation	L&D	Mon/Baby	NICU	MFM/CNM	Nurse Adm
A	x				x	x		7	4
В	x	x	x	x	x	x	x	100	x
С	x	x	x	x	x	x	x	x	x
D	x	x	x	x	x	x	x	x	x
E	x	x	x	x	x	x	x	x	x
F	x	x	x	x	x	x	x		x
G	x	x	x	x	x	x	x	x	x
Н	x	x	x	x	x	x	x	x	x
I	x	x	x	x	x	x	x	x	x
J	x	x			x	x		-	
K	x	x	x		x	x	x		x
L (peds)							x		

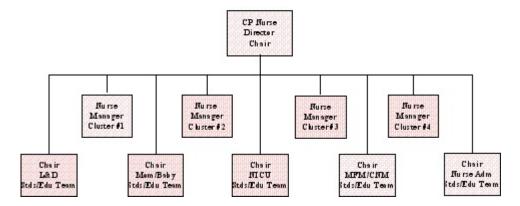
Note: Some cells in the table are blank, representing the reality that smaller facilities may not be able to provide a representative to every team, in which case they simply implement the work products developed by the members of that team.

The chair of each front-line practice team presents the work products of the front-line team to the applicable Development Team for review, critique, refinement and approval.

The work products of the standards/education teams are presented to the Nursing Operations Sub-team of the Clinical Program, which consists of the cluster nurse managers who are members of the Clinical Program Guidance Team.

The following organizational diagram depicts a Nursing Operations Sub-Team organized under the Women and Newborns Clinical Program:

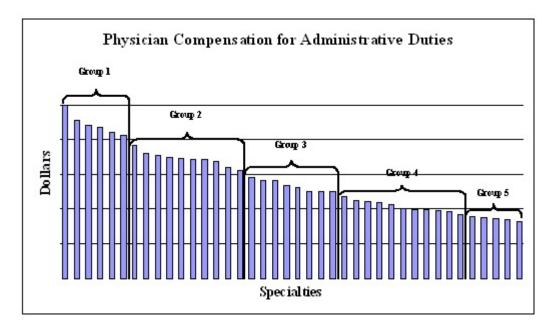
NURSING OPERATIONS SUB-TEAM W&N CLINICAL PROGRAM



Physician Compensation

You will do well to come to grips with the issue of physician compensation sooner rather than later. In doing so, you will need to develop answers to questions like the following:

- Compensate or Not? The first branch in this algorithm is whether to ask physicians who participate in leadership or clinical expert capacities should be expected to contribute their time or whether they should be compensated for it.
 - It is recommended that you compensate physicians because the amount of time you will need from them in order to be successful will be substantial enough that if you do not compensate them, you will create an opportunity cost that will work a hardship on them which can cause resentment and/or sporadic attendance.
- At What Rate? If you decided to compensation them for their time, the next question is, "At what compensation rate"? Getting to an answer to this question raises many philosophic and practical questions. Here are some things to consider.
 - You want to recruit physicians who are respected by their peers. Those physicians are usually busy and successful. It is very difficult for them or you to know how much they make per hour because they usually do not have a very precise idea of how many hours per week or per year they work. Physicians tend to estimate how many hours they work and understate how much money they make.
 - You do not want to create an incentive for physicians to perform administrative duties in preference to clinical practice, so paying them slightly lower than what they would make if they "did the case" instead of attending the meeting is probably the right direction in which to err
 - You will do well to find an objective basis and a consistent methodology for determining what you will pay. This usually means getting information from a reliable survey of physician compensation (e.g., RSM McGladrey Large Clinic Physician Compensation Survey, or Medical Group Management Association Physician Compensation and Production Survey).
 - You probably do not need a different hourly compensation rate for every specialty. If you decide to purchase or subscribe to a physician compensation survey, you will notice if you graph the data that there are clusters of specialties for which the annual compensation is relatively similar. The following graph illustrates this principle. You will note from the graph that between these groupings of specialties there are more substantial "step functions" than there are within the groupings. This example suggests that five administrative rates would probably suffice.



- **How Much Time?** The next logical question is how much time will you need? One good way to approach this is to make your time estimates an explicit part of the contract you negotiate with each physician. Go through the discipline of writing down in the contract what you want the physician to do and an estimate of how much time you estimate it will take, including, for example:
 - System wide meetings (e.g., Clinical Program Guidance Team, Development Team or Work Group)
 - Geographic cluster meetings (e.g., for implementation planning, medical staff department and division/section presentations)
 - One-on-one mentoring and providing feedback to physicians
 - Administrative processing (E-mails, telephone calls)
- What About Travel Time? The combination of a two-hour meeting and one hour of travel each way can consume half of a physician's day. You should seriously consider paying for travel time, especially if it is an hour or more one way
- **Retainer or Time Sheet?** The most accurate way to account for time is a time sheet. The problem with time sheets is that physicians (and just about everyone else) hates to be burdened with keeping track. You will find that some physicians have such an aversion to keeping a time sheet that it will cause them to reject participation.

The other alternative is to establish a retainer based on a sufficient level of detail to provide adequate documentation of the exchange of value. You will need to check with your legal counsel to see whether a simple format like the following is acceptable:

"The following represent initial estimates of the time required of Physician to meet his/ her responsibilities under this Attachment, including meeting attendance, preparation, presentations, providing feedback to colleagues and training activities, as applicable. These time estimates will be reviewed annually and adjusted as necessary. Physician shall notify _____ [name of organization] if actual time expended is substantially greater or less than estimated as follows:

A. Clinical Program Guidance Council

- A. Frequency = monthly
- B. Duration = 2 hours
- C. Preparation = 2 hours
- D. Travel = 2 hours

Total = 6 hours/month

B. Clinical Program Development Team

- A. Frequency = monthly
- B. Duration = 2 hours
- C. Preparation = 1 hour
- D. Travel = 0 (included in Guidance Council)

Total = 3 hours/month

C. Coordination with Managed Care Plans

- A. Frequency = every other month
- B. Duration = 1 hour
- C. Preparation = 1 hour

Total = 1 hour/month

D. <u>Administrative Processing</u> (E-mails, phone calls, meetings with Nurse Director)

- A. Frequency = weekly
- B. Duration = 2 hours

Total = 8.6 hours/month

E. ...

How Much Should We Bite Off?

While you are in the formative stages of implementing Clinical Programs, your senior leaders will need to spend a good deal of personal time mentoring new leaders and staff and keeping the initiative on track. For this reason, you will do well to limit your appetite initially to starting up two or possibly three Clinical Programs.

Which ones to start will be informed by the key clinical work process analysis outlined in Chapter Two, but in choosing among the several large possibilities (e.g., CV, Women and Newborns, Intensive Medicine, Surgery, Neuromusculoskeletal, Primary Care), perhaps the most important thing you will consider is clinical leadership. In which of these potential Clinical Programs you could organize do you have the strongest potential physician and nursing leaders.

In addition to readiness of clinical leaders, you will need to evaluate what data you have available in our current data systems. Generally, you will have enough data in your case mix system to start up one or more of the campus-based Clinical Programs (CV, Women and Newborns, Intensive Medicine, Surgery, Neuromusculoskeletal).

You will, however, probably find it difficult to start up a Primary Care Clinical Program, if you do not have: 1) your own managed care plan; 2) a strong partnership with one or more large third-party payer; and/or 3) a highly aligned, numerically substantial clinical network.

Within the two or three Clinical Programs you decide to start up, you should limit your appetite to one or two Development Teams (e.g., if you were start a Women and Newborns Clinical Program, you will probably want to start up an OB-Gyn Development Team and possibly either a Normal or an Abnormal (NICU) Development Team. Then limit yourself to one relatively straightforward Clinical Work Process within each Development Team (e.g., Labor and Delivery Clinical Work Process for the OB-Gyn Development Team; Discharge Clinical Work Process for the NICU Development Team).

How Long Will It Take?

You need to have realistic expectations as you embark on implementing a clinical management structure. It will take two to three years not two to three months to build the relationships of trust and undo the misunderstandings that have developed over the years between physicians and administration, nursing and administration and nursing and physicians. It will take time for administrators to convince clinicians that they are really interested in clinical outcomes, not just financial outcomes and to cultivate a learning environment based on the principles of quality improvement. As you begin, you will do well to think in terms of a roughly three year cycle, as follows:

• Year 1: You will spend the first year communicating the vision, recruiting and orienting key physician, nursing and administrative leaders, together with the support staff you will need to get engagement (e.g., data manager, outcomes analyst, data architect).

You will want to facilitate quality improvement training for these key leaders either through an external program or an internal one. As a general rule of thumb, you need to plan on about six to nine months, even with consultative expertise to establish and enroll your first set of leaders in an internal program you start up from scratch. You will also be engaged during the first year in deciding which Clinical Programs and which clinical work processes within those Clinical Programs you should pursue. Once those decisions are made it will take most of the rest of the first year to build a measurement system and establish a baseline from which goals can be set for the second year.

So, during your first year most or all of your goals will be process goals (e.g., select Clinical Programs, recruit and orient leaders, select a Clinical Work Process, develop flow charts, identify key indicators, build a measurement system, collect data, establish a baseline)

- Year 2: If all goes well, sometime in the second year you should be ready to set a clinical outcome goal pertaining to the Clinical Work Process(es) you and your clinicians have selected. Your physician and nursing colleagues will engage much more readily around clinical (quality) goals than they will around cost goals. You should build your data systems so that you can capture the data you will need to measure cost outcomes, but let improvements in cost come as a by-product of doing the right thing for patients and doing it right the first time, thus reducing waste and variation in clinical processes.
- Year 3: Sometime in the third year, if all has gone well you should have built enough trust and should have established firmly enough that your objective in investing in measurement systems is aimed at creating an environment of learning and improvement, not to punish those who are outliers that you can set a cost outcome goal to go with your clinical outcome goal. In the ideal, you work with your clinicians on your clinical outcome goal, they will begin to identify variation as wasteful and will be ready to talk about the denominator of the value equation (value = quality/cost). Now you should be ready to discuss a balance between goals that aim to improve clinical outcomes (including patient safety) and those that aim to improve cost outcomes.

As you pursue this journey you need to be aware that some of your data for measuring clinical outcomes will be extracted from systems which were designed primarily to produce a bill or measure financial outcomes. You need to acknowledge to your clinician partners from the outset and all along the way that some of the variation you identify using these financially oriented systems will be due to differences in data systems and/or how the data systems are used. For example, it is often the case that a nursing unit at one facility will allocate fixed and variable and direct and indirect costs differently. If you approach this matter openly, your clinicians will not only help you identify variation that is truly assignable to differences in clinical practice, but they will also help you standardize the financial aspects of your data systems, which will reduce the noise in the measurement of these processes (e.g., standardization of the chargemaster from facility to facility).

How Much Will It Cost?

Assuming that you have four geographic clusters and 10-15 facilities, you will need to budget \$500,000-750,000 per year per Clinical Program to cover the expenses of the following key personnel:

• **Physician Leaders:** Part-time compensation for Guidance Team chair, Guidance Team physician members from each cluster, Development Team chairs, Development Team

- physician members from each facility which provides Clinical Work Process Services and Work Group physician Clinical Experts for each Clinical Work Process undertaken.
- **Nurse or Technologist Director:** Full-time salary and benefits for a masters-prepared RN with management experience.
- **Full-Time Technical Support Staff:** Data manager, outcomes analyst (statistician) and data architect, dedicated to one specific Clinical Program.
- Shared Technical Support Staff: Education and knowledge engineering support staff (or license fees if suitable commercially available materials can be found) and shared EDW operations staff.

The \$500,000-750,000 figure **does not** include:

- Clinical Leadership Team Members: Administrators, physician or nurse leaders who participate in the Clinical Leadership Team
- Administrators: Administrators (operations officers) who participate in Guidance Teams
- Clinical Managers: Geographic cluster or facility nurse or technologist managers who participate in the Guidance Team or Development Teams or nurse or technologist Clinical Experts who participate in Work Groups
- **Capital Expense:** For hardware or software license fees or development costs for EMR or EDW

What About Return on Investment?

You should realize tangible (dollar) returns as well as important intangible (non-dollar) returns on your investment in quality improvement. Here are some suggestions to help you manage your expectations:

- Hard-dollar, cost-per-unit savings: The earliest, most definable, hard-dollar savings will come through more effective contracting/purchasing contracts. These savings will come in the form of reduced cost per unit. System wide clinical organization can greatly facilitate discussions of standardization and the resulting volume-based purchasing leverage. It is important to foster a partnership between the supply chain managers in your organization and your Clinical Program leaders
- Campus-based Clinical Program cost structure improvement: As your Clinical Programs reduce variation and quality waste, you should be able to demonstrate improvements in cost in the form of reduced length of stay and reduced ancillaries.

To the extent that you are paid based on a fixed price (e.g., DRGs), these savings will inure to your benefit; however, for whatever residual fee-for-service business you have, these improvements will reduce your revenue stream.

Because the systems which demonstrate the improvement in clinical outcomes and the systems which track the financial implications are based on different units of measure, it is often difficult to demonstrate the cause-and-effect link robustly enough to inspire the necessary confidence to include the reductions in the budget and manage out the costs.

There is also a cost-avoidance benefit in connection with the CMS "Present on Admission" or "POA" program. Complications are a form of quality waste which Clinical Program initiatives can reduce. If third-party payers reimburse only for problems documented as present on admission and not for complications which occur during the hospitalization, there should be a cost-avoidance benefit to higher quality, error-free care.

• Community-based Clinical Programs: As your Primary Care Clinical Program succeeds in managing patients with chronic diseases more effectively, in the near term costs to managed care plans are likely to increase. This will almost certainly be true if the management of patients with chronic diseases has been reactionary in the past (primary care physicians responding mostly to acute exacerbations of the disease). Best practice management of chronic diseases usually increases the frequency of office visits and of diagnostic testing (e.g., HbA1c and LDL for diabetics). This will result in increased cost per diabetic member from the managed care plan perspective.

Unless a managed care plan has a very stable population over time (very low voluntary disenrollment rate) it may be difficult to replicate the long-term benefits of reduced complications of the disease (e.g., complications of diabetes such as end-stage renal disease, retinopathy, amputations, macrovascular events as demonstrated in the DCCT and UK studies). The benefits may also be so far out in time (e.g., treatment of hypertension and stroke prevention), that Medicare is the likely financial beneficiary.

These considerations should not dissuade you from initiating chronic disease management programs, but they should help you avoid the trap of overselling the financial returns.

• Intangible Benefits: There are many intangible benefits which are more difficult to tie to budgets and bottom-line. They include public relations, demonstration of "gift to the community" in support of not-for-profit status, improved physician relations as a result of demonstrated commitment to quality, and improved nursing relations as a result of involving them in an important way in the strategic direction of the organization.

Tracking costs and continual vigilance to link clinical, patient safety and cost outcomes to each other should be a goal of your measurement and system design efforts.

CHAPTER FOUR MEASUREMENT SYSTEM

Why Develop a Measurement System

When performance is measured, performance improves. You can accelerate the rate of improvement if performance is measured and reported. A measurement system is a learning tool, which can be used to provide feedback to Clinical Program participants. Good data and information engage participants.

Overview of Measurement System Development Process

The Work Group and the Development Team are the keys to the process of developing a measurement system. The Work Group goes through the following steps for each Clinical Work Process in preparation for presentation to the members of the Development Team:

- Create a **high level flow chart** which describes at a summary level (e.g., 4-5 PowerPoint slides) the scientific flow of the Clinical Work Process ("Care Process Model").
- Use the Care Process Model to identify key indicators. Key indicators are clinical
 findings and results of diagnostic tests which are critical to the management of the
 Clinical Work Process.
- Generate **sample reports** for each key indicator (from real data where available or as mock-ups if data are not available)
- Test the sample/mock-up reports with clinical leaders (and others) and with end users
- Generate a list of **data elements** required to produce the reports
- Identify the **source of data elements** which are present in existing data sources
- Identify **data elements** that will **require new acquisition** (i.e., are not present in existing data sources)
- **Negotiate** "the reports we need to manage the care" versus the "reports we can generate," and drop reports we cannot generate or build an interim plan for new data acquisition

The following sections illustrate the steps in this process.

High Level Flow Chart - Diabetes Care Process Model

The following high level flow chart describes at a summary level the Care Process Model for the diagnosis and management of diabetes:

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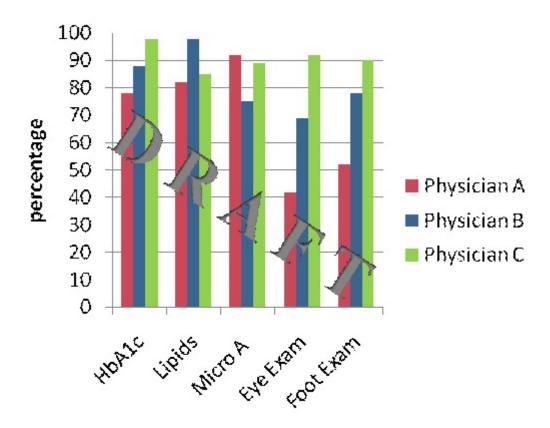
Key Indicators - Diabetes

The following key indicators and goals were identified from the information generated by the Work Group in order to produce the Diabetes Care Process Model:

Measure	Goal
HbA1c (test at least 2 times a year)	<7.0%
Blood Pressure (check at each office visit)	<130/80 mm Hg
LDL Cholesterol (test at least every 2 years)	<100 mg/dL
Triglycerides (test at least every 2 years)	<150 mg/dL
Foot Exam (perform at least annually)	norm al
Urine Microalbumin/Creatinine Ratio (test at least annually)	<30
Dilated Eye Exam (check annually, or every 2 years if well controlled)	norm al

Sample Reports

The following sample reports (e.g., HbA1c, lipids, urinary microalbumin, eye exam) and mockups (e.g., foot exam) were generated for review with the Development Team:



Data Elements, Availability and Sources

The following table shows the key indicator data elements, their availability and the source from which the data which are available would be extracted:

Measure	Goal	Availability
HbA1c (test at least 2 times a year)	<7.0%	Sunquest
Blood Pressure	<130,80 mm Hg	New
LDL Cholesterol	<100 mg/dL	Sunquest
Trigl yoerides	<150 mg/dL	Sunquest
Foot Exam (perform at least)	nomal	New
Urine Microalbumin/Creatinine Ratio	<30	Sunquest
Dilated Eye Exam	nomal	Claims, HELP2

As can be seen from the graphic, blood pressure and foot exam require new data acquisition, i.e., are not available in current data systems. Each of these data elements would require manual chart abstraction or data entry in the clinicians office.

Negotiation

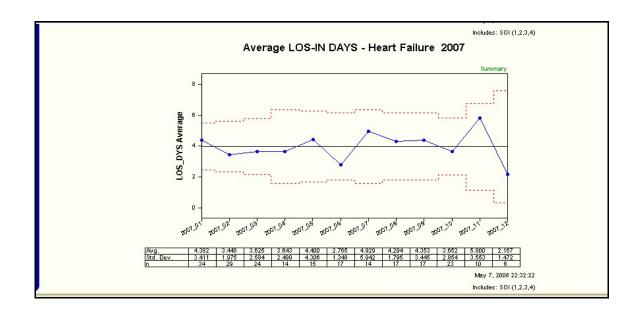
The final step in this development process is to negotiate "the reports we need to manage the care" versus the "reports we can generate," and drop reports we cannot generate or build an interim plan for new data acquisition. This discussion takes place in the Development Team.

Sample Report Formats

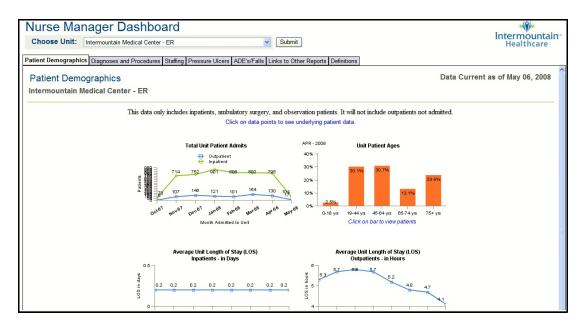
The goal of every report should be to convert data into information that his usable by the user of the report. There are many different report formats, each of which has specific applications. The following examples illustrate some important report formats:

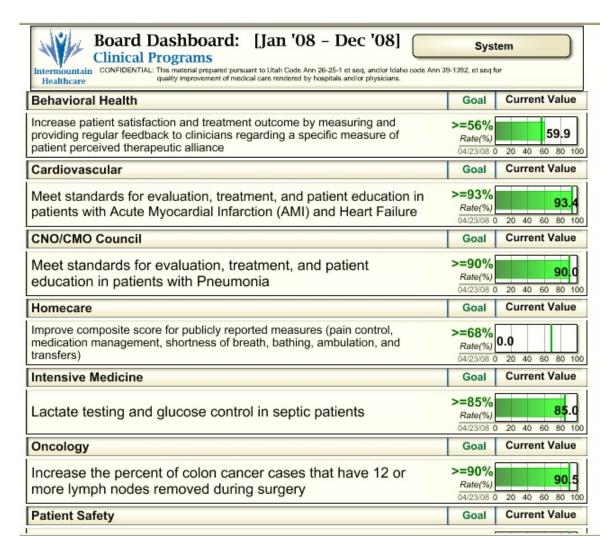
statistical Process Control Charts (SPC charts or "Run" Charts): SPC or run charts are used to show statistically significant trends over time. SPC charts help you determine whether a process is in a state of statistical control, i.e., whether the measurement you make lies within statistically defined control limits. The patterns an SPC chart reveals help you take the right actions to bring or keep the process in control and to avoid "tampering" with the process by reacting to random variation "noise," by helping you determine whether a point or series of points reflect statistically significant (assignable) variation or whether the point lies within the range or corridor of random variation for the process you are measuring. SPC charts can also help you evaluate a series of points to determine whether the process is trending in a statistically significant direction (either favorable or unfavorable). In the following SPC charts, the control limits, which show statistical significance, are represented by shading in the first example and by the dotted red lines in the second one:





• **Dashboards and Scorecards:** Dashboards and scorecards are other effective report formats. Dashboards provide a real-time or near real-time view of a given process or metric. Scorecards provide a cumulative view of data (e.g., year-to-date performance). These tools are useful at a nursing unit or departmental level as well as at the highest levels of the organization (e.g., Governing Board). Here are two such examples:





Measurement System Implementation Process

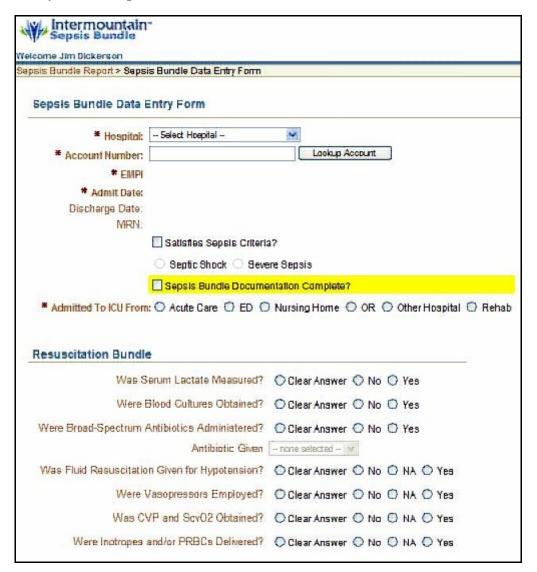
The analtyics team (outcomes analyst/EDW team) go through the following steps in order to implement the measurement system, produce reports and monitor their use by clinicians and others:

- Lay out the internal structure of the data mart
- Identify the major databases that will supply the data elements
- Program the extraction queries and the pre-processing required to transform the data elements into the format needed by the data mart
- Program the data flows (e.g., timing and sequencing) to load/update the data in the EDW data marts

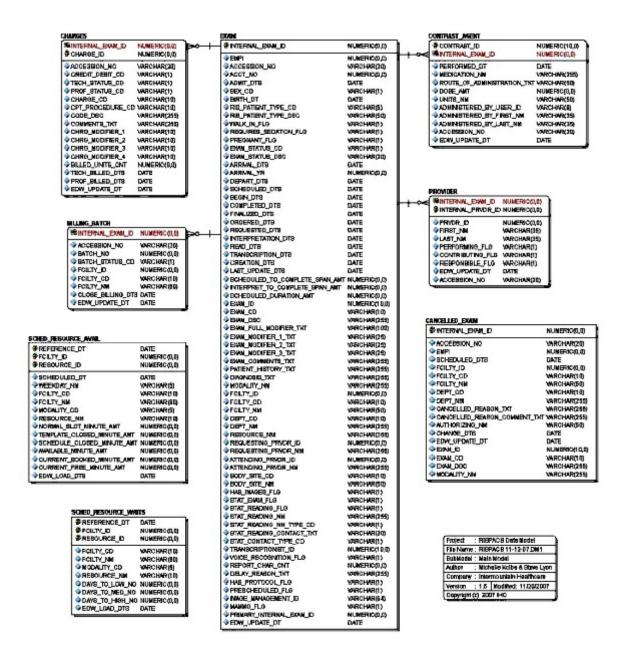
- Write the queries and statistical routines to convert the data in the data mart into final reports
- Execute the routine to extract, transform, load, quality assure, query, analyze the data and produce repots
- Implement monitoring of utilization (e.g., hits) for each knowledge asset (e.g., order set, report, protocol)

The following graphics illustrate some of the steps in the process of implementing the measurement system from data collection through report production and monitoring:

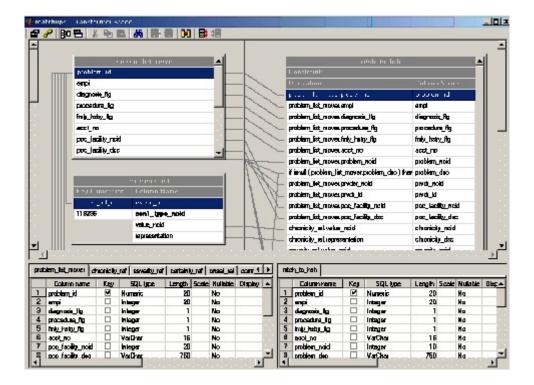
Data Entry Form - Sepsis Bundle



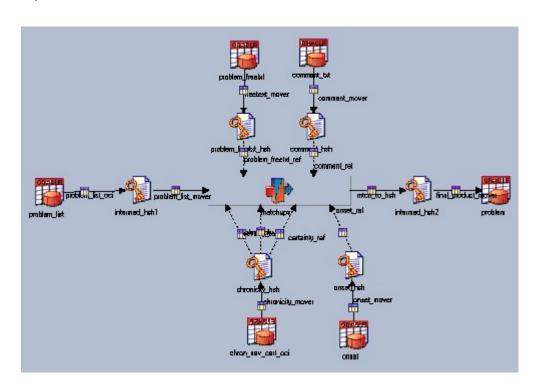
Data Model



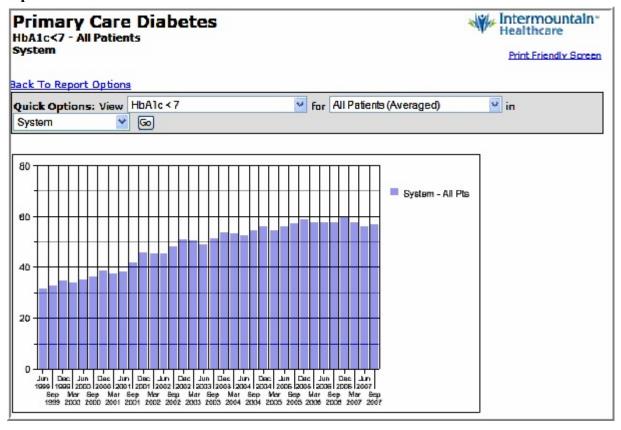
Data Map

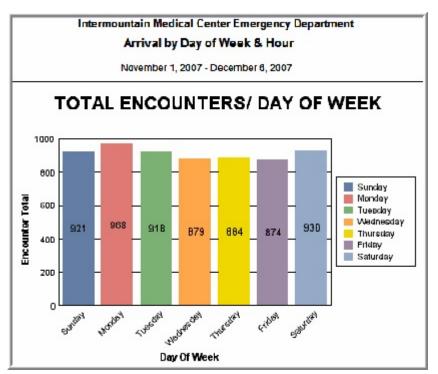


Extract, Transform and Load Routine

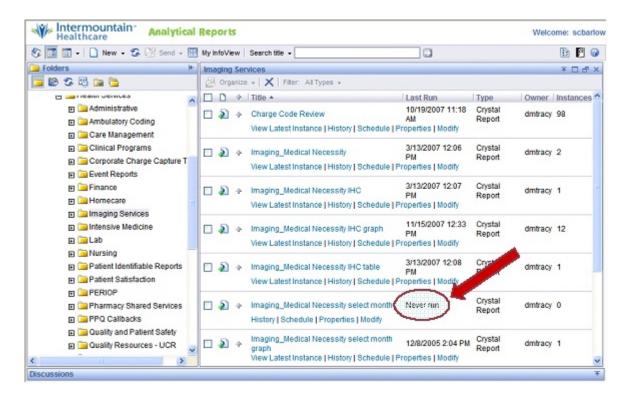


Reports





Use Monitoring



Registries

Another important concept in measurement system development and implementation is that of a registry. Registries are particularly important in providing optimal care to patients in the chronic recurrent sub-domain of the ambulatory management domain. Patients with chronic illness require ongoing, proactive care to monitor progression of the disease, track compliance with and results of the treatment cascade, and to detect the occurrence of treatable complications.

A computerized disease registry of chronically patients which combines office visit or other encounter information with laboratory and pharmacy data can be very helpful in providing clinicians with information to manage their patients more effectively (e.g., as action list of all diabetic patients in the practice of a general internist with HBA1c values greater than 9.0%).

In order to create a registry, criteria must be developed to identify patients who belong in the registry. In some cases standard criteria such as those published by HEDIS can be used. In other cases, you may want to make modifications to tailor such criteria to your specific circumstances.

CHAPTER FIVE IMPLEMENTATION

Types of Implementation Tools

The development of Care Process Models for each of the key Clinical Work Processes may seem to you to be a daunting task. It is, in reality, easier than implementing best practice. In order to be successful, you will need to develop implementation tools.

Each section of Chapter One included a sample Clinical Knowledge Asset (e.g., diagnostic algorithm). Clinical Knowledge Assets are one form of implementation tool. There are three broad categories of implementation tools, including:

- Data acquisition tools
- Knowledge management tools
- Analytic tools, including the EDW

Current Data Systems

Most data systems in use in healthcare today have some fundamental weaknesses which you will find frustrating as you seek to measure outcomes. These systems collect some data at the point of care, but most of the systems rely heavily on retrospective chart audits. After the chart is sent from the floor to the record room, "armies" of abstractors working in a parallel redundant fashion pore over the chart to try to intuit what was going on at the bedside when the care actually took place. The major categories of these "armies" include:

- HIS coding specialists who belong to hospital information management departments and who are responsible for converting the information in the record of each patient (physician observations, prescription history, diagnoses, procedures performed, disease tracking) into ICD-9-CM diagnosis and procedure codes, which are then fed into a DRG-grouper to ensure appropriate DRG assignment and to optimize reimbursement. Coders are also responsible for assigning CPT-4 procedure and ASC assignment codes.
- **Quality assurance personnel** who belong to hospital quality resource departments who abstract the same patient record, but whose purpose is to identify and extract measures which pertain to quality assurance or quality improvement projects.
- **Utilization management personnel** who may be hospital employees or managed care personnel who use the same patient record to try to determine whether the process of patient care complies with certain utilization management criteria established by managed care companies (e.g., length of stay, authorization or certification indications).

• **Compliance personnel** who belong to burgeoning hospital compliance departments who abstract the same patient record looking for documentation of compliance with regulatory and/or accreditation requirements (e.g., HIPAA, CMS, JCAHO)

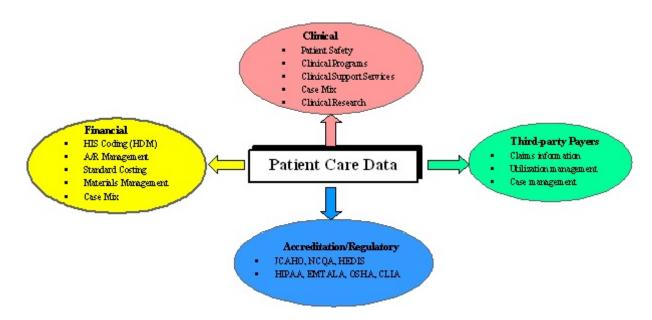
This system of chart abstraction is inaccurate and wasteful (because of its redundancy). As the acuity of care increases (e.g., care in an ICU), some estimates place the rate of inaccuracy as high as 25%! Clearly a better approach is needed.

Need for Automated Clinical Information Systems

Clinical Programs can develop the knowledge based needed to implement best practice without computerized information systems. They can use manual processes (e.g., chart stickers, paper forms, abstraction of medical records) successfully to implement best practice and measure outcomes. However, the number of key Clinical Work Processes to be managed exceeds the capacity of manual information management. Also, manual systems are labor intensive and prone to error due to their retrospective nature.

Patient Care Data Customers - Analysis and Reconciliation of Data Elements Needed

As noted earlier, there are numerous customers of patient care data. Many of the data elements they need for their "reports" overlap and are collected multiple times in today's approach. You can gain significant efficiencies by identifying the reports which are needed by each category of customer, the data elements required to produce the reports, and then reconciling the data elements so that they are collected once and made available to all who need them. The following graphic illustrates these data customers and their needs:



Data System Design/Evaluation Principles

As you design and/or evaluate commercial data systems to help you automate data acquisition, here are some principles you should bear in mind:

- **Require** patient care data "customers" to **define how they will use data elements** (e.g., define the reports to be produced) before authorizing collection
- Define the *clinical task as the unit of measure* for clinical and financial outcomes
- Understand and optimize the *operations work flow* (clinical, financial, administrative)
- Collect at the point of care, data elements needed to produce all essential routine reports
- Store the data collected in a database accessible to authorized patient care data customers

The functionality of your data system should not be limited to data acquisition. Your system should also be able to help you accomplish tasks such as the following:

- Present *real-time operations information* (e.g. work lists) and *decision support* (prompts/alerts) to help implement best practice
- Integrate data acquisition into work flow and use automated data gathering technologies (e.g. instrumentation interfaces, bar coding) whenever possible to collect data
- *Generate information* (e.g., reports) which is essential and/or useful to business sponsors (clinical, financial, administrative)
- Use *knowledge to drive workflow* and to *connect shared modules* into a clinically meaningful sequence of steps
- Include automated tracking and regular review of report utilization in order to facilitate continuous *overhead value analysis*

Data Acquisition Tools

In Chapter Four, Measurement System, we discussed a process which began with definition of reports and then used reverse engineering to identify the data elements which you will need to generate the reports. In some cases these data elements are already collected and available in your current data systems. In other cases, you will need to develop data collection tools to capture them. Initially these data collection tools will usually be manual. Use paper forms to work out the bugs before committing programmers to automate the forms or to integrate them into your EMR. In the ideal, data acquisition should be a by-product of documentation.

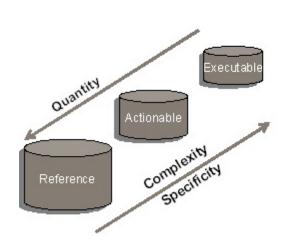
Development and Management of Clinical Knowledge Assets

Clinical Knowledge Assets are an important form of implementation tools. Unless you provide a strategic framework or construct within which you charge Clinical Program Work Groups to develop Clinical Knowledge Assets your efforts may fall short of their full potential. As you develop such a strategic construct, you may find the following considerations helpful:

- "Look and Feel" Branding: You may want to develop and implement a style guide (e.g., for your patient and provider educational materials) which has a "look and feel" that is consistent within and across Clinical Programs. This represents an opportunity for branding and the creation among your clinicians and other employees of a sense of "pride in your outfit."
- Unstructured Clinical Knowledge Assets: If you do not provide strategic direction and technical support, members of Work Groups will use development tools with which they are familiar, which usually means that Clinical Knowledge Assets will take the form of hard copy MS Word or PowerPoint documents. Such documents are useful for capturing content in graphical ways, but access to them from a computer is usually limited to manual look-up.
- Structured Clinical Knowledge Assets: By providing a strategic framework and technical resource (e.g., knowledge engineers and Knowledge Management Infrastructure see next section), your Work Groups will be able to produce Clinical Knowledge Assets that can be accessed from computers used for clinical care and eventually can be implemented using clinical decision support engines and software.

Knowledge or Content Hierarchy

There is a logical hierarchy of knowledge or content, which is illustrated in the following:

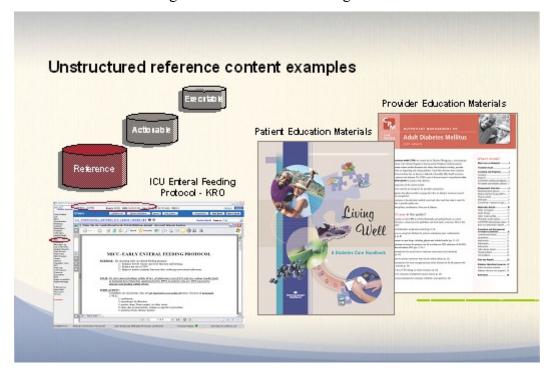


Content categories:

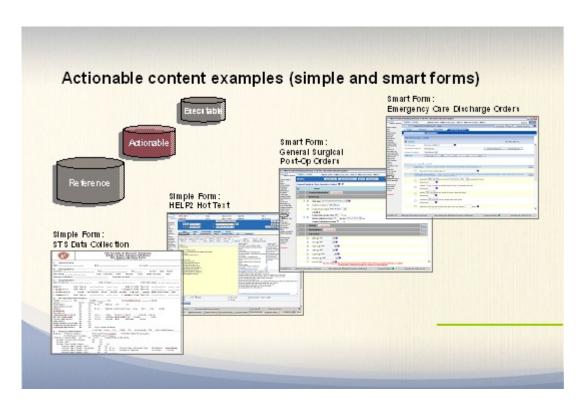
Type of Content	Decision Support
Refe	rence
Unstructure di (HTML, PDF)	UpToDate, Micromedex, Care Process Models, Provider Education, Patient Education
Strictured (XML)	CPGs, Dischange Instructons, Polibles
Actio	onable
Shipë data captile	Web-based data entry forms, Hottext
"Sm art" data captue	Order sets, Calculations
Exec	utable
Shipë ndës and alerts	Oritbal labs , Medibation alerts, Billimbin interpretation
Piotocoband guidelines	G Ir cose , Antico agulation , Shock , Liver Transplant

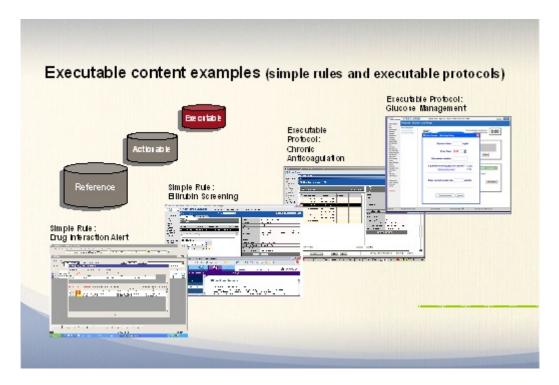
- **Unstructured Reference Content:** Most content we have today is unstructured reference content. It comes in a variety of formats such as hard copy, HTML or PDF files.
- Structured Reference Content: Unstructured reference content can be converted to structured reference content by using a markup language (e.g., XML) to annotate the text of the reference document. These annotations describe how the text is to be structured, laid out, or formatted. Markup languages facilitate the sharing of structured data across different information systems, including the Internet.
- Actionable Content: Actionable content is the simpler of the two forms of clinical decision support content (actionable and executable). There is no "bright line" between actionable and executable. Actionable usually refers to simpler decision support logic (e.g., "if, then" decision support rules).
- **Executable Content:** Executable content involves more complex rules than actionable content. It is the most difficult to develop and requires the most sophisticated implementation infrastructure.

As you can see from the graphic, as you move from reference content to executable content the complexity increases, but so does the specificity. Reference content pertains to populations of patients. Actionable content applies to classes of patients (e.g., within a Clinical Work Process) and can be adapted to an individual patient by manually checking or un-checking options (e.g., automated standing order set). Executable content applies to a specific patient, gathering data and executing rules to provide recommendations to providers regarding care. The following are samples from each of these categories of Clinical Knowledge Assets:









Knowledge Management - CD Metaphor

Perhaps a metaphor of creating and playing a CD can help us understand the development and implementation of clinical knowledge.

• A composer writes a score from which an orchestra plays and records the music



• **CD Burner:** A CD-burner is used to encode and format the recording onto a CD.



• **CD Player:** The CD is loaded into a CD player, which reads the digital recording and plays the music recorded by the orchestra.



In Clinical Knowledge Management:

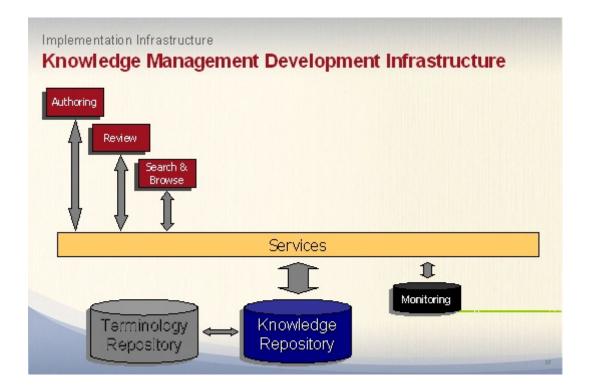
• The clinical experts of the Clinical Program Work Group develop a Clinical Knowledge Asset in Unstructured Reference Content format

- Technical experts develop CD burners (knowledge management infrastructure) and teach clinical experts to use them or use the CD burners to assist clinical experts in converting the Unstructured Reference Content into one of the following clinical decision support elements:
 - Structured Reference Content CDs
 - Actionable Content CDs
 - Executable Content CDs
- Clinicians use properly equipped CD burners (properly designed EMRs) to play the clinical decision support CDs created using the CD burner

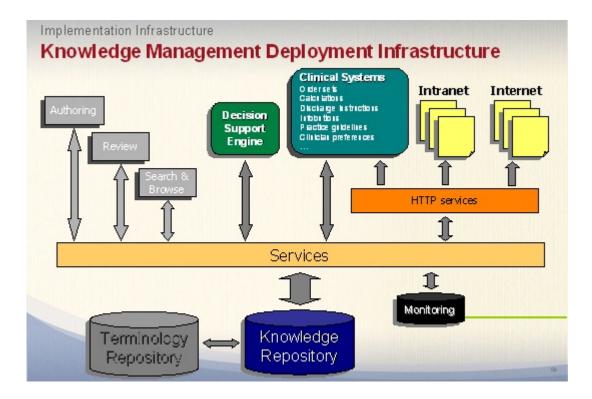
Knowledge Management Infrastructure ("KMI" - CD Burner)

If you essay to rise to your full potential in implementing best practice, you will eventually need a CD Burner, i.e., an infrastructure to develop and deploy Clinical Knowledge Assets. This Knowledge Management Infrastructure consists of two elements:

• **Knowledge Management Development Infrastructure**, including tools to author Clinical Knowledge Assets (knowledge authoring tools), a repository in which the tools reside and from which they can be retrieved for review and use (knowledge repository) and a monitoring system to track how often a given Clinical Knowledge Asset is used.



• Knowledge Management Deployment Infrastructure, including a decision support engine, linkages to clinical information systems and HTTP services for deployment of Clinical Knowledge Assets via the Intranet and Internet.



Knowledge Management - EMR Considerations (CD Player)

As you move up the clinical knowledge hierarchy from unstructured to structured to actionable to executable content, you will require more of your electronic medical record system (EMR). Taking advantage of the full potential of clinical decision support will require a robust architecture and a system that is compliant with standards, including essential elements such as the following:

- Standard terminology (vocabulary)
- Standard data models
- Services-oriented architecture (standard application programming interfaces or APIs)

National standards organizations (e.g., LOINC, HL7, SNOMED, CPT) working collaboratively with federal entities (HHS, NLM) have made substantial progress over the past several years toward standardization of terminology. Healthy discussions are occurring today in the technical community regarding standardization of data models and APIs (e.g., interoperability forums), but no clear consensus has evolved as yet.

Analytic Implementation Tools

The Enterprise Data Warehouse ("EDW") is a library which houses important data and is used to turn those data into information that can be used in implementing best practice.

There is an important relationship between the patients' medical records and the EDW. An enlightened EMR will include in its design the ability to capture and store in a clinical data repository ("CDR") a longitudinal medical record for each patient which includes all encounters the patient has with the health care system across the continuum of the clinical domains. The CDR is transactional in nature.

It may be helpful to think of the CDR as a mile-long filing cabinet which contains one file folder for each patient served by the system. In that file folder, the system maintains an electronic record of each interaction of the patient with the system (e.g., each visit to a primary care physician, each lab or X-ray diagnostic test, each admission to the hospital, each surgical procedure, each home health visit, each prescription filled).

The CDR serves well in its task of keeping track of clinical events in the life of each patient over time, but it is not well-suited to analysis and tracking of cohorts or populations of patients who have similar diseases (disease management) or for data mining. The reason for this is that in order to use the CDR for analytic purposes, the analyst must have the computer open each file folder in the mile-long file cabinet and inquire whether that patient has any information pertinent to the analytic question being asked. It is also important to understand that if many analysts are asking the computer to open each file folder over and over again, it is likely to slow the system down in the performance of its primary function, i.e., recording the real-time interaction of patients with the system.

These considerations have led to the development of the EDW and its data marts. It may be helpful for you to think of the EDW as a library full of books, which are organized into sections and which have sophisticated indexes. The books in the EDW contain excerpts of the information contained in the CDR. On a regular basis (usually at a time when the real-time demands on the CDR are lowest), the computer opens every file on every patient and extracts certain information into analytic tables. These analytic tables make up data marts, which group together information on patients with similar conditions or diseases. One form of data mart is a registry. A registry pertains to a Clinical Work Process such as diabetes, so the diabetic registry contains information pertaining to all patients in the system who meet diagnostic criteria for inclusion in the registry.

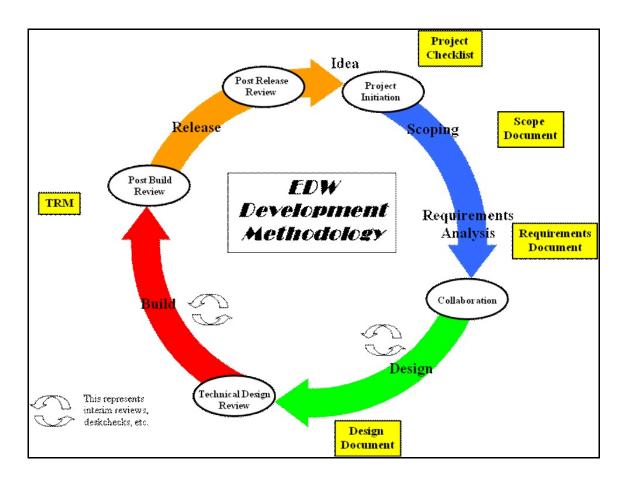
Data marts may also aggregate Clinical Work Processes into Development Teams, which you may recall, are organized around like medical specialists. So, the Endocrinology Development Team of the Primary Care Clinical Program would contain the diabetic registry or data mart as well as the thyroid registry or data mart. Development Team data marts are then aggregated into Clinical Program data marts, which include all Clinical Work Processes, which belong to each of the Development Teams.

EDW Development Methodology

The EDW represents one of the main implementation tools used by the leaders who make up the Clinical Management Structure in order to engage clinicians (and others) and help them improve patient care by implementing best practice and to gain new insights through research conducted as a part of the process of care.

There is an orderly process for building the data marts which make up the EDW, for providing access to the resources which it contains, for teaching analysts a process which will optimize their ability to use its resources and to prioritize EDW projects.

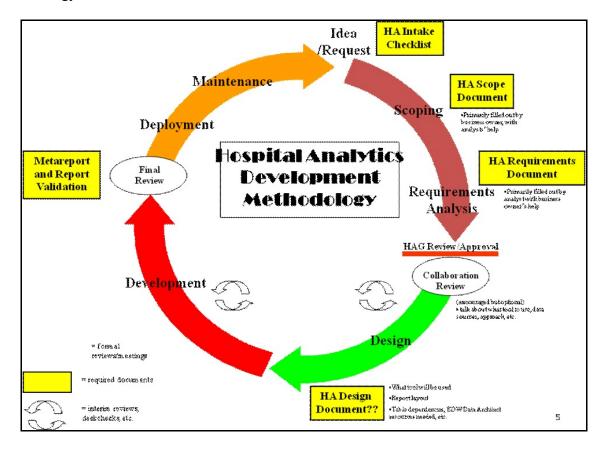
The following graphic summarizes the methodology or process for EDW development:



Regardless of the project, you are much more likely to achieve your desired outcome if you follow rigorously the product development steps outlined in the graphic, including: 1) scoping; 2) requirements analysis; 3) design; 4) build and 5) release. If you succumb to the temptation to jump from concept to release, you will spend more time in the long run in "rework" cycles than you would have spent to do it right the first time.

Using the EDW

Similarly, once the EDW and its data marts are developed, there is an orderly sequence which you should be sure your analysts understand in order for them and you to maximize the return on your EDW investment. The following graphic illustrates this analytics development process or methodology:

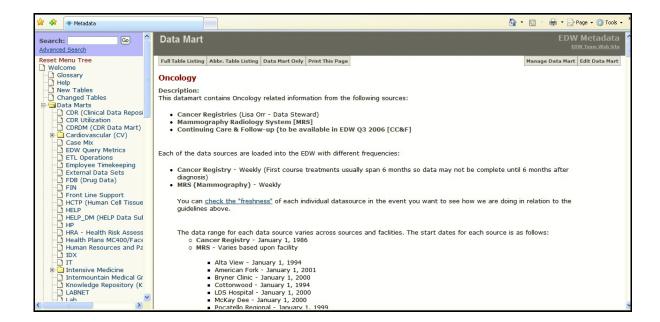


Another tool you can build, which can increase significantly the efficiency and effectiveness of the analysts who use the EDW is a metatdata repository. The key concept inside the idea of "metadata" is to provide data (information) about "data".

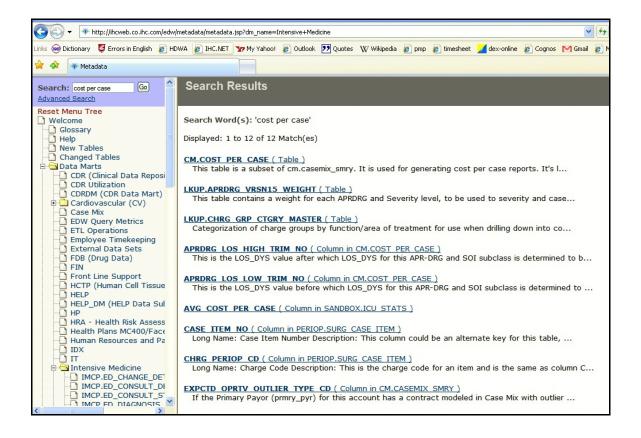
Metadata are stored in a metadata repository, which is a navigable and searchable knowledge base which contains descriptions of the EDW data marts, data structures, reports and data movement processes. The analyst wishing to "discover" what information is available in the EDW can easily search the metadata repository to find the precise location of a given data set.

The following graphics show some sample views of a:

- Data mart description for the oncology data mart
- Results of a search of the metadata repository for "cost per case"
- Report information regarding a diabetes provider level summary report



Metadata Repository Information - Oncology Data Mart



Metadata Repository Search - "Cost Per Case"



Metadata Repository Information - Diabetes Provider-Level Summary Report

Governance of Information and Analytic Resources

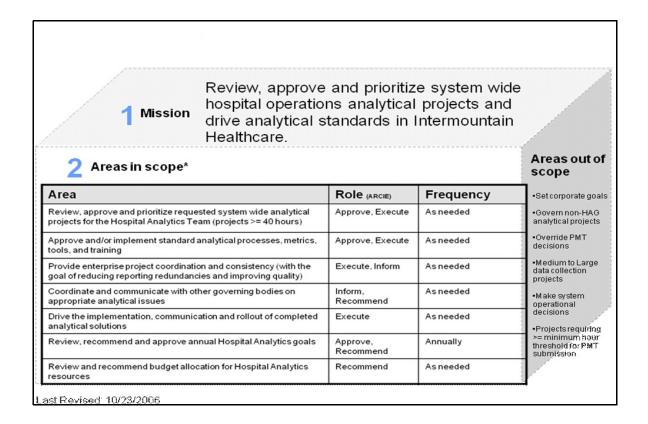
In order to develop and implement effective analytical strategies you will need a system and structure of governance to oversee management of the rich information resources that will grow from your commitment to measurement of your Clinical Work Processes.

Information governance includes the following elements:

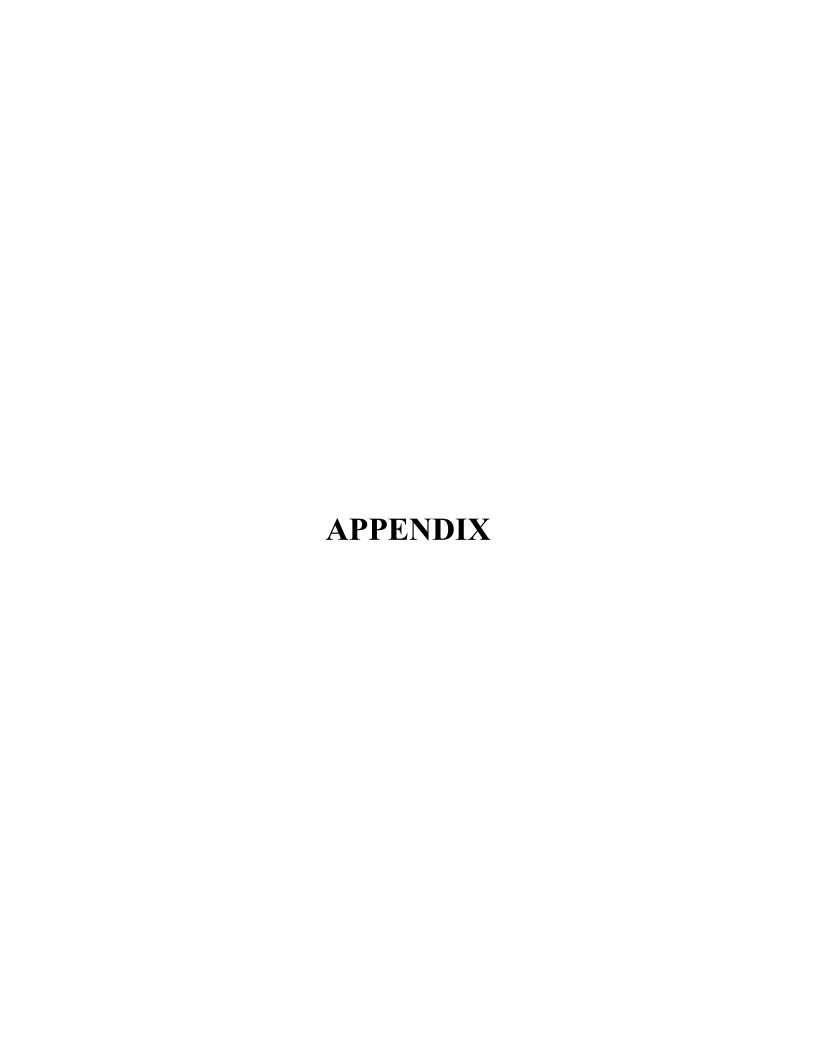
- **Data Stewardship:** You should identify a data steward for each subject area or domain. The data steward is responsible for the quality of the information and to authorize its use. He/she should be conversant with the business and/or clinical processes of the domain and the nuances of the information included in it.
- **Business Intelligence Competency Center ("BICC"):** You should organize a Business Intelligence Competency Center, consisting of a representative cross-section of senior-level information users and analysts, who are charged to lead definition, standardization and implementation of:

- Analytical tools and processes
- Data definition
- Analytical best practices
- Analytical training and education offerings
- Brokerage of mentoring and support
- **Prioritization and Resource Allocation:** Where a given project is not being sponsored by a an organized clinical or business entity (e.g., a Clinical Program), you will need to designate an organizational team or body to review and approve analytical resources required for such proposed projects.

The following is a sample Hospital Analytics Governance("HAG") Charter:



The HAG Charter is overseen and carried out under the auspices of the Clinical Leadership Team.



POSITION DESCRIPTION CLINICAL OPERATIONS DIRECTOR

(PDF)

POSITION DESCRIPTION DATA MANAGER - CLINICAL OPERATIONS (MS WORD FILE)

DATA MANAGER JOB FAMLY GRID (MS EXCEL FILE)

POSITION DESCRIPTION OUTCOMES ANALYST (MS WORD FILE)

JOB FAMILY GRID OUTCOMES ANALYST (MS EXCEL FILE)

POSITION DESCRIPTION

AND

JOB FAMILY GRID

DATA ARCHITECT

(MS WORD FILE)