Best Practices – Measuring and Demonstrating Clinical Pharmacist Impact in Hematopoietic Stem Cell Transplantation

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Learning Objectives

- Describe the role of a PharmD in various hematopoietic stem cell transplant (HCT) settings.
- Develop tools to measure the impact of pharmacy services in HCT.
- Explain how pharmacists can impact the clinical, humanistic, and economic outcome of patients undergoing HCT.
- Compare the achievements and challenges of establishing and maintaining HCT pharmacy services in a variety of settings

Audience Response Question #1

- Which of the below best describes the size of your institution's HCT program?
  - A. <50 transplants per year
  - B. 50-100 transplants per year
  - C. 100-250 transplants per year
  - D. 250-400 transplants per year
  - E. >400 transplants per year

Audience Response Question #2

- How is your HCT program resourced with regards to clinical pharmacist services?
  A. <1 FTE
  B. 1-2 FTE's
  C. 3-4 FTE's
  D. >4 FTE's

Audience Response Question #3

- How can pharmacists impact the care of patients in BMT?
  1. Improve patient understanding of medication regimens
  2. Standardize and streamline the approach to medication management
  3. Enhance patient satisfaction with their care
  4. All of the above

Introduction

- Despite widespread acceptance of the importance of pharmacists as part of the Blood and Marrow Transplantation (BMT) care team, to date, clear demonstration of pharmacist-driven outcomes are lacking
- Demonstrating the impact of pharmacists can help:
  – Justify needed additional pharmacy resources
  – Define most beneficial activities for pharmacists
  – Build confidence and satisfaction in jobs

Economic Outcomes

- Impact of an intervention on costs
- Evaluated using economic or pharmacoeconomic analyses
  - E.g., cost-benefit, cost-effectiveness, cost-minimization, cost-utility, budget impact model
- Examples:
  - Cost per cure, cost per asthma attack avoided, cost per hospital day, incremental cost effectiveness ratio (ICER)
- Types of costs
  - *Direct medical costs:* physician visits, hospitalizations, medication
  - *Direct non-medical costs:* caregiver-related , transportation
  - *Indirect costs:* productivity, loss of work

Clinical Outcomes

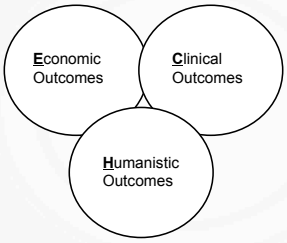
- Measurable changes in health status due to an intervention
  - *Intermediate:* blood pressure, glucose, LDL-cholesterol, A1c
  - *Final:* stroke, myocardial infarction, death
- Evaluated using clinical trials/post-marketing reports
- Examples:
  - Disease impact on patient
  - Drug impact on patient
  - Adherence and compliance impact on patient
  - Health care delivery system impact on patient

Humanistic Outcomes

- Impact of an intervention on patient reported endpoints
- Evaluated using patient questionnaires or survey
  - E.g., Health related quality of life (HRQOL), Consumer Assessment of Health Plan Survey (CAHPS)
- Examples:
  - Health-related quality of life
  - Patient satisfaction
  - Patient preference

Types of Outcomes

ECHO Model



What outcome should I look for?

- Depends on your institution, your department, and your current role.
- Examples from:
  - Clinicians early in BMT practice
    - Megan McKee – South Texas VA, San Antonio, TX
  - Mid-level BMT clinician
    - Kelley Carlstrom – Cleveland Clinic, Cleveland, OH
  - Established BMT clinician
    - Kamakshi Rao – UNC Hospitals and Clinics, Chapel Hill, NC

Audience Response Question #4

- Which of the following best defines a humanistic outcomes?
  1. Patient satisfaction scores
  2. Patient adherence to medication regimens
  3. Patient survival

Megan McKee, PharmD, BCPS, BCOP

South Texas Veterans Health Care System
San Antonio, Texas

South Texas Veterans Health Care System (STVHCS)

- STVHCS is a tertiary care hospital
  - Inpatient and outpatient hematology/oncology
  - 8-bed blood and marrow transplant unit (BMTU)
- BMTU Staff
  - 3 BMT attending physicians
  - 2 midlevel providers (physician assistant/nurse practitioner)
  - 1 clinical pharmacy specialist (CPS)
    - Board certified in pharmacotherapy (BCPS) & oncology (BCOP)

BMT Specific Statistics

- ~ 75 transplants annually
  - ¼ allogeneic
  - ¾ autologous
- All transplants are done as inpatients
- Adult only population
- 8 bed unit (2 outpatient beds)

Pharmacist Responsibilities

Inpatient BMT

- Daily rounding
- Chemotherapy order writing/review
- Admission counseling
- Initial chemotherapy note
- PK and TDM
  - Busulfan
  - Cyclosporine, tacrolimus
  - Anti-infectives

Outpatient Infusion Clinic

- Assess all patients prior to chemotherapy
  - Review labs
  - Toxicity check
  - Medication reconciliation
- Chemotherapy order review
  - Chemotherapy order entry
  - Compounding check

Additional Pharmacist Responsibilities

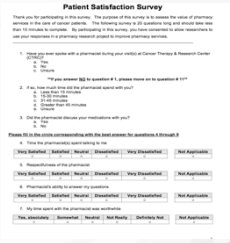
- Scope of practice
  - Concurrence of the physician with the patient care responsibility for the service in which the pharmacist functions
  - Prescriptive authority within certain domains
- My role
  - Manage supportive care issues (nausea/vomiting, GI issues, dermatological care, pain clinic, etc.)

Research - Past and Present

- Cancer Therapy & Research Center
  - One of three academic research and treatment centers in Texas
  - Serves more than 4 million people in the central and south corridor of Texas
  - Recognized for phase I clinical trials and conventional treatment options for cancer patients
- Pharmacy responsibilities
  - Drug distribution/dispensing
  - Clinical pharmacy services

Research at CTRC

- Design
  - Observational study to evaluate patient satisfaction with pharmacy services
  - Survey of patients actively undergoing cancer treatment
- Tools
  - 20-item, 2-page survey was administered to patients in an outpatient chemotherapy infusion center



Patient Satisfaction Survey

Thank you for participating in this survey. The purpose of this survey is to assess the value of pharmacy services in the care of cancer patients. The following survey is 20 questions long and should take less than 10 minutes to complete. By participating in this survey, you have consented to allow researchers to use your responses in a pharmacy research project to improve pharmacy services.

1. Have you ever spoke with a pharmacist during your visit(s) at Cancer Therapy & Research Center
   a. Yes
   b. No
   c. Unsure

   If you answer NO to question # 1, please move on to question # 11

2. If so, how much time did the pharmacist spend with you?
   a. Less than 15 minutes
   b. 15-30 minutes
   c. 30-45 minutes
   d. Greater than 45 minutes
   e. Unsure

3. Did the pharmacist discuss your medications with you?
   a. Yes
   b. No

Please fill in the circle corresponding with the best answer for questions 4 through 9

4. Time the pharmacist(s) spent talking to me

Very Satisfied	Satisfied	Neutral	Dissatisfied	Very Dissatisfied	Not Applicable
a	b	c	d	e	f

5. Responsiveness of the pharmacist

Very Satisfied	Satisfied	Neutral	Dissatisfied	Very Dissatisfied	Not Applicable
a	b	c	d	e	f

6. Pharmacist's ability to answer my questions

Very Satisfied	Satisfied	Neutral	Dissatisfied	Very Dissatisfied	Not Applicable
a	b	c	d	e	f

7. My time spent with the pharmacist was worthwhile

Yes, absolutely	Somewhat	Neutral	Not Really	Definitely Not	Not Applicable
a	b	c	d	e	f

Research at CTRC

- Data collected
  - Basic social and demographic information
  - Satisfaction with pharmacy services
  - Patient's perceived knowledge of medication therapy
  - Patient's willingness to pay for clinical 'counseling' services
- Primary outcome
  - Impact of the pharmacist–patient relationship
    - Defined by interaction between time spent with pharmacist, understanding of medications, and desire for future pharmacy services

Results

- Survey distribution
  - 112 surveys were administered and 77 completed by patients over a 2 month period
- Demographics
  - Mean age = 55
  - Majority female
  - Primary diagnosis – solid tumor (lung, GI, breast)
  - Majority of patients were Hispanic/Latino (47%)
  - Majority living in urban area

Outcomes

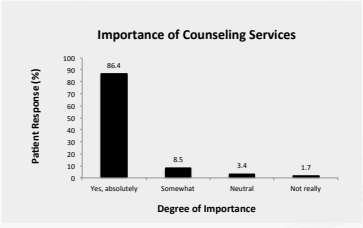
- Impact of pharmacy services (humanistic)
  - 93.2% of patients were satisfied or very satisfied with respectfulness of pharmacist
  - 91.5% of patients were very satisfied with the pharmacists' ability to answer questions
  - Majority of patients stated that counseling by a pharmacist was "absolutely necessary and desirable"

Audience Response Question #5

- Which types of outcomes are best addressed in your practice setting?
  - A. Clinical
  - B. Humanistic
  - C. Economic
  - D. Combination of above

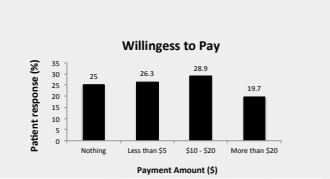
Pharmacist-Patient Relationship

- How important is counseling by a pharmacist when starting a new chemotherapy regimen?



Pharmacist-Patient Relationship

- Would you be willing to pay for pharmacy counseling services (medication therapy management)?



Current Initiatives

- Evaluate the effectiveness of a 14 day follow up program by pharmacists on patients starting oral chemotherapy
- Policy requires all patients initiating oral chemotherapy to pick up medication in person for counseling and return in 14 days for follow up
  - Adherence (humanistic)
  - Toxicity (clinical)
  - Cost (economic)

Current Initiatives

- Expanding pharmacy services
  - Outpatient BMT PharmD
  - Oral chemotherapy PharmD
- Improving documentation services
  - Theradoc®
    - Software that integrates electronic patient records with clinical data and institution protocols
    - Provides cost data for specific interventions

Biggest Accomplishments

- Patient centered
  - CTRC
    - Demonstrated importance patient-pharmacist relationship
      - Improve compliance
      - Increase understanding
      - Prevent toxicities
    - Supported additional FTE for clinical pharmacist
  - VA
    - Providing pharmacy directed follow up for patients on oral chemotherapy
      - Decrease costs
      - Increase adherence
      - Prevent toxicities

Challenges/Future Directions

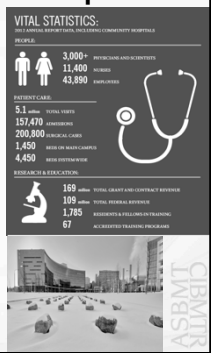
- Challenges
  - Expanding role of pharmacy services in outpatient BMT
  - Defining value and quality in pharmacy initiatives and services
  - Documenting and evaluating interventions
- Future directions
  - Establishing PharmD oral chemotherapy clinic
  - Survey providers to determine humanistic value of the pharmacist to the multidisciplinary team

Kelley D. Carlstrom, PharmD, BCOP

Cleveland Clinic Taussig Cancer Center
Cleveland, Ohio

Cleveland Clinic Main Campus

- Nonprofit academic medical center
- 1450 total beds
- Over 30,000 oncology patients seen annually
- Three dedicated inpatient adult oncology units
  - G70: solid tumor (36 beds)
  - G110: bone marrow transplant (22 beds)
  - G111: leukemia (22 beds)
- 73 outpatient chemotherapy chairs



Taussig Cancer Institute

- Ranked #9 in the nation in cancer care, and #1 in Ohio, by U.S. News & World Report
- National Cancer Institute (NCI)-designated cancer center
- >359,000 patient visits
- Treatment at main campus or 12 other locations throughout northeast Ohio
- >250 highly skilled doctors, nurses and other healthcare professionals
- 37 "Top Docs" listed in Cleveland Magazine

Patient Education and Support

- 4th Angel Mentoring
- Chemocare.com
- Music/Art Therapy
- Cancer Answer Line and Patient Resource Center
- High Tea
- Studio Fifty-One
- JADE Comfort Cart
- Reflections Wellness Program
- Social Work and Psycho-Oncology Program
- Support Groups
- Tobacco Cessation
- Financial Services

http://my.clevelandclinic.org/cancer

Blood and Marrow Transplantation (BMT)

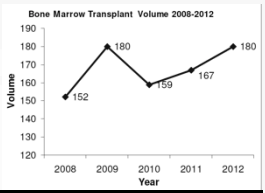
- Adult:
  - Staffing
    - 12 BMT staff physicians
    - 6 RN outpatient coordinators
    - 5 inpatient midlevel practitioners (2 CNP, 3 PA)
    - 2 pharmacists (1 inpatient, 1 outpatient)
    - 3 social workers
    - Numerous support staff
  - Inpatient BMT
    - All autologous
    - All myeloablative and reduced-intensity allogeneic
  - Outpatient BMT
    - Non-myeloablative (NMA)
- Pediatrics:
  - Staffing
    - 2 BMT staff physicians
    - 1 midlevel practitioner, 1 RN/BSN/CPON
    - Support staff (social work, research coordinator)
    - 2 inpatient pharmacists (not BMT specific)
  - All pediatric BMT inpatient

Blood and Marrow Transplantation

- Accreditations
  - Foundation for Accreditation of Cellular Therapy (adult and pediatrics)
- Associations
  - Bone Marrow Transplant Clinical Trials Network (CTN)
  - Chronic Graft-versus-host Disease Consortium – Rare Disease Clinical Research Network
  - Radiation Injury Treatment Network (RITN)
  - Center for International Blood and Marrow Research (CIBMTR)
  - National Marrow Donor Program – Be The Match ®
    - Transplant Center and Marrow Collection Center

http://my.clevelandclinic.org/cancer/treatments-procedures/bone-marrow-transplants

Cleveland Clinic BMT Statistics



2012 TOTAL VOLUME OF STEM CELL INFUSIONS

Age at Transplant	Allogeneic Related	Reduced Intensity Related		Allogeneic Unrelated		Reduced Intensity Unrelated		Auto	TOTAL
	PSC / BM	PSC	BM	PSC/BM	CORD	PSC/BM	CORD	PSC / BM	
Pediatric	1	1	0	3	0	0	1	0	**6**
Adult	21	14	0	23	6	6	2	102	**174**
TOTAL	**22**	**15**	**0**	**26**	**6**	**6**	**3**	**102**	**180**

BMT PharmD Responsibilities: Inpatient

- Monday – Friday service
- Daily rounding
- Discharge medication education sheet and counseling on all allogeneic BMT
- Chemotherapy order review and computer entry
- Assists with medication bedside delivery
- Busulfan pharmacokinetic pilot/roll-out
- Weekly medication rounds for patient questions
- Education of pharmacy students/residents
- Committee participation

BMT PharmD Responsibilities: Adult Outpatient

- Monday – Friday service, began February 2013
- Chemotherapy order writing (paper orders) and order entry on hospital admission
- Pre-transplant evaluation (all patients)
  - PharmD meets patient prior to physician visit and consent process
  - Services:
    - Medication reconciliation
    - Drug interaction screening
    - Patient education
    - Outpatient NMA BMT medication counseling
    - Drug information
- Education of pharmacy students/residents
- Committee participation
- Creation and updates of patient education materials

Evaluating Pharmacist Impact

- Goals of research: describe new service and determine pharmacist workflow
  - Methods:
    - Real time data collection
    - IRB-approved database maintained in Excel
  - Evaluated outcomes:
    - Accurate medication list
      - Changes made to medication list
        - » Updates
        - » Discontinuations
        - » Additions
    - Drug interactions (clinical)
    - Cost savings through dose rounding pilot (economic)

Pre-BMT Pharmacy Appointments

Total patients seen as of 12/11/13 – n		149
Patients with an accurate medication list – n (%)		16 (10.7)
Total number of changes made to medication list in all patients		589
	Median (range)	3.5 (0,14)
Drug discontinuations – total		337
	Median (range)	3 (0,10)
Rx – n (%)		253 (75)
OTC – n (%)		84 (25)
Drug additions – total		145
	Median (range)	1 (0,8)
Rx – n (%)		54 (37)
OTC – n (%)		91 (63)
Drug updates – total		107
	Median (range)	1 (0,4)
Rx – n (%)		71 (66)
OTC – n (%)		36 (34)
Patients with drug interactions requiring therapy change – n (%)		7 (4.7)
Additional clinical recommendations – n		20

Expansion of Outpatient PharmD Services

- Post-transplant evaluation (allogeneic)
  - New service began 10/21/13
  - Evaluated outcomes
    - Accurate medication list
      - Changes made to medication list
        - » Updates
        - » Discontinuations
        - » Additions
    - Estimated pharmacist time (economic)
    - Patient compliance (humanistic)
    - **Drug therapy recommendations** (clinical)
      - Blood pressure
      - Cholesterol
      - Bone health

Achievements and Challenges

- Achievements
  - Fully integrated outpatient PharmD
  - Improved efficiency of chemotherapy order process and admission medication reconciliation
  - Management of drug interactions prior to admission
  - Recent expansion of clinical pharmacy services to post-allogeneic patients
- Challenges
  - Training for cross-coverage
  - Determining best methods to measure value of clinical pharmacist
  - Qualitative versus quantitative value

What Does the Future Hold?

- PGY2 oncology resident research project of new post-allogeneic service
- Clinical pharmacist involvement in chemotherapy consent process?
- Collaborative practice agreement?
- Billing for pharmacy services – is it necessary?

Audience Response Question #6

- Which organization accredits BMT programs to ensure safe and quality cellular therapy treatment?
  1. Center for International Blood and Marrow Transplant Research (CIBMTR)
  2. Board of Pharmacy Specialties (BPS)
  3. National Marrow Donor Program (NMDP)
  4. Foundation for Accreditation of Cellular Therapy (FACT)

Audience Response Question #7

Do you have a collaborative practice agreement at your site?

A. Yes
B. No

Kamakshi Rao, PharmD, BCOP, CPP, FASHP

University of North Carolina Medical Center
Chapel Hill, NC

UNC Hospitals / NC Cancer Hospital

- Program Staff
  - 7 BMT attending physicians
  - 5 adult/1 pediatric nurse coordinators
  - 7 BMT advanced practice professionals
  - 4 Clinical Pharmacist Practitioners
    - CPP's recognized by Boards of Pharmacy and Medicine, credentialed by hospital, with prescriptive and billing authority
    - All PGY2 Oncology Trained practitioners

BMT Specific Statistics

- ≈ 180 transplants annually
  - 1/3 allogeneic
  - 2/3 autologous
- All transplants done as inpatients
- Pediatric and adult transplants
- 16 bed inpatient unit, expanding to 24 beds in late 2014

Pharmacist Responsibilities

Inpatient Service (7d/week)

- Daily rounding
- Chemotherapy order prep
- Admission counseling
- Discharge coordination and counseling
- PK and TDM
  - Busulfan
  - CNI, anti-infectives
- Insurance oversight and medication access
- Education of pharmacy learners

Ambulatory Clinic (M-F)

- Structured visits
  - Mobilization
  - Preadmission
  - Post-discharge
- Mobilization management
- Supportive care visits (DM, pain, etc.)
- Chemotherapy order prep
- Insurance oversight and medication access
- Prescriptive authority
- Education of pharmacy learners

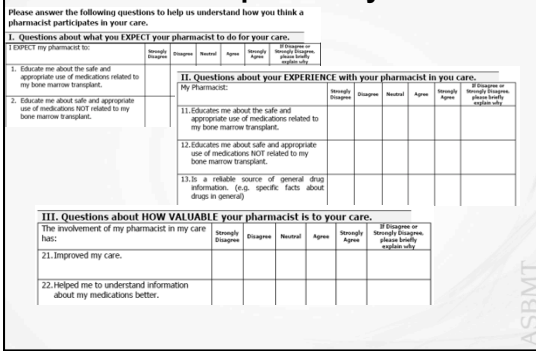
Evaluating the pharmacist's impact

- Evaluation involved 2 separate projects
  - Patient and provider perception surveys
  - Intervention-based impact tracker
- Combined efforts evaluated outcomes
  - Clinical Outcomes – impact on common medication related issues
  - Adherence/Understanding – Patient comfort/trust levels in pharmacists
  - Patient Satisfaction – patient perception and satisfaction
  - Provider Satisfaction – provider perception and satisfaction
  - Cost and time savings – provider time savings

Patient and Provider Surveys

- Conducted from 2011-2012
- Survey was created with 3 domains
  - Patient/provider expectations
  - Patient/provider experiences
  - Patient/provider perceived value
- 25 patients surveyed pre-transplant (prior to any interaction with a pharmacist)
- 86 patients surveyed post-transplant (after meeting inpt and outpt pharmacists)
  - 25 were surveyed both pre and post
  - 59 surveyed only post-transplant
- 50 providers surveyed (MD's, APP's, nurses)

Sample Survey



Please answer the following questions to help us understand how you think a pharmacist participates in your care.

I. Questions about what you EXPECT your pharmacist to do for your care.

I EXPECT my pharmacist to:	Strongly Disagree	Disagree	Neutral	Agree	Strongly Agree	If Disagree or Strongly Disagree, please briefly explain why
1. Educate me about the safe and appropriate use of medications related to my bone marrow transplant.						
2. Educate me about safe and appropriate use of medications NOT related to my bone marrow transplant.						

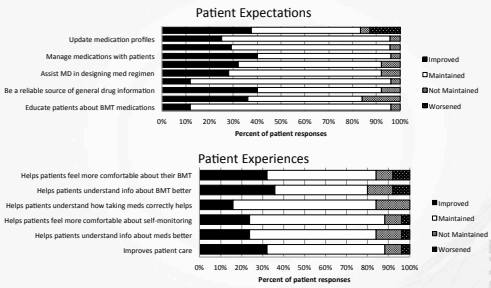
II. Questions about your EXPERIENCE with your pharmacist in you care.

My Pharmacist:	Strongly Disagree	Disagree	Neutral	Agree	Strongly Agree	If Disagree or Strongly Disagree, please briefly explain why
11. Educates me about the safe and appropriate use of medications related to my bone marrow transplant.						
12. Educates me about safe and appropriate use of medications NOT related to my bone marrow transplant.						
13. Is a reliable source of general drug information. (e.g. specific facts about drugs in general)						

III. Questions about HOW VALUABLE your pharmacist is to your care.

The involvement of my pharmacist in my care has:	Strongly Disagree	Disagree	Neutral	Agree	Strongly Agree	If Disagree or Strongly Disagree, please briefly explain why
21. Improved my care.						
22. Helped me to understand information about my medications better.						

Survey Results

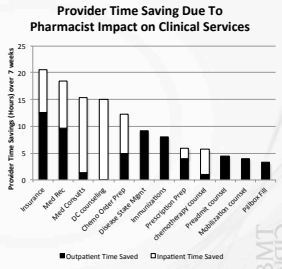


Impact Tracker

- To best quantify the impact of pharmacists on patient care and provider time, created a database tool
- Polled providers (MD's, APP's, nurses) about the various activities of a pharmacist and asked them to determine time savings
  - Discharge counseling – 30 minutes
  - Diabetic counseling – 10 minutes

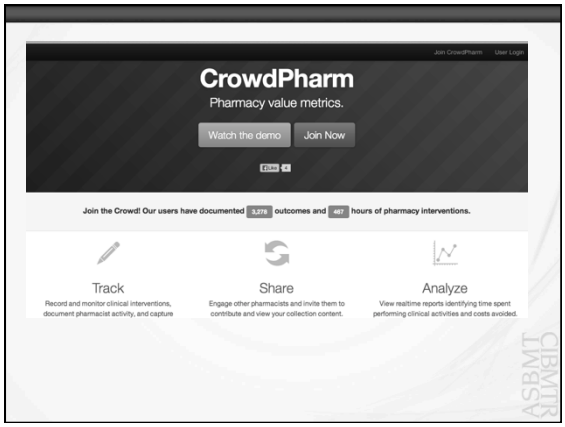
Impact Tracker – Phase 1

- Straight time savings evaluation
- For 7 weeks, pharmacists tracked all interventions made to determine total time savings imparted to providers
- Demonstrated 117 hours of time saved



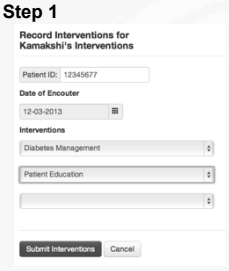
Impact Tracker – Phase 2

- Based on success of Impact Tracker phase 1 (which allowed us to justify 2 additional pharmacist resources), created version 2, now called “CrowdPharm”, to assess not only time savings, but also to assess impact on clinical outcome

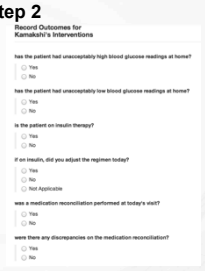


CrowdPharm

Step 1



Step 2



CrowdPharm
Sample Outcome Screenshot

has the patient had unacceptably high blood glucose readings at home?

Result	N	Percent
Yes	11	52.4%
No	10	47.6%

has the patient had unacceptably low blood glucose readings at home?

Result	N	Percent
Yes	2	9.5%
No	19	90.5%

is the patient on insulin therapy?

Result	N	Percent
Yes	17	81%
No	4	19%

if on insulin, did you adjust the regimen today?

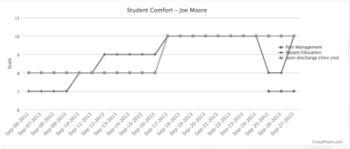
Result	N	Percent
Yes	10	47.6%
No	7	33.3%

CrowdPharm
Preliminary Results

- Medication Reconciliation
  - 39.2 % revealed an error or omission
  - 6%of these were serious enough to cause patient harm
- Diabetes management
  - 47.6% of patients had poorly controlled blood sugars at consult, requiring changes in insulin management
- Pain management
  - 28% of patients evaluated were on inappropriate pain regimens
- Pillbox fills
  - 28.6% of patients did not have adequate/appropriate medications to fill boxes

Educational Outcomes

- Bonus
  - Programmed to allow learners to log interventions and gauge comfort level, need for preceptor assistance, and time spent per patient



Accomplishments/Highlights

- Data garnered from these evaluations have resulted in positive results:
- Outside of UNC
  - ASHP Best Practice Award 2012
  - HOPA Research Grant Recipient 2013
- Within UNC
  - Funding for 2 additional pharmacists and 2 additional oncology residents based on physician demand
  - Establishment of a 7 day/week clinical specialist service for BMT, including dedicated weekend clinical pharmacy services for the BMT unit and clinics

Challenges/Future Directions

- Challenges
  - Embracing nontraditional justification methods (and convincing your administrators to do that too!)
  - Creating disparities between BMT and other clinical pharmacy services
- Future directions
  - Further developing and heightening the patient education that pharmacists can provide
  - Resurveying patients after implementation of expanded pharmacists model
  - Provider status! CPP and beyond….

Audience Response Question #8

- Which of the following outcomes can a pharmacist's intervention affect?
  1. Clinical outcomes
  2. Economic outcomes
  3. Humanistic outcomes
  4. All of the above
  5. None of the above

Audience Response Question #9

- What tools do you use to track or measure pharmacy services at your institution
  - A. Surveys (patients or providers)
  - B. Intervention documentation system (Theradoc, EPIC)
  - C. Simple database (Excel, Access)
  - D. Advanced database
  - E. Other
  - F. None. We do not track or measure services at this time

Summary

- Opportunities exist to examine and define the impact and contributions pharmacists make to the care of patients in the BMT setting, no matter the size or complexity of the institution.
- Collaboration amongst pharmacists can help to expand and improve the definition of measurable outcomes.
- Benefits of demonstrating outcomes can include not only job satisfaction, but the justification of additional resources.