

Collaborative Oncology Pharmacy Practice in the United States: The UCSF Experience

Robert J. Ignoffo, PharmD, FASHP
Clinical Professor of Pharmacy
University of California, San Francisco

Goals and Objectives

- Discuss Collaborative Practice in the USA
- Discuss the type of education and training required of oncology pharmacists in the USA

Describes strategies for developing collaborative practice

Background

- Evolution of Expanded Scope of Practice
 - ✓ Utilizes the Collaborative Practice Model
 - ✓ Premise—improve communications with other health care practitioners and responsibilities of pharmacists
 - ✓ As of 1999, 24 states in the USA allow some form of collaborative practice agreement with physicians.

Expanded Scope of Practice

- 2000: legislative changes in many states
- Specific activities
 - ✓ Prescriptive authority for certain drugs
 - ✓ Drug administration for first dosages and emergencies
 - ✓ Drug therapy monitoring
 - ✓ Selection of Therapeutic Devices
 - ✓ Modification of Drug Therapy: case-by-case based on written protocol

Drug Therapy Monitoring

- Physical Assessment
 - ✓ Blood Pressure
 - ✓ Oral integrity
- Serum glucose
- Lipid management
- Therapeutic drug level monitoring

Do physicians accept such practice?

- American College of Physicians
 - ✓ Endorse the all-PharmD degree in the USA
 - ✓ Endorse activities listed in previous slide
 - ✓ Position paper on “Pharmacist Scope of Practice”
in the journal Ann Intern Med 2002;136:79-85

American College of Physicians

- Supports physician-directed collaborations limited to pharmacist involvement in patient education and hospital rounds
- Referral system to pharmacists
- Compensation for pharmacists
- Support pharmacists as a primary information source, host for immunizations sites, and immunizer. Allowed in 30 states
- Oppose independent prescribing by a pharmacist

Pharmacist Training in the USA

- All-PharmD Curriculum
- 6 years of education
- Licensure exam (NAPLEX, North American Pharmacist Licensure Exam—given in all but 1 state (California)
- 1976: The American Pharmaceutical Assoc (APhA) developed the Board of Pharmaceutical Specialties (BPS) to recognize specialty areas of Pharmacy Practice

Board of Pharmaceutical Specialties

- Nuclear Pharmacy (1978)
- Nutrition Support (1988)
- Pharmacotherapy (1988)
- Psychiatric Pharmacy (19920)
- Oncology (1996)

Post Graduate Training

- Residency Training: one year training
 - ✓ 472 programs in 2000 listing in ACCP
 - ✓ 23 institutions provide oncology residencies, many are 2nd year programs given after a 1st Pharmacy Practice Residency.
 - ✓ Some residencies are not listed, e.g. MD Anderson Hospital (30 specialists)

Collaborative Care and Value of Oncology Pharmacist Interventions

- Collaborative Drug Therapy
 - ✓ Designed to maximize quality of life, reduce drug-related problems, and improve social benefits of pharmaceuticals
 - ✓ Process involves the physician, pharmacists, and other health care professionals
 - ✓ Procedures include dispensing, drug information, drug problem solving, and therapeutic decision making.

Collaborative Drug Therapy (CDT) Studies

- Overwhelmingly successful when associated with
 - ✓ Clinical services in hospitals
 - ✓ Clinical research
 - ✓ Drug information
 - ✓ Medication administration histories
 - ✓ Participation on CPR teams

CDT (cont)

- Lower hospital costs (41%) are realized for
 - ✓ Drug information services
 - ✓ Drug use evaluation
 - ✓ Adverse drug reaction reporting
 - ✓ Drug protocol management
 - ✓ Medical rounds
 - ✓ Antibiotics had greatest cost reduction

McMullin, et al. Arch Intern Medo 1999;159:2306

CDT (cont)

- In intensive care units
 - ✓ Adverse drug reaction rate is reduced by 66%
 - ✓ Physicians accepted recommendations by pharmacist in 362/365 instances (99%)

McMullin, et al. Arch Intern Medo 1999;159:2306

Clinical Services in Clinics

- Disease Management Programs
 - ✓ Anticoagulation Diabetes
 - ✓ Asthma
 - ✓ Immunizations
- National Institute for Standards in Pharmacist Credentialing
- Improvement in Patient Outcomes documented for heart failure management and diabetes monitoring

Reimbursement & Liability

- Medicare (National): pharmacists are not approved providers except for immunizations
- Medicaid (State)
 - ✓ Demonstration projects on patient education and monitoring
 - ✓ Improved cost effectiveness in states of Mississippi
 - Reimbursement for Asthma, diabetes, hyperlipidemia, anticoagulation

Collaborative Practice Programs in Oncology--UCSF

- Inpatient (Hospital)
 - ✓ Adult Leukemia-BMT Pharmacy Protocol
- Outpatient (Ambulatory Infusion Center)
- Credentials needed
 - ✓ California Pharmacist License
 - ✓ Curriculum Vitae
 - ✓ Documentation of Continuing Education
 - ✓ Current Cardiopulmonary Resuscitation Certificate
- Certification and Peer Review of Pharmacy Practitioners
 - ✓ Physician
 - ✓ Clinical Pharmacists

BMT Pharmacists at UCSF

Standardized Pharmacy Protocol

Adult Leukemia

- CP may perform the following activities
 - ✓ Routine management of chemotherapy toxicities
 - antiemetics
 - analgesic pain control
 - electrolyte management
 - TPN management
 - discharge medications

Standardized Pharmacy Protocol

Adult Leukemia

- CP may perform the following procedures
 - ✓ Ordering and interpreting drug therapy related lab tests
 - ✓ Administering immunizations pursuant to a prescriber's order
 - ✓ Initiating or adjusting the drug regimen (standardized chemotherapy orders)

Standardized Pharmacy Protocol

Adult Leukemia

- Practice Guidelines have been developed for:
 - ✓ TPN
 - ✓ Antiemetics
 - ✓ Pain Control
 - ✓ Clarification of Chemotherapy Orders
 - ✓ Discharge Medication Ordering

Standardized Pharmacy Protocol

Adult Leukemia--Results

- Antiemesis Monitoring (1996),
 - ✓ Monitor ~6 pts/day using the modified Rhodes Scale.
 - ✓ Oral 5HT3-based regimen
 - ✓ ~15% of pharmacist interventions arose from assessment of the Rhodes Scale
 - ✓ 5HT3 usage has decrease by 57% (24.6 to 10.5 doses/pt) since implementation

Standardized Pharmacy Protocol

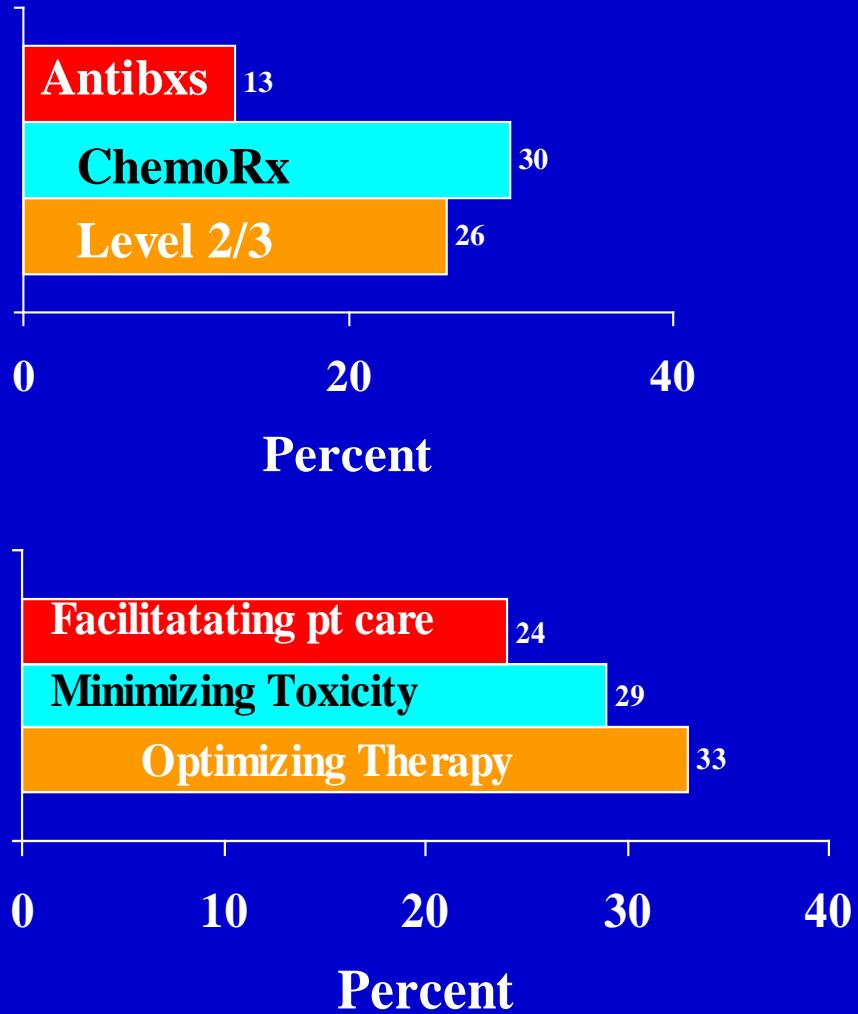
Adult Leukemia--Results

- Avoidance of Chemotherapy Errors
 - ✓ 30% of interventions concerned with chemotherapy orders
 - ✓ Rate of chemotherapy order clarification was 32.3% physician vs. 2.6% for pharmacists over 3 months. Some errors were class 2 & 3 (serious, usually related to incorrect dose)

Standardized Pharmacy Protocol Adult Leukemia--Results

All Interventions

- ✓ 4 audits performed— intervention outside the guidelines amount to 100 per 40 patients/week
- ✓ Staffing included 2 pharmacists, 1 pharmacy resident, and 2 pharmacy students
- ✓ Acceptance rate = 97%
- ✓ Interventions rated by independent pharmacists



Standardized Pharmacy Protocol

Adult Leukemia--Outcomes

- Outcomes not assessed
 - ✓ Patient Survival
 - ✓ Bounce-back hospitalizations
 - ✓ Emergency Department Visits
 - ✓ Unscheduled clinic visits
 - ✓ Consumption of Unnecessary Drugs

Ambulatory Infusion Center Oncology Pharmacy

- Pictures

Ambulatory Infusion Center

Collaborative Oncology Pharmacy Practice

- Guidelines for chemotherapy order verifications, antiemetics per pharmacy, Pending guidelines for cancer pain management
- Evidence-based chemotherapy regimens are frequently used by prescribers, but a standard method for writing orders was not in place.
- Director of Medical Oncology requested an assessment of chemotherapy errors by prescriber
- Oncology pharmacists developed Standardized chemotherapy orders similar to the inpatient setting

UCSF Guidelines on Chemotherapy Orders (1)

All orders should contain the following information:

1. 1. Patient name
- 2. Diagnosis
- 3. Weight, height, BSA (if needed)
- 4. Dates to be given.
- 5. Protocol name or regimen (if not a standard regimen, include refs)
- 6. Generic drug name (may also include brand name as a double check)
- 7. The dose in mg/kg or mg/m² (or desired AUC for carboplatin) and the calculated dose
- 8. Route of administration and rate of administration.
- 9. Antidotes as indicated, for example leucovorin for high dose methotrexate, mesna for ifosfamide.
 - a. Premedications as indicated, example for paclitaxel.
 - b. Hydration if needed, for example with cisplatin.
 - c. Anti-emetics as indicated for emetogenicity of chemotherapy drug.
- 10. Prescriber's signature and day/month/year

UCSF Guidelines on Chemotherapy Orders (2)

Recommended Prescribing Guidelines: to avoid chemotherapy errors

1. Write the full name of the drug. Avoid using abbreviations for drug names.
2. Include the cycle number on the order.
3. If the chemotherapy dose is adjusted for toxicity, include the percent reduction and the reason for the dose reduction. This helps the nurses and pharmacists to monitor the patient and check the dose.
4. Whenever possible, order practical doses of chemotherapy. The pharmacist will confer with you on rounding of certain drugs to their most practical dose as long as it does not vary by more than 5% of the original dose. (study drugs are excluded)
5. Write medication doses in milligrams whenever possible, rather than in grams.
6. Write “micrograms” or “mcg” clearly: “ μg ” may be misinterpreted as “mg” (milligram).
7. Avoid trailing zeros: 2.0 mg may be misinterpreted as 20 mg.
8. Use a leading zero for doses less than a whole unit: .4 mg may be misinterpreted as 4 mg.
9. Write out “units.” A “u” or “U” may be interpreted as a 0 (zero).

Audit of ChemoRx Errors

- N = 200 shadow charts including chemotherapy orders were reviewed retrospectively during 2 time periods (6/1/01-10/31/01; 2/1/02 – 3/31/02)
- Errors were coded by prescriber. An error included non compliance with the UCSF guidelines.
- During the 2nd audit period, a set of chemotherapy standardized orders were developed and implemented

■ Chemotherapy Orders for Topotecan

- Dates to be given: _____ Allergies _____ Height: _____ in/cm
Weight: _____ lb/kg BSA: _____ m²
- Diagnosis: _____ ICD-9 codes: _____
- Cycle: _____ Day(s): _____
- Antiemetics: Pre-chemotherapy (*moderately low emetogenic potential*)
 Prochlorperazine _____ mg IV or prochlorperazine 10 mg po or
- Chemotherapy: (plan to be given daily for 5 days every 21 days)
Topotecan 1.25 mg/m² or _____ mg/m² = _____ mg IV in D5W 100 ml over 30 minutes daily for five days (days 1-5) or Laboratory work: (Dose adjustment recommendation for CrCl: If \geq 40 ml/min give usual dose, if CrCl 20 to 39 ml/min give 50% of usual dose, if CrCl < 20 ml/min dose reduction is unknown)
- Pre-chemotherapy on Day 1 CBC with differential and platelets
Creatinine
- If ANC \geq 1.5 x 10⁹/L, platelets \geq 100 x 10⁹/L, give 100% of dose.
- If ANC < 1.5 x 10⁹/L, platelets < 100 x 10⁹/L, Cr > _____ mg/dL call
Additional orders: (filgrastim should not be given until at least 6 days after the last dose of topotecan)
- Filgrastim (Neupogen) 300 mcg 480 mcg subcutaneous injection to start on date _____ and continue daily for _____ days or

- **Chemotherapy Orders for Bleomycin, Cisplatin and Etoposide (PEB)**

- (*see page 2 for bleomycin orders*)

- Dates to be given: _____
Allergies _____ Height _____ in/cm Weight: _____ lb/kg BSA: _____ m²
- Diagnosis: _____ ICD-9 codes: _____
- Cycle: _____ Day(s): _____
- **Antiemetics:** give prior to chemotherapy days 1-5 (select a steroid and a serotonin antagonist)
 - Dexamethasone 10 mg IV or Dexamethasone _____ mg
 - Granisetron _____ mcg IV (10 mcg/kg) (round up to nearest 100 mcg)
Granisetron 2 mg po
 - Ondansetron 8 mg IV Ondansetron 16 mg po or
- **Pre-hydration:** NS 1000 ml IV over 2 hours on days 1-5
- **Chemotherapy (cisplatin and etoposide)** (plan to repeat every 21 days)
 - Cisplatin 20 mg/m² = _____ mg (or _____ mg/m² = _____ mg) in NS 500 ml IV over 1 hour on days 1-5
 - Etoposide 100 mg/m² = _____ mg (or _____ mg/m² = _____ mg) in NS 500 ml IV over 1 hour on days 1-5
- **Post-hydration:** NS 500 ml IV over 1-2 hours on days 1-5
- **Laboratory work:**
- **On Day 1** CBC with differential, platelets Electrolytes, Cr, BUN, Ca, Mg
Total bilirubin, AST, ALT, LDH β HCG, α FP, LDH
Other _____

Data parameters	Audit 1	Audit 2		
	# of error-containing charts (n=100)	# of error-containing handwritten charts (n=76)	# of error-containing pre-printed charts (n=24)	Total # of error-containing charts (n=100)
1. Patient ID/name	0	0	0	0
2. Diagnosis*	6	3	0	3
3. Weight*	13	8	2	10
4. Height*	11	8	2	10
5. BSA*	8	4	1	5
6. Specific protocol/dosing regimen*	16	12	0	12
7. Dose**	4	2	0	2
8. Route*	14	7	0	7
9. Dose in mg/kg or mg/m ² **	9	8	0	8
10. Calculated dose*	3	1	0	1
11. Rate of administration*	41	23	0	23
12. Supportive meds**	1	1	2	3
13. Physician's signature*	1	0	0	0
14. Provider ID*	17	17	0	17
15. Day/month/year of prescription*	12	13	0	13
16. Date to be given*	1	0	0	0
17. Cycle # noted*	24	14	2	16
18. Dose in grams, not mg	3	4	0	4
19. Dose in "µg" not "mcg"	0	0	0	0
20. Trailing zeros	2	1	0	1
21. Doses in "U" not "units"	0	1	0	1
22. Brand name, not generic	56	48	0	48 (31***)
23. Drug abbreviations (ie5-FU, VCR)	6	0	0	0
24. Units for total calculated dose*	3	3	0	3
25. Crossed out errors	1	0	0	0
26. Legibility	1	0	0	0
27. Diluent**	1			
Total	254	178	9	187

* missing

** incorrect

*** Excludes Doxil

Unpublished data from Althaus, et al by permission

Prescriber Code	First Audit		Second Audit					
	Handwritten Orders (N=100)	Handwritten Orders (N=76)	Pre - printed Orders (N=24)	All orders (N=100)				
	# of charts	EPC	# of charts	EPC	# of charts	EPC	# of charts	EPC
D	12	2.17	16	1.0 (0.94**)	5	0.4	21	0.86 (0.81**)
E	11	3.91	12	2.83 (2.25**)	0	0	12	2.8 (2.25**)
F	8	5.88	8	4.0 (3.88**)	0	0	8	4.0 (3.88**)
G	6	0.5	4	1.25	0	0	4	1.25
H	17	1.94	8	2.0 (1.5**)	2	0	10	1.6 (1.2**)
K	7	2.29	6	2.5	0	0	6	2.5
L	4	0.5	2	0.5	9	0.67	11	0.64
M	2	1.0	1	1.0	0	0	1	1.0
N	1	1.0	1	2.0	0	0	1	2.0
O	1	1.0	1	2.0 (1.0**)	2	0	3	0.67 (0.33**)
P	3	4.0	4	3.75	0	0	4	3.75
U	4	1.5	5	1.0 (0.6**)	2	0	7	0.71 (0.43**)
V	0		2	1.0 (0.5**)	0	0	2	1.0 (0.5**)
W	0		1	1.0	2	0.5	3	0.67
Total	100	2.54	76	2.34	24	0.38	100	1 1.87

Chemotherapy Orders

Audit

- Handwritten orders resulted in a much higher frequency of error than printed orders
- After Audit 1, individual prescribers were notified of their errors
- Most prescribers were very appreciative of the information and were more diligent in writing subsequent chemotherapy orders
- Communication of results regarding chemotherapy orders resulted in a 26% reduction in errors
- However, the most significant intervention was the implementation of standardized chemotherapy orders

Chemotherapy Orders

Audit (cont)

- Use of type-written standardized orders decreased the error rate by 95% (0.38 EPC).
- We currently have developed more than 50 standardized chemotherapy orders, which are available in the pharmacy or on the institution web site.
- Development of new orders must be signed by members of the Collaborative Practice Committee and include an oncologist, oncology pharmacist, and oncology nurse
- Changes in the standardized orders must only go through pharmacist coordinator

Keys to Successful Collaborative Practice

- There are several methods of collaborative practice in oncology
- Partnering with physicians and nurses will avoid “turf” battles and focus on their primary mission—high quality patient care
- Pharmacists should utilize their knowledge to educate colleagues on drug interactions and collaborate in the management of side effects
- Pharmacists should take a proactive role in reducing errors, especially with regard to chemotherapy

Acknowledgements

- Physicians
- Nurses
- Pharmacists