Oral Pill Compliance and Source Documentation

Barbara Barrett, MS, CCRP - Audit Program Director

Brenda Gebhart, RPh - Investigational Pharmacist

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Objectives

- Reasons pill compliance can be common audit issue

- Examples of audit acceptable source documents for pill compliance in pharmacy

- Examples of audit acceptable source documents for pill compliance in the medical records

- Examples of unclear source documents to confirm pill counts

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Recent Audit Deficiencies for Oral Compliance

Example #1

- CALGB 50303

There was no source documentation for cycles 2, 3, and 6 of oral prednisone.

Recent Audit Deficiencies for Oral Compliance

Example #2

- CALGB 50604

Lack of source documentation for oral medications of procarbazine and prednisone with BEACOPP cycles 1 and 2.

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Recent Audit Deficiencies for Oral Compliance

Example #3

- CALGB 90802

All protocol required medication calendars were never completed or submitted. There was little to no documentation of pill counts at f/u visits.

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Recent Audit Deficiencies for Oral Compliance

Example #4

- N0877

Could not confirm total dose of dasatinib/ placebo or temozolamide taken by patient. CRFs indicated only 30 days of temozolamide, should have been 42 days. Patient diaries not completed (optional).

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Recent Audit Deficiencies for Oral Compliance

Example #5

- N0877

1) Per pt diaries, total dose of dasatinib/placebo = 7350 mg. CRF reported dose = 6860 mg.

2) Total dose temozolamide s/b 6860 mg, but reported as 4340 mg. No documentation to explain or verify differences.

3) No documentation of C4 dasatinib/placebo or temozolamide including pt diaries.

Recent Audit Deficiencies for Oral Compliance

Example #6

- S0931

There was source documentation for only 4 of the 9 cycles of dispensed everolimus/placebo.

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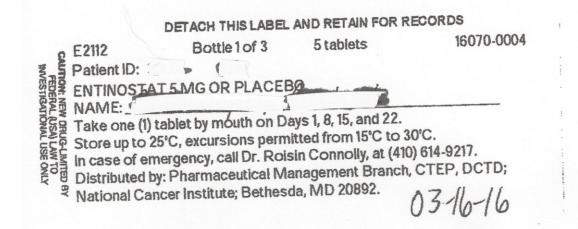# Reasons Pill Compliance Can Be An Issue At Audit Time

- Just plain patient non-compliance and/or unwillingness to complete pill diaries

- Cultural/language barriers

- Pain meds can affect compliance in taking p.o. meds and/or accuracy of completing pill diaries

- Little or no documentation in medical records

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Example of Source Document for Pill Compliance in Pharmacy

Dispensing of Pill Bottle Tear Off Label

Note to File in Pharmacy Binder

- Pharmacist makes a note to file to document pt did not return any pill bottles.

Most Common Issues of Tracking Pill Compliance in Pharmacy

1) Pharmacist not aware of patient visit and/or drug return.

2) Pharmacist not aware of dose reduction/ increase (i.e., new Rx written).

3) ?? Another Brenda??

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Examples of Source Documents That Are Audit Acceptable for Oral Pill Compliance In Medical Records/Study Charts

Oral Study Drug Dispensing Log

Patient/Participant Name: _____   Pt ID #: _____
Study #: _____   Study Arm_____
Study Drug: _____

Cycle/ Follow-up date	Date dispensed	# pills dispensed	Lot #	Date returned	# pills returned	Notes	Recorder's Signature

DRUG DELIVER SHEET

Patient: _____ (DOB: _____)

Study: CALGB 40903; **Study ID**: _____

Drug: LETROZOLE (1 Bottle = 30 tablets; 1 tablet = 2.5 mg)

Concentration & Amount: 2.5 mg tables x __1__ Bottles

Lot #: __L74032_____

Administration Instructions: *Letrozole will be taken orally, at a dose of 2.5 mg (1 tablet), once daily without regard to meals. (store bottles at room temperature).*

Person delivering: _____   _____   _____
                              Print name   Signature   Date

Person Receiving: _____   _____   _____
                              Print name   Signature   Date

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Alliance Oral Medication Policy Compliance-Cycle 1

Cycle 1 Day 1: Date_____

Date of first follow up (should be no later than 7 days from C1D1): _____

- Is subject correctly taking medication? ☐Yes ☐No

- Patient's stated dose and schedule:_____

- Is subject correctly filling out pill diary? ☐Yes ☐No ☐NA

- Comments:

  _____

- Initials:_____ Date_____

Date of second follow up (should be between 8-14 days from C1D1): _____

- Is subject correctly taking medication? ☐Yes ☐No

- Patient's stated dose and schedule:_____

- Is subject correctly filling out pill diary? ☐Yes ☐No ☐NA

- Comments: _____

- Initials:_____ Date_____

Most Common Issues of Tracking Pill Compliance From Medical Records

1) Forgetting to inquire and document if patient is compliant, any missed doses, etc.

2) Infrequent to no documentation of checking compliance from patient visits.

3) Unclear pill count documentation, such as containing math errors or not accounting for all bottles.

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Pill Counts at Office Visits
Are Key to Confirm Compliance

Remember:

- Pill diaries are often included in protocols for optional use, but if you develop your own they may need to be submitted to your IRB. Check with your IRB.

- Patient diaries are not always completed on a daily basis - often completed in full, all at one time, in the waiting room.

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Pill Counts at Office Visits Are Key to Confirm Compliance

- When doing pill counts remember there may be pills at home in a weekly pill box.

- If pt forgets pill bottles, ask them to call you back with a pill count. Document, document, document!

IDEA: Call patients the day before their appointments to remind them to bring **all** bottles with them.

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Example of Note of Non-Compliance

Shadow chart nursing note:

Mr. S returns today for monthly evaluation. States he took all pills every day since last visit. Pill count shows 4 capsules remaining, which means he missed 2 days of taking drug. Of note, pt was completing past pill diary during our discussion.

Example of Note of Non-Compliance

Shadow Chart entry for MA32 patient:

6/16/14 Called pt. left VM new bottle ready to p/u

6/26/14 Called pt. left VM again same message

7/1/14 No response from pt; sent pt letter to call & p/u new bottle.

8/19/14. Pt arrives to clinic. States she lost her last bottle 1 mo ago when out of town. Confirmed she wants to continue treatment on-study.

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Patient Pill Diaries – Unclear Source Documents

Alliance A031201

CYCLE #: _2_   # of WEEKS _4_

DAY	Medication	DATE	TIME		Number of 250 mg tablets taken	Comments
Example	Abiraterone	07/01/2012	9:00	PM	4	
1	Abiraterone	6/5/14	9:00	PM	4	
2	Abiraterone	6/6	9:00	PM	4	
3	Abiraterone	6/7	9:00	PM	4	
4	Abiraterone	6/8	9:00	PM	4	
5	Abiraterone	6/9	9:00	PM	4	
6	Abiraterone	6/10	9:00	PM	4	
7	Abiraterone	6/11	9:00	PM	4	
8	Abiraterone	6/12	9:00	PM	4	
9	Abiraterone	6/13	9:00	PM	4 + 4?	might have taken 2 doses
10	Abiraterone	6/14	9:00	PM	4	
11	Abiraterone	6/15	9:30	PM	4	
12	Abiraterone	6/16	9:30	PM	4	
13	Abiraterone	6/17	10:30	PM	4	

Patient Pill Diaries – Unclear Source Documents

Audience Sharing
of Best Practices

Reminder: New Expiration Date on NCI DARF and Oral DARFs

REMINDER Note: Old DARFS expired 3/31/2016

NEW DARF and Oral DARF expiration date is: **03/31/2019**

Even though no changes were made, the new DARF & Oral DARF should be used when starting a new page or a new study.

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Thank You!

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