

RAND 36-Item Health Survey Questionnaire (Version 1.0)

1. In general, would you say your health is:	
Excellent	1
Very good	2
Good	3
Fair	4
Poor	5

2. Compared to one year ago , how would you rate your health in general now ?	
Much better now than one year ago	1
Somewhat better now than one year ago	2
About the same	3
Somewhat worse now than one year ago	4
Much worse now than one year ago	5

The following items are about activities you might do during a typical day. Does **your health now limit you** in these activities? If so, how much?

(Circle One Number on Each Line)

	Yes, Limited a Lot	Yes, Limited a Little	No, Not limited at All
3. Vigorous activities , such as running, lifting heavy objects, participating in strenuous sports	[1]	[2]	[3]
4. Moderate activities , such as moving a table, pushing a vacuum cleaner, bowling, or playing golf	[1]	[2]	[3]

5. Lifting or carrying groceries	[1]	[2]	[3]
6. Climbing several flights of stairs	[1]	[2]	[3]
7. Climbing one flight of stairs	[1]	[2]	[3]
8. Bending, kneeling, or stooping	[1]	[2]	[3]
9. Walking more than a mile	[1]	[2]	[3]
10. Walking several blocks	[1]	[2]	[3]
11. Walking one block	[1]	[2]	[3]
12. Bathing or dressing yourself	[1]	[2]	[3]

During the **past 4 weeks**, have you had any of the following problems with your work or other regular daily activities **as a result of your physical health**?

(Circle One Number on Each Line)

	Yes	No
13. Cut down the amount of time you spent on work or other activities	1	2
14. Accomplished less than you would like	1	2
15. Were limited in the kind of work or other activities	1	2
16. Had difficulty performing the work or other activities (for example, it took extra effort)	1	2

During the **past 4 weeks**, have you had any of the following problems with your work or other regular daily activities **as a result of any emotional problems** (such as feeling depressed or anxious)?

(Circle One Number on Each Line)

	Yes	No
17. Cut down the amount of time you spent on work or other activities	1	2
18. Accomplished less than you would like	1	2
19. Didn't do work or other activities as carefully as usual	1	2

20. During the **past 4 weeks**, to what extent has your physical health or emotional problems interfered with your normal social activities with family, friends, neighbors, or groups?

(Circle One Number)

Not at all 1

Slightly 2

Moderately 3

Quite a bit 4

Extremely 5

21. How much **bodily** pain have you had during the **past 4 weeks**?

(Circle One Number)

None 1

Very mild 2

Mild 3

Moderate 4

Severe 5

Very severe 6

22. During the **past 4 weeks**, how much did **pain** interfere with your normal work (including both work outside the home and housework)?

(Circle One Number)

Not at all 1

A little bit 2

Moderately 3

Quite a bit 4

Extremely 5

These questions are about how you feel and how things have been with you **during the past 4 weeks**. For each question, please give the one answer that comes closest to the way you have been feeling.

How much of the time during the **past 4 weeks** . . .

(Circle One Number on Each Line)

	All of the Time	Most of the Time	A Good Bit of the Time	Some of the Time	A Little of the Time	None of the Time
23. Did you feel full of pep?	1	2	3	4	5	6
24. Have you been a very nervous person?	1	2	3	4	5	6
25. Have you felt so down in the dumps that nothing could cheer you up?	1	2	3	4	5	6
26. Have you felt calm and peaceful?	1	2	3	4	5	6
27. Did you have a lot of energy?	1	2	3	4	5	6
28. Have you felt downhearted and blue?	1	2	3	4	5	6
29. Did you feel worn out?	1	2	3	4	5	6
30. Have you been a happy person?	1	2	3	4	5	6
31. Did you feel tired?	1	2	3	4	5	6

32. During the **past 4 weeks**, how much of the time has your **physical health or emotional problems** interfered with your social activities (like visiting with friends, relatives, etc.)?

(Circle One Number)

- All of the time 1
- Most of the time 2
- Some of the time 3
- A little of the time 4
- None of the time 5

How TRUE or FALSE is each of the following statements for you.

(Circle One Number on Each Line)

	Definitely True	Mostly True	Don't Know	Mostly False	Definitely False
33. I seem to get sick a little easier than other people	1	2	3	>4	5
34. I am as healthy as anybody I know	1	2	3	4	5
35. I expect my health to get worse	1	2	3	4	5
36. My health is excellent	1	>2	3	4	5

This questionnaire was developed at RAND as a part of the Medical Outcomes Study and is provided here with permission from RAND.

RAND 36-Item Health Survey 1.0 Scoring Rules

INTRODUCTION

The RAND 36-Item Health Survey (Version 1.0) taps eight health concepts: physical functioning, bodily pain, role limitations due to physical health problems, role limitations due to personal or emotional problems, emotional well-being, social functioning, energy/fatigue, and general health perceptions. It also includes a single item that provides an indication of perceived change in health. These 36 items, presented here, are identical to the MOS SF-36 described in Ware and Sherbourne (1992). They were adapted from longer instruments completed by patients participating in the Medical Outcomes Study (MOS), an observational study of variations in physician practice styles and patient outcomes in different systems of health care delivery (Hays & Shapiro, 1992; Stewart, Sherbourne, Hays, et al., 1992). A revised version of the RAND 36-Item Health Survey (Version 1.1) that differs slightly from Version 1.0 in terms of item wording is currently in development.

SCORING RULES FOR THE RAND 36-ITEM HEALTH SURVEY (Version 1.0)

We recommend that responses be scored as described below. A somewhat different scoring procedure for the MOS SF-36 has been distributed by the International Resource Center for Health Care Assessment (located in Boston, MA). Because the scoring method described here (a simpler and more straightforward procedure) differs from that of the MOS SF-36, persons using this scoring method should refer to the instrument as the RAND 36-Item Health Survey 1.0.

Scoring the RAND 36-Item Health Survey is a two-step process. First, precoded numeric values are recoded per the scoring key given in Table 1. Note that all items are scored so that a high score defines a more favorable health state. In addition, each item is scored on a 0 to 100 range so that the lowest and highest possible scores are set at 0 and 100, respectively. Scores represent the percentage of total possible score achieved. In step 2, items in the same scale are averaged together to create the 8 scale scores. Table 2 lists the items averaged together to create each scale. Items that are left blank (missing data) are not taken into account when calculating the scale scores. Hence, scale scores represent the average for all items in the scale that the respondent answered.

Example: Items 20 and 32 are used to score the measure of social functioning. Each of the two items has 5 response choices. However, a high score

(response choice 5) on item 20 indicates extreme limitations in social functioning, while a high score (response choice 5) on item 32 indicates the absence of limitations in social functioning. To score both items in the same direction, Table 1 shows that responses 1 through 5 for item 20 should be recoded to values of 100, 75, 50, 25, and 0, respectively. Responses 1 through 5 for item 32 should be recoded to values of 0, 25, 50, 75, and 100, respectively. Table 2 shows that these two recoded items should be averaged together to form the social functioning scale. If the respondent is missing one of the two items, the person's score will be equal to that of the nonmissing item.

Table 3 presents information on the reliability, central tendency and variability of the scales scored using this method.

References

1. Ware, J.E., Jr., and Sherbourne, C.D. "The MOS 36-Item Short-Form Health Survey (SF-36): I. Conceptual Framework and Item Selection," *Medical Care*, 30:473-483, 1992.
2. Hays, R.D., & Shapiro, M.F. "An Overview of Generic Health-Related Quality of Life Measures For HIV Research," *Quality of Life Research*, 1: 91-97, 1992.
3. Stewart, A. L., Sherbourne, C., Hays, R. D., et al. "Summary and Discussion of MOS Measures," In A. L. Stewart & J. E. Ware (eds.), *Measuring Functioning and Well-Being: The Medical Outcome Study Approach* (pp. 345-371). Durham, NC: Duke University Press, 1992.

Table 1
STEP 1: RECODING ITEMS

ITEM NUMBERS	Change original response category (a)	To recoded value of:
1,2,20,22,34,36	1 ----->	100
	2 ----->	75
	3 ----->	50
	4 ----->	25
	5 ----->	0
3,4,5,6,7,8,9,10,11,12	1 ----->	0
	2 ----->	50
	3 ----->	100
13,14,15,16,17,18,19	1 ----->	0
	2 ----->	100
21,23,26,27,30	1 ----->	100
	2 ----->	80
	3 ----->	60
	4 ----->	40
	5 ----->	20
	6 ----->	0
24,25,28,29,31	1 ----->	0
	2 ----->	20
	3 ----->	40
	4 ----->	60
	5 ----->	80
	6 ----->	100
32,33,35	1 ----->	0
	2 ----->	25
	3 ----->	50
	4 ----->	75
	5 ----->	100

(a) Pre-coded response choices as printed in the questionnaire.

Table 2
STEP 2: AVERAGING ITEMS TO FORM SCALES

Scale	Number Of Items	After Recoding Per Table 1, Average The Following Items:
Physical functioning	10	3 4 5 6 7 8 9 10 11 12
Role limitations due to physical health	4	13 14 15 16
Role limitations due to emotional problems	3	17 18 19
Energy/fatigue	4	23 27 29 31
Emotional well-being	5	24 25 26 28 30
Social functioning	2	20 32
Pain	2	21 22
General health	5	1 33 34 35 36

Table 3
RELIABILITY, CENTRAL TENDENCY AND VARIABILITY OF SCALES IN THE
MEDICAL OUTCOMES STUDY

Scale	Items	Alpha	Mean	SD
Physical functioning	10	0.93	70.61	27.42
Role functioning/physical	4	0.84	52.97	40.78
Role functioning/emotional	3	0.83	65.78	40.71
Energy/fatigue	4	0.88	52.15	22.39
Emotional well-being	5	0.90	70.38	21.97
Social functioning	2	0.85	78.77	25.43
Pain	2	0.78	70.77	25.46
General health	5	0.78	56.99	21.11
Health change	1	----	59.14	23.12

Note: Data is from baseline of the Medical Outcomes Study (N = 2471), except for Health change, which was obtained one-year later.

Ferrans and Powers
QUALITY OF LIFE INDEX®
GENERIC VERSION - III

PART 1. For each of the following, please choose the answer that best describes how satisfied you are with that area of your life. Please mark your answer by circling the number. There are no right or wrong answers.

	Very Dissatisfied	Moderately Dissatisfied	Slightly Dissatisfied	Slightly Satisfied	Moderately Satisfied	Very Satisfied
HOW SATISFIED ARE YOU WITH:						
1. Your health?	1	2	3	4	5	6
2. Your health care?	1	2	3	4	5	6
3. The amount of pain that you have?	1	2	3	4	5	6
4. The amount of energy you have for everyday activities?	1	2	3	4	5	6
5. Your ability to take care of yourself without help?	1	2	3	4	5	6
6. The amount of control you have over your life?	1	2	3	4	5	6
7. Your chances of living as long as you would like?	1	2	3	4	5	6
8. Your family's health?	1	2	3	4	5	6
9. Your children?	1	2	3	4	5	6
10. Your family's happiness?	1	2	3	4	5	6
11. Your sex life?	1	2	3	4	5	6
12. Your spouse, lover, or partner?	1	2	3	4	5	6
13. Your friends?	1	2	3	4	5	6
14. The emotional support you get from your family?	1	2	3	4	5	6
15. The emotional support you get from people other than your family?	1	2	3	4	5	6

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HOW SATISFIED ARE YOU WITH:

	Very Dissatisfied	Moderately Dissatisfied	Slightly Dissatisfied	Slightly Satisfied	Moderately Satisfied	Very Satisfied
16. Your ability to take care of family responsibilities?	1	2	3	4	5	6
17. How useful you are to others?	1	2	3	4	5	6
18. The amount of worries in your life?	1	2	3	4	5	6
19. Your neighborhood?	1	2	3	4	5	6
20. Your home, apartment, or place where you live?	1	2	3	4	5	6
21. Your job (if employed)?	1	2	3	4	5	6
22. Not having a job (if unemployed, retired, or disabled)?	1	2	3	4	5	6
23. Your education?	1	2	3	4	5	6
24. How well you can take care of your financial needs?	1	2	3	4	5	6
25. The things you do for fun?	1	2	3	4	5	6
26. Your chances for a happy future?	1	2	3	4	5	6
27. Your peace of mind?	1	2	3	4	5	6
28. Your faith in God?	1	2	3	4	5	6
29. Your achievement of personal goals?	1	2	3	4	5	6
30. Your happiness in general?	1	2	3	4	5	6
31. Your life in general?	1	2	3	4	5	6
32. Your personal appearance?	1	2	3	4	5	6
33. Yourself in general?	1	2	3	4	5	6

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PART 2. For each of the following, please choose the answer that best describes how *important* that area of your life is to you. Please mark your answer by circling the number. There are no right or wrong answers.

HOW IMPORTANT TO YOU IS:	Very Unimportant	Moderately Unimportant	Slightly Unimportant	Slightly Important	Moderately Important	Very Important
1. Your health?	1	2	3	4	5	6
2. Your health care?	1	2	3	4	5	6
3. Having no pain?	1	2	3	4	5	6
4. Having enough energy for everyday activities?	1	2	3	4	5	6
5. Taking care of yourself without help?	1	2	3	4	5	6
6. Having control over your life?	1	2	3	4	5	6
7. Living as long as you would like?	1	2	3	4	5	6
8. Your family's health?	1	2	3	4	5	6
9. Your children?	1	2	3	4	5	6
10. Your family's happiness?	1	2	3	4	5	6
11. Your sex life?	1	2	3	4	5	6
12. Your spouse, lover, or partner?	1	2	3	4	5	6
13. Your friends?	1	2	3	4	5	6
14. The emotional support you get from your family?	1	2	3	4	5	6
15. The emotional support you get from people other than your family?	1	2	3	4	5	6

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HOW IMPORTANT TO YOU IS:

	Very Unimportant	Moderately Unimportant	Slightly Unimportant	Slightly Important	Moderately Important	Very Important
16. Taking care of family responsibilities?	1	2	3	4	5	6
17. Being useful to others?	1	2	3	4	5	6
18. Having no worries?	1	2	3	4	5	6
19. Your neighborhood?	1	2	3	4	5	6
20. Your home, apartment, or place where you live?	1	2	3	4	5	6
21. Your job (if employed)?	1	2	3	4	5	6
22. Having a job (if unemployed, retired, or disabled)?	1	2	3	4	5	6
23. Your education?	1	2	3	4	5	6
24. Being able to take care of your financial needs?	1	2	3	4	5	6
25. Doing things for fun?	1	2	3	4	5	6
26. Having a happy future?	1	2	3	4	5	6
27. Peace of mind?	1	2	3	4	5	6
28. Your faith in God?	1	2	3	4	5	6
29. Achieving your personal goals?	1	2	3	4	5	6
30. Your happiness in general?	1	2	3	4	5	6
31. Being satisfied with life?	1	2	3	4	5	6
32. Your personal appearance?	1	2	3	4	5	6
33. Are you to yourself?	1	2	3	4	5	6

Functional Status Questionnaire

Overview:

The Functional Status Questionnaire can be used as a self-administered functional assessment for a patient seen in primary care. It provides information on the patient's physical, psychological, social and role functions. It can be used both to screen initially for problems and to monitor the patient over time.

Sections

- (1) physical function in the activities of daily living
- (2) psychological function
- (3) role function
- (4) social function
- (5) variety of performance measures

Physical Function (Activities of Daily Living, or ADL)

Basic ADL: During the past month have you had difficulty with

- (1) Taking care of yourself, that is, eating, dressing or bathing?
- (2) Moving in or out of a bed or chair?
- (3) Walking indoors, such as around your home?

Response	Points
usually did with no difficulty	4
some difficulty	3
much difficulty	2
usually did not do because of healty	1
usually did not do for other reason	0

where:

- I will assume that "usually did not do for other reasons" is not a "valid" response, so that the ((maximum response score) - (minimum response score)) = 3; see scoring example on page 145

Intermediate ADL: During the past month have you had difficulty with

- (1) Walking several blocks?
- (2) Walking one block or climbing one flight of stairs?
- (3) Doing work around the house, such as cleaning, light yard work or home maintenance?
- (4) Doing errands such as grocery shopping?
- (5) Driving a car or using public transportation?

(6) Doing vigorous activities such as running, lifting heavy objects or participating in strenuous sports?

Response	Points
usually did with no difficulty	4
some difficulty	3
much difficulty	2
usually did not do because of healty	1
usually did not do for other reason	0

where:

• I will assume that "usually did not do for other reasons" is not a "valid" response, so that the ((maximum response score) - (minimum response score)) = 3; see scoring example on page 145

Psychological Function (Mental Health)

During the past month,

- (1) Have you been a very nervous person?
- (2) Have you felt calm and peaceful?
- (3) Have you felt downhearted and blue?
- (4) Were you a happy person?
- (5) Do you feel so down in the dumps that nothing could cheer you up?

Response to 1, 3 and 5	Points
all of the time	1
most of the time	2
a good bit of the time	3
some of the time	4
a little of the time	5
none of the time	6

Response to 2 and 4	Points
all of the time	6
most of the time	5
a good bit of the time	4

some of the time	3
a little of the time	2
none of the time	1

where:

• ((maximum response score) - (minimum response score)) = 5

- The subgroups of questions are scored in reverse. Since Table2 indicates that 0% is poor and 100% is good, I have scored as in the tables above.

Social/Role Function

If you were employed during the past month, how was your work performance?

- (1) Done as much work as others in similar jobs?
- (2) Worked for short periods of time or taken frequent rests because of your health?
- (3) Worked your regular number of hours?
- (4) Done your job as carefully and accurately as others with similar jobs?
- (5) Worked at your usual job, but with some changes because of your health?
- (6) Feared losing your job because of your health?

Response to 2, 5 and 6	Points
all of the time	1
most of the time	2
some of the time	3
none of the time	4

Response to 1, 3 and 4	Points
all of the time	4
most of the time	3
some of the time	2
none of the time	1

where:

• ((maximum response score) - (minimum response score)) = 3

- The subgroups of questions are scored in reverse. Since Table2 indicates that 0% is poor and 100% is good, I

have scored as in the tables above.

Social Activity: During the past month have you :

- (1) Had difficulty visiting with relatives or friends?
- (2) Had difficulty participating in community activities, such as religious services, social activities, or volunteer work?
- (3) Had difficulty taking care of other people such as family members?

Response	Points
usually did with no difficulty	4
some difficulty	3
much difficulty	2
usually didn't do because of health	1
usually did not do for other reasons	0

where:

- I will assume that "usually did not do for other reasons" is not a "valid" response, so that the ((maximum response score) - (minimum response score)) = 3; see scoring example on page 145

Quality of social interaction: During the past month, have you:

- (1) Isolated yourself from people around you?
- (2) Acted affectionate toward others?
- (3) Acted irritable toward those around you?
- (4) Made unreasonable demands on your family and friends?
- (5) Gotten along well with other people?

Response to 1, 3 and 4	Points
all of the time	1
most of the time	2
a good bit of the time	3
some of the time	4
a little of the time	5
none of the time	6

Response to 2 and 5	Points
all of the time	6

most of the time	5
a good bit of the time	4
some of the time	3
a little of the time	2
none of the time	1

where:

- $((\text{maximum response score}) - (\text{minimum response score})) = 5$
- The subgroups of questions are scored in reverse. Since Table 2 indicates that 0% is poor and 100% is good, I have scored as in the tables above.

Single Item Questions

(1) Which of the following statements describes your work situation during the past month?

- working full-time
- working part-time
- unemployed looking for work
- unemployed because of my health
- retired because of my health
- retired for some other reason

(2) During the past month, how many days did illness or injury keep you in bed all or most of the time:

- Responses: from 0 to 31 days

(3) During the past month, how many days did you cut down on the things you usually do for one-half day or more because of your illness or injury?:

- Responses: from 0 to 31 days

(4) During the past month, how satisfied were you with your sexual relationships?

- very satisfied
- satisfied
- not sure
- dissatisfied
- very dissatisfied
- did not have any sexual relationships

(5) How do you feel about your health?

- very satisfied
- satisfied
- not sure
- dissatisfied
- very dissatisfied

(6) During the past month, about how often did you get together with friends or relatives, such as going out together, visiting in each other's home, or talking on the telephone?

- every day
- several times a week
- about once a week
- 2 or 3 times a month
- about once a month
- not at all

Scoring

transformed scale score =

$$= (((\text{SUM of response scores for each grouping}) / (\text{number of questions with valid information})) - 1) * (100 / ((\text{maximum valid response score}) - (\text{minimum valid response score})))$$

where:

- The equation used for the transformed scale score in the original article was corrected in an erratum.
- In the implementation I have made it so that there are no unanswered questions, while the original article allows for unanswered questions.

Interpretation

Based on the diagram in Table 2 (page 145), the following are approximations were made from the length of the lines for the indicated warning zones.

Parameter	Warning Zone	Good
basic activities of daily living	0 - 87	88 - 100
intermediate activities of daily living	0 - 77	78 - 100
mental health	0 - 70	71 - 100
work performance (see note)	0 - 78	79 - 100
social activities	0 - 78	79 - 100
quality of interactions	0 - 69	70 - 100

Note: Work performance not shown in table, so made same was social activities.

If the person scores within the warning zone, then the patient has a problem that needs to be investigated more.

References:

Erratum. J Gen Intern Med. 1986; 1: 427.

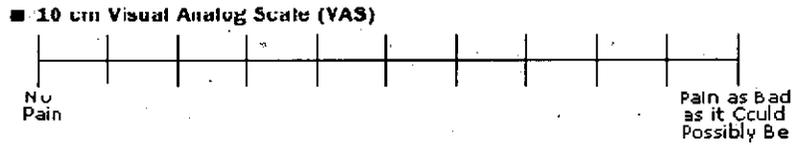
Jette AM, Davies AR, et al. The Functional Status Questionnaire: Reliability and validity when used in primary care. J Gen Intern Med. 1986; 1: 143-149.

Pain Intensity Rating Scales

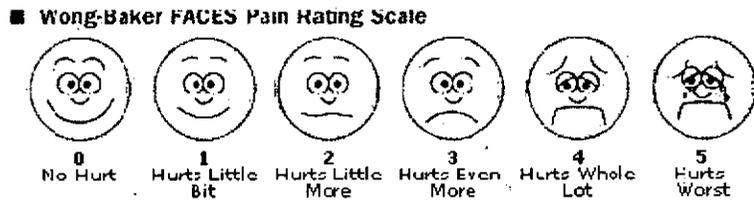
(A) Numerical Verbal Scale



(B) Visual Analog Scale Figure 1. Pain intensity Scales



(C)



A. Numerical Verbal Scale. B. Visual Analog Scale. C. FACES Pain Rating Scale.

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C. Walking ability

0	1	2	3	4	5	6	7	8	9	10
Does not interfere									Completely interferes	

D. Normal work (includes both work outside the home and housework)

0	1	2	3	4	5	6	7	8	9	10
Does not interfere									Completely interferes	

E. Relations with other people

0	1	2	3	4	5	6	7	8	9	10
Does not interfere									Completely interferes	

F. Sleep

0	1	2	3	4	5	6	7	8	9	10
Does not interfere									Completely interferes	

G. Enjoyment of life

0	1	2	3	4	5	6	7	8	9	10
Does not interfere									Completely interferes	

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 Source: Dr. Charles Cleeland, Anderson Cancer Center, Pain Research
 Group, 1100 Holcombe, Houston, TX 77030.

1F

Questions Concerning Activities of Daily Living (ADL)

1. How well can you perform personal self care activities including washing, dressing, using the bathroom, etc?

- I can look after myself normally without extra discomfort
- I can look after myself normally but have extra discomfort
- Self care activities are uncomfortable and are done slowly
- I manage most of my personal self care with some help
- I need a lot of help daily in most aspects of my self care
- I cannot perform self care activities

2. How well can you lift and carry?

- I can lift and carry heavy objects without extra discomfort
- I can lift and carry heavy objects but I get extra discomfort
- I can lift and carry heavy objects
- I can only lift and carry light to medium objects
- I can only lift very light objects
- I cannot lift or carry anything at all

3. How well can you walk (you may check more than one box)?

- There is no change from before my injury
- Symptoms prevent me from walking more than 1 mile
- Symptoms prevent me from walking more than 1/2 mile
- Symptoms prevent me from walking more than 1/4 mile
- I walk only short distances
- I use a cane, crutches or walker
- I am limited to use of a wheelchair

4. What is the most strenuous level of activity that you can do for at least 2 minutes?

- Very heavy activity
- Heavy activity
- Moderate activity
- Light activity
- Very light activity
- Extremely light to no activity

5. How well can you climb one flight of stairs?

- No difficulty (and you can easily perform the activity)
- Some difficulty (but you can still perform the activity)
- A lot of difficulty (but you can still perform the activity)
- Cannot climb one flight of stairs

6. How well can you sit for a period of time (even with some pain or discomfort) before you absolutely have to stand, walk or lay down?

- I can sit without any time limitations
- I can only sit between 1 hour to 2 hours at a time
- I can only sit between 30 and 60 minutes at a time
- I can only sit between 15 and 30 minutes at a time
- I can only sit for less than 15 minutes at a time
- I can not sit at all

7. How well can you stand or walk for a period of time (even with some pain or discomfort) before you absolutely have to sit or lay down?

- I can stand/walk without any time limitations
- I can only stand/walk between 1 hour to 2 hours at a time
- I can only stand/walk between 30 and 60 minutes at a time
- I can only stand/walk between 15 and 30 minutes at a time
- I can only stand/walk for less than 15 minutes at a time
- I can not stand or walk at all

8. How well can you reach and grasp something off a shelf at chest level?

- No difficulty (and you can easily perform the activity)
- Some difficulty (but you can still perform the activity)
- A lot of difficulty (but you can still do the activity)
- Unable (you cannot do this activity)

9. How well can you reach and grasp something off a shelf overhead?

- No difficulty (and you can easily perform the activity)
- Some difficulty (but you can still perform the activity)
- A lot of difficulty (but you can still do the activity)
- Unable (you cannot do this activity)

10. How well can you push or pull (even with some pain or discomfort)?

- I can push or pull very heavy objects
- I can push or pull heavy objects
- I can push or pull light objects
- I can push or pull very light objects
- I can not push or pull anything

11. Do you have any difficulty with gripping, grasping, holding and manipulating objects with your hands?

- No difficulty (and you can easily perform the activity)
- Some difficulty (but you can still perform the activity)
- A lot of difficulty (but you can still do the activity)
- Unable (you cannot do this activity)

12. Do you have any difficulty with repetitive motions such as typing on a computer?

- No difficulty (and you can easily perform the activity)
- Some difficulty (but you can still perform the activity)
- A lot of difficulty (but you can still do the activity)
- Unable (you cannot do this activity)

13. Do you have any difficulty with forceful activities with your arms and hands?

- No difficulty (and you can easily perform the activity)
- Some difficulty (but you can still perform the activity)
- A lot of difficulty (but you can still do the activity)
- Unable (you cannot do this activity)

14. Do you have any difficulty with kneeling, bending or squatting?

- No difficulty (and you can easily perform the activity)
- Some difficulty (but you can still perform the activity)
- A lot of difficulty (but you can still do the activity)
- Unable (you cannot do this activity)

15. Do you have any difficulty with sleeping?

- I have no trouble sleeping because of my injury
- My sleep is slightly disturbed (less than 1 hour sleepless)
- My sleep is mildly disturbed (1-2 hours sleepless)
- My sleep is moderately disturbed (2-3 hours sleepless)
- My sleep is greatly disturbed (3-5 hours sleepless)
- My sleep is completely disturbed (5-7 hours sleepless)

16. In regards to sexual function (orgasm, ejaculation, lubrication, erection) changes since and because of your injury:

- There has not been a change because of my injury
- There has been a slight change because of my injury
- There has been a moderate change because of my injury
- There has been a major change because of my injury
- No sexual functioning because of my injury

17. In regards to your pain at the moment:

- I have no pain at the moment
- My pain is mild at the moment
- My pain is moderate at the moment
- My pain is severe at the moment
- My pain is the worst imaginable at the moment

18. In regards to your pain most of the time:

- I have no pain most of the time
- My pain is very mild most of the time
- My pain is moderate most of the time
- My pain is fairly severe most of the time
- My pain is the worst imaginable most of the time

19. How much do your injury and/or pain interfere with your ability to travel?

- None
- Some or a little of the time
- A lot or most of the time
- All of the time - I can't travel

20. How much do your injury and/or pain interfere with your ability to engage in social activities?

- None
- Some or a little of the time
- Most of the time
- All of the time - I can't engage in social activities

21. How much do your injury and/or pain interfere with your ability to engage in recreational activities??

- None
- Some or a little of the time
- A lot or most of the time
- All of the time - I can't engage in recreational activities

22. How much do your injury and/or pain interfere with concentrating and thinking?

- None
- Some or a little of the time
- A lot or most of the time
- All of the time - I can't concentrate or think very clearly

23. How much has your injury and/or pain caused emotional distress with depression or anxiety?

- None
- Some or a little of the time (mild depression or anxiety)
- A lot or most of the time (moderate depression or anxiety)
- All of the time (severe depression or anxiety)

24. Has there been any change in your ability to communicate (writing, typing, seeing, hearing, speaking) since and because of you injury?

	No Change	Mild Change	Moderate Change	Severe Change
Writing				
Typing				
Seeing				
Hearing				
speaking				

25. If zero indicates "no pain" and ten indicates "pain as bad as it can be," on a scale of 0 to 10, what is your level of pain for the following questions?

<p>What was your pain level on average during the past week (circle the appropriate number)?</p> <p>No Pain 0 1 2 3 4 5 6 7 8 9 10 Pain as bad as it can be</p>
<p>What was your pain level at its worst during the past week (circle the appropriate number)?</p> <p>No Pain 0 1 2 3 4 5 6 7 8 9 10 Pain as bad as it can be</p>

Figure 12. Instrumental Activities of Daily Living Scale (IADL)

A. Ability to use telephone

- 1. Operates telephone on own initiative; looks up and dials numbers, etc. 1
- 2. Dials a few well-known numbers 1
- 3. Answers telephone but does not dial 1
- 4. Does not use telephone at all. 0

B. Shopping

- 1. Takes care of all shopping needs independently 1
- 2. Shops independently for small purchases 0
- 3. Needs to be accompanied on any shopping trip. 0
- 4. Completely unable to shop. 0

C. Food Preparation

- 1. Plans, prepares and serves adequate meals independently 1
- 2. Prepares adequate meals if supplied with ingredients 0
- 3. Heats, serves and prepares meals or prepares meals but does not maintain adequate diet. 0
- 4. Needs to have meals prepared and served. 0

D. Housekeeping

- 1. Maintains house alone or with occasional assistance (e.g. "heavy work domestic help") 1
- 2. Performs light daily tasks such as dish-washing, bed making 1
- 3. Performs light daily tasks but cannot maintain acceptable level of cleanliness. 1
- 4. Needs help with all home maintenance tasks. 1
- 5. Does not participate in any housekeeping tasks. 0

E. Laundry

- 1. Does personal laundry completely 1
- 2. Launders small items; rinses stockings, etc. 1
- 3. All laundry must be done by others. 0

F. Mode of Transportation

- 1. Travels independently on public transportation or drives own car. 1
- 2. Arranges own travel via taxi, but does not otherwise use public transportation. 1
- 3. Travels on public transportation when accompanied by another. 1
- 4. Travel limited to taxi or automobile with assistance of another. 0
- 5. Does not travel at all. 0

G. Responsibility for own medications

- 1. Is responsible for taking medication in correct dosages at correct time. 1
- 2. Takes responsibility if medication is prepared in advance in separate dosage. 0
- 3. Is not capable of dispensing own medication. 0

H. Ability to Handle Finances

- 1. Manages financial matters independently (budgets, writes checks, pays rent, bills goes to bank), collects and keeps track of income. 1
- 2. Manages day-to-day purchases, but needs help with banking, major purchases, etc. 1
- 3. Incapable if handling money. 0

Lawton MP, Brody EM. Assessment of older people: Self-maintaining and instrumental activities of daily living. *Gerontologist*. 1969;9:179-86. ~~Permission to reprint still pending.~~

ACCEM draft.

PAIN SCREEN

Date ____/____/____

Resident Name _____ Age _____ Room _____

Diagnosis _____

Physician _____ Nurse _____

Objective: This interview will help to identify the level of pain education and history of the resident to provide optimal resident comfort in the process of easing, controlling and/or diminishing pain. The following documentation may be mutually established with the help of the resident, family members and staff. If the resident is *nonverbal*, ask a family member or significant other if they can answer any of the questions. If not, note "not able to obtain from resident or significant other."

Who Answered the following questions:

Resident Family Member (name) _____ Relationship to Resident: _____

RESIDENT INTERVIEW:

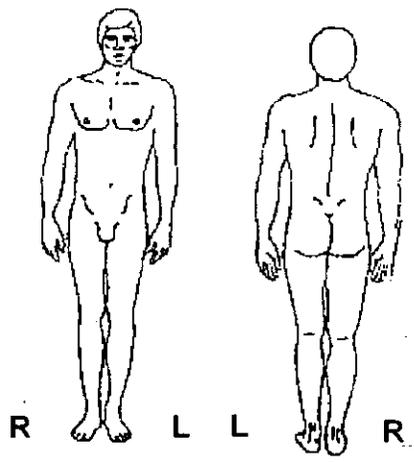
1. Do you have pain now? Yes No If yes, PAIN SCORE of _____ using: Wong-Baker Numerical FLACC
2. Do you ever have pain? Yes No If Yes, how often and where: _____
3. Within the last two weeks, have you taken any medications or treatments to control pain? Yes No If yes, list details: _____
4. Are you able to report your pain to the nurse? Yes No If No, why not: _____
5. Do you feel that it is normal to have pain? Yes No If No, why not: _____
6. Do you feel that all pain should be treated? Yes No If No, why not: _____
7. Do you have any cultural or religious beliefs that would influence the management of pain? Yes No
 If Yes, please explain: _____
8. How intense does your pain need to be to be treated? Rate on a Scale of 1—10 _____ Or, explain: _____
9. How have you treated your pain in the past? (Explain) (medications, other modalities): _____
10. Have you ever used alcohol to relieve your pain? Yes No
11. What drugs, legal or illegal, have you used in the past to relieve your pain? None List drugs: _____

INTERVIEWER OBSERVATIONS:

1. If the resident is not able to describe pain, please check below if there are any current *nonverbal* signs of pain:
 Moaning/Yelling Rocking Restless Movements Combative Grimacing Guarding Rubbing Area
 No Signs of pain Other: _____
2. EDUCATION: Resident educated to report pain to the nurse Family/significant other educated to report signs of resident's pain to the nurse Family/significant other not available at admission to discuss/educate re: pain management
3. OTHER OBSERVATIONS: _____

SECTION II—

INDICATE LOCATION OF PAIN:



PAIN SITE #1 - PAIN MANAGEMENT HISTORY AND RESIDENT GOALS:

1. What causes or increases the pain? _____
2. What medications and other methods have been used to relieve the pain? _____
3. How well have these medications and methods worked? _____
4. What is the resident's goal for pain management? Decrease pain Improved mobility Improved sleep
 Other: (explain) _____

PAIN SITE #2 - PAIN MANAGEMENT HISTORY AND RESIDENT GOALS:

1. What causes or increases the pain? _____
2. What medications and other methods have been used to relieve the pain? _____
3. How well have these medications and methods worked? _____
4. What is the resident's goal for pain management? Decrease pain Improved mobility Improved sleep
 Other: (explain) _____

OBSERVATIONS AND/OR COMMENTS:

1. **Accompanying symptoms associated with pain:** (Example: Nausea, Headache) _____
2. **Appetite:** No change Loss of appetite Difficult to sit and eat Other: (explain) _____
3. **Sleeping:** No change Difficult to sleep at night Other: (explain) _____
4. **Physical Activity:** No change Difficult to sit-up/get-up/walk Non-participation in favorite activity
 Other: (explain) _____
5. **Relationship to others:** No change Decrease in social action Totally withdrawn from friends, family, etc.
 Other: (explain) _____
6. **Concentration:** No change Loss of concentration Other: _____
7. **Emotions** (complacent, agitated or aggressive behavior, etc.) No change Emotional change (Explain): _____
8. **Personal Hygiene:** No change Unable to wash, dress or perform personal care Other: _____

Note: Information is to be used to formulate the Resident's Pain Treatment Plan. (Care Plan)

RN Signature _____

General Recommendations for Management of Chronic Non-Malignant Pain

General Recommendations for Management of Chronic Non-Malignant Pain

The general recommendations for the management of chronic non-malignant pain are outlined as follows:

- Establish a diagnosis and rule out serious causes of pain.
- Assess degree of distress and functional disability caused by pain (inquire about activities altered by pain such as work, home, leisure, ADL). Obtain pain ratings at the outset, and then at regular intervals to monitor progress. A suggestion is as follows:

My present pain is:

0	1	2	3	4	5
(No pain)	(mild)	(discomforting)	(distressing)	(horrible)	(excruciating)

My worst pain today was:

0	1	2	3	4	5
(No pain)	(mild)	(discomforting)	(distressing)	(horrible)	(excruciating)

My least pain today was:

0	1	2	3	4	5
(No pain)	(mild)	(discomforting)	(distressing)	(horrible)	(excruciating)

- Identify aggravating and relieving factors.
- Conduct a mental status examination to rule out depression, anxiety and other conditions that might contribute to pain.
- Take alcohol and drug history. In particular, inquire about alcohol, benzodiazepines, prescription opioids, over-the-counter drugs containing opioids like Tylenol #1 and 222s, barbiturates like Fiorinal, and illicit drugs such as cannabis and cocaine.
- Inquire about psychosocial history
- Obtain records from previous physicians in order to avoid delays and duplicate investigations

My present pain is:

0 1 2 3 4 5
(No pain) (mild) (discomforting) (distressing) (horrible) (excruciating)

My worst pain today was:

0 1 2 3 4 5
(No pain) (mild) (discomforting) (distressing) (horrible) (excruciating)

My least pain today was:

0 1 2 3 4 5
(No pain) (mild) (discomforting) (distressing) (horrible) (excruciating)

1K

PAIN RATING SCALE

Date _____ / _____ / _____

Resident Name _____ Age _____ Room _____

GENERAL INSTRUCTIONS: Choose only one appropriate scale based upon the resident's ability to respond. Identify the scale used and the score for that scale on the bottom of this form. *Any score above 0 requires a Pain Assessment.*

WONG-BAKER SCALE:

Initial Instructions: Explain to the resident that each face is for a person who feels happy because he or she has no pain (hurt) or sad because he or she has some or a lot of pain. **FACE 0** is happy because he or she doesn't hurt at all. **FACE 2** hurts just a little bit. **FACE 4** hurts a little more. **FACE 6** hurts even more. **FACE 8** hurts a whole lot. **FACE 10** hurts as much as you can imagine, although you don't have to be crying to feel this bad. Ask the resident to choose the face that best describes how he or she is feeling.

					
NO HURT	HURTS LITTLE BIT	HURTS LITTLE MORE	HURTS EVEN MORE	HURTS WHOLE LOT	HURTS WORST
0	2	4	6	8	10

NUMERIC SCALE: Choose a number from 0 to 10 that best describes the level of pain.

NO
PAIN

MILD PAIN,
ANNOYING
Pain is present
but does not
limit activity.

NAGGING PAIN,
UNCOMFORTABLE,
TROUBLESOME
Can do most
activities with
rest periods.

MISERABLE,
DISTRESSING
Unable to do
some activities
because of pain.

INTENSE,
DREADFUL,
HORRIBLE
Unable to do
most activities
because of pain.

WORST PAIN
POSSIBLE,
UNBEARABLE
Unable to do any
activities because
of pain.

0 1 2 3 4 5 6 7 8 9 10

FLACC SCALE:

Initial Instructions: The FLACC is a behavior pain assessment scale for use with nonverbal residents who are unable to provide reports of pain. Rate the resident in each of the five measurement categories, add the scores together, and document the total pain score.

FACE	0 No particular expression of smile.	1 Occasional grimace or frown, withdrawn, disinterested.	2 Frequent to constant frown, clenched jaw, quivering chin.
LEGS	0 Normal Position or relaxed.	1 Uneasy, restless, tense.	2 Kicking, or legs drawn up.
ACTIVITY	0 Lying quietly, normal position, moves easily.	1 Squirming, shifting back and forth, tense.	2 Arched, rigid, or jerking.
CRY	0 No crying (awake or asleep).	1 Moans or whimpers, occasional complaint	2 Crying steadily, screams or sobs, frequent complaints.
CONSOLABILITY	0 Content, relaxed.	1 Reassured by occasional touching, hugging, or "talking to." Distractible.	2 Difficult to console or comfort.

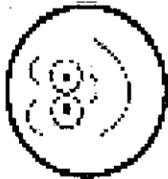
Scale Used: Wong-Baker Score: _____
 Numerical Score: _____
 FLACC Score: _____

Nurse Signature _____

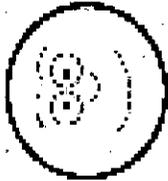
FK

WONG-BAKER SCALE:

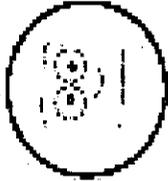
Initial Instructions: Explain to the resident that each face is for a person who feels happy because he or she has no pain (hurt) or sad because he or she has some or a lot of pain. **FACE 0** is happy because he or she doesn't hurt at all. **FACE 2** hurts just a little bit **FACE 4** hurts a little more. **FACE 6** hurts even more. **FACE 8** hurts a whole lot. **FACE 10** hurts as much as you can imagine, although you don't have to be crying to feel this bad. Ask the resident to choose the face that best describes how he or she is feeling.



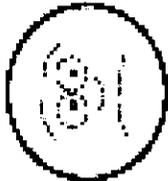
NO HURT
0



HURTS LITTLE BIT
2



HURTS LITTLE MORE
4



HURTS EVEN MORE
6



HURTS WHOLE LOT
8



HURTS WORST
10

NUMERIC SCALE: Choose a number from 0 to 10 that best describes the level of pain.

NO PAIN	MILD PAIN, ANNOYING Pain is present but does not limit activity.	NAGGING PAIN, UNCOMFORTABLE, TROUBLESOME Can do most activities with rest periods.	MISERABLE, DISTRESSING Unable to do some activities because of pain.	INTENSE, DREADFUL, HORRIBLE Unable to do most activities because of pain.	WORST PAIN POSSIBLE, UNBEARABLE Unable to do any activities because
---------	---	---	---	--	--

0 1 2 3 4 5 6 7 8 9 10

FLACC SCALE:

Initial Instructions: The FLACC is a behavior pain assessment scale for use with nonverbal residents who are unable to provide reports of pain. Rate the resident in each of the five measurement categories, add the scores together, and document the total pain score.

FACE	0 No particular expression of smile.	1 Occasional grimace or frown, withdrawn, disinterested.	2 Frequent to constant frown, clenched jaw, quivering chin.
LEGS	0 Normal Position or relaxed.	1 Uneasy, restless, tense.	2 Kicking, or legs drawn up.
ACTIVITY	0 Lying quietly, normal position, moves easily.	1 Squirming, shifting back and forth, tense.	2 Arched, rigid, or jerking.
CRY	0 No crying (awake or asleep).	1 Moans or whimpers, occasional complaint	2 Crying steadily, screams or sobs, frequent complaints.
CONSOLABILITY	0 Content, relaxed.	1 Reassured by occasional touching, hugging, or "talking to." Distractible.	2 Difficult to console or comfort.

General Instructions:

1. Choose only one appropriate scale based upon the resident's ability to respond.
2. Identify the scale used and the score for that scale on the other side of this form by using the following key:

WONG-BAKER SCALE

NUMERICAL SCALE

FLACC SCALE

Side 2 of 2
of Pain Management: Rating /
MEDICATION Administration Record



Screener and Opioid Assessment for Patients with Pain- Revised (SOAPP®-R)

The Screener and Opioid Assessment for Patients with Pain- Revised (SOAPP®-R) is a tool for clinicians to help determine how much monitoring a patient on long-term opioid therapy might require. This is an updated and revised version of SOAPP V.1 released in 2003.

Physicians remain reluctant to prescribe opioid medication because of concerns about addiction, misuse, and other aberrant medication-related behaviors, as well as liability and censure concerns. Despite recent findings suggesting that most patients are able to successfully remain on long-term opioid therapy without significant problems, physicians often express a lack of confidence in their ability to distinguish patients likely to have few problems on long-term opioid therapy from those requiring more monitoring.

SOAPP®-R is a quick and easy-to-use questionnaire designed to help providers evaluate the patients' relative risk for developing problems when placed on long-term opioid therapy. SOAPP®-R is:

- A brief paper and pencil questionnaire
- Developed based on expert consensus regarding important concepts likely to predict which patients will require more or less monitoring on long-term opioid therapy (content and face valid)
- Validated with 500 chronic pain patients
- Simple to score
- 24 items
- <10 minutes to complete
- Ideal for documenting decisions about the level of monitoring planned for a particular patient or justifying referrals to specialty pain clinic.
- The SOAPP®-R is for clinician use only. The tool is not meant for commercial distribution.
- The SOAPP®-R is **NOT** a lie detector. Patients determined to misrepresent themselves will still do so. Other clinical information should be used with SOAPP®-R scores to decide on a particular patient's treatment.
- The SOAPP®-R is **NOT** intended for all patients. The SOAPP®-R should be completed by chronic pain patients being considered for opioid therapy.
- It is important to remember that all chronic pain patients deserve treatment of their pain. Providers who are not comfortable treating certain patients should refer those patients to a specialist.

SOAPP®-R

The following are some questions given to patients who are on or being considered for medication for their pain. Please answer each question as honestly as possible. There are no right or wrong answers.

	Never	Seldom	Sometimes	Often	Very Often
	0	1	2	3	4
1. How often do you have mood swings?	<input type="radio"/>				
2. How often have you felt a need for higher doses of medication to treat your pain?	<input type="radio"/>				
3. How often have you felt impatient with your doctors?	<input type="radio"/>				
4. How often have you felt that things are just too overwhelming that you can't handle them?	<input type="radio"/>				
5. How often is there tension in the home?	<input type="radio"/>				
6. How often have you counted pain pills to see how many are remaining?	<input type="radio"/>				
7. How often have you been concerned that people will judge you for taking pain medication?	<input type="radio"/>				
8. How often do you feel bored?	<input type="radio"/>				
9. How often have you taken more pain medication than you were supposed to?	<input type="radio"/>				
10. How often have you worried about being left alone?	<input type="radio"/>				
11. How often have you felt a craving for medication?	<input type="radio"/>				
12. How often have others expressed concern over your use of medication?	<input type="radio"/>				
13. How often have any of your close friends had a problem with alcohol or drugs?	<input type="radio"/>				



	Never	Seldom	Sometimes	Often	Very Often
	0	1	2	3	4
14. How often have others told you that you had a bad temper?	<input type="radio"/>				
15. How often have you felt consumed by the need to get pain medication?	<input type="radio"/>				
16. How often have you run out of pain medication early?	<input type="radio"/>				
17. How often have others kept you from getting what you deserve?	<input type="radio"/>				
18. How often, in your lifetime, have you had legal problems or been arrested?	<input type="radio"/>				
19. How often have you attended an AA or NA meeting?	<input type="radio"/>				
20. How often have you been in an argument that was so out of control that someone got hurt?	<input type="radio"/>				
21. How often have you been sexually abused?	<input type="radio"/>				
22. How often have others suggested that you have a drug or alcohol problem?	<input type="radio"/>				
23. How often have you had to borrow pain medications from your family or friends?	<input type="radio"/>				
24. How often have you been treated for an alcohol or drug problem?	<input type="radio"/>				

Please include any additional information you wish about the above answers.
Thank you.



Scoring Instructions for the SOAPP®-R®

All 24 questions contained in the SOAPP®-R have been empirically identified as predicting aberrant medication-related behavior six months after initial testing.

To score the SOAPP, add the ratings of all the questions. A score of 18 or higher is considered positive.

Sum of Questions	SOAPP®-R Indication
> or = 18	+
< 18	-

What does the Cutoff Score Mean?

For any screening test, the results depend on what cutoff score is chosen. A score that is good at detecting patients at-risk will necessarily include a number of patients that are not really at risk. A score that is good at identifying those at low risk will, in turn, miss a number of patients at risk. A screening measure like the SOAPP®-R generally endeavors to minimize the chances of missing high-risk patients. This means that patients who are truly at low risk may still get a score above the cutoff. The table below presents several statistics that describe how effective the SOAPP®-R is at different cutoff values. These values suggest that the SOAPP®-R is a sensitive test. This confirms that the SOAPP®-R is better at identifying who is at high risk than identifying who is at low risk. Clinically, a score of 18 or higher will identify 81% of those who actually turn out to be at high risk. The Negative Predictive Values for a cutoff score of 18 is .87, which means that most people who have a negative SOAPP®-R are likely at low-risk. Finally, the Positive likelihood ratio suggests that a positive SOAPP®-R score (at a cutoff of 18) is nearly 4 times (3.80 times) as likely to come from someone who is actually at high risk (note that, of these statistics, the likelihood ratio is least affected by prevalence rates). All this implies that by using a cutoff score of 18 will ensure that the provider is least likely to miss someone who is really at high risk. However, one should remember that a low SOAPP®-R score suggests the patient is very likely at low-risk, while a high SOAPP®-R score will contain a larger percentage of false positives (about 30%); at the same time retaining a large percentage of true positives. This could be improved, so that a positive score has a lower false positive rate, but only at the risk of missing more of those who actually do show aberrant behavior.

SOAPP®-R Cutoff Score	Sensitivity	Specificity	Positive Predictive Value	Negative Predictive Value	Positive Likelihood Ratio	Negative Likelihood Ratio
Score 17 or above	.83	.65	.56	.88	2.38	.26
Score 18 or above	.81	.68	.57	.87	3.80	.29
Score 19 or above	.77	.75	.62	.86	3.03	.31



How does the SOAPP®-R help determine appropriate treatment?

The SOAPP®-R should only be one step in the assessment process to determine which patients are high-risk for opioid misuse. The following discussion examines the assessment and treatment options for chronic pain patients who are at risk (high risk or medium risk) and those who are likely not at risk.

Who is at a high risk for opioid misuse? (SOAPP®-R score = 22 or greater*)

Patients in this category are judged to be at a high risk for opioid misuse. These patients have indicated a history of behaviors or beliefs that are thought to place them at a higher risk for opioid misuse. Some examples of these behaviors or beliefs include a current or recent history of alcohol or drug abuse, being discharged from another physician's care because of his/her behavior, and regular noncompliance with physicians' orders. These patients may have misused other prescription medications in the past. It is a good idea to review the SOAPP®-R questions with the patient, especially those items the patient endorsed. This will help flesh out the clinical picture, so the provider can be in the best position to design an effective, workable treatment plan.

Careful and thoughtful planning will be necessary for patients in this category. Some patients in this category are probably best suited for other therapies or need to exhaust other interventions prior to entering a treatment plan that includes chronic opioid therapy. Others may need to have psychological or psychiatric treatment prior to or concomitant with any treatment involving opioids. Patients in this category who receive opioid therapy should be required to follow a strict protocol, such as regular urine drug screens, opioid compliance checklists, and counseling.

Specific treatment considerations for patients in this high-risk category:

- Past medical records should be obtained and contact with previous and current providers should be maintained.
- Patients should also be told that they would be expected to initially give a urine sample for a toxicology screen during every clinic visit. They should also initially be given medication for limited periods of time (e.g., every 2-weeks).
- Ideally, family members should be interviewed and involvement with an addiction medicine specialist and/or mental health professional should be sought.
- Less abusable formulations should be considered (e.g., long-acting versus short-acting opioids, transdermal versus oral preparation, tamper-resistant medications).
- Early signs of aberrant behavior and a violation of the opioid agreement should result in a change in treatment plan. Depending on the degree of violation, one might consider more restricted monitoring, or, if resources are limited, referring the patient to a program where opioids can be prescribed under stricter conditions. If violations or aberrant behaviors persist, it may be necessary to discontinue opioid therapy.

** Note these are general ranges. Clinicians should also complement SOAPP scores with other clinical data such as urine screens and psychological evaluations.*



Who is at a moderate risk for opioid misuse? (SOAPP®-R score = 10 to 21*)

Patients in this category are judged to be at a medium or moderate risk for opioid misuse. These patients have indicated a history of behaviors or beliefs that are thought to place them at some risk for misuse. Some examples of these behaviors or beliefs are family history of drug abuse, history of psychological issues such as depression or anxiety, a strong belief that medications are the only treatments that will reduce pain and a history of noncompliance with other prescription medications. It is a good idea to review the SOAPP®-R items the patient endorsed with the patient present.

Some of these patients are probably best treated by concomitant psychological interventions in which they can learn to increase their pain-coping skills, decrease depression and anxiety, and have more frequent monitoring of their compliance. They may need to be closely monitored until proven reliable by not running out of their medications early and having appropriate urine drug screens.

Additional treatment considerations for patients in this category:

- Periodic urine screens are recommended.
- After a period in which no signs of aberrant behavior are observed, less frequent clinic visits may be indicated. If there are any violations of the opioid agreement, then regular urine screens and frequent clinic visits would be recommended.
- After two or more violations of the opioid agreement, an assessment by an addiction medicine specialist and/or mental health professional should be mandated.
- After repeat violations referral to a substance abuse program would be recommended. A recurrent history of violations would also be grounds for tapering and discontinuing opioid therapy

** Note these are general ranges. Clinicians should also complement SOAPP scores with other clinical data such as urine screens and psychological evaluations.*

Who is at a low risk for opioid misuse? (SOAPP®-R score < 9*)

Patients in this category are judged to be at a low risk for opioid misuse. These patients have likely tried and been compliant with many other types of therapies. They should be able to handle their medication safely with *minimal monitoring*. They are apt to be responsible in their use of alcohol, not smoke cigarettes, and have no history of previous difficulties with alcohol, prescription drugs, or illegal substances. This patient probably reports few symptoms of affective distress, such as depression or anxiety.

As noted previously, the SOAPP®-R is not a lie detector. The provider should be alert to inconsistencies in the patient report or a collateral report. Any sense that the patient's story "doesn't add up" should lead the provider to take a more cautious approach until experience suggests that the person is reliable.

Patients in this category would be likely to have no violations of the opioid treatment agreement. These patients are least likely to develop a substance abuse disorder. Additionally, they may not require special monitoring or concomitant psychological treatment.

Additional treatment considerations for patients in this category:

- Review of SOAPP®-R questions is not necessary, unless the provider is aware of inconsistencies or other anomaly in patient history/report.

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The Screener and Opioid Assessment for Patients with Pain was developed with a grant from the National Institutes of Health (#2R44DA015617-02)

- Frequent urine screens are not indicated.
- Less worry is needed about the type of opioid to be prescribed and the frequency of clinic visits.
- Efficacy of opioid therapy should be re-assessed every six months, and urine toxicology screens and update of the opioid therapy agreement would be recommended annually.

** Note these are general ranges. Clinicians should also complement SOAPP scores with other clinical data such as urine screens and psychological evaluations.*



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Current Opioid Misuse Measure (COMM)

The Current Opioid Misuse Measure (COMM) is a brief patient self-assessment to monitor chronic pain patients on opioid therapy. The COMM was developed with guidance from a group of pain and addiction experts and input from pain management clinicians in the field. Experts and providers identified six key issues to determine if patients already on long-term opioid treatment are exhibiting aberrant medication-related behaviors:

- *Signs & Symptoms of Intoxication*
- *Emotional Volatility*
- *Evidence of Poor Response to Medications*
- *Addiction*
- *Healthcare Use Patterns*
- *Problematic Medication Behavior*

The COMM will help clinicians identify whether a patient, currently on long-term opioid therapy, may be exhibiting aberrant behaviors associated with misuse of opioid medications. In contrast, the Screener and Opioid Assessment for Patients with Pain (SOAPP) is intended to predict which patients, being considered for long-term opioid therapy, may exhibit aberrant medications behaviors in the future. Since the COMM examines concurrent misuse, it is ideal for helping clinicians monitor patients' aberrant medication-related behaviors over the course of treatment. The COMM is:

- A quick and easy to administer patient-self assessment
- 17 items
- Simple to score
- Completed in less than 10 minutes
- Validated with a group of approximately 500 chronic pain patients on opioid therapy
- Ideal for documenting decisions about the level of monitoring planned for a particular patient or justifying referrals to specialty pain clinic.
- The COMM is for clinician use only. The tool is not meant for commercial distribution.
- The COMM is **NOT** a lie detector. Patients determined to misrepresent themselves will still do so. Other clinical information should be used with COMM scores to decide if and when modifications to particular patient's treatment plan is needed.
- It is important to remember that all chronic pain patients deserve treatment of their pain. Providers who are not comfortable treating certain patients should refer those patients to a specialist.



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COMM

Please answer each question as honestly as possible. Keep in mind that we are only asking about the **past 30 days**. There are no right or wrong answers. If you are unsure about how to answer the question, please give the best answer you can.

Please answer the questions using the following scale:	Never	Seldom	Sometimes	Often	Very Often
	0	1	2	3	4
1. In the past 30 days, how often have you had trouble with thinking clearly or had memory problems?	○	○	○	○	○
2. In the past 30 days, how often do people complain that you are not completing necessary tasks? (i.e., doing things that need to be done, such as going to class, work or appointments)	○	○	○	○	○
3. In the past 30 days, how often have you had to go to someone other than your prescribing physician to get sufficient pain relief from medications? (i.e., another doctor, the Emergency Room, friends, street sources)	○	○	○	○	○
4. In the past 30 days, how often have you taken your medications differently from how they are prescribed?	○	○	○	○	○
5. In the past 30 days, how often have you seriously thought about hurting yourself?	○	○	○	○	○
6. In the past 30 days, how much of your time was spent thinking about opioid medications (having enough, taking them, dosing schedule, etc.)?	○	○	○	○	○
7. In the past 30 days, how often have you been in an argument?	○	○	○	○	○
8. In the past 30 days, how often have you had trouble controlling your anger (e.g., road rage, screaming, etc.)?	○	○	○	○	○
9. In the past 30 days, how often have you needed to take pain medications belonging to someone else?	○	○	○	○	○



Please answer the questions using the following scale:	Never	Seldom	Sometimes	Often	Very Often
	0	1	2	3	4
10. In the past 30 days, how often have you been worried about how you're handling your medications?	○	○	○	○	○
11. In the past 30 days, how often have others been worried about how you're handling your medications?	○	○	○	○	○
12. In the past 30 days, how often have you had to make an emergency phone call or show up at the clinic without an appointment?	○	○	○	○	○
13. In the past 30 days, how often have you gotten angry with people?	○	○	○	○	○
14. In the past 30 days, how often have you had to take more of your medication than prescribed?	○	○	○	○	○
15. In the past 30 days, how often have you borrowed pain medication from someone else?	○	○	○	○	○
16. In the past 30 days, how often have you used your pain medicine for symptoms other than for pain (e.g., to help you sleep, improve your mood, or relieve stress)?	○	○	○	○	○
17. In the past 30 days, how often have you had to visit the Emergency Room?	○	○	○	○	○



Scoring Instructions for the COMM

To score the COMM, simply add the rating of all the questions. A score of 9 or higher is considered a positive

Sum of Questions	COMM Indication
> or = 9	+
< 9	-

As for any scale, the results depend on what cutoff score is chosen. A score that is sensitive in detecting patients who are abusing or misusing their opioid medication will necessarily include a number of patients that are not really abusing or misusing their medication. The COMM was intended to over-identify misuse, rather than to mislabel someone as responsible when they are not. This is why a low cut-off score was accepted. We believe that it is more important to identify patients who have only a possibility of misusing their medications than to fail to identify those who are actually abusing their medication. Thus, it is possible that the COMM will result in false positives – patients identified as misusing their medication when they were not.

The table below presents several statistics that describe how effective the COMM is at different cutoff values. These values suggest that the COMM is a sensitive test. This confirms that the COMM is better at identifying who is misusing their medication than identifying who is not misusing. Clinically, a score of 9 or higher will identify 77% of those who actually turn out to be at high risk. The Negative Predictive Values for a cutoff score of 9 is .95, which means that most people who have a negative COMM are likely not misusing their medication. Finally, the Positive likelihood ratio suggests that a positive COMM score (at a cutoff of 9) is nearly 3 times (3.48 times) as likely to come from someone who is actually misusing their medication (note that, of these statistics, the likelihood ratio is least affected by prevalence rates). All this implies that by using a cutoff score of 9 will ensure that the provider is least likely to miss someone who is really misusing their prescription opioids. However, one should remember that a low COMM score suggests the patient is really at low-risk, while a high COMM score will contain a larger percentage of false positives (about 34%), while at the same time retaining a large percentage of true positives. This could be improved, so that a positive score has a lower false positive rate, but only at the risk of missing more of those who actually do show aberrant behavior.

COMM Cutoff Score	Sensitivity	Specificity	Positive Predictive Value	Negative Predictive Value	Positive Likelihood Ratio	Negative Likelihood Ratio
Score 9 or above	.77	.66	.66	.95	3.48	.08



Date _____

Patient Name _____

OPIOID RISK TOOL

		Mark each box that applies	Item Score If Female	Item Score If Male
1. Family History of Substance Abuse	Alcohol	[]	1	3
	Illegal Drugs	[]	2	3
	Prescription Drugs	[]	4	4
2. Personal History of Substance Abuse	Alcohol	[]	3	3
	Illegal Drugs	[]	4	4
	Prescription Drugs	[]	5	5
3. Age (Mark box if 16 – 45)		[]	1	1
4. History of Preadolescent Sexual Abuse		[]	3	0
5. Psychological Disease	Attention Deficit Disorder	[]	2	2
	Obsessive Compulsive Disorder			
	Bipolar Schizophrenia			
	Depression	[]	1	1
TOTAL		[]		

Total Score Risk Category. Low Risk 0 – 3 Moderate Risk 4 – 7 High Risk ≥ 8

Box V:2. The CAGE-AID Questionnaire:

Adapted from the CAGE alcohol-screening tool to include drugs.

In the past have you ever:

1. Tried to Cut down or Change your pattern of drinking or drug abuse?
2. Been Annoyed or Angry by others' concern about your drinking or drug use?
3. Felt Guilty about the consequences of your drinking or drug use?
4. Had a drink or used a drug in the morning (Eye-opener) to decrease hangover or withdrawal symptoms?

Implications for prescribing:

- One positive response to any question suggests caution.
- Two or more positive responses may have a sensitivity of 60%-95% and specificity of 40%-95% for diagnosing alcohol or drug problems. Strongly suggest assessment by an addiction specialist before opioids are prescribed
- CAGE screen may have less predictive value in the elderly, college students, women and certain ethnic groups.

Box V:3. TICS: A Two-Item Conjoint Screen:

- 1) In the last year, have you ever drunk or used drugs more than you meant to?
- 2) Have you felt you wanted or needed to cut down on your drinking or drug use in the last year?

In primary care patients, at least one affirmative answer to these two questions yielded nearly 80 percent sensitivity and specificity.

Box V:4. The Drug Abuse Screening Test (DAST):

The following questions concern information about your involvement and abuse of drugs.

Drug abuse refers to:

- (1) The use of prescribed or "over-the-counter" drugs in excess of the directions.
- (2) Any non-medical use of drugs.

The questions DO NOT include alcoholic beverages.

The questions refer to the past 12 months. Carefully read each statement and decide whether your answer is yes or no. Please give the best answer or the answer that is right most of the time. Click on the box for Yes or No.

1. Have you used drugs other than those required for medical reasons?	<input type="checkbox"/> Yes <input type="checkbox"/> No
2. Have you abused prescription drugs?	<input type="checkbox"/> Yes <input type="checkbox"/> No
3. Do you abuse more than one drug at a time?	<input type="checkbox"/> Yes <input type="checkbox"/> No
4. Can you get through the week without using drugs?	<input type="checkbox"/> Yes <input type="checkbox"/> No
5. Are you always able to stop using drugs when you want to?	<input type="checkbox"/> Yes <input type="checkbox"/> No
6. Have you had "blackouts" or "flashbacks" as a result of drug use?	<input type="checkbox"/> Yes <input type="checkbox"/> No
7. Do you ever feel bad or guilty about your drug use?	<input type="checkbox"/> Yes <input type="checkbox"/> No
8. Does your spouse (or parents) ever complain about your involvement with drugs?	<input type="checkbox"/> Yes <input type="checkbox"/> No

<p>9. Has drug abuse created problems between you and your spouse or your parents?</p>	<input type="checkbox"/> Yes <input type="checkbox"/> No
<p>10. Have you lost friends because of your use of drugs?</p>	<input type="checkbox"/> Yes <input type="checkbox"/> No
<p>11. Have you neglected your family because of your use of drugs?</p>	<input type="checkbox"/> Yes <input type="checkbox"/> No
<p>12. Have you been in trouble at work because of your use of drugs?</p>	<input type="checkbox"/> Yes <input type="checkbox"/> No
<p>13. Have you lost a job because of drug abuse?</p>	<input type="checkbox"/> Yes <input type="checkbox"/> No
<p>14. Have you gotten into fights when under the influence of drugs?</p>	<input type="checkbox"/> Yes <input type="checkbox"/> No
<p>15. Have you engaged in illegal activities in order to obtain drugs?</p>	<input type="checkbox"/> Yes <input type="checkbox"/> No
<p>16. Have you been arrested for possession of illegal drugs?</p>	<input type="checkbox"/> Yes <input type="checkbox"/> No
<p>17. Have you ever experienced withdrawal symptoms (felt sick) when you stopped taking drugs?</p>	<input type="checkbox"/> Yes <input type="checkbox"/> No
<p>18. Have you had medical problems as a result of your drug use (e.g., memory loss, hepatitis, convulsions, bleeding, etc.)?</p>	<input type="checkbox"/> Yes <input type="checkbox"/> No
<p>19. Have you gone to anyone for help for a drug problem?</p>	<input type="checkbox"/> Yes <input type="checkbox"/> No
<p>20. Have you been involved in a treatment program especially related to drug use?</p>	<input type="checkbox"/> Yes <input type="checkbox"/> No

Box V:5. RAFFT:

- R: Do you drink/drug to relax, feel better about yourself or fit in?
A: Do you ever drink/drug while you are by yourself, alone?
F: Do any of your closest friends drink/drug?
F: Does a close family member have a problem with alcohol/drugs?
T: Have you ever gotten into trouble from drinking/drugging?

Three affirmative responses constitute a positive score. This test detected a larger number of false positives in an adult sample than in adolescents.

Box V:6. Severity of Opiate Dependence Scale (SODO):

NAME _____ AGE _____ SEX _____

First of all, we would like you to recall a month when you were using opiates heavily in a way that, for you, was fairly typical of a heavy use period. Please fill in the month and the year.

MONTH _____ YEAR _____

Answer every question by circling one response only

1. On waking, and before my first dose of opiates:

a. My body feels stiff:
NEVER OR SOMETIMES OFTEN ALWAYS OR
ALMOST NEVER NEARLY ALWAYS

b. I get stomach cramps:
NEVER OR SOMETIMES OFTEN ALWAYS OR
ALMOST NEVER NEARLY ALWAYS

c. I feel sick:
NEVER OR SOMETIMES OFTEN ALWAYS OR
ALMOST NEVER NEARLY ALWAYS

d. I notice my heart pounding:
NEVER OR SOMETIMES OFTEN ALWAYS OR
ALMOST NEVER NEARLY ALWAYS

e. I have hot and cold flushes:
NEVER OR SOMETIMES OFTEN ALWAYS OR
ALMOST NEVER NEARLY ALWAYS

f. I feel miserable or depressed:
NEVER OR SOMETIMES OFTEN ALWAYS OR
ALMOST NEVER NEARLY ALWAYS

g. I feel tense or panicky:
NEVER OR SOMETIMES OFTEN ALWAYS OR
ALMOST NEVER NEARLY ALWAYS

h. I feel irritable or angry:
NEVER OR SOMETIMES OFTEN ALWAYS OR
ALMOST NEVER NEARLY ALWAYS

i. I feel restless or unable to relax:
NEVER OR SOMETIMES OFTEN ALWAYS OR
ALMOST NEVER NEARLY ALWAYS

j. I have a strong craving:
NEVER OR SOMETIMES OFTEN ALWAYS OR
ALMOST NEVER NEARLY ALWAYS

2. Please complete all sections (a-f) of this question:

a. I try to save some opiates to use on waking:
NEVER OR SOMETIMES OFTEN ALWAYS OR

ALMOST NEVER NEARLY ALWAYS

b. I like to take my first dose of opiates within two hours of waking up:

NEVER OR SOMETIMES OFTEN ALWAYS OR

ALMOST NEVER NEARLY ALWAYS

c. In the morning, I use opiates to stop myself feeling sick:

NEVER OR SOMETIMES OFTEN ALWAYS OR

ALMOST NEVER NEARLY ALWAYS

d. The first thing I feel like doing when I wake up is to take some opiates:

NEVER OR SOMETIMES OFTEN ALWAYS OR

ALMOST NEVER NEARLY ALWAYS

e. When I wake up I take opiates to stop myself aching or feeling stiff:

NEVER OR SOMETIMES OFTEN ALWAYS OR

ALMOST NEVER NEARLY ALWAYS

f. The first thing I do after waking up is to take some opiates:

NEVER OR SOMETIMES OFTEN ALWAYS OR

ALMOST NEVER NEARLY ALWAYS

3. Please think of your opiate use during a typical period of drug taking for these Questions:

a. Did you think your opiate use was out of control?

NEVER OR SOMETIMES OFTEN ALWAYS OR

ALMOST NEVER NEARLY ALWAYS

b. Did the prospect of missing a fix (or dose) make you very anxious or worried?

NEVER OR SOMETIMES OFTEN ALWAYS OR

ALMOST NEVER NEARLY ALWAYS

c. Did you worry about your opiate use?

NEVER OR SOMETIMES OFTEN ALWAYS OR

ALMOST NEVER NEARLY ALWAYS

d. Did you wish you could stop?

NEVER OR SOMETIMES OFTEN ALWAYS OR

ALMOST NEVER NEARLY ALWAYS

e. How difficult would you find it to stop or go without?

IMPOSSIBLE VERY QUITE NOT DIFFICULT

Scoring

Answers to each question are rated on a four-point scale. A score indicative of dependence has not yet been developed.

Box V:7. Prescription Drug Use Questionnaire (PDUQ) :

Evaluation of the Pain Condition:

1. Does the patient have more than one painful condition (i.e., chronic back pain complicated by acute migraines or frequent dental work)?
2. Is the patient disabled by pain (i.e., unable to complete social or vocational activities of daily living)?
3. Is the patient receiving disability (i.e., SSI, worker comp.)?
4. Is the patient involved in litigation around the pain-precipitating incident?
5. Has the patient explored and/or tried nonopioid or nonpharmacological pain management techniques (i.e., physical therapy, TENS unit, relaxation, biofeedback) to manage pain?
6. Does the patient believe that his/her pain has been adequately treated over the past 6 months?
7. Does the patient express anger/mistrust of past health care providers?
8. Does the patient believe that he/she is addicted to opioid analgesics?
9. Does the referring physician believe that the patient is addicted to opioid analgesics?

Opioid Use Patterns:

- 9a. How long has the patient been on continuous opioids?
10. Does the patient have more than one prescription provider (including dentists, ER physicians)?
11. Is there a pattern of the patient increasing prescribed analgesic doses or frequency?
12. Is there a pattern of the patient calling in for early prescription refills?
13. Does the patient report using analgesics for symptoms other than those prescribed for (i.e., insomnia, anxiety, depression)?
14. Does the patient save/hoard unused medication or have partially unused bottles of medication at home?

15. Does the patient report supplementing analgesics with alcohol or other psychoactive drugs (i.e., Soma, benzodiazepines)?

15a. If yes, please list:

16. Has the patient ever forged a prescription?

17. Is there a pattern of the patient reporting losing his/her medication?

18. Does the patient have preferences for specific analgesics and/or routes of administration (i.e., IV, IM routes over oral)?

19. Is there a pattern of the patient making emergency room visits for analgesics?

20. Has the patient ever obtained analgesic from nonmedical (street) sources?

21. Has any M.D./D.D.S. limited care, expressed concern, or refused to prescribe opioid analgesics because of patient's opioid use patterns?

Social/Family Factors:

22. Have family members expressed concern that the patient is addicted?

23. Are family members concerned about opioid analgesic side effects or tolerance?

24. Is there a pattern of family interaction that sustains the patient's opioid analgesic use? (i.e., family member overly concerned re: pain or withdrawal)

25. Is there a pattern of family interaction that sustains the patient's illness behavior or pain symptoms? (i.e., family member assuming caretaker role)

26. Does the spouse/significant other have a history of alcoholism/drug abuse/drug misuse?

27. Has a family member or friend ever obtained analgesic for the patient?

28. Has the patient ever taken analgesics prescribed for a friend or family member?

29. Does a family member or friend have access (either legal or illegal) to opioid analgesics (i.e., a family member in the medical profession)

Family History:

30. Is there a positive history of addiction (to any drug including alcohol) in the patient's mother, father, sibling or blood relative?

31. Is there a positive family history of chronic pain in the patient's mother, father, sibling or blood relative?

Patient History of Substance Abuse:

32. Did intoxication play a role in pain-precipitating incident?

33. Has the patient ever been diagnosed with addiction to any drug or alcohol?

34. Does the patient have a drug or alcohol treatment history?

35. Has opioid analgesic detoxification been previously attempted?

Psychiatric History:

36. Has the patient ever been diagnosed with a psychiatric disorder?

37. Did psychiatric symptoms precede onset of pain?

38. Is there a large psychological component to the pain condition, other than those related to addiction (i.e., multiple psychological stressors)

39. Is there evidence of a somatoform disorder?

40. Does the patient report a history of sexual or physical abuse?

41. Does the patient currently meet DSM-IV criteria for any Axis I, II or III conditions?

41a. If so, please list diagnoses:

42. Please list all pain-producing medical conditions:

Box V:9. SOAPP Version 1.0:

Name: _____ Date: _____

The following are some questions given to all patients at the Pain Management Center who are on or being considered for opioids for their pain. Please answer each question as honestly as possible. This information is for our records and will remain confidential. Your answers alone will not determine your treatment. Thank you.

Please answer the questions below using the following scale:

0 = Never, 1 = Seldom, 2 = Sometimes, 3 = Often, 4 = Very Often

1. How often do you feel that your pain is "out of control?" 0 1 2 3 4
2. How often do you have mood swings? 0 1 2 3 4
3. How often do you do things that you later regret? 0 1 2 3 4
4. How often has your family been supportive and encouraging? 0 1 2 3 4
5. How often have others told you that you have a bad temper? 0 1 2 3 4
6. Compared with other people, how often have you been in a car accident? 0 1 2 3 4
7. How often do you smoke a cigarette within an hour after you wake up? 0 1 2 3 4
8. How often have felt a need for higher doses of medication to treat your pain?
0 1 2 3 4
9. How often do you take more medication than you are supposed to? 0 1 2 3 4
10. How often have any of your family members, including parents and grandparents, had a problem with alcohol or drugs? 0 1 2 3 4
11. How often have any of your close friends had a problem with alcohol or drugs? 0
1 2 3 4
12. How often have others suggested that you have a drug or alcohol problem? 0 1 2 3
4
13. How often have you attended an AA or NA meeting? 0 1 2 3 4

- 14. How often have you had a problem getting along with the doctors who prescribed your medicines? 0 1 2 3 4
- 15. How often have you taken medication other than the way that it was prescribed? 0 1 2 3 4
- 16. How often have you been seen by a psychiatrist or a mental health counselor? 0 1 2 3 4
- 17. How often have you been treated for an alcohol or drug problem? 0 1 2 3 4
- 18. How often have your medications been lost or stolen? 0 1 2 3 4
- 19. How often have others expressed concern over your use of medication? 0 1 2 3 4
- 20. How often have you felt a craving for medication? 0 1 2 3 4
- 21. How often has more than one doctor prescribed pain medication for you at the same time? 0 1 2 3 4
- 22. How often have you been asked to give a urine screen for substance abuse? 0 1 2 3 4
- 23. How often have you used illegal drugs (for example, marijuana, cocaine, etc.) in the past five years? 0 1 2 3 4
- 24. How often, in your lifetime, have you had legal problems or been arrested? 0 1 2 3 4

Of the 24 questions contained in the SOAPP version 1.0, 16 have been identified as empirically predicting aberrant behavior six months after initial testing.

To score the SOAPP, ratings of the following questions are added:

2, 6, 7, 10, 11, 12, 13, 14, 15, 17, 18, 19, 20, 22, 23, 24

A score of 7 or higher is considered positive.

Information on the SOAPP is available at <http://www.painedu.org/soap-development.asp>.

Box V:10. Screening Instrument For Substance Abuse Potential (SISAP):

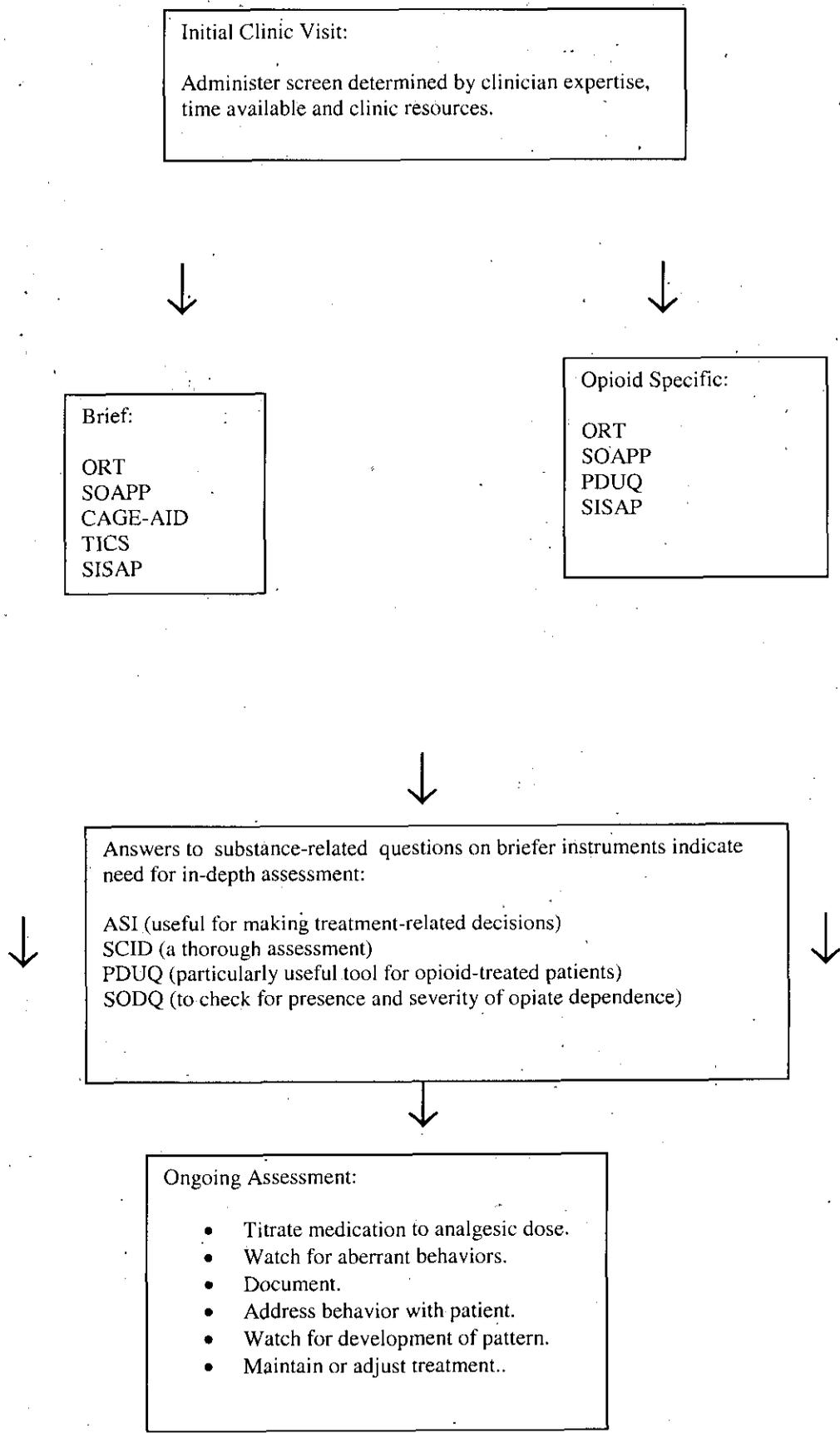
1. If you drink alcohol, how many drinks do you have on a typical day?
2. How many drinks do you have in a typical week?
3. Have you used marijuana or hashish in the past year?
4. Have you ever smoked cigarettes?
5. What is your age?

Interpretation of SISAP results.

Use caution when prescribing opioids for the following patients:

1. Men who consume five or more drinks per day or 17 or more drinks per week.
2. Women who consume four or more drinks per day or 13 or more drinks per week
3. A patient who admits to marijuana or hashish use in the past year.
4. A patient under 40 who smokes.

Box V:11. Protocol to Assess Patients for Risk of Opioid Abuse:



What To Do if Opioid Abuse or Dependence Is Suspected

People diagnosed with either substance abuse or dependence can be effectively treated for pain—even with opioids—provided their substance use disorder is addressed (Passik and Kirsh 2004). Healthcare providers who are treating patients for pain who are known to be or suspected of being psychologically dependent on opioids or other drugs should follow these guidelines to promote effective pain management treatment:

- **Immediately address the substance use problem** (Passik and Kirsh 2004, 2005; Weaver and Schnoll 2002).
- **Increase monitoring.** Initiate more frequent visits, and limit the amount of medication available at one time (Coluzzi and Pappagallo 2005; Jones et al. 2003; Lussier and Pappagallo 2004; Passik and Kirsh 2004; Savage 2002; Weaver and Schnoll 2002). Random urine drug tests detect the presence of illicit drugs or substances not prescribed for pain management and verify that the patient is taking the prescribed opioid instead of selling it (Coluzzi and Pappagallo 2005; Lussier and Pappagallo 2004; Passik and Kirsh 2004; Weaver and Schnoll 2002).
- **Include treatment for substance dependence in the pain management plan.** Refer to a certified substance abuse treatment provider, initiate appropriate medication-assisted treatment, and/or encourage participation in 12-Step programs (Compton and Athanasos 2003; Passik and Kirsh 2004; Savage 2002; Weaver and Schnoll 2002). With the patient's permission, consult and coordinate with the designated substance abuse treatment provider on an ongoing basis (Compton and Athanasos 2003; Jones et al. 2003; Lussier and Pappagallo 2004; Savage 2002; Weaver and Schnoll 2002).
- **Discontinue opioid treatment when warranted.** Providing opioid analgesia to patients who are psychologically dependent does not necessarily worsen their dependence, nor will withholding opioids increase their likelihood of recovery (Alford et al. 2006; Compton and Athanasos 2003). However, unrelieved pain can trigger relapse (Alford et al. 2006; Compton and Athanasos 2003; Gourlay et al. 2005). Opioid therapy should be discontinued if more serious problems occur, such as prescription forgery, diversion of opioids, or continued inappropriate opioid use (Coluzzi and Pappagallo 2005; Lussier and Pappagallo 2004; Weaver and Schnoll 2002). If discontinuation is called for, the opioid dosage should be tapered to avoid withdrawal symptoms and other forms of nonopioid pain treatment should be offered (Weaver and Schnoll 2002).

How To Talk to Patients With Pain About Substance Use Problems

- Be nonjudgmental—patients are more likely to be forthcoming.
- Start with sweeping questions (e.g., “How helpful have your medications been for you?”) rather than begin with questions about medication misuse.
- Avoid yes/no questions that do not allow patients to express their feelings.
- Ask questions about warning signs (e.g., “Have you ever taken your pain medication for other reasons?”).
- Listen to what patients says about how and why they take their medications.
- Inquire about their willingness to try alternative, nonopioid forms of pain therapy.
- Use existing tools such as the screening instruments discussed above.

Source: Passik and Kirsh 2005.

Table 7 Alcohol and pain: important considerations

- Use of alcohol can increase in response to distress related to chronic pain
- Problems with alcohol intoxication including carelessness with other medication and accidents
- Alcohol related physical comorbidity
- Interactions between alcohol and other drugs
- Risk of respiratory depression (high risk when alcohol, opioids and benzodiazepines used chaotically)
- Use of alcohol correlates with depression and anxiety compounding distress from pain
- Alcohol reduces quality of sleep compounding distress from pain

Table 3

Aberrant drug related behaviour

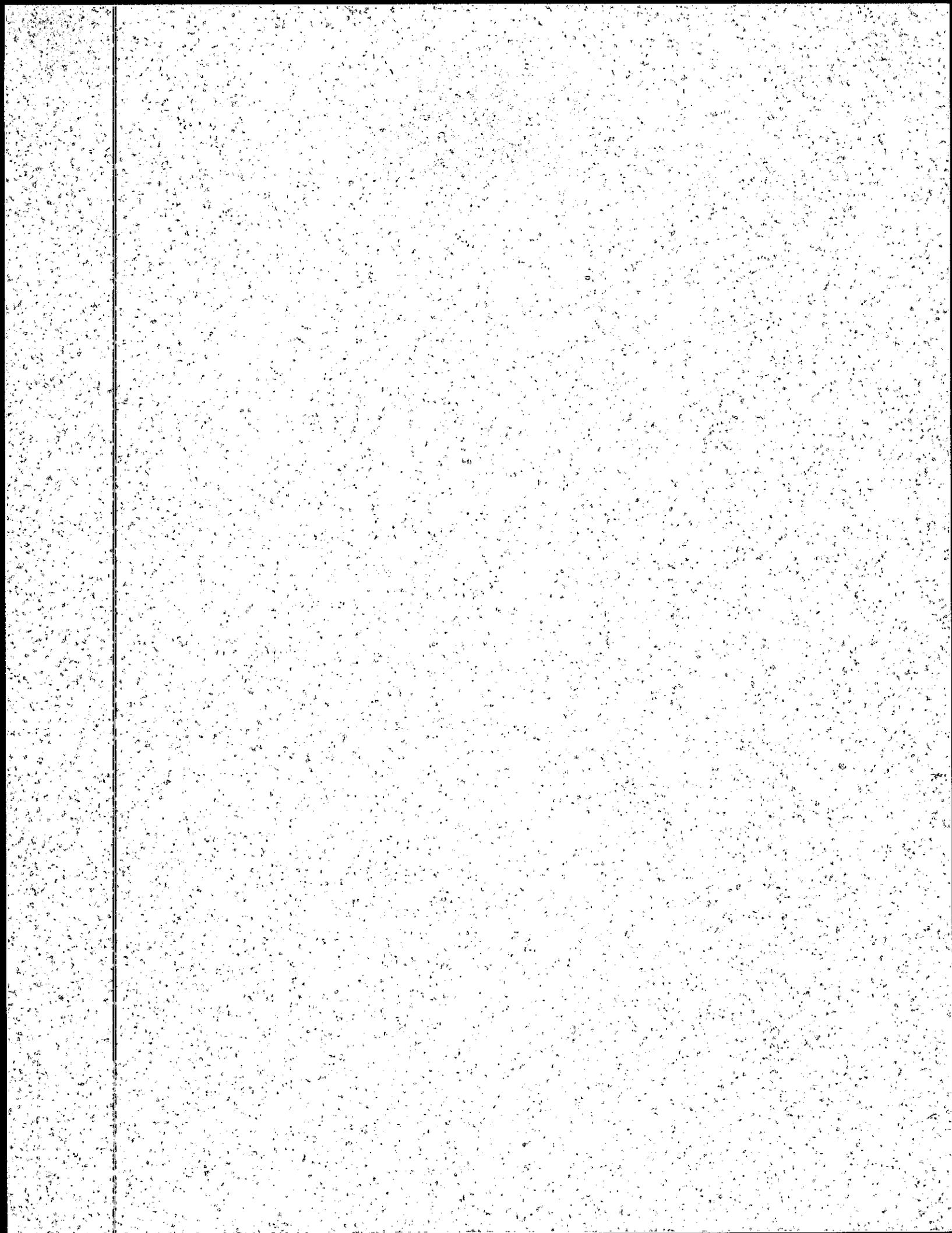
More predictive features	Less predictive features
Selling prescription drugs	Aggressive complaining about the need for
Prescription forgery	more drug
Stealing or borrowing drugs from others	Drug hoarding during periods of reduced symptoms
Injecting oral formulations	Requesting specific drugs
Obtaining prescription drugs from non medical sources	Openly acquiring similar drugs from other medical sources
Concurrent abuse of alcohol or illicit drugs	Unsanctioned dose escalation
Multiple non sanctioned dose escalations	Unapproved use of the drug to treat other symptoms
Multiple episodes of prescription loss	
Repeatedly seeking prescriptions from other physicians or emergency departments without informing the prescriber or after warnings to desist	
Evidence of deterioration in function, at work, in the family, or socially that appear to be drug related	
Repeated resistance to therapy changes despite clear evidence of adverse physical or psychological effects from the drug	

Handwritten notes at the bottom of the page, possibly a signature or additional comments.

Table 2
PATIENTS IDEALLY REFERRED TO A MULTIDISCIPLINARY PAIN MANAGEMENT CENTRE BEFORE OPIOIDS COMMENCED
<ol style="list-style-type: none">1. History of previous drug addiction2. Previous opiate use resulting in problems3. Psychologically unstable4. Young patients with obscure pathology5. Complex compensable patients

Table 6 Features of presentation that may alert practitioner to the possibility of substance misuse

- Cutaneous signs of drug abuse - skin tracks and related scars on the neck, axilla, groin, neck, forearm, wrist, foot and ankle. Such marks are usually multiple, hyper-pigmented and linear. New lesions may be inflamed. Shows signs of "pop" scars from subcutaneous injections.
- Being assertive, aggressive or emotionally labile
- Current intoxication/withdrawal
- May show unusual knowledge of controlled substances.
- Gives medical history with textbook symptoms or gives evasive or vague answers to questions regarding medical history.
- Reluctant or unwilling to provide reference information. May have no General Practitioner.
- Will often request a specific controlled drug and is reluctant to try a different drug.
- Generally has no interest in diagnosis - fails to keep appointments for further diagnostic tests or refuses to see another practitioner for consultation;



Assistive Tool for Determining Type of Pain

	Type of Pain		
	Somatic Pain	Visceral Pain	Neuropathic Pain
Location	Localized	Generalized	Radiating or specific
Patient Description	Pin prick, or stabbing, or sharp	Ache, or pressure, or sharp	Burning, or prickling, or tingling, or electric shock-like, or lancinating
Mechanism of Pain	A-delta fiber activity. Located in the periphery*	C Fiber activity. Involved deeper innervation*	Dermatomal *** (peripheral), or non-dermatomal (central)
Clinical Examples	<ul style="list-style-type: none"> • Superficial laceration • Superficial burns • Intramuscular injections, venous access • Otitis media • Stomatitis • Extensive abrasion 	<ul style="list-style-type: none"> • Periosteum, joints, muscles • Colic and muscle spasm pain** • Sickle cell • Appendicitis • Kidney stone 	<ul style="list-style-type: none"> • Trigeminal • Avulsion neuralgia • Post-traumatic neuralgia • Peripheral neuropathy (diabetes, human immunodeficiency virus [HIV]) • Limb amputation • Herpetic neuralgia
Most Responsive Treatments	<ul style="list-style-type: none"> • Acetaminophen • Cold packs • Corticosteroids • Local anesthetic either topically or by infiltration • Non-steroidal anti-inflammatory drugs (NSAIDs) • Tactile stimulation 	<ul style="list-style-type: none"> • Corticosteroids • Intraspinal local anesthetic agents • NSAIDs via any route 	<ul style="list-style-type: none"> • Anticonvulsants • Corticosteroids • Neural blockade • NSAIDs • Tricyclic antidepressants

*Most post-operative patients experience A-delta and C fiber pain and respond best to narcotic of any route and NSAIDs.

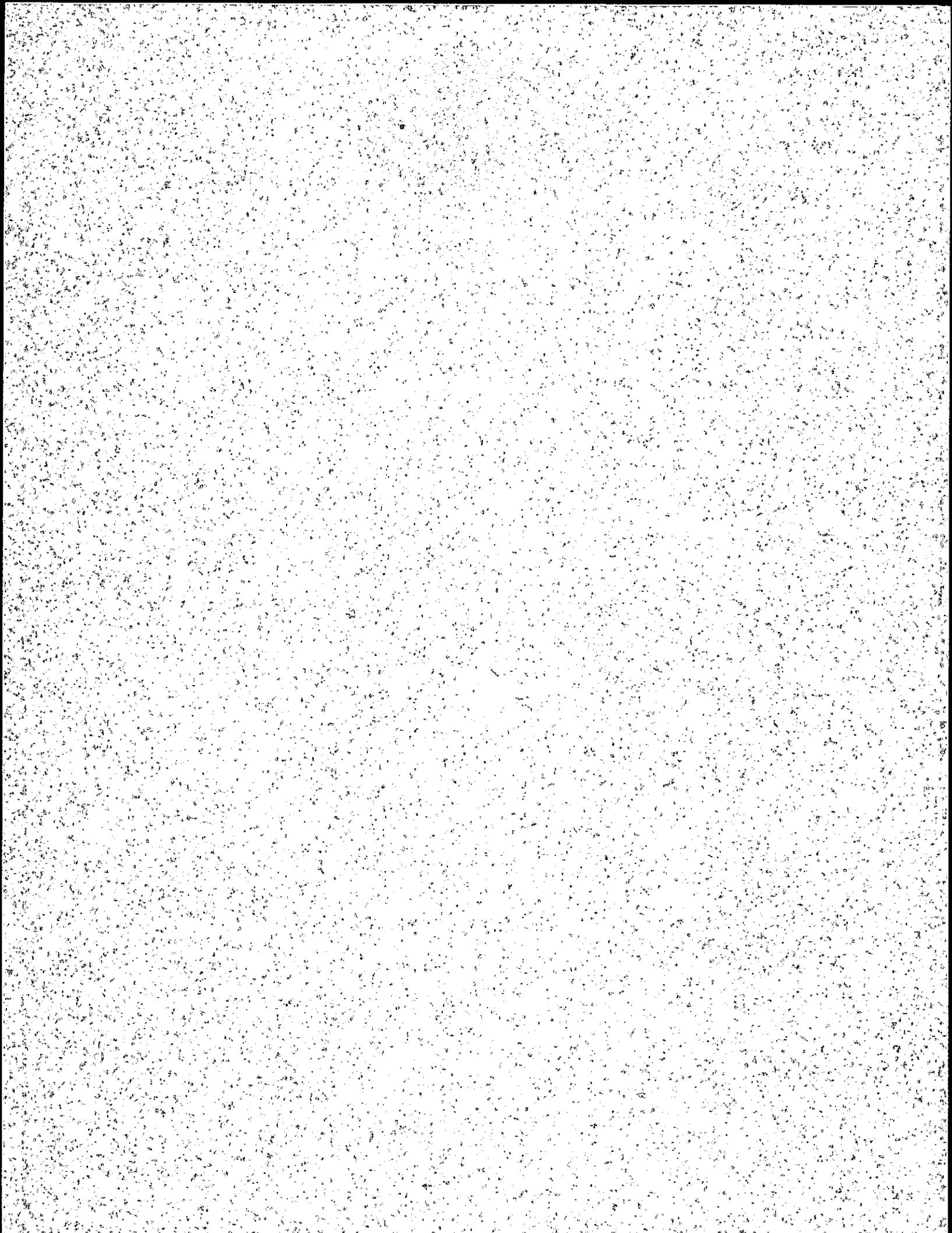
Colic and muscle spasms may be less responsive to **opioids. Respond best to antispasmodics, NSAIDs, benzodiazepines, baclofen.

***Segmental distribution follows a dermatome chart. This traces the pathway of sensation to its nerve root.

Role of Opioid Analgesics in the Treatment of Chronic Non-Malignant Pain

	Nociceptive Pain	Neuropathic Pain	Visceral Pain	Chronic Pain with Psychological Factors	Headache
Examples of Type of Pain	Severe Degenerative changes (multi-level or joint)	Diabetic neuropathy, causalgia, central pain (stroke, spinal cord injury)	Chronic pancreatitis Crohn's	Somatoform pain disorder, depression, conversion disorder	Tension, migraine
First Line Medications	WHO analgesic ladder; Acetaminophen NSAIDs	Tricyclic antidepressants, Anticonvulsants e.g. carbamazepine Membrane stabilizers e.g. lidocaine	Smooth muscle relaxants, Antacids, H ₂ blockers	Anxiolytics or anti-depressants in presence of clinically significant anxiety or depression	Prophylactic Treatment - Beta blockers, calcium channel blockers, serotonin receptor antagonists, tricyclic anti-depressants, anti-epileptics Acute Treatment - NSAIDs, DHE, sumatriptan, ketorolac, chlorpromazine, dexamethasone
Effectiveness of opioids in therapy	Often of value	Limited but definite value in selected cases	May be of value	Limited value	Tension: Rarely indicated. Migraine: Limited value
Caveats	Document significant organic pathology before long-term prescribing	Opioids less effective in neuropathic pain. Higher doses may be required but dosing limited by side effects.			Use combination meds (e.g. Tylenol #3) intermittently for short periods. May cause rebound headache.

Before prescribing opioids, physicians need to define and prioritize targets for treatment, bearing in mind that most chronic pain syndromes have a mix of mechanisms, and psychiatric co-morbidity is common. For example, in a depressed patient with diabetic neuropathy, treatment should be targeted towards depression, insomnia, and neuropathic pain. Tricyclic antidepressants would be the treatment of choice, because they are effective for all three targets.



Example of Agreement for Long-term Opioid Use:¹

The purpose of this agreement is to protect your access to controlled substances and to protect our ability to prescribe for you.

The long-term use of such substances as opioids (narcotic analgesics), benzodiazepine tranquilizers and barbiturate sedatives is controversial because of uncertainty regarding the extent to which they provide long-term benefit. There is also the risk of an addictive disorder developing or of relapse occurring in a person with a prior addiction. The extent of this risk is not certain.

Because these drugs have potential for abuse or diversion, strict accountability is necessary when use is prolonged. For this reason the following policies are agreed to by you, the patient, as consideration for, and a condition of, the willingness of the physician whose signature appears below to consider the initial and/or continued prescription of controlled substances to treat your chronic pain.

1. Unless specific authorization is obtained for an exception, all controlled substances must come ONLY from the physicians or nurse practitioners at _____ Clinic. You will not attempt to get pain medication from any other healthcare provider without telling them that you are taking pain medication prescribed by this clinic. You understand it is against the law to do so. If your primary care physician is willing to prescribe your medications, this clinic will have to approve the arrangements to make sure there is no duplication. You will discontinue all previously used pain medications unless told to continue them.
2. All controlled substances must be obtained at the same pharmacy where possible. Should the need arise to change pharmacies, our office must be informed. The pharmacy that you have selected is:

Phone: _____

3. You are expected to inform our office of any new medications or medical conditions and of any adverse effects you experience from any of the medications that you take.
4. The prescribing physician has permission to discuss all diagnostic and treatment details with dispensing pharmacists or other professionals who provide your health care for purposes of maintaining accountability. You agree to waive any applicable privilege or right of privacy or confidentiality with respect to the prescribing of your

¹ Example is from the author's pain clinic; adapted from: Long-term controlled substances therapy for chronic pain: sample agreement. A consent form from the American Academy of Pain Medicine (AAPM). Available at the AAPM Web site: <http://www.painmed.org>.

pain medication, and you authorize the clinic and your pharmacy to cooperate fully with any city, state, or federal law enforcement agency, including the state Department of Professional and Occupational Licensing, in the investigation of any possible misuse, sale or other diversion of your pain medication. You authorize the clinic to provide a copy of this agreement to your pharmacy.

5. You may not share, sell or otherwise permit others to have access to these medications.
6. These drugs should not be stopped abruptly as an abstinence syndrome will likely develop.
7. Unannounced urine or serum toxicology screens may be requested, and your cooperation is required. Presence of unauthorized substances may prompt adjustment in your treatment and monitoring.
8. Prescriptions and bottles of these medications may be sought by other individuals with chemical dependency and should be closely safeguarded. It is expected that you will take the highest possible degree of care with your medications and prescriptions. They should not be left where others might see or otherwise have access to them.
9. Original containers of medications may be required for you to bring to office visits.
10. Since the drugs may be hazardous or lethal to a person who is not tolerant to their effects, especially a child, you must keep them out of reach of such people.
11. Medications may not be replaced if they are lost, get wet, are destroyed, are left on an airplane, etc. A reassessment of your treatment will occur and may result in an alternative therapy.
12. Refills will be given only on the decision of the provider. All refills require three (3) business days advance notice (per prescription refill policy). Early refills will not be given unless the provider feels there is justification.
13. Renewals are contingent on keeping scheduled appointments. All prescriptions will be given on weekdays (specifically Monday through Friday, from 9:00 a.m. – 4:00 p.m.). Prescriptions will NOT be given at any other times unless extreme extraordinary circumstances apply.
14. If the responsible legal authorities have questions concerning your treatment, as might occur, for example, if you were obtaining medications at several pharmacies, all confidentiality is waived and these authorities may be given full access to our records of controlled-substance administration (as stated in item #4).

- 15. It is understood that failure to adhere to these policies may result in cessation of therapy with controlled-substance prescribing by this physician or referral for further specialty assessment.
- 16. It should be understood that any medical treatment is initially a trial, and that continued prescribing is contingent on evidence of benefit.
- 17. The risks and potential benefits of these therapies are explained elsewhere [and you acknowledge that you have received such explanation].
- 18. You affirm that you have full right and power to sign and be bound by this agreement, and that you have read, understood and accepted all of its terms.
- 19. You are advised not to drive while using any medication we prescribe without an appropriate drivers test indicating it is safe for you to drive.

If any of the above conditions are violated, the provider may chose to wean me off opioid medication and the painful condition will be managed without the use of opioids. Further opioids may not be prescribed for any chronic, painful condition that may develop. Violations of the above stated terms might also result in my being discharged from the clinic (with appropriate written notice and warning) without receiving weaning medications or treatment from Clinic.

Physician signature

Patient signature

Date

Patient name (printed)

Example of Informed Consent for Chronic Opioid Therapy:

The Providers at _____ Clinic are prescribing opioid medicine, sometimes called narcotic analgesics, to me for a diagnosis of:

This decision was made because my condition is serious or other treatments have not helped my pain.

I am aware that the use of such medicine has certain risks associated with it, including, but not limited to: sleepiness or drowsiness, constipation, nausea, itching, vomiting, dizziness, allergic reaction, slowing of breathing rate, slowing of reflexes or reaction time and possibility that the medicine will not provide complete pain relief.

I am aware about the possible risks and benefits of other types of treatments that do not involve the use of Opioids. The other treatments discussed included:

I will tell my doctor about all other medicines and treatments that I am receiving.

I will not be involved in any activity that may be dangerous to me or someone else if I feel drowsy or am not thinking clearly. I am aware that even if I do not notice it, my reflexes and reaction time might still be slowed. Such activities include but are not limited to: using heavy equipment or a motor vehicle, working in unprotected heights or being responsible for another individual who is unable to care for himself or herself. I have been advised not to drive while using any medication prescribed without an appropriate driver's test indicating it is safe to drive.

I am aware that addiction is defined as the use of a medication even if it causes harm, having cravings for a drug, feeling the need to use a drug and a decreased quality of life. I am aware that the chance of becoming addicted to my pain medicine is very low. I am aware that the development of addiction has been reported rarely in medical journals and is much more common in a person who has a family or personal history of addiction. I agree to tell my doctor my complete and honest personal drug history and that of my family to the best of my knowledge.

I understand that physical dependence is a normal, expected result of using these medicines for a long time. I understand that physical dependence is not the same as addiction. I am aware physical dependence means that if my pain medicine use is markedly decreased, stopped, or reversed by some of the agents mentioned above, I will experience a withdrawal syndrome. This means I may have any or all of the following: runny nose, yawning, large pupils, goose bumps, abdominal pain and cramping, diarrhea, irritability, aches throughout my body and a flu-like feeling. I am aware that opioid withdrawal is uncomfortable but not life threatening.

I am aware that tolerance to analgesia means that I may require more medicine to get the same amount of pain relief. I am aware that tolerance to analgesia does not seem to be a big problem for most patients with chronic pain; however, it has been seen and may occur to me. If it occurs, increasing doses may not always help and may cause unacceptable side effects. Tolerance or failure to respond well to opioids may cause my doctor to choose another form of treatment.

(Males ONLY) I am aware that chronic opioid use has been associated with low testosterone levels in males. This may affect my mood, stamina, sexual desire and physical and sexual performance. I understand that my doctor may check my blood to see if my testosterone level is normal.

(Females ONLY) If I plan to become pregnant or believe that I have become pregnant while taking this pain medicine, I will immediately call my obstetric doctor and this office to inform them. I am aware that, should I carry a baby to delivery while taking these medicines, the baby will be physically dependent upon opioids. I am aware that the use of opioids is not generally associated with a risk of birth defects. However, birth defects can occur whether or not the mother is on medicines and there is always the possibility that my child will have a birth defect while I am taking an opioid.

I have read this form or have had it read to me. I understand all of it. I have had a chance to have all of my questions regarding this treatment answered to my satisfaction. By signing this form voluntarily, I give my consent for the treatment of my pain with opioid pain medicines.

Physician signature

Patient signature

Date

Patient name (printed)



Consent for Chronic Opioid Therapy

A consent form from the American Academy of Pain Medicine

Dr. _____ is prescribing opioid medicine, sometimes called narcotic analgesics, to me for a diagnosis of _____

This decision was made because my condition is serious or other treatments have not helped my pain.

I am aware that the use of such medicine has certain risks associated with it, including, but not limited to: sleepiness or drowsiness, constipation, nausea, itching, vomiting, dizziness, allergic reaction, slowing of breathing rate, slowing of reflexes or reaction time, physical dependence, tolerance to analgesia, addiction and possibility that the medicine will not provide complete pain relief.

I am aware about the possible risks and benefits of other types of treatments that do not involve the use of opioids. The other treatments discussed included:

I will tell my doctor about all other medicines and treatments that I am receiving.

I will not be involved in any activity that may be dangerous to me or someone else if I feel drowsy or am not thinking clearly. I am aware that even if I do not notice it, my reflexes and reaction time might still be slowed. Such activities include, but are not limited to: using heavy equipment or a motor vehicle, working in unprotected heights or being responsible for another individual who is unable to care for himself or herself.

I am aware that certain other medicines such as nalbuphine (Nubain™), pentazocine (Talwin™), buprenorphine (Buprenex™), and butorphanol (Stadol™), may reverse the action of the medicine I am using for pain control. Taking any of these other medicines while I am taking my pain medicines can cause symptoms like a bad flu, called a withdrawal syndrome. I agree not to take any of these medicines and to tell any other doctors that I am taking an opioid as my pain medicine and cannot take any of the medicines listed above.

I am aware that addiction is defined as the use of a medicine even if it causes harm, having cravings for a drug, feeling the need to use a drug and a decreased quality of life. I am aware that the chance of becoming addicted to my pain medicine is very low. I am aware that the development of addiction has been reported rarely in medical journals and is much more common in a person who has a family or personal history of addiction. I agree to tell my doctor my complete and honest personal drug history and that of my family to the best of my knowledge.

I understand that physical dependence is a normal, expected result of using these medicines for a long time. I understand that physical dependence is not the same as addiction. I am aware physical dependence means that if my pain medicine use is markedly decreased, stopped or reversed by some of the agents mentioned above, I will experience a withdrawal syndrome. This means I may have any or all of the following: runny nose, yawning, large pupils, goose bumps, abdominal pain and cramping, diarrhea; irritability, aches throughout my body and a flu-like feeling. I am aware that opioid withdrawal is uncomfortable but not life threatening.

I am aware that tolerance to analgesia means that I may require more medicine to get the same amount of pain relief. I am aware that tolerance to analgesia does not seem to be a big problem for most patients with chronic pain, however, it has been seen and may occur to me. If it occurs, increasing doses may not always help and may cause unacceptable side effects. Tolerance or failure to respond well to opioids may cause my doctor to choose another form of treatment.

(Males only) I am aware that chronic opioid use has been associated with low testosterone levels in males. This may affect my mood, stamina, sexual desire and physical and sexual performance. I understand that my doctor may check my blood to see if my testosterone level is normal.

(Females Only) If I plan to become pregnant or believe that I have become pregnant while taking this pain medicine, I will immediately call my obstetric doctor and this office to inform them. I am aware that, should I carry a baby to delivery while taking these medicines, the baby will be physically dependent upon opioids. I am aware that the use of opioids is not generally associated with a risk of birth defects. However, birth defects can occur whether or not the mother is on medicines and there is always the possibility that my child will have a birth defect while I am taking an opioid.

I have read this form or have it read to me. I understand all of it. I have had a chance to have all of my questions regarding this treatment answered to my satisfaction. By signing this form voluntarily, I give my consent for the treatment of my pain with opioid pain medicines.

Patient signature _____ Date _____

Witness to above _____

Approved by the AAPM Executive Committee on January 14; 1999.



4700 W. Lake Avenue
Glenview, IL 60025-1485
847/375-4731
Fax 877/734-8750
E-mail aapm@amctec.com
Web site www.painmed.org

means that if my opioid use is markedly decreased, stopped, or reversed, I will experience a withdrawal syndrome. This means I may have any or all of the following: runny nose, yawning, large pupils, goose bumps, abdominal pain and cramping, diarrhea, vomiting, irritability, aches throughout my body and a flu-like feeling. I am aware that opioid withdrawal can be very uncomfortable, but is not normally life threatening.

14. For female patients, if I plan to become pregnant or believe that I have become pregnant while taking this medication, I am aware that, should I carry the baby to delivery while taking these medications, the baby will be physically dependent upon opioids. I will immediately call my obstetrician and this office to inform them of my pregnancy. I am also aware that opioids may cause a birth defect, even though it is extremely rare.

15. I am aware that many opioid users develop a tolerance to opioids. This means that I will have to be increasing the dosages of the opioids to get the same amount of pain relief because my receptors are not as sensitive to the opioid. If tolerance occurs, increasing doses may not always help and may cause unacceptable side effects. Tolerance or failure to respond well to opioids may cause my doctor to stop their use and this will lead to the withdrawal symptoms stated above.

16. I understand that the opioids that my physician is prescribing are controlled substances and that it is a felony for me to share, sell, or otherwise permit others, including my spouse or family members, to have access to any controlled substances that I have been prescribed. I understand that anyone found in possession of my prescribed opioids is guilty of a crime and can be fined or imprisoned.

17. All controlled substances must come from the physician whose signature appears below or during his/her absence, by the covering physician, unless specific authorization is obtained for an exception.

18. I understand that I must tell the physician whose signature appears below or during his/her absence, the physician who is covering for him or her, all drugs that I am taking, have purchased, or have obtained, even over-the-counter medications. Failure to do so may result in drug interactions or overdoses that could result in harm to me, including death.

19. I will not seek prescriptions for controlled substances from any other physician, health care provider, or dentist. I understand it is unlawful to be prescribed the same controlled medication by more than one physician at a time without each physician's knowledge.

20. I also understand that it is unlawful to obtain or to attempt to obtain a prescription for a controlled substance by knowingly misrepresenting facts to a physician or his/her staff or knowingly withholding facts from a physician or his/her staff (including failure to inform the physician or his/her staff of all controlled substances that I have been prescribed).

21. All controlled substances must be obtained at the same pharmacy where possible. Should the need arise to change pharmacies, our office must be informed. The pharmacy that I have selected is: _____; Phone: _____

22. Early refills will not be given. Renewals are based upon keeping scheduled appointments. Please do not make excessive phone calls for prescriptions or early refills and do not phone for refills after hours or on weekends.

23. Unannounced pill counts and random drug screening may be requested from me and my cooperation is required. Presence of unauthorized substances in urine or blood toxicology screens may result in my discharge from the facility.

24. I understand that consuming alcohol in conjunction with opioid use can result in serious problems. I understand that other legal and illegal drugs can create problems in how the opioids are metabolized and this can create potentially serious adverse drug reactions.

25. I will not use, purchase, or otherwise obtain any other legal or illegal drugs except as specifically authorized by the physician whose signature appears below or during his/her absence, by the covering

OPIOID CONTRACT

We are committed to doing all we can to treat your chronic pain condition. In some cases, controlled substances are used as a therapeutic option in the management of chronic pain and related anxiety and depression, which is strictly regulated by both state and federal agencies. This agreement is a tool to protect both you and the physician by establishing guidelines, within the laws, for proper controlled substance use. The words "we" and "our" refer to the facility or the doctor and the words "I", "you", "your", "me", or "my" refer to you, the patient. The word "opioids" refers to the class of narcotic painkillers like hydrocodone or oxycodone with brand names like Percocet, Lortab, OxyContin and Vicodin.

1. I understand that chronic opioid therapy has been associated with not only addiction and abuse, but also multiple medical problems including the suppression of endocrine function resulting in low hormonal levels in men and women which may affect mood, stamina, sexual desire, and physical and sexual performance.

2. I understand that constipation, vomiting, headaches, nausea, somnolence (feeling sleepy), pruritus (intense itchiness), asthenia (a loss of strength), and excessive sweating are additional common side effects.

3. I acknowledge receipt of a copy of the side effects and dangerous drug interactions contained on the FDA-required label for the opioid that I am prescribed, and I agree that I will read it and if I have questions, I will get them answered before I start taking the opioids.

4. I understand that if I take other medications to treat the above side effects, that these additional medications may create even more uncomfortable side effects.

5. I understand that the active ingredient in most opioids is molecularly interchangeable with heroin and is actually "legal heroin."

6. I understand that opioids can cause respiratory depression and this can lead to respiratory failure and death.

7. I understand that opioids are particularly dangerous and life-threatening if taken by children and others who have not previously taken opioids, and I agree that I will ensure that I always keep a count of my drugs and keep them out of the reach of others, adults and children alike, because opioids can be as lethal as a loaded gun.

8. I understand that if someone obtains opioids prescribed to me and the improper use of these opioids causes the death or injury of another, that I may have criminal and civil liability.

9. I understand that in most cases long-term opioid therapy is only blocking the pain signals but is not treating the actual cause of the pain.

10. I understand that because the opioid blocks pain signals to my brain, it will likely also block pain signals from other sources of pain, and this may prevent me from realizing that I am harming other parts of my body-like muscle tears, muscle sprains and even tooth decay. Not being able to sense harm to other parts of my body may result in damage to other areas of my body.

11. I have been informed that long-term and/or high doses of pain medication often cause increased levels of pain known as opioid-induced hyperalgesia (pain medicine causing more pain) where simple touch will be predicted as pain, and that pain can gradually increase in intensity and also by location, causing the body to hurt all over. I understand that opioid-induced hyperalgesia is a normal, expected result of using these medications for a long period of time.

12. I have been informed and understand that there are alternative treatments for my condition which do not involve drugs or surgery, but I have decided that I would rather take the opioids.

13. I am aware that continued use of opioids will lead to physical dependence. Physical dependence

physician. I will not use, purchase, or otherwise obtain any illegal drugs, including marijuana, cocaine, etc.

26. I understand that driving while under the influence of any substance, including a prescribed controlled substance or any combination of substances (e.g., alcohol and prescription drugs), which impairs my driving ability, may result in DUI charges, and I agree not to drive until my physician is comfortable that the opioids will not adversely affect my ability to drive.

27. Medications or written prescriptions may not be replaced if they are lost, stolen, get wet, are destroyed, left on an airplane, etc. If my medication has been stolen, it will not be replaced unless explicit proof is provided with direct evidence from the authorities. A report narrating what I told the authorities is not enough.

28. In the event I am arrested or incarcerated related to legal or illegal drugs (including alcohol), refills on controlled substances will not be given.

29. I understand that failure to adhere to these policies may result in cessation of therapy with controlled substances prescribed by this physician and other physicians at the facility and that law enforcement officials may be contacted.

30. I also understand that the prescribing physician has permission to discuss all diagnostic and treatment details, including medications, with dispensing pharmacists, other professionals who provide my health care, or appropriate drug and law enforcement agencies for the purpose of maintaining accountability.

31. I affirm that I have full right and power to sign and to be bound by this agreement, that I have read it, and understand and accept all of its terms. A copy of this document has been given to me.

PATIENT'S FULL NAME

PATIENT'S SIGNATURE Date: _____

PHYSICIAN'S SIGNATURE Date: _____

Figure 13. Therapeutic Agreement – Trial of Opioid Therapy

(Adapted from Opioid Use in Non-Cancer Pain – WCB British Columbia)

WorkSafeBC is only giving us permission to use figure for 3 years (until Dec. 19, 2010).

This agreement is being undertaken between _____, (the patient), and Dr. _____, (the doctor), to define the responsibilities of the patient during a trial of treatment of a chronic pain problem using scheduled opioid therapy.

1. I agree that the purpose of this ____ month trial of treatment has been explained to me as has been the purpose, the side-effects of the medication and the risks involved. I understand that drowsiness can be a temporary side effect, especially during dosage adjustments, and agree not to drive a vehicle nor perform other tasks that could involve danger to self or others during these times. My doctor will advise me when these activities are safe to perform again.
2. I understand that using scheduled opioids to treat chronic pain will result in the development of a physical dependence on this medication, and that sudden decreases or discontinuation of the medication will lead to symptoms of opioid withdrawal. I understand that opioid withdrawal is uncomfortable but not physically life threatening.
3. I agree not to change the dose or the frequency of taking this medication without first consulting the doctor who prescribed it, and to follow-up with the doctor, as instructed for monitoring of treatment.
4. I agree to keep the prescribed medication in a safe and secure place, and that lost, damaged or stolen medication will not be replaced until the next regularly scheduled visit.
5. I agree not to give, sell, lend or in any way provide my medication to any other person, nor to obtain medication from anyone but one previously agreed upon, licensed pharmacist.
6. I agree not to seek or obtain, **ANY** mood-modifying medication, especially pain relievers or tranquilizers, from **ANY** other physician, without first discussing this with my doctor. If a situation arises in which I have no alternative but to obtain my necessary prescription except from another physician, I will advise that physician of this agreement, and immediately advise my doctor that I obtained a prescription from another physician.
7. In patients taking chronic opioid therapy, there is a small but definite risk that opioid addiction can occur. Almost always, this occurs in patients with a current or past history of other drug/alcohol abuse. I therefore agree to refrain from the use of **ALL** other mood-modifying drugs, including alcohol, unless agreed to by my doctor. The moderate use of nicotine and caffeine are an exception to this restriction. I patient agree to submit to timely, random urine, blood or saliva testing, at my doctor's request, to verify compliance with this, and to be seen by an addiction specialist if requested.
8. I understand that opioids were prescribed to make my pain tolerable but may not cause it to disappear. I also understand that one of the main goals by which the success of this treatment will be judged is by monitoring of my ability to perform various functions, including return to work, that were not possible previously. I also understand that if significant demonstrable improvement in my functional capabilities does not result from this trial of treatment; my physician may determine that continued use of the opioid beyond the period of time necessary to withdraw me from the medication is no longer justified.
9. I agree to attend and participate fully in any other assessments or pain treatment programs which may be recommended by the doctor at any time. Furthermore, the patient understands that failure to comply with recommendations or referrals for other interventions (focused primarily on rehabilitation), including recommendations for a trial of return to work, may lead the physician to determine that further opioid use is no longer clinically warranted.

4E

I understands that ANY deviation from the above agreement may be grounds for the doctor to discontinue opioid therapy at any time, and that the WCB may discontinue providing payment for the opioid beyond that which is necessary to withdraw the patient from the medication.

Signed at _____ on _____, 200_____

(patient) (witness)

(doctor) (witness)

Medical Treatment Guidelines

APPENDIX 3

SAMPLE OPIOID TREATMENT AGREEMENT

Patient Name: _____

Date: _____

Opioid (narcotic) treatment for chronic pain is used to reduce pain and improve what you are able to do each day. Along with opioid treatment, other medical care may be prescribed to help improve your ability to do daily activities. This may include exercise, use of non-narcotic analgesics, physical therapy, psychological counseling or other therapies or treatment. Vocational counseling may be provided to assist in your return to work effort.

may ask me to follow through with a program to address this issue. Such programs may include the following:

- 12-step program and securing a sponsor
- Individual counseling
- Inpatient or outpatient treatment
- Other: _____

To the doctor: Keep signed originals in your file; give a photocopy to the patient. Renew at least every 6 months.

I, _____, understand that compliance with the following guidelines is important in continuing pain treatment with Dr. _____.

2. I understand that in the event of an emergency, this doctor should be contacted and the problem will be discussed with the emergency room or other treating physician. I am responsible for signing a consent to request record transfer to this doctor. No more than 3 days of medications may be prescribed by the emergency room or other physician without this doctor's approval.

1. I understand that I have the following responsibilities:

- a. I will take medications only at the dose and frequency prescribed.
- b. I will not increase or change medications without the approval of this doctor.
- c. I will actively participate in RTW efforts and in any program designed to improve function (including social, physical, psychological and daily or work activities).
- d. I will not request opioids or any other pain medicine from physicians other than from this doctor. This doctor will approve or prescribe all other mind and mood altering drugs.
- e. I will inform this doctor of all other medications that I am taking.
- f. I will obtain all medications from one pharmacy, when possible known to this doctor with full consent to talk with the pharmacist given by signing this agreement.
- g. I will protect my prescriptions and medications. Only one lost prescription or medication will be replaced in a single calendar year. I will keep all medications from children.
- h. I agree to participate in psychiatric or psychological assessments, if necessary.
- i. If I have an addiction problem, I will not use illegal or street drugs or alcohol. This doctor

3. I understand that I will consent to random drug screening. A drug screen is a laboratory test in which a sample of my urine or blood is checked to see what drugs I have been taking.

4. I will keep my scheduled appointments and/or cancel my appointment a minimum of 24 hours prior to the appointment.

5. I understand that this doctor may stop prescribing opioids or change the treatment plan if:
- a. I do not show any improvement in pain from opioids or my physical activity has not improved.
 - b. My behavior is inconsistent with the responsibilities outlined in #1 above.
 - c. I give, sell or misuse the opioid medications.
 - d. I develop rapid tolerance or loss of improvement from the treatment.
 - e. I obtain opioids from other than this doctor.
 - f. I refuse to cooperate when asked to get a drug screen.
 - g. If an addiction problem is identified as a result of prescribed treatment or any other addictive substance.
 - h. If I am unable to keep follow-up appointments.

Patient Signature

Date

Physician Signature

Date

Photocopy for use by clinician

Sample Treatment Contract

Treatment Contract

I understand that I am receiving opioid medication from Dr. _____ to treat my pain condition. I agree to the following conditions under which this medication is prescribed:

- I will not seek opioid medications from another physician. Only Dr. _____ will prescribe opioid for me.
- I will not take opioid medications in larger amounts or more frequently than is prescribed by Dr. _____.
- I will not give or sell my medication to anyone else, including family members; nor will I accept any opioid medication from anyone else.
- I will not use over-the-counter opioid medications such as 222's and Tylenol #1.
- I understand that if my prescription runs out early for any reason (for example, if I lose the medication or take more than prescribed), Dr. _____ will not prescribe extra medications for me; I will have to wait until the next prescription is due.
- I understand that if I break these conditions, Dr. _____ may choose to cease writing opioid prescriptions for me.

Patient's Signature: _____

Physician's Signature: _____

Date: _____

Photocopy for use by clinician

Information for Patients - Opioid (Narcotic) Analgesics for Non-Cancer Pain

FOR:

FROM: Dr.

DATE:

Making Pain Tolerable

The main reason for using an opioid (narcotic) analgesic for chronic non-cancer pain is to make the pain tolerable - not to eliminate it. This treatment is usually only considered after more standard treatments such as anti-inflammatory drugs have failed. If you are agreeable, your physician will prescribe an opioid analgesic for you in gradually increasing doses to minimize side effects. It is extremely important that you follow the directions exactly. Your physician will be the only one prescribing this medication to you. If you increase the dose without your physician's permission, give the medication to another person or obtain this medication from another physician without the consent of your primary physician, the physician may stop prescribing the opioid analgesic for you.

Pain medication is only part of your chronic pain treatment program. Equally important is a gradual exercise program that will increase your activity level despite ongoing pain. You and your physician should agree on specific ongoing treatment goals.

What is My Risk of Addiction?

There is increasing scientific evidence that strong painkillers can relieve some pain in selected patients without causing addiction. It is important to be careful, however, when defining what "addiction" is. Addiction, or psychological dependence, is a pattern of drug use in which the patient craves a drug for its ability to produce a "high" rather than for its pain-relieving properties. This can lead to the selling and injection of drugs and attempts to obtain drugs from multiple physicians - activities generally referred to as "drug abuse". Studies have shown that if a person has no past history of drug abuse and the pain is physical in origin, the risk of addiction is extremely low. If you are placed on an opioid analgesic for a period of weeks, however, and then are suddenly taken off the medication, it is possible to experience a short withdrawal reaction. Although this can be prevented by withdrawing the drug slowly, it does not mean that you have developed a craving for the drug or developed a drug addiction.

What are the Side Effects?

Although opioid analgesics can produce side effects (drowsiness, confusion, nausea, constipation), these can be minimized by slowly increasing the dose of the drug and by using anti-nausea drugs and bowel stimulants. Pain medication as prescribed will not depress your respiration or prevent you from breathing normally.

Remember Your Follow-up

If you seem to benefit from the pain medications, your physician will see you about every 4 to 6 weeks for the first few months and about every two to three months thereafter. During each visit, you and your physician will assess pain relief, any side effects from the pain medication and your ability to meet your established activity goals.

Other Instructions:

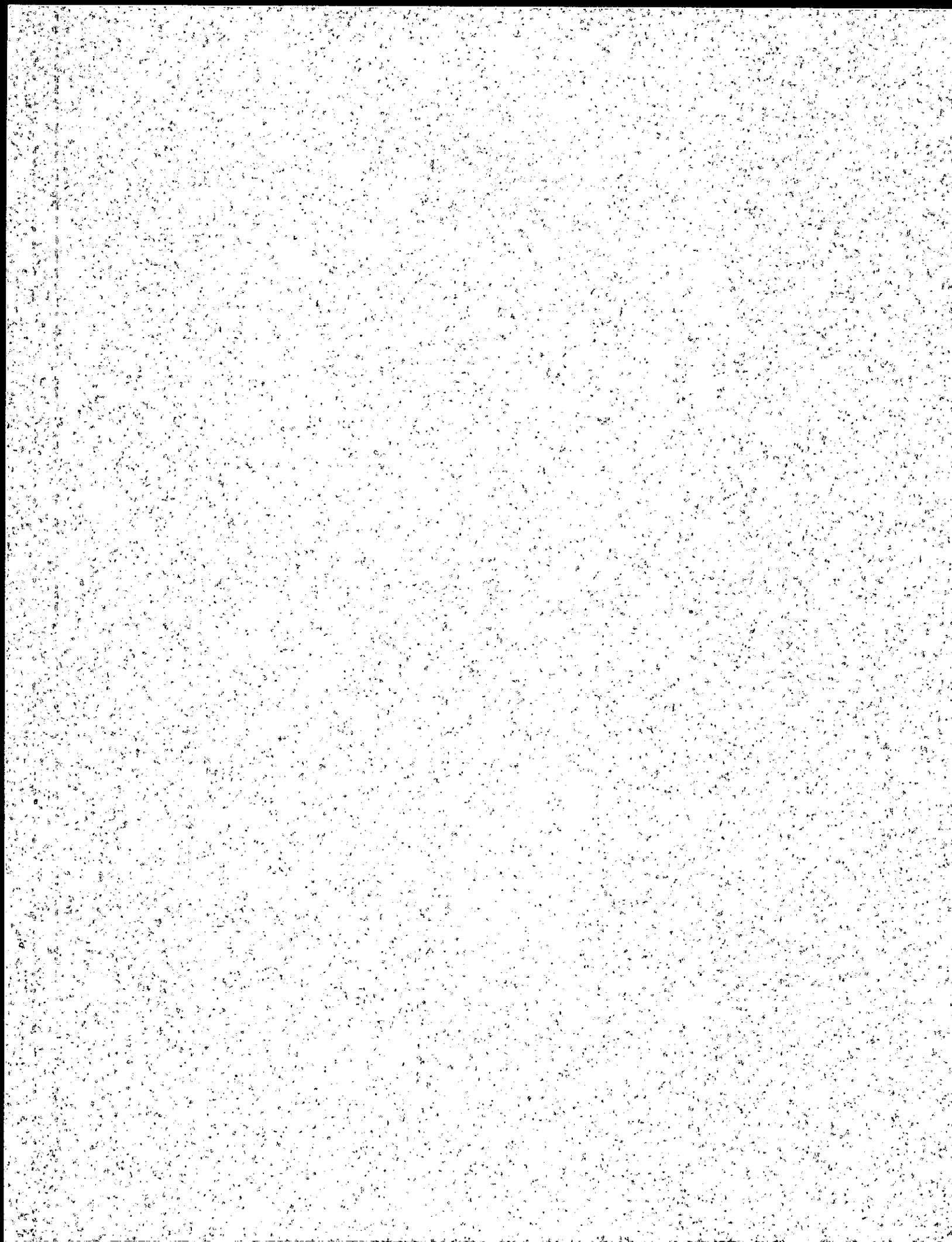


Table 2. Dosing Threshold for Selected Opioids*			
Opioid	Recommended dose threshold for pain consult (not equianalgesic)	Recommended starting dose for opioid-naïve patients	Considerations
Codeine	800mg per 24 hours	30mg q 4–6 hours	See individual product labeling for maximum dosing of combination products. Avoid concurrent use of any OTC products containing same ingredient. See acetaminophen warning, below.
Fentanyl Transdermal	50mcg/hour (q 72 hr)		Use only in opioid-tolerant patients who have been taking \geq 60mg MED daily for a week or longer
Hydrocodone	120mg per 24 hours	5-10mg q 4–6 hours	See individual product labeling for maximum dosing of combination products. Avoid concurrent use of any OTC products containing same ingredient. See acetaminophen warning, below.
Hydromorphone	30mg per 24 hours	2mg q 4-6 hours	
Methadone	40mg per 24 hours	2.5-5mg BID – TID	Methadone is difficult to titrate due to its half-life variability. It may take a long time to reach a stable level in the body. Methadone dose should not be increased more frequently than every 7 days. Do not use as PRN or combine with other long-acting (LA) opioids.
Morphine	120mg per 24 hours	Immediate-release: 10mg q 4 hours Sustained-release: 15mg q 12 hours	Adjust dose for renal impairment.
Oxycodone	80mg per 24 hours	Immediate-release: 5mg q 4–6 hours Sustained Release: 10mg q 12 hours	See individual product labeling for maximum dosing of combination products. Avoid concurrent use of any OTC products containing same ingredient. See acetaminophen warning, below.
Oxymorphone	40mg per 24 hours	Immediate-release: 5-10mg q 4–6 hours Sustained Release: 10mg q 12 hours	Use with extreme caution due to potential fatal interaction with alcohol or medications containing alcohol.

*Meperidine and propoxyphene products should not be prescribed for chronic non-cancer pain pain.

Table 3: MED for Selected Opioids	
Opioid	Approximate Equianalgesic Dose (oral & transdermal)
Morphine (reference)	30mg
Codeine	200mg
Fentanyl transdermal	12.5mcg/hr
Hydrocodone	30mg
Hydromorphone	7.5mg
Methadone	Chronic: 4mg†
Oxycodone	20mg
Oxymorphone	10mg

*Adapted from VA 2003 & FDA labeling
†Equianalgesic dosing ratios between methadone and other opioids are complex, thus requiring slow, cautious conversion (Ayonrinde 2000)

OPIOID DOSE CALCULATOR		
Optional:	Patient name:	
	Today's date:	July 8, 2008
Instructions:	Fill in the mg per day* for whichever opioids your patient is taking. The spreadsheet will automatically calculate the total morphine equivalents per day.	
Opioid (oral or transdermal):	mg per day*:	Morphine equivalents:
codeine		0
fentanyl transdermal (in mcg/hr)		0
hydrocodone		0
hydromorphone		0
methadone		0
up to 20mg per day		0
21 to 40mg per day	Since doses at or below 40mg per day are below the threshold for pain management consultation no opioid conversion calculations are necessary for this dosing range (assuming no other opioids are being taken).	
41 to 60mg per day		0
>60mg per day		0
morphine		0
oxycodone		0
oxymorphone		0
		0
TOTAL daily morphine equivalent dose (MED) =		0
* Note: All doses expressed in mg per day with exception of fentanyl transdermal, which is expressed in mcg per hour		
If this value is less than 120mg Morphine Equivalent Dose (MED), please follow Part I of the AMDG Interagency Guideline on Opioid Dosing for Chronic Non-cancer Pain. Referral for pain management consultation is recommended before exceeding 120mg MED daily. See www.agencymeddirectors.wa.gov/guidelines.asp		
If this value is greater than 120mg MED, please follow Part II of the AMDG Interagency Guideline on Opioid Dosing for Chronic Non-cancer Pain. See www.agencymeddirectors.wa.gov/guidelines.asp		
CAUTION: This calculator should NOT be used to determine doses when converting a patient from one opioid to another. This is especially important for fentanyl and methadone conversions. For converting patients from one opioid to another, refer to (website). Equianalgesic dosing ratios are only approximations and do not account for genetic factors, incomplete cross-tolerance, and pharmacokinetics.		

* Refer to www.agencymeddirectors.wa.gov/ in the right, upper corner to download the active "Opioid Dosing calculator"



7A

PAIN MANAGEMENT: RATING/MEDICATION ADMINISTRATION RECORD

Month: _____ Year: _____

Instructions: Complete this form as you would complete a Medication Administration Record (MAR) document specifying the pain site, pain rating, & post treatment pain rating. (see other side for Pain Scale)
 Pain Rating Scale used: **WONG-BAKER SCALE** **NUMERICAL SCALE** **ELACC SCALE**

Medication	Date: _____ Scale ___ Level ___ Pain Site _____ Time ___ am pm Initial _____ RESULTS: Scale ___ Level ___ Time ___ am pm Initial _____	Date: _____ Scale ___ Level ___ Pain Site _____ Time ___ am pm Initial _____ RESULTS: Scale ___ Level ___ Time ___ am pm Initial _____	Date: _____ Scale ___ Level ___ Pain Site _____ Time ___ am pm Initial _____ RESULTS: Scale ___ Level ___ Time ___ am pm Initial _____	Date: _____ Scale ___ Level ___ Pain Site _____ Time ___ am pm Initial _____ RESULTS: Scale ___ Level ___ Time ___ am pm Initial _____	Date: _____ Scale ___ Level ___ Pain Site _____ Time ___ am pm Initial _____ RESULTS: Scale ___ Level ___ Time ___ am pm Initial _____	Date: _____ Scale ___ Level ___ Pain Site _____ Time ___ am pm Initial _____ RESULTS: Scale ___ Level ___ Time ___ am pm Initial _____
Medication	Date: _____ Scale ___ Level ___ Pain Site _____ Time ___ am pm Initial _____ RESULTS: Scale ___ Level ___ Time ___ am pm Initial _____	Date: _____ Scale ___ Level ___ Pain Site _____ Time ___ am pm Initial _____ RESULTS: Scale ___ Level ___ Time ___ am pm Initial _____	Date: _____ Scale ___ Level ___ Pain Site _____ Time ___ am pm Initial _____ RESULTS: Scale ___ Level ___ Time ___ am pm Initial _____	Date: _____ Scale ___ Level ___ Pain Site _____ Time ___ am pm Initial _____ RESULTS: Scale ___ Level ___ Time ___ am pm Initial _____	Date: _____ Scale ___ Level ___ Pain Site _____ Time ___ am pm Initial _____ RESULTS: Scale ___ Level ___ Time ___ am pm Initial _____	Date: _____ Scale ___ Level ___ Pain Site _____ Time ___ am pm Initial _____ RESULTS: Scale ___ Level ___ Time ___ am pm Initial _____
Medication	Date: _____ Scale ___ Level ___ Pain Site _____ Time ___ am pm Initial _____ RESULTS: Scale ___ Level ___ Time ___ am pm Initial _____	Date: _____ Scale ___ Level ___ Pain Site _____ Time ___ am pm Initial _____ RESULTS: Scale ___ Level ___ Time ___ am pm Initial _____	Date: _____ Scale ___ Level ___ Pain Site _____ Time ___ am pm Initial _____ RESULTS: Scale ___ Level ___ Time ___ am pm Initial _____	Date: _____ Scale ___ Level ___ Pain Site _____ Time ___ am pm Initial _____ RESULTS: Scale ___ Level ___ Time ___ am pm Initial _____	Date: _____ Scale ___ Level ___ Pain Site _____ Time ___ am pm Initial _____ RESULTS: Scale ___ Level ___ Time ___ am pm Initial _____	Date: _____ Scale ___ Level ___ Pain Site _____ Time ___ am pm Initial _____ RESULTS: Scale ___ Level ___ Time ___ am pm Initial _____

Resident Name: _____ Room # _____ Doctor: _____
 Diagnosis: _____

7C

**DATA COLLECTION FOR ANALYSIS, OUTCOME EVALUATION
AND PERFORMANCE IMPROVEMENT FORM**

Pain Management Program: Pain Screen

Pain Screen Standard: A Pain Screen, including a Pain Rating Scale is documented for each new admission.

• Sample:

Dates:
From _____ to _____. Sample based upon a _____% of _____ number of residents.

• Audit Findings:

- All sampled new admissions had properly documented Pain Screen and Rating Scale (when applicable).
- _____% of sampled new admissions who had properly completed Pain Screen and Rating Scale.

Comments: _____

• Preliminary Analysis: Based upon sample data, compliance with the facility's pain management/pain screen policy and procedure has been:

- fully achieved, no referral.
- partially achieved, referred to CQI Committee for analysis.
- not achieved, immediately referred to Administrator for analysis and action plan.

Comments: _____

• CQI Committee Analysis Findings: _____

• Action Plan to improve outcome/performance: _____

7D

PROGRESS NOTE Pain Assessment and Documentation Tool (PADT™)

Patient Stamp Here

Patient Name: _____ Record #: _____

Assessment Date: _____

Current Analgesic Regimen

Drug name	Strength (eg, mg)	Frequency	Maximum Total Daily Dose
_____	_____	_____	_____
_____	_____	_____	_____

The PADT is a clinician-directed interview; that is, the clinician asks the questions, and the clinician records the responses. The Analgesia, Activities of Daily Living, and Adverse Events sections may be completed by the physician, nurse practitioner, physician assistant, or nurse. The Potential Aberrant Drug-Related Behavior and Assessment sections must be completed by the physician. Ask the patient the questions below, except as noted.

Analgesia

If zero indicates "no pain" and ten indicates "pain as bad as it can be," on a scale of 0 to 10, what is your level of pain for the following questions?

1. What was your pain level on average during the past week? (Please circle the appropriate number)

No Pain 0 1 2 3 4 5 6 7 8 9 10 Pain as bad as it can be

2. What was your pain level at its worst during the past week?

No Pain 0 1 2 3 4 5 6 7 8 9 10 Pain as bad as it can be

3. What percentage of your pain has been relieved during the past week? (Write in a percentage between 0% and 100%) _____

4. Is the amount of pain relief you are now obtaining from your current pain reliever(s) enough to make a real difference in your life?
 Yes No

5. Query to clinician: Is the patient's pain relief clinically significant?
 Yes No Unsure

Activities of Daily Living

Please indicate whether the patient's functioning with the current pain reliever(s) is Better, the Same, or Worse since the patient's last assessment with the PADT.* (Please check the box for Better, Same, or Worse for each item below.)

	Better	Same	Worse
1. Physical functioning	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
2. Family relationships	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
3. Social relationships	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
4. Mood	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
5. Sleep patterns	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
6. Overall functioning	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

* If the patient is receiving his or her first PADT assessment, the clinician should compare the patient's functional status with other reports from the last office visit.

(Continued on reverse side)

PROGRESS NOTE

Pain Assessment and Documentation Tool (PADT™)

Adverse Events

1. Is patient experiencing any side effects from current pain reliever(s)? Yes No

Ask patient about potential side effects:

	None	Mild	Moderate	Severe
a. Nausea	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
b. Vomiting	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
c. Constipation	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
d. Itching	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
e. Mental cloudiness	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
f. Sweating	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
g. Fatigue	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
h. Drowsiness	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
i. Other _____	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
j. Other _____	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

2. Patient's overall severity of side effects?
 None Mild Moderate Severe

Potential Aberrant Drug-Related Behavior
 This section must be completed by the physician.

Please **check** any of the following items that you discovered during your interactions with the patient. Please note that some of these are directly observable (eg, appears intoxicated), while others may require more active listening and/or probing. Use the "Assessment" section below to note additional details.

- Purposeful over-sedation
- Negative mood change
- Appears intoxicated
- Increasingly unkempt or impaired
- Involvement in car or other accident
- Requests frequent early renewals
- Increased dose without authorization
- Reports lost or stolen prescriptions
- Attempts to obtain prescriptions from other doctors
- Changes route of administration
- Uses pain medication in response to situational stressor
- Insists on certain medications by name
- Contact with street drug culture
- Abusing alcohol or illicit drugs
- Hoarding (ie, stockpiling) of medication
- Arrested by police
- Victim of abuse

Other: _____

Assessment: (This section must be completed by the physician.)
 Is your overall impression that this patient is benefiting (eg, benefits, such as pain relief, outweigh side effects) from opioid therapy? Yes No Unsure

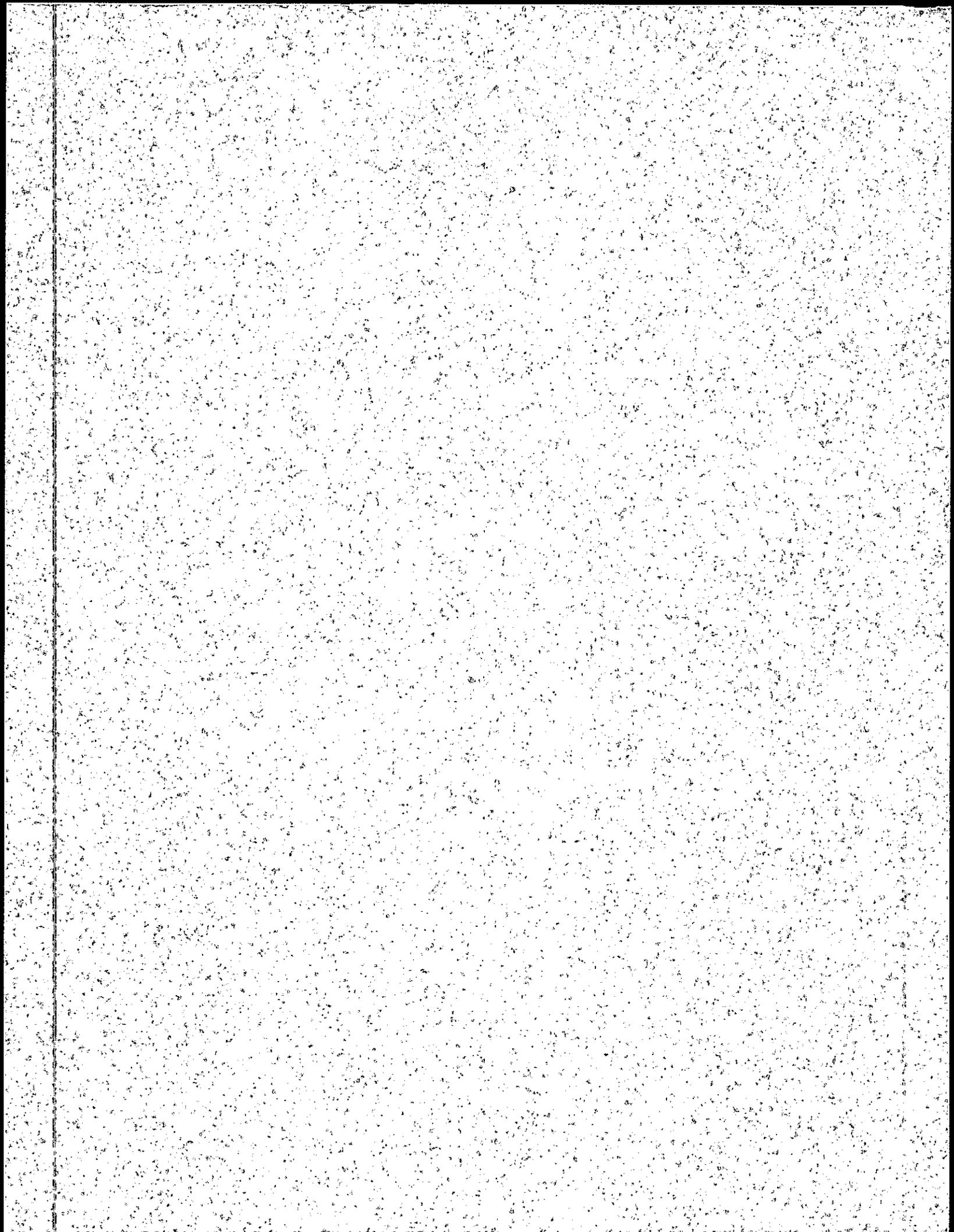
Comments: _____

Specific Analgesic Plan:

- Continue present regimen
- Adjust dose of present analgesic
- Switch analgesics
- Add/Adjust concomitant therapy
- Discontinue/taper off opioid therapy

Comments: _____

Date: _____ Physician's signature: _____



The Role of Methadone in the Management of Chronic Non-Malignant Pain: Specific Considerations

Overview

Although the literature on methadone for non-malignant pain is scanty and based on case studies, the increasing use of methadone for this purpose requires recommendations to guide practice. There is extensive literature on the use of methadone as a potent analgesic agent for cancer pain and therefore recommendations for the use of methadone in the management of chronic non-malignant pain must be extrapolated from the cancer pain literature.

Methadone is a synthetic opioid analgesic with excellent oral bioavailability, a side effect profile similar to other opioid analgesics and a duration of action of at least eight hours with repetitive dosing. These qualities make it an attractive drug for outpatient pain management. Methadone also has an opioid receptor profile different from that of morphine and has N-methyl-D-aspartate (NMDA) antagonist activity that may confer advantages over morphine. However, experience in the use of methadone for cancer pain has revealed that methadone is far more potent as an analgesic agent than has been suggested by equianalgesic tables derived from single dose studies. With repetitive dosing, methadone is approximately ten times more potent than indicated in these standard tables. The main reason for this is probably the long elimination half-life of methadone (24-36 hours) which allows for much higher drug levels to be reached than could be predicted from single dose studies. This has obvious clinical implications since methadone takes 5-7 days to reach steady state at any particular dose. Therefore, the use of methadone as an analgesic agent requires the same pain assessment skills as for any other opioid drug, but even greater scrutiny in patient monitoring of analgesic and side effects.

Methadone use in the Management of Chronic Non-Malignant Pain

In Canada, methadone is available at low cost as an elixir which is usually made up at a concentration of 1 mg/ml. In opioid-naive patients or patients taking codeine preparations, methadone 2.5 mg q8h is safe and usually well-tolerated. For patients already on a major opioid analgesic like oxycodone or morphine, a reasonable starting dose of methadone is 5 mg q8h with dose increments of 5 mg q8h every 5-7 days. A general rule is to provide careful dose titration until adequate pain relief is achieved or side effects limit further dose escalation. However, one should look for a graded analgesic response to incremental dosing. The absence of a graded analgesic response may mean that the patient is not

Other A

opioid-responsive. Patients should be seen weekly during the titration phase and every month or two during the maintenance phase.

For patients being switched from relatively large doses of an opioid analgesic (> 200 mg oral morphine or morphine equivalents daily), the table below should be used to calculate equianalgesic doses. For patients taking more than 500 mg oral morphine or morphine equivalents daily, the conversion to methadone should be staged with a third of the anticipated methadone dose being introduced every five days so that the entire conversion takes fifteen days. The dose of the previous opioid is decreased by a third every five days in inverse fashion.

Equianalgesic Doses of Common Opioid Analgesics Relative to Oral Methadone with Repetitive Dosing

Drug	Per Os (PO)	Intramuscular/Subcutaneous
Methadone	2 mg	
Morphine	30 mg	10 mg
Hydromorphone	8 mg	2 mg
Oxycodone	15 mg	

Patients and co-habitants should be warned about potential side effects (especially drowsiness and respiratory depression) and the possibility that side effects can continue to evolve for five to seven days after each dose adjustment. The spouse or significant other should be available at least twice daily to monitor for toxicity. Since drowsiness commonly precedes respiratory depression, they should be instructed to call the prescribing physician if drowsiness develops to obtain advice about further dosing. This obviously requires physician availability 24 hours a day during the titration phase. Elderly patients (over the age of 65), patients with severe lung disease and patients who cannot be adequately monitored at home should be considered for inpatient initiation of methadone treatment.

Note: The CPSO involvement in the opioid dependence program mentioned is unrelated to the use of Methadone for analgesic purposes. If a physician wishes to obtain a permit to prescribe Methadone for analgesic purposes, he or she needs to apply to the Office of Controlled Substances in Ottawa (613) 946-5139.



URINE DRUG SCREENS

Drugs of Abuse/Opiate Panel

Order number 7233541

ARUP # 0090364-Drugs of Abuse Confirmation Opiates-Medical

CDCO OPI

Codeine

Morphine

Hydrocodone

Oxycodone

Hydromorphone (metabolite of Hydrocodone)

Drugs of Abuse/Medical

Order # 7233540

ARUP# 0090487

CDAS9A

Marijuana

Cocaine

Opiates

PCP

Amphetamines

Barbituates

Meth

Benzos

Propoxyphene

Alcohol

If the screen comes up positive for opioids it is then automatically sent for the opiate panel above that gives you the specific opioid

Confirmation for methadone

ARUP# 0090362

CHRONIC PAIN MANAGEMENT

No. 1-1 Review Date: 2/25/05

Revision Date: March 22,2005

I. Purpose

The purpose of this policy is to ensure that chronic pain patients are consistently treated in accordance with accepted treatment guidelines for managing chronic pain. All providers within the Community Clinics are expected to participate in the management of chronic pain patients. A chronic pain patient is defined as a patient having consistent pain for three or more months.

II. Policy

All appropriate chronic pain patients requiring controlled substances will sign an agreement yearly with their primary care provider in order to protect patient access to controlled substances and to protect the providers' ability to prescribe. This agreement will be the foundation of a working relationship between the provider and the patient. If the patient is deemed to not be appropriate, documentation with rationale will be documented in the medical record.

A consent form will be signed by every patient.

Educational materials will be provided.

III. Procedure

- A. The attached standardized agreement shall be used throughout the Community Clinics.
- B. The provider and the patient will retain a copy and a copy will be forwarded to the patient's designated pharmacy
- C. Pharmacies may be instrumental in identifying breaches of the contract by working in alliance with the provider.
- D. If the contract is broken, the level of breach should determine the action to be taken. These may include:
 1. Tightening of the restrictions ie. Fewer pills per prescription with more frequent visits
 2. Referral to pain or addiction specialist
 3. Dismissal according to dismissal policy
- E. Providers will be familiar with and utilize appropriate medication protocols. See attachment B

Review of provider prescribing will be accomplished. If prescribing practices appear to be a problem, pain management CME may be required.

Medication Agreement

I understand that the intent of taking _____ medication is to treat my chronic pain with the goal being to increase my ability to do more. I understand that the medication is unlikely to completely eliminate pain.

I will take the medications as prescribed. I will not take any sedatives, alcohol, or other pain medications, including OTC preparations without the prior approval of my doctor.

I understand that the medication will be prescribed only by _____ and only according to the agreed-upon schedule.

I will not seek or accept any medications for pain other than those prescribed by my doctor. "Medications for pain" includes prescriptions from other doctors, medications borrowed or accepted from family or friends, and any illicit or street drugs. I will not share or sell any medication.

I will get all my prescriptions filled at _____ pharmacy. A copy of this agreement will be provided to that pharmacy.

I agree to keep all scheduled appointments. If I am unable to keep an appointment, I agree to call in advance and discuss the reason and reschedule the appointment.

I understand that lost, stolen or damaged medications will not be refilled under any circumstances. It is my responsibility to protect and secure any medications.

I understand that no prescriptions will be refilled early and no changes in dosage or medication will be made over the phone. I will not request phone-refills from on-call provider.

I agree to provide any requested urine or blood samples for unannounced drug screens.

I understand that periodic checks will be made to monitor prescriptions written by other providers and/or filled at other pharmacies.

I understand that it is my responsibility to arrange for copies of records from prior providers to be sent to my provider. Pain medications may not be prescribed until such records are received.

I agree to comply with all aspects of my treatment program which may include physical therapy, behavioral health, diagnostic testing, or specialist evaluation. Treatment may be discussed among providers.

I understand that failure to comply with this agreement may result in discontinuation of my medication and may lead to dismissal from the practice in accordance with the dismissal policy.

Rare emergencies can occur. Any exceptions to this agreement will be at the discretion of the provider.

I understand the above agreement and have had all my questions answered.

Patient Signature Date

Physician Signature Date

Recognizing and Managing Side Effects of Opioids

Medications may have many possible side effects. Discussed below are some of the more common possible side effects of opioid pain medication. You may experience some of the following:

CONSTIPATION—Constipation is a frequent side effect of opioids. Often with will respond to over-the-counter products. For example:

1. Take two Senokot-S® tablets at bedtime.
 2. If you do not have a bowel movement in the morning, take two Senokot-S® tablets after breakfast.
 3. If you do not have a bowel movement by evening, take three Senokot-S® tablets at bedtime.
 4. If you do not have a bowel movement in the morning, take three Senokot-S® tablets after breakfast.
 5. If there is no bowel movement within 48 hours after starting this regimen, add _____ after breakfast, while **continuing** to take three Senokot-S® in the morning and in the evening.
- If constipation persists despite the above, talk to your doctor about other options.
 - Once you start having bowel movements, use the **two steps prior to your last one** as your daily regimen. For example, if you had a bowel movement after Step 4, use Steps 2 and 3 (that is, two Senokot-S® tablets in the morning and three at bedtime) as your daily regimen.

FATIGUE or DROWSINESS—Fatigue or drowsiness is possible with these medications. Especially when first starting or increasing your dose or when changing medications. Your body will often adjust to this effect within a week or two, but use caution when driving or performing activities until you know how your body will react. If taking your medication produces any confusion, stop the medication until you contact your doctor.

DEPRESSION—Some people develop symptoms of depression while taking opioid medication. Your doctor may manage this by changing medication, adding a medication for depression, or through counseling. Be sure to inform your doctor if you are feeling sad or "down".

RASH, HIVES, or DIFFICULTY BREATHING—Some people have a true allergic reaction to some of the opioids. If you experience any of these, inform your doctor immediately or go to the nearest urgent care or emergency room. Do not take any more of your medication unless your are directed to do so.

NAUSEA—Nausea is common with certain of the opioid preparations. Often this improves, goes away with time, or can be helped with a change to another form of pain medication, but sometimes anti-nausea medication is needed.

PHYSICAL DEPENDENCE—Physical dependence to an opioid is common. This means that, after you have taken an opioid for awhile, your body adapts to it and you may experience symptoms of withdrawal if you stop taking the medication suddenly. Withdrawal symptoms may be avoided by tapering off a medication slowly to stop it. More medication may be needed over time to continue to control your pain. **Physical dependence is NOT the same thing as addiction.** Addiction means that a person is seeking opioid medications for emotional or physical gratification rather than for pain relief. Addicts often abuse the frequency or amount of the medication taken even if doing so results in personal or social harm. Many of the regulations set forth in your contract are designed to prevent addicts from abusing the health care system, which could result in a loss of pain medication for people with true pain management needs. When pain medication is used appropriately for pain relief, the changes of becoming addicted are low.

Keeping Yourself Safe With Opioids

Read and familiarize yourself with the sheet on common side effects of opioids. Direct any questions to your doctor or pharmacist.

Unfortunately, some people may take advantage of another's misfortune in order to profit themselves. These people often look for those who are elderly or who have pain, knowing that they can find medications that can be abused. These people may be strangers, but often may be family or friends. For your protection, we recommend the following:

- Keep your opioid medication in a locked box away from view. Remove only what you will need for the day each morning and put the rest back under lock and key. Never keep your supply in a purse, a cabinet, a bathroom, or on an open shelf. These are obvious places someone would look.
- Keep count of your medication and bring it to every visit with your doctor or pain provider. Keeping track of your medication will allow you to know if any is disappearing or being substituted with another medication by someone.
- If your medication suddenly stops working or gives you unusual side effects, bring it in for examination by a pharmacist.
- If any of your medication is stolen, report this to the police immediately. Write down the police case number and report it to the clinic. Do not ignore missing medication—this invites the opportunity for you to become a victim again.
- If you have been told by a doctor that you suffer from memory loss or if you get confused when you get sick, have a trusted family member or friend set your medication out for you. It is easy to forget you have taken your medication and then take a second dose, which may worsen your condition. The use of a pillbox may also help.
- If you have concerns about family members having access to your medication, arrange with your pharmacy to only allow the person you designate to pick up your medication if you cannot do it personally.
- **Remember, lost, stolen, or destroyed medication cannot be replaced. You will not receive a new supply, so please protect yourself!**



University of Utah Hospitals & Clinics

DRAFT

Resigning from providing care to patients receiving controlled Substances

No: 1-1 Review Date: 02/25/2005 Revision Date: March 22, 2005 Chapter: Narcotics

I. **PURPOSE**

The University of Utah Hospitals and Clinics – Community Clinics (UUHC-CC) is committed to providing the highest level of customer service. The purpose of this policy and procedure is to define those conditions whereby a medical provider may elect to resign from providing any additional medical care, including but not limited to controlled substances.

II. **DEFINITIONS**

- A. **Abuse of Controlled Substances** is defined as any person receiving controlled medications from more than one provider without the knowledge of the primary care provider *or* any person who after receiving controlled substances requests early refills regardless of the reason for the refill, including but not limited to, stolen or lost medications, taking medications contrary to provider instructions.
- B. **Criminal Acts** is defined within the context of this policy as any act which violates Utah law and interferes with a therapeutic-patient-physician relationship, including but not limited to altering prescriptions or calling a prescription into a pharmacy under false pretenses or selling or sharing prescription medications.
- C. **Transfer of Care** is defined as the act of terminating the physician-patient relationship and establishing a new relationship with a new primary care provider (PCP) either within the University of Utah or with a PCP not affiliated with the University of Utah.
- D. **Dismissal or Resignation or Resign** is defined as the act of termination the physician-patient relationship for cause and informing the patient that they must seek primary care with a PCP not affiliated with the University of Utah.

III. **POLICY**

It is the policy of the University of Utah Hospitals and Clinics-Community Clinics to provide a caring and compassionate environment for all staff and patients, while adhering to the state and federal laws governing the distribution of controlled substances. Any patient who contributes to the detriment of a caring and compassionate environment or violates federal or state laws will be allowed three (3) opportunities to change their behavior before being involuntarily dismissed from the University of Utah Hospitals and Clinic-Community Clinics, according the procedure below.

It is the policy of the University of Utah Hospitals and Clinics-Community Clinics to *immediately* dismiss any patient who intentionally violates federal or state laws relating to controlled substances.

IV. **PROCEDURE**

- A. **Immediate Resignation:** Whenever there is a violation of federal and state controlled substance laws including but not limited to any event as described in Section II (A), the medical provider may resign from care immediately after following the following steps:

1. Document the incident including names of witnesses
 2. Send a request for dismissal with documentation to the Center Medical Director for approval. If approved by the Center Medical Director, then he/she should send a resignation request with documentation to Community Clinics Risk Management for final approval and header change in the electronic health record.
 3. Center Management is responsible for sending the resignation letter after approval of the Center Medical Director and Risk Management.
 4. The PCP and Medical Director will use discretion as to whether to refill the medications.
 5. Center Management will call Case Management of the patient's health plan to notify them of the plan to resign.
- B. Non- Immediate Dismissal with 30-days notice of intent** is appropriate for most situations which interfere with the physician-patient relationship but do not rise to the level of immediate dismissal as outlined in section IV(a)
- a. **1st Incident – Contract Required**
 - Document incident
 - The PCP should have a discussion with the patient focusing on expectations concerning the use of controlled substances and document the discussion in the medical record.
 - Patient **must** enter into a pain management agreement and the PCP should have a discussion with the patient focusing on the consequences of violating the agreement and document the discussion in the medical record.
 - Care may be transferred to any another physician only if there is complete disintegration of the physician-patient relationship as determined by the primary care provider and the center medical director.
 - A copy of the pain management contract should be scanned into the medical record.
 -
 - b. **2nd Incident**
 - Document incident
 - The PCP should have a second discussion with the patient focusing on the consequences of violating the agreement and document the discussion in the medical record. Specifically, the patient should be warned that any further violations would result in a resignation letter in effect dismissing the patient from all University outpatient clinics.
 - Upon physician request, care may be transferred to any another physician only if there is complete disintegration of the physician-patient relationship as determined by the primary care provider and the center medical director.
 - c. **3rd Incident**
 - Document incident
 - Send request for resignation with documentation to Center Medical Director for approval. If approved by Medical Director, then he/she

sends request to Community Clinic Risk Management for final approval and resignation letter and header change in Epic.

- Center Management is responsible for sending letter after approved of Medical Director and Risk Management.
- The patient should be given thirty days notice with urgent medical care and medication refills provided during the 30-day period.
- Center Management will notify the case management department of the patient's health plan of its intent to dismiss the patient.
- The patient's header will be marked as "dismissed" and an explanatory note provided in the demographics section of the EHR by UUHC-CC Risk Management.
- Care may not be transferred to another willing provider within the UUHC-CC system.

APPROVAL BODY: UUHC-CC Narcotics Policy Steering Committee
APPROVAL DATE:
POLICY OWNER: UUHC-CC
ORIGIN DATE: February 24, 2005

References and Attachments

Chronic Pain Pharmacotherapy Pamphlet Potential Information

Medications to be avoided:

- *Meperidine* (principal metabolite is normeperidine which produces significant adverse effects such as tremulousness, dysphoria, myoclonus, and seizures)
- *Propoxyphene* (provides minimal analgesia, chronic use leads to accumulation of a toxic metabolite)
- *Mixed opioid agonist-antagonists* (e.g. butorphanol, nalbuphine, and pentazocine); maintain dose ceilings and should not be used in the patient already taking a pure/full opioid agonist; associated with a relatively high risk of psychotomimetic adverse effects.
- *Partial opioid agonists* (buprenorphine) maintain dose ceilings and should not be used in the patient already taking a pure/full opioid agonist; associated with a relatively high risk of psychotomimetic adverse effects.

Medication Selection Process

Step 1: Mild Pain (1-3 on NRS)

For episodic or fluctuating pain

- If inflammation suspected to be a cause: Ibuprofen 400 mg PO every 4 hours as needed (Naproxen 220 mg PO Q8H is an alternative)
- If no inflammation suspected: Acetaminophen 325 mg PO every 4 hours as needed

For persistent or chronic pain

- If inflammation suspected to be a cause: Ibuprofen 800 mg PO every 8 hours scheduled (Naproxen 500 mg PO Q12H is an alternative)
- If no inflammation suspected: Acetaminophen 650 – 1,000 mg PO every 6 hours scheduled

Adjuvant Analgesics

Neuropathic pain or pain requiring an adjuvant analgesic

- Desipramine 10- 25 mg PO HS scheduled. Increase dose in 10 to 25 mg increments every 3 to 5 days as tolerated until satisfactory pain relief attained.
- For Neuropathic pain or pain requiring an adjuvant analgesic unresponsive to a TCA consider gabapentin. (Note: attempt to spread doses equally throughout day; slow taper if excessive adverse effects encountered. If adequate analgesia encountered or if adverse effects dictate, discontinue further escalation and leave dose at best tolerated level.)
- Gabapentin titration schedule:
Day 1 100mg PO HS

Day 2	100mg PO BID
Day 3	100mg PO TID
Day 4	100mg PO BID and 200 mg HS
Day 5	200 mg PO AM and HS, 100 mg Midday
Day 6	200 mg PO TID day six
Day 7	200 mg PO BID and 300 mg HS
Day 8	300 mg PO AM and HS 200 mg Midday
Day 9	300 mg PO TID

Step 2: Mild to Moderate Pain(4-6 NRS) and Step 3: Moderate to Severe Pain (7-10 NRS)

- If inflammation suspected add an NSAID (if not already used) as indicated to opioid and acetaminophen
- If neuropathic pain or pain that requires an adjuvant exists use adjuvant approach described in step 1 above.
- Step 2 consider Tramadol in lieu of opioids (Can also be used as an adjuvant at any step)
- Oral Opioids
 - *Opioid naïve patients with episodic or fluctuating pain*
 - Step 2 Opioid: Hydrocodone 5 mg/APAP 500 mg (e.g. Vicodin, Lortab) 1 to 2 tablets PO every 4 hours as needed (not to exceed 8 tablets in 24 hours) Reassess routinely to determine if pain is appropriately assessed and/or treated.
 - Step 3 Opioid: Morphine Sulfate 10 mg PO every 3 hours as needed for pain. If during reassessment the pain is not controlled with morphine 10 mg per dose, upward titration is reasonable. If pain remains uncontrolled after 24 hours, increase the routine dose by 25% to 50% for reports of mild to moderate pain, by 50% to 100% for severe to uncontrolled pain, or by an amount at least equal to the total dose of PRN medication used during the previous 24 hours.
 - When indicated determine if pain is chronic/persistent and possibly better managed with long-acting formulations.
 - Opioid naïve patients with persistent or chronic pain: Initiate Step 2 or 3 opioid as appropriate on an as needed approach (as above) and monitor use to determine opioid requirements. Following further assessment, consider switching to a long-acting opioid formulation such as extended-release morphine (e.g. MS Contin, Oramorph SR) as soon as pain stabilized. Continue to provide breakthrough opioid doses.
 - Patients already receiving opioid pharmacotherapy - If the patient regularly utilizes short-acting opioids on a regular basis and it is appropriate to continue with opioid pharmacotherapy, calculate the average 24 hour opioid dose and then consider utilizing a long-acting opioid alternative to provide around the clock analgesia where appropriate (e.g. MS Contin,

Oramorph SR). If using long-acting opioids continue using breakthrough short-acting doses as well.

Breakthrough or PRN Analgesia

Provide patients utilizing long-acting opioids with rescue analgesia for "breakthrough" pain in the event of worsening pain, episodic pain, or pain that is inadequately controlled by the long-acting opioid regimen. A simple approach is to provide doses that are 5% to 15% of the total 24 hour long-acting opioid dose in use. Normally these doses are offered to the patient on a PRN every 3 hours. ALWAYS recalculate the breakthrough opioid dose after changing the long-acting regimen so that it is always 5% to 15% of this total daily dose.

Opioid Dose Escalation

Patients requiring more than 2 to 4 daily breakthrough doses on a routine basis may need to have their long-acting opioid regimen increased. A simple approach is to determine the total amount of opioid used in an average 24 hour period (routine + breakthrough) and administer this new total in divided doses as indicated by the product used.

Changing Opioid

When changing opioids, there may be differences between published equianalgesic doses of different opioids and the effective ratio for a given patient. For patients with well-controlled pain use 50% to 75% of the published equianalgesic dose of the new opioid to compensate for incomplete cross-tolerance and individual variation. If the patient has moderate to severe pain, reduce the dose by 25% or less. An important exception is methadone, which appears to have higher than expected potency during chronic dosing compared with published equianalgesic doses for acute dosing. Consult a pain specialist before switching to methadone.

Constipation

Constipation due to opioids is almost a universal problem. Tolerance to constipation very rarely, if ever, develops. Management should be proactive, utilizing stimulant laxatives (eg, senna, bisacodyl, glycerin, casanthranol, etc) that are titrated to effect. Stool softeners (eg, docusate sodium) are not usually effective by themselves, but can provide a useful addition to the stimulant laxative. Bulk-forming agents (eg, psyllium) should be avoided in the vast majority of patients since they require substantial fluid intake and are poorly tolerated in patients with advanced disease and poor gastrointestinal mobility. For patients unable or unwilling to use a stimulant laxative, the addition of an osmotic agent (e.g. milk of magnesia, lactulose, or sorbitol) may be useful.

A Clinical Guide to Urine Drug Testing

CME Certified Monograph



AUGMENTING PAIN MANAGEMENT
& ENHANCING PATIENT CARE

Sponsored by



University of Medicine & Dentistry of
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PharmaCom Group, Inc.

An educational activity designed for
primary care physicians, family physicians,
and pain physicians.

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Faculty

Catherine A. Hammett-Stabler, PhD, DABCC, FACB
Associate Professor
Department of Pathology & Laboratory Medicine
University of North Carolina
School of Medicine

Director of Clinical Toxicology, Clinical Pharmacology,
Endocrinology, Pediatric Metabolism, & Special Chemistry
McLendon Clinical Laboratories
UNC Hospitals
Chapel Hill, NC

Lynn R. Webster, MD, FACPM, FASAM
Medical Director
Lifetree Clinical Research® & Pain Clinic
President
Utah Academy of Pain Medicine

Chief of Anesthesiology
Health South Salt Lake Surgical Center
Salt Lake City, UT

Educational Overview

Urine drug testing (UDT) has expanded beyond the workplace and now is utilized in a number of contexts. Clinically, UDT is regularly performed in drug treatment centers to monitor abstinence from illicit drugs and to confirm adherence to maintenance drugs, in emergency departments to support both acute treatment decisions and efforts to prevent future events (illicit drug use is considered a marker for future trauma), in pain clinics, and in primary care settings. This monograph will focus on patient-centered UDT used to enhance the management of chronic pain patients. In this context, UDT can serve as a useful tool to help verify patient-reported compliance or demonstrate unreported drug exposure.

Three key elements of UDT must be appreciated to best utilize this tool: the pharmacologic characteristics of the drugs tested; their relationship to the sample, and the analyses performed by the laboratory. Physicians who order UDT should frequently consult with laboratory scientists to select appropriate tests, and keep informed of laboratory changes, such as adoption of new agents or assays. Physicians should consider UDT results in the context of all the clinical information, and contact the laboratory scientist to clarify test results when there is a discrepancy. Unfortunately, in a study among family medicine physicians, only 23% would consult with the laboratory director when confronted with an abnormal or unexpected UDT result.

The purpose of this monograph is to provide the knowledge necessary to interpret most UDT results in the context of pain management.

Target Audience

This activity is designed for primary care, family, and pain medicine practitioners interested in or involved with the clinical management of patients receiving opioid therapy and the utilization of UDT in the clinical setting to aid in treatment.

Learning Objectives

After completing this educational activity, participants should be better able to:

1. Distinguish between the needs of forensic testing and UDT used in clinical practice.
2. Describe the 2 main types of UDT methodologies.
3. Develop a strategy to incorporate UDT into practice and order appropriate tests.
4. Interpret UDT results within the limitations of current technologies.

Method of Instruction

To obtain CME credit for this activity, participants are required to read the learning objectives and review the activity in its entirety. Register online at <http://ccoe.umdj.edu/online/activities/09MC07> and complete the post-test consisting of a series of multiple-choice questions. Upon achieving a passing score of 70% or more on the post-test, and successfully completing the evaluation, participants can immediately print a CME credit letter. No additional credit letters will be mailed. Participants may take the activity as many times as necessary to fulfill the requirements.

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This activity was peer-reviewed for relevance, accuracy of content, and balance of presentation by Iris G. Udasin, MD; and pilot-tested for time required for participation by Stephen Lemke, DO, Kinshasa Morton, MD, and Adam L. Palance, MD.

CME Academic Advisor

Iris G. Udasin, MD
Clinical Associate Professor of Environmental &
Occupational Medicine
UMDNJ–Robert Wood Johnson Medical School
Piscataway, NJ

Faculty Disclosure Declarations

Dr. Hammett-Stabler has no relevant financial relationships.

Dr. Webster has received grant/research support from Abbott Laboratories, Ameritox, Arrya, AstraZeneca, Boehringer Ingelheim, CoMentis, DURECT, Forest Laboratories, GlaxoSmithKline, Jazz Pharmaceuticals, Merck & Co, NeurogesX, Orthocon, Predix Pharmaceuticals, Pain Therapeutics, QRxPharma, Respiroics, Takeda Pharmaceuticals, TorreyPines Therapeutics, Wyeth, and ZARS Pharma; has been a consultant for and has received grant/research support from Advanced Bionics, Alpharma Pharmaceuticals, Elan, Elite Pharmaceuticals, King Pharmaceuticals, Medtronic, and Nektar Therapeutics; has been a consultant for Cephalon, Covidien, and Nervo; and has served on the advisory board of and has received grant/research support from Purdue Pharma.

The CME academic advisor, Iris G. Udasin, MD, and pilot-testers Stephen Lemke, DO, Kinshasa Morton, MD, and Adam L. Palance, MD, have no relevant financial relationships.

Planning committee members, James Barrett and Angela Casey, PharmaCom Group, and Patrick Dwyer, UMDNJ, have no relevant financial relationships.

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INTRODUCTION

The technologic advancements that enable laboratories to detect exquisitely low concentrations of drugs in biologic fluids began in the late 1950s with the development of the immunoassay and the coupling of gas chromatography (GC) and mass spectrometry (MS). These technologies serve as the backbone of the 2-tiered testing program that has grown out of the Federal Drug Free Workplace Act established in the 1980s.^{1,2} The majority of urine drug testing (UDT) is still performed in regulated workplace programs as a means to deter and detect illicit drug use.³ Spurred by insurance and injury compensation coverage, many non-federal agencies and companies have adopted the *Mandatory Guidelines for Federal Workplace Drug Testing Programs* into their own employee protocol.³ In these settings, UDT is routinely performed prior to hiring and in response to any accident. Additional testing may occur with or without announcement, depending on the company's policies.

UDT has expanded beyond the workplace and now is performed in a number of contexts, such as in sports organizations, schools, and the criminal justice system, to provide objective data on drug exposure.⁴⁻⁷ Depending on the circumstances, consequences for using illicit substances are quite severe and include incarceration, termination of employment, suspensions, and fines.^{4,7} Clinically, UDT is regularly performed in drug treatment centers to monitor abstinence from illicit drugs and to confirm adherence to maintenance drugs, in emergency departments (EDs) to support both acute treatment decisions and efforts to prevent future events (illicit drug use is considered a marker for future trauma), in pain clinics, and in primary care settings.⁴⁻¹² This monograph will focus primarily on patient-centered UDT used to enhance the management of chronic pain patients. In this context, UDT can serve as a useful tool to help verify patient-reported compliance or demonstrate unreported drug exposure. However, 3 key elements of UDT must be appreciated to best utilize this tool: the pharmacologic characteristics of the drugs tested, their relationship to the sample, and the analyses performed by the laboratory. The purpose of this monograph is to provide the knowledge necessary to interpret most UDT results encountered in the management of patients with pain. ■

OPIOID THERAPY IN PAIN MANAGEMENT

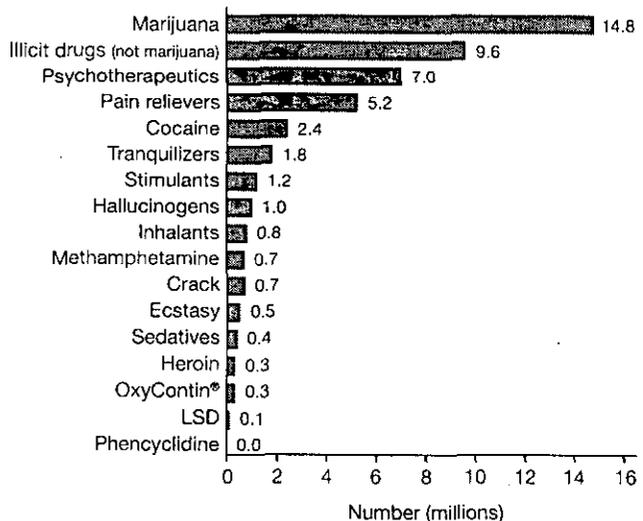
The use of opioids in pain management is a double-edged sword: while they are absolutely necessary to manage the pain and improve the function of many patients, their misuse is a significant national public health problem.¹³⁻¹⁸ Concerns about addiction, drug abuse, and diversion can be major barriers when managing chronic pain patients.¹³⁻¹⁶ In one study, physicians were most reluctant to prescribe opioids due to concerns about drug abuse (84%) and addiction (75%), followed by side effects (68%) and tolerance (61%).¹⁹ In addition, time constraints, skepticism regarding overall benefit for patients, and high-profile legal ramifications have deterred many physicians from prescribing opioids.^{17,20,21}

In order to overcome these barriers to pain management, a practical approach is needed to monitor patient adherence and response to prescribed opioids.^{13,17,18,22} Objective UDT data accompanied by appropriate surveillance and follow-up can contribute to patient management, particularly when there is uncertainty about the pain diagnosis or the patient's level of risk.^{6,14,19}

Scope of Drug Abuse

The 2006 *National Survey on Drug Use and Health* estimated that 20.4 million Americans aged 12 years or older (8.3% of the population) were current (past-month) illicit drug users.²³ While it is clear that marijuana was the most commonly used illicit drug (14.8 million current users) (Figure 1), 7.0 million

Figure 1 Past-Month Use of Specific Illicit Drugs: 2006²³



*Among persons aged 12 years and older
LSD=lysergic acid diethylamide

persons also used prescription-type psychotherapeutic drugs nonmedically*—of these, 5.2 million misused analgesics, an increase from 4.7 million in 2005.²³ The number of people who initiated nonmedical prescription analgesic use in 2006 was similar to the number of new initiates of marijuana use in that year (Figure 2).²³

Source of Opioid Analgesic: Among persons who used analgesics nonmedically in the past year, 56% reported that they obtained their most recent drug from a friend or relative for free, 19% from a single physician, and 4% from a drug dealer or other stranger.²³ Less than 1% reported buying the drug on the Internet, although some sources suggest the volume of online analgesic sales is underreported.^{23,24}

Abuse/Misuse in Chronic Pain Patients

The majority of patients on long-term opioid therapy for chronic pain will not develop opioid-use disorders. However, the rates of opioid abuse are usually somewhat higher in these patients than in the general population. In a sample of patients receiving opioid therapy from their primary care physician (PCP), the frequency of opioid use disorders was 4 times higher compared with general population samples (3.8% vs 0.9%).²⁶ In another primary care sample of chronic pain patients receiving opioids, lifetime drug problems were common—with 17% of men and 10% of women reporting drug abuse treatment at least once in their lifetime.¹⁴

Any departure from medical direction in the consumption of pain medication calls for a clinical intervention. Aberrant drug-related behaviors (ADRBs) should be documented and addressed with the patient to help understand his or her motivation for noncompliance. For example, is he/she suffering from:

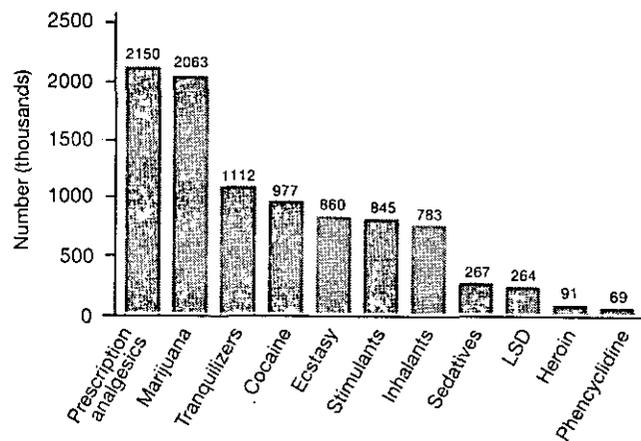
- Undertreated pain?
- Active addiction?
- A comorbid anxiety or depressive disorder?

Rates of psychiatric comorbidity among chronic pain patients are higher than the general population, but similar to those of addiction treatment samples.¹⁴ Because pain management is complicated by alcohol and drug use, stress, depression, and a variety of other comorbid medical and social issues, it is important to deal with these underlying problems in order to optimize treatment.¹⁴ Monitoring measures may need to be increased and referrals to specialists made when appropriate.

Patient Risk of Displaying ADRBs

The basis for selecting, excluding, or terminating chronic pain patients from opioid treatment is not well-defined.^{13,17,22} As a

Figure 2. Past-Year Initiates of Illicit Drugs: 2006²³



*Among persons aged 12 years and older
LSD=lysergic acid diethylamide

result, physicians frequently rely on demographic information, assumed risk factors, and “gut instinct” to determine whether a patient will misuse opioids prescribed to relieve pain.²⁷ Unfortunately, several reports demonstrate the difficulty in predicting medication misuse and ADRBs based on patient demographics, as well as medical and behavioral variables.^{23,27-30} For example, in 2006, 18.5% of unemployed adults were current illicit drug users, compared with 8.8% of those employed full-time and 9.4% of those employed part-time—however, 74.9% of current illicit drug users were employed full- or part-time.²³ In another study, 45% of chronic pain patients on opioid therapy in an urban pain management center had confirmed abnormal UDT results: 20% were found to have used illicit substances, 14% had used additional prescription drugs, and another 10% had not used the drugs prescribed.²⁷ However, patient gender, pain site, and the number, type, and dose of prescribed opioids were poor predictors of abnormal UDT results.²⁷ At an academic

Table 1. Serious ADRBs Among Chronic Pain Patients (N=196)³¹

ADRB	Number (%)
Positive UDT result for stimulants (cocaine or amphetamines)	25 (40.3%)
Negative UDT result for prescribed opioids	15 (24.2%)
Doctor shopping	10 (16.1%)
Inconsistent UDT result (nonprescribed)	9 (14.5%)
Prescription forgery	2 (3.2%)
Diversion	1 (1.6%)
Total	62 (100%) [31.6% of total]

*Nonmedical use was defined as use without a prescription of the individual's own or simply for the experience or feeling the drugs caused.

pain management program, 62 of 196 patients exhibited ADRBs over 1 year (Table 1): 25 had confirmed positive UDT results for stimulants, 15 had repeated confirmed negative results for prescribed opioids despite being counseled on scheduling of their medication, and 9 had repeated positive results for nonprescribed opioids.³¹

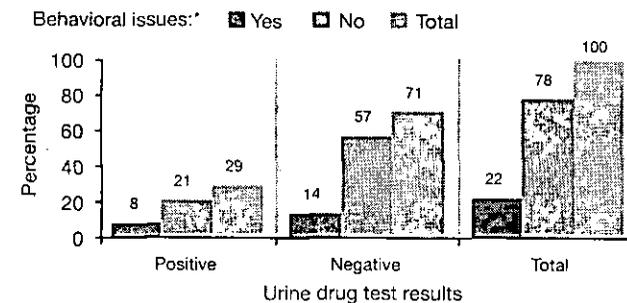
Other investigators have also found that both monitoring behavior and requiring UDT for individuals receiving long-term opioid therapy captures more patients with inappropriate drug-taking behavior than either method alone.²⁸ A total of 43% of patients had a “problem,” identified by either a positive UDT result or an ADRB—21% had positive UDT results alone for either an illicit drug or a nonprescribed controlled substance, 14% had behavioral issues alone, and only 8% had both positive results and behavioral issues (Figure 3).²⁸

Patient Self-Reporting

Although self-report may identify some patients with ADRBs, studies in a number of settings have demonstrated that a significant percentage of chronic pain patients inaccurately report nonadherence and illicit drug abuse.^{6,11,28,32} Therefore, it is unwise to rely on the patient’s word alone that drugs are being taken as prescribed.⁹ Deception is notoriously difficult to detect, and physicians are particularly susceptible because they practice with a “truth bias”—the physician-patient relationship is traditionally based on the physician accepting the veracity of a patient’s self-report.^{28,33} Researchers at Cornell University found that physicians detect a bogus patient only 10% of the time, even when warned of a visit by an actor with a “pain” condition; in addition, physicians were liable to mistakenly identify real patients as actors.³³

In a primary care sample of adults receiving daily opioid therapy for chronic pain, there was a 24% rate of positive UDT results for

Figure 3. Proportion of Chronic Pain Patients With Behavioral Issues or Positive UDT Results²⁸



*Lost/stolen prescriptions, consumption in excess of the prescribed dosage, visits without appointments, multiple drug intolerances, frequent telephone calls

Table 2. Opioid Risk Tool^{35,38}

Factor	Male	Female
Family history of substance abuse		
■ Alcohol	<input type="checkbox"/> 3 points	<input type="checkbox"/> 1 point
■ Illegal drugs	<input type="checkbox"/> 3 points	<input type="checkbox"/> 2 points
■ Prescription drugs	<input type="checkbox"/> 4 points	<input type="checkbox"/> 4 points
Personal history of substance abuse		
■ Alcohol	<input type="checkbox"/> 3 points	<input type="checkbox"/> 3 points
■ Illegal drugs	<input type="checkbox"/> 4 points	<input type="checkbox"/> 4 points
■ Prescription drugs	<input type="checkbox"/> 5 points	<input type="checkbox"/> 5 points
Age 16-45 yrs	<input type="checkbox"/> 1 point	<input type="checkbox"/> 1 point
History of preadolescent sexual abuse	<input type="checkbox"/> 0 points	<input type="checkbox"/> 3 points
Psychologic disease		
■ ADD, OCD, bipolar disorder, schizophrenia	<input type="checkbox"/> 2 points	<input type="checkbox"/> 2 points
■ Depression	<input type="checkbox"/> 1 point	<input type="checkbox"/> 1 point
Total Points		
0-3 points=low risk; 4-7 points=moderate risk; ≥8 points=high risk		

ADD=attention deficit disorder; OCD=obsessive-compulsive disorder

illicit drugs, but significant underreporting—46% of patients with positive results denied illicit drug use even when guaranteed anonymity.²⁶ In some cases, patients may underreport or deny nonmedical use of drugs or alcohol for fear of being taken off their pain medications or jeopardizing their ability to receive future prescriptions.¹⁴ Furthermore, the perceived social stigma associated with some drugs, such as heroin and cocaine, may compound inaccurate self-reported use.^{25,34} Incorrect accounts of drug use may also be the unintentional consequences of impaired memory or misunderstanding instructions or questions.^{32,34}

Screening Instruments

There is growing evidence that the use of risk-assessment instruments may provide a more rational basis for which patients can be selected for treatment.^{15,17,22,27} Stratification of patients based on their risk for opioid misuse and ADRBs can be used to establish appropriate levels of monitoring and/or identify patients who warrant referral.^{22,35-37} Examples of screening instruments include the Screener and Opioid Assessment for Patients with Pain-Revised (SOAPP®-R) and the Opioid Risk Tool (ORT).^{17,22,35,38,39} In the ORT, each factor is assigned a point value reflecting its contribution towards an individual’s likelihood of displaying ADRBs if opioids are prescribed—the tallied score is indicative of the patient’s overall risk (Table 2).^{35,38} Systematically collecting such information can help physicians develop a comprehensive treatment plan so that pain patients can receive opioids, when indicated, under controlled conditions based on their risk level.^{14,15,35} ■

UTILIZING URINE DRUG TESTING IN CLINICAL PRACTICE

Given that self-reporting of substance use is unreliable and that risk-assessment instruments are screening rather than diagnostic tools, a management strategy utilizing UDT in addition to a careful history, appropriately directed physical examination, and observation of patient behavior is useful prior to initiating and during opioid therapy. Data support that adding UDT identifies more nonadherent patients than monitoring behaviors or self-reporting alone.^{6,13,28}

Clinical Versus Forensic/ Workplace UDT

There is a significant difference between the standards and needs of forensic testing for the detection of illicit drug use and clinical testing to monitor adherence to a treatment regimen.^{9,11,40} This basic fact is important to recognize, as many "standard" urine drug tests were designed for or adapted from workplace requirements and are not optimized for clinical applications.^{9,11} Firstly, the drugs for which UDT is conducted in these 2 settings differ. In the workplace, opiate testing is performed to identify heroin, morphine, or codeine use. In the pain management setting, this list is expanded to include other opioids, such as hydrocodone, hydromorphone, or oxycodone. Secondly, in contrast to forensic testing, which generally assumes that most donors will be negative for the substance of abuse, physicians in therapeutic settings often expect to detect the presence of prescribed drugs as evidence of their use. Thirdly, forensic testing is governed by strict requirements for chain of custody that are generally not considered necessary in a clinical setting.^{9,40}

Pain Management

Patients being considered for long-term opioid therapy should understand the likely benefits and risks, and agree to the requirements of such therapy, including intensive monitoring and responsibly managing their medications. UDT can be a valuable tool in the pain management setting (Table 3) to help monitor compliance to an agreed-upon treatment plan, identify possible new or recurrent drug misuse, support medical decisions, and assist in diagnosis, although it does not itself "diagnose" addiction nor abuse.^{9,11,28,40} UDT can also serve as a deterrent to illicit drug use and provide objective evidence of abstinence in high-risk patients.^{10-12,28} In addition, documentation of UDT policies and results can demonstrate to regulatory authorities physicians' efforts in monitoring patients.⁹ Whatever the reason for testing, the level of understanding of physicians using UDT in a clinical setting must be appropriate, and communication with the testing laboratory is key.^{9,11}

Treatment Agreements

A written opioid treatment agreement that outlines physician and patient responsibilities is often used to clarify the likely benefits and risks, mutually agreed-upon treatment goals, terms of treatment, and the consequences of misuse.^{13,42-45} Some physicians require all patients to sign a written treatment agreement before prescribing opioids for chronic pain as a routine part of care, so as not to stigmatize "at-risk" patients. However, it is unclear if such agreements should be implemented for all patients in all circumstances. The Federation of State Medical Boards of the United States recommends a written treatment agreement for patients "at high risk for medication abuse or with a substance abuse history."⁴⁶ The most important elements in a written agreement include listing prohibited behaviors and a process for discontinuing treatment, should this become necessary.^{9,13,22,43} An example of a treatment agreement can be found on the American Academy of Pain Medicine Web site: www.painmed.org/pdf/controlled_substances_sample_agrmt.pdf.⁴⁷ Very often, agreements include the provision of a urine specimen when requested to monitor illicit drug use and adherence to treatment.^{29,43,48}

Table 3. Pain Clinic Studies of UDT^{13,27,29,31,32}

Study	Number of patients	Problem UDT result (%)	Findings
Hariharan J, et al. <i>J Gen Intern Med.</i> 2007;22:485-90.	330	53 (38%)	<ul style="list-style-type: none"> ■ Illicit substances (cocaine, THC) ■ No confirmations ■ Did not consider opiates
Michna E, et al. <i>Clin J Pain.</i> 2007;23:173-9.	470	210 (45%)	<ul style="list-style-type: none"> ■ 20.2% illicit substances ■ 14.5% nonprescribed opioid ■ 10.2% missing opioid
Ives TJ, et al. <i>BMC Health Serv Res.</i> 2006;6:46.	196	62 (32%)	<ul style="list-style-type: none"> ■ 38.7% cocaine ■ 1.6% amphetamine ■ 24.2% missing opioid ■ 14.5% nonprescribed opioid
Manchikanti L, et al. <i>Pain Physician.</i> 2006;9:123-9.	500	80 (16%)	<ul style="list-style-type: none"> ■ 11% THC ■ 5% cocaine ■ 2% amphetamine
Katz NP, et al. <i>Anesth Analg.</i> 2003;97:1097-102.	122	36 (29%)	<ul style="list-style-type: none"> ■ 16.7% cocaine ■ 55.6% THC ■ 22.2% nonprescribed opioid
Fishbain DA, et al. <i>Clin J Pain.</i> 1999;15:184-91.	226	105 (46.5%)	<ul style="list-style-type: none"> ■ 6.2% THC ■ 2.2% cocaine ■ 8.8% incorrect self-report of current drug use

THC=11-nor-delta-9-tetrahydrocannabinol-9-carboxylic acid

Ongoing Monitoring

Patients should be monitored in accordance with their risk level for displaying ADRBs. Random or scheduled UDT can be utilized along with other measures (eg, contacting pharmacists, querying prescription monitoring programs/pharmacy databases, conducting pill counts) to help determine appropriate intake of prescribed drugs; help identify nonadherence, diversion, or illicit drug abuse; support referral for substance abuse assessment; and facilitate accurate documentation in the medical record.^{9,15,22,48,49}

A structured UDT strategy can be approached as a consensual test that is part of the effort to monitor the clinical efficacy of pain treatment, just as glucose analysis is essential for the evaluation and ongoing management of diabetic patients.^{9,13} Appropriate use of UDT may help overcome barriers to opioid analgesic use for chronic pain.

Appropriate use of UDT may help overcome barriers to opioid analgesic use for chronic pain.

Addressing UDT Results

Clearly established and consistently enforced policies around UDT minimize the potential for legal consequences, and vice versa.⁴⁹⁻⁵¹ For example, if nonprescribed/illicit drugs are present, will:^{9,27,31,49,50}

- Controlled substances be discontinued?
- The patient be referred to drug abuse treatment, a psychologist/psychiatrist, or a pain specialist?
- The patient be discharged from the practice?

It is recommended that all UDT results be promptly reviewed, interpreted, and documented in the medical chart, together with communications to the patient about the results.^{9,50} For physicians working in a group or multipractice setting, or when the patient has been referred to other health care professionals for treatment of comorbid conditions, it is important to indicate a plan for follow-up in the progress notes so that the patient receives a consistent message.⁵⁰ Electronic medical records, or another recordkeeping system that allows multiple physicians within a group practice to access UDT results and prescriptions written for a patient, may help to improve prescribing and monitoring practices. UDT results that are inconsistent with the prescribed medications should prompt the physician to delve more deeply

into the patient's problems by considering the results within the context of the "4 A's":^{9,52}

- Analgesia
- Activities of daily living
- Adverse effects
- ADRBs

This may require a psychologic/psychiatric referral, because those who misuse their opioids to self-medicate and relieve symptoms such as anxiety, depression, or insomnia may require different treatment than those who abuse prescription opioids for euphoric effects or who are addicted.^{6,27,28}

Underutilized UDT

An audit of medical records to assess the medical management of chronic pain patients found that only 8% of PCPs utilized UDT.⁵³ Patients had a variety of pain syndromes, but must have been using opioids for the treatment of chronic pain for at least 3 months prior to the audit date.⁵³ In a more recent survey of PCPs, 7% ordered UDT before prescribing opioids, and 15% had—at least once—tested established chronic pain patients already prescribed opioids.¹⁹ The low frequency of UDT is surprising in view of the data indicating that patient self-reporting of current illicit drug use and physician observation alone are not reliable.^{19,26} ■

URINE DRUG TESTING METHODOLOGIES

The classification of UDT methods grew out of their use in the forensic setting according to the type of result they provide. In these programs, methods are designated as either screening or confirmatory, and the use of these terms has carried over into the clinical setting.

Immunoassay Screening

Despite the depiction of laboratories in the media, the term “screening” does not indicate that a test can detect the presence of all drugs in the sample, nor identify all drugs within a class.¹¹ Laboratories use a variety of testing methodologies for screening, but immunoassay is widely employed because the technique is relatively cost-effective, has a rapid analysis time, and is readily available. Similar to the risk-assessment tools discussed previously, immunoassay tests are designed to identify individuals, or samples, that need closer scrutiny. Laboratory screening methods provide a qualitative determination as to the presence or absence of drugs in a sample. They are used within the forensic arena to eliminate negative samples from additional, more costly testing. They are usually relatively sensitive, but may not necessarily be specific. Screening tests are further classified according to the drug or class of drugs the method is designed to detect.

Most of the immunoassays used for UDT are based on a competitive antigen-antibody reaction, where drug molecules in the sample compete with a labeled version of that drug to bind with an antibody. In some cases, the assay is targeted to detect a drug metabolite rather than the parent drug. Enzymes and compounds that fluoresce or chemiluminesce are used to measure the antibody-drug reaction.⁵⁴ There are many types of immunoassays available, from point-of-care testing (POCT) devices to reagents for use on fully automated, large, laboratory-based platforms.¹¹

Laboratory-based methods typically target the compounds required in forensic or workplace settings. These compounds were chosen because they are excreted over a reasonable period of time and therefore provide a good window of opportunity in which to detect prior use. Some are also considered representative of the drug class. For example, cocaine assays do not target cocaine because it has a short period of excretion. Instead, these assays target benzoylecgonine—an inactive metabolite unique to cocaine—because it has a much longer window of excretion (Figure 4).

An immunoassay's ability to detect a drug or metabolite in a sample is affected by the specificity of the antibody, the assay cutoff, and the drug concentration within the sample. The antibodies employed may be very specific in their recognition of a given drug and fail to recognize similarly structured drugs within the class.^{11,54} Conversely, other antibodies may recognize an antigen site common to many drugs or metabolites within a class or even shared by drugs of other classes. The term cross-reactivity is used to convey an antibody's reactivity with another compound, including those totally unrelated to the targeted compound. The specificity of an immunoassay and the concept of cross-reactivity partially explain conflicting results between screening and confirmation testing.^{11,54} When the antibody cross-reacts with a compound outside the class of drugs it is designed to detect, a false-positive may result. Cross-reactivity patterns for immunoassays differ between manufacturers and even between lots of reagents from a single manufacturer.^{11,54} For this reason, it cannot be assumed that a cross-reaction documented for one assay will affect another, or that a compound previously not interfering will never interfere (see page 13).

Laboratory-Based Specific Drug Identification

At this time, GC/MS remains the “gold standard” for confirmation testing. This technique uses GC to separate the analytes in a specimen, and the highly specific and sensitive MS to identify the specific molecular structures of the drug and metabolites.⁹ One of the advantages of this technique is that it provides the chemical equivalent of a “fingerprint” of an analyte. Additionally, it can quantify the amount of drug/metabolite present in the sample. In the clinical setting, the technique can not only be used to confirm the results using screening assays, but also to identify the presence of drugs that are not reliably detected by those methods.

Figure 4. Excretion Patterns of Cocaine and Metabolites

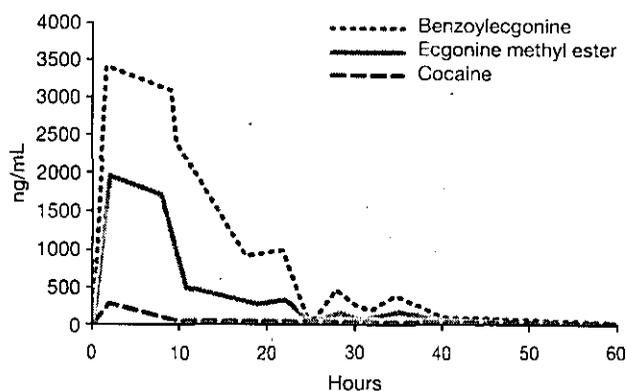


Figure courtesy of Hammett-Stabler CA.

Table 4. Drugs Included in Federally Regulated Testing^{54,64}

Drug/metabolite	Immunoassay screen cutoff concentration (ng/mL)	Confirmation cutoff concentration (ng/mL)
Marijuana metabolites	50	-
THC	-	15
Cocaine metabolites	300	-
Benzoylcegonine	-	150
Opiates	2000	-
Morphine	-	2000
Codeine	-	2000
6-MAM*	-	10
Phencyclidine	25	25
Amphetamines	1000	-
Amphetamine	-	500
Methamphetamine	-	500

THC=11-nor-delta-9-tetrahydrocannabinol-9-carboxylic acid

6-MAM=6-monoacetylmorphine

*When morphine concentration is ≥ 2000 ng/mL

GC/MS refers to the technique used for the analysis, but does not describe the method used by the laboratory. There are many methods described in laboratory sciences literature for each drug or metabolite. A laboratory may have adopted or modified one of these or possibly developed its own. These methods detail how samples are prepared for testing on GC/MS, as well as the conditions or settings for the instrumentation, and the criteria used to judge acceptability of the results. Although these methods are not approved by the US Food and Drug Administration, they are regulated and all laboratories follow guidelines to assure the results are accurate and reliable.

Other Confirmatory Testing

Other detection systems are being evaluated for UDT. Most rely on a type of chromatography to separate the various constituents of the sample before identification. Liquid chromatography (LC)/tandem MS (LC/MS/MS) can be a more time-efficient method for the simultaneous quantification of multiple abused and therapeutic drugs and metabolites in urine.⁵⁵⁻⁵⁹ Another technique gaining interest for the analysis of drugs in biologic samples is ultra-performance liquid chromatography (UPLC). Coupled with the appropriate detection system, such as MS or diode-array ultraviolet spectrophotometry, methods using UPLC have been developed to both screen for large numbers of drugs and for confirmation analysis.⁶⁰ Technologic advances associated with UPLC allow for high-throughput testing compared with classic high performance liquid chromatography (HPLC).⁶¹ UPLC is also being utilized in the development of biomarkers for drug/alcohol abuse.⁶²

Reporting of Results

The cutoff of an assay, whether screening or confirmatory, defines when a result is considered positive or negative and is based upon the analytic capabilities of the method.⁴⁰ Results at or above this level are considered positive; results below are considered negative. How a laboratory reports results varies: some use the terms present or positive, while a few report the result as above or equal to the designated cutoff. Any result below the cutoff is considered negative. These results may be reported as negative, below the cutoff, or, perhaps inaccurately, as absent or none detected. In a forensic setting, positive results from screening methods are considered "presumptive" until verified using a more sensitive and specific confirmatory method.

While federally mandated cutoffs are typically adopted in workplace or forensic settings (Table 4), different cutoffs may be more appropriate in a clinical setting. For example, the 2000 ng/mL immunoassay cutoff for opiates, chosen to minimize the issue of positive results due to poppy seed ingestion, is clearly not useful in the clinical setting. It may be desirable to ask the laboratory to customize the cutoffs it uses or to use other versions of an assay, but keep in mind that they may be limited by the available technology. Only a few immunoassay systems currently allow laboratories to alter cutoffs, although they have greater flexibility to do so when using GC/MS or other similar technologies. A laboratory should never alter cutoffs without carefully and consistently documenting the method's performance and accuracy at a given level. There is always a concentration below which results are not reliable or accurate, so laboratories should not usually eliminate a cutoff altogether.⁶³

Testing Menu

No single urine drug "screen" is suitable for all clinical uses, but rather a multitude of options exist that can be adapted to clinical needs.¹¹ Which drugs are included in the testing menu vary greatly between and even within laboratories.¹¹ Most menus for automated immunoassays include those desired for workplace drug testing, sometimes referred to as the "NIDA Five" after the original federal agency involved (National Institute of Drug Abuse); ie, amphetamine, cocaine, opiates, marijuana, and phencyclidine.^{9,11,64} Tests for additional drugs or classes, such as benzodiazepines, barbiturates, lysergic acid diethylamide (LSD), propoxyphene, methadone, and semisynthetic/synthetic opioids, are available on automated immunoassay platforms.^{5,9,11} Although this has been an area of great expansion in recent years, with several "new" tests coming to market, immunoassays are still not available for every drug pertinent to pain management or for use with all instruments.

Multidrug panels commonly include an opiate immunoassay screen that is designed to detect heroin, morphine, or codeine use. In most cases, the metabolic pattern of heroin results in morphine, which is therefore the target compound for these assays. How readily an opiate assay detects other opioids varies considerably. Physicians should speak with their laboratories to better understand what is usually detected by the immunoassays they use, but recognize that some manufacturers provide limited data for drugs other than the target compounds. It is also important to understand what is identified and measured by the confirmation assays. Most GC/MS opioid confirmations include morphine, codeine, hydrocodone, hydromorphone, oxycodone, and oxycodone, but not fentanyl or methadone—the latter 2 are available as separate tests.

Efficient use of laboratory resources begins with knowledge of the drugs prescribed for the patient as well as those currently abused in the locality.

Customizing a Pain Management Profile

Pain management clinics commonly test for prescribed drugs and drugs with high abuse potential.⁹ Physicians must decide whether to screen for illegal drugs and, if so, which—some degree of testing is advisable because an abuser of illicit drugs is at increased risk for prescription drug abuse, but selecting everything the laboratory has available is neither cost-effective nor clinically useful.^{9,11} Efficient use of laboratory resources begins with knowledge of the drugs prescribed for the patient as well as those currently abused in the locality.⁹ Several resources are useful in this endeavor, including law enforcement, the medical examiner's office, and clinical laboratories. The next step is to review the drug screening and confirmatory testing menu available through the laboratory and select accordingly. Some laboratories offer groups of drug assays for convenience, but these are also available as single tests; ie, it is not necessary to order a phencyclidine or LSD assay that the laboratory offers to meet ED needs.^{5,9,11} Also consider asking patients what they think will show up in the results—patients may admit to taking drugs that the tests you planned to order do not detect.⁵⁰ Depending on the drug in question, confirmation testing may be necessary to reliably detect it. Another approach is to customize appropriate menus with the laboratory for patient populations; for example, one with a rapid analysis time and another that is more comprehensive.¹¹

Point-of-Care Testing

POCT refers to any testing performed outside the traditional laboratory, typically by personnel whose primary training is not in the laboratory sciences.¹² POCT is available for many tests, and most physicians are familiar with the devices used for glucose or coagulation monitoring. The demand for rapid turnaround time to detect drugs of abuse in certain clinical, employment, and ED settings has increased use of POCT immunoassay devices as an alternative to collection, transport, and subsequent laboratory analysis.^{9,12} Federal workplace drug testing programs are considering allowing the use of POCT devices in order to quickly identify specimens that are negative for drugs.³

There are several issues to consider before implementing a POCT system for UDT in clinical practice. It should be understood that these devices are intended to be used only for screening, and that POCT is not interchangeable with traditional laboratory confirmation tests.^{9,12} The staff chosen to perform the testing must be able to carry out the required steps exactly as described by the manufacturer. Theoretically, POCT can shorten the interval between sample collection, test completion, and therapeutic intervention, but this is not a justification for POCT if the quality of results is compromised.^{9,12,65}

POCT devices are generally noninstrumented immunoassay tests with endpoints that are visually read by the operator. The "device" may be a dipstick, cup, card, or cassette. The amount of urine needed for testing ranges from a few drops to approximately 30 mL.^{3,12} The simplest-to-use POCT devices combine collection and testing, but most require the operator to perform multiple steps, including sample application, timing of reaction, and reading/interpreting the endpoint.¹² Data recording from typical POCT devices is performed manually, in contrast to laboratory testing that both reads results and captures this data on a computer system—although POCT devices are becoming available that are read by a meter and may interface to an information system.¹² One often-cited issue with POCT devices for drugs of abuse testing is that some give a negative visual sign when the drug of interest is at or above the defined threshold; ie, absence of a line or color indicates a drug is above the threshold and vice versa.¹²

These devices have a varied but limited menu in terms of the drugs, drug classes, or groups of drugs detected.^{9,12} The antibodies used in the POCT devices target the same drug and/or metabolites detected by laboratory immunoassays, and a positive result is similarly obtained when the drug(s) or metabolite(s) of interest is present at or above a designated cutoff concentration.¹² These devices are also subject to the same challenges and limitations of laboratory-based immunoassays, but recognition and resolution of these rest in the hands of the POCT operator.¹²

When results may direct or influence treatment, clinical staff using the data should understand the limitations of testing and order a laboratory confirmation test, such as GC/MS, before taking any definitive action.¹²

POCT devices vary in accuracy of analytic performance, cutoff concentrations, cross-reactivity, reproducibility, and ease-of-use.^{9,12,66} The POCT literature contains numerous reports in which devices are compared to laboratory testing. Unfortunately, many of these were conducted using trained laboratory personnel rather than in the field by individuals who were likely to be performing the testing on a routine basis.¹² Under these controlled conditions, the current devices were generally found to agree with comparable laboratory methods, although none were 100% concordant with the comparator methods—disagreement was greatest for samples near the designated cutoffs.¹² In addition, there are anecdotal reports of discrepancies in interpretation of subjective results by nonlaboratory personnel and quality control practices that fall short of laboratory standards.^{12,65,67}

Evaluating POCT

The clinical and economic impact of POCT should be established prior to introduction at a site.¹² The staff should conduct evaluations under conditions in which testing will be performed.¹² Some devices have very rapid color development that must be read soon after application of the specimen. Staff need time to perform POCT without interruptions as the reaction typically continues beyond that point and may be incorrectly interpreted if read 5, 10, or 15 minutes later.⁶⁸

The fixed-unit cost of POCT devices often exceeds that of laboratory-based methods.^{12,68} A significant value-added component needs to be justified for obtaining immediate access to results for patients.⁶⁸ Some clinicians have found performing the test in front of the patient useful, while others have found this can negatively affect the clinician-patient relationship when subsequent, more specific testing reveals a conflicting result.

Specimen Tampering/Validity

In many contexts, particularly in the workplace, school, and within law enforcement, there are significant consequences for illicit drug use, including termination of employment, suspension, expulsion, ineligibility for federal student loans, athletic bans, incarceration, loss of custody, and fines.^{4,7} Theoretically, the greater the negative consequences of substance use, the greater the likelihood of tampering with a sample to produce a false-negative result.⁷ Although the number of pain patients who tamper with their urine samples appears to be low, consequences in the clinical setting include discharge from treatment or change in clinical management.^{7,9,27}

The Internet is a common source of information, providing drug users with broad advice, recipes, and commercial products to circumvent detection.^{7,69,70} Methods to mask illicit drugs in urine fall into 3 categories:^{3,7,71}

- Dilution and cleansing products
- Additives to prevent drug detection
- Urine substitutes

The type of UDT method will determine whether or not an adulterant will successfully produce a false-negative result.^{7,71}

Although the number of pain patients who tamper with their urine samples appears to be low, consequences in the clinical setting include discharge from treatment or change in clinical management.

In Vivo Adulteration

Although many commercial products purport more elaborate mechanisms of action to “flush” the body of toxins and drive the drug concentration below the level of detection, most in vivo adulterants work by excessively hydrating the individual and thus diluting the urine before excretion.^{3,5,7} Ingesting as little as one half to a full liter of water or other fluid prior to micturition will work just as well and be more cost-effective.^{3,5,7,71} The drawback to water alone is that the urine produced is usually pale or colorless. Some products attempt to avoid visual detection by adding ingredients, such as niacin and vitamin B, which produce a yellow color consistent with that of urine.⁷

In Vitro Adulteration

In vitro adulterants are added to urine after micturition into the collection cup to:^{3,5,7,71}

- Drive the concentration of the illicit drug below the threshold detection level of a test
- Interfere with immunoassay detection
- Convert a target drug to compounds that are not detected

The addition of water from the toilet bowl or sink is a common method to dilute the sample, although the use of saline or other medical solution has been documented. Several commercial adulterants, designed to be added to the sample either during or after collection and specifically marketed for the purpose of “passing” UDT, are sold via Web sites, magazines, and shops devoted to recreational drug use.^{7,9} The active ingredients of some

include glutaraldehyde, sodium or potassium nitrate, pyridinium chlorochromate, or peroxide/peroxidase.⁷ Common household products used as in vitro adulterants include bleach, vinegar, eye drops, caustic soda, detergent/soap, ammonia, and sodium chloride.⁷ Formulations constantly change as laboratories implement methods to identify their use.³

Urine Substitution

Urine substitution methods involve obtaining and substituting either commercially available fluids formulated to chemically resemble urine or a “clean” urine specimen from a nonusing acquaintance.^{3,7} Substitute products may include reservoirs, prosthetic devices, and hand warmers or a heating unit strapped to the body to maintain specimen temperature.^{3,7} Some deliver drug-free or synthetic urine through a color-matched artificial penis—the “Whizzinator®” kit received media coverage in 2005, as well as discussion in Congress, after a professional National Football League player caught in possession of one at a US airport was subsequently suspended.⁷² An alternative to external urine storage is urine substitution within the bladder (recatheterization), where an individual voids and uses a catheter to refill the bladder with clean urine via the urethra.⁷

Validity Testing

Many attempts to dilute, substitute, and adulterate urine are detected by a combination of close visual inspection and on-site or laboratory analyses (Table 5).^{7,71} Urine is typically translucent and light yellow in appearance, although color may vary due to diet and other factors.⁷ Household adulterants may create a specimen that is unusually foamy, bubbly, cloudy, clear, or dark, but visual inspection alone is not sufficient to confirm tampering, and samples with these appearances may be caused by pathologic conditions.⁷ A useful on-site test is the recording of urine temperature within 4 minutes of voiding. In this time

period, the temperature of a urine specimen collected from a healthy patient should range from 90°F to 100°F—temperatures outside these values suggest that a substitute specimen was provided.^{3,7,9} Specimen containers that have a temperature strip impregnated within the collection cup provide a convenient way to measure temperature, but again, these are effective only if read within the prescribed time.^{3,7} A sample that is outside of the expected temperature range should be recollected immediately. In addition, urinary creatinine, specific gravity, and pH are 3 clinically useful tests that have been adopted by workplace programs as indicators of specimen integrity or validity.^{3,7,71} Use of the SAMHSA-mandated criteria may be helpful in the decision process when visual inspection suggests tampering. Brief descriptions of the rationale for the use of these 3 tests, as well as the SAMHSA-mandated thresholds for interpretation, are as follows:^{3,7,71}

- **Creatinine concentration:** Creatinine is a byproduct of muscle metabolism. Its concentration in the blood is related primarily to muscle mass and, to a smaller degree, diet. Since it is freely filtered by the glomeruli and secreted by the tubules at a relatively constant rate, it serves as a good indicator of hydration. A randomly collected urine sample from an adult should contain 15 to 400 mg/dL creatinine.⁷³ Because of their lower body mass, women tend to excrete less creatinine than men and, as a result, a urinary creatinine in the lower part of the reference range is not unexpected for a small-framed woman. For similar reasons, very low concentrations are common in young pediatric populations; however, by adolescence, excretion usually reaches the adult range. Workplace programs have adopted the finding of a creatinine concentration <20 mg/dL as an indicator of possible dilution, either by excessive fluid ingestion or the physical addition of fluid to the sample. Creatinine <5 mg/dL is usually inconsistent with adult urine, and SAMHSA has designated a creatinine <2 mg/dL as indicative of substitution. Although low creatinine concentrations may be produced by healthy individuals during the course of a day, finding a urinary creatinine <20 mg/dL in the pain management setting raises a “red flag” and should be investigated.
- **Specific gravity:** Specific gravity compares the density of a solution to that of pure water. It is routinely used to evaluate the concentration of urine—the specific gravity increases as substances are added to urine and, conversely, decreases if water is added. The expected specific gravity of a randomly collected urine sample from an adult is 1.002 to 1.030, with the caveat that the individual has not restricted or ingested excess fluids.⁷³ As shown in Table 5, SAMHSA has established criteria using specific gravity along with a urinary creatinine measurement to evaluate urine samples for dilution or possible substitution.

Table 5. SAMHSA Criteria for Validity Testing of a Urine Specimen^{3,64}

Urine specimen is reported as:	When:
Dilute	Creatinine concentration ≥ 2 mg/dL; but <20 mg/dL, & specific gravity* > 1.001 , but < 1.003
Substituted	Creatinine concentration < 2 mg/dL & specific gravity* ≤ 1.001 or ≥ 1.020
Adulterated	pH [†] < 3 or ≥ 11 , nitrite concentration ≥ 500 $\mu\text{g/mL}$; chromium (VI) concentration ≥ 50 $\mu\text{g/mL}$; presence of a halogen (eg, from bleach, iodine, fluoride), glutaraldehyde, pyridine, surfactant

*Using refractometry; †using a pH meter

- pH: The pH of a freshly collected urine sample is typically in the range of 4.5 to 8.0.⁷³ This measurement is useful to detect the addition of chemicals such as bleach and vinegar. A pH of <3 or ≥11 is suggestive of adulteration.^{3,61}

Finally, testing is available to detect the presence of the aforementioned compounds that are added to a urine sample in an attempt to avoid detection; for example, glutaraldehyde, nitrates, and peroxide. Keep in mind that these tests are not routinely performed by many laboratories—ask if this type of testing is conducted and under what circumstances.

Collecting the Sample

In the workplace setting, the possibility a donor will attempt to alter his or her sample is a concern, and steps are routinely enforced to prevent this from happening. Unfortunately, the clinical setting is not immune to these occurrences—for example, a study of adolescent patients in a primary care setting revealed that the creatinine measurements of 6% of specimens were below 20 mg/dL (ie, dilute).⁵ In a survey of PCPs, only 7% of those who ordered UDT also requested both specific gravity and urinary creatinine to ensure sample validity, and 61% ordered neither.^{7,74} Usually, specific gravity, pH, and urinary creatinine must be ordered separately.

Proper collection procedures can minimize in vitro adulteration and dilution.⁵ Simple steps can be taken to limit access to water that could be used to dilute the specimen:³

- Turn off the water supply to the bathroom sink
- Place a blue dye dispenser in the toilet water tank
- Remove cleaning agents and soaps from the bathroom
- Do not allow the patient to carry unnecessary outer clothing or personal belongings into the bathroom
- Only allow designated staff access to the specimen after collection

However, even rigorous collection procedures cannot prevent determined individuals from adulterating their urine specimens—when suspected, consider collecting another specimen under direct observation.^{3,5} In vivo dilution resulting from the ingestion of excess fluid and/or a diuretic will only be detected if samples are checked for adequate concentration.⁵ Advise patients who provide dilute samples to decrease fluid intake prior to testing, or collect samples in the early morning when urine is most concentrated.^{9,40} ■

INTERPRETATION OF URINE DRUG TESTING RESULTS

As a clinical tool used in conjunction with other monitoring measures, UDT provides significant benefits, and even the knowledge that it will be performed can increase patient adherence.^{5,9} But no test has value—and can even cause harm—if the end user cannot correctly interpret the results. Because the results of UDT often carry possible repercussions, false-negatives and false-positives are a major concern. A false-positive result carries greater consequences in the workplace setting, but in the clinical setting either can cause harm. When using UDT, physicians must recognize issues resulting from collection practices, understand the limitations imposed by the currently available analytic methods, have a sound grasp of the pharmacology of the drugs tested, be able to decide when screening is sufficient or confirmation is needed, and put all of these together for each patient. However, in a 7-question survey assessing UDT interpretation, none of the physicians who employed UDT to monitor patients receiving chronic opioid therapy correctly answered all questions, and only 30% correctly answered more than half (Figure 5).⁷⁵ The questions most frequently answered incorrectly related to what substance(s) would likely be detected in urine following heroin use or following oxycodone use together with the consumption of poppy seeds, and plausible explanations for a negative opiate immunoassay result in a patient on chronic opioid therapy.

False-Negative Results

Analytically, a result is considered false-negative when a drug is present above the cutoff but not detected by the test. A false-negative result may give a physician misplaced confidence that drug abuse is not occurring, delay diagnosis, and reinforce ADRBs by the patient; it may also lead to accusations of diversion.^{5,75} As explained in previous sections of this monograph, UDT methods, whether screening or confirmatory, have a threshold below which results are not accurate or reliable. The threshold is set at a level the laboratory is confident can be achieved routinely. A result below that number is considered negative. A negative UDT result for a patient prescribed an opioid may be due to several factors:^{5,9,75-77}

- Absence of recent use
- A dilute urine sample
- An immunoassay test that does not cross-react with that particular opiate or is not sufficiently sensitive to detect the drug level
- Pharmacogenetic variability in drug metabolism (eg, ultra-rapid metabolizer)

Many immunoassays do not readily detect synthetic/semisynthetic opioids at therapeutic doses; however, in the above-mentioned survey, only 12% of PCPs correctly knew that a test for oxycodone,

a semisynthetic opioid, must be specifically ordered.^{9,25,40,74} Before testing, physicians should take a history of recent use of the prescribed drug to assess the patient for nonadherence—he or she may have missed 1 to 2 days by misunderstanding instructions, but the patient could also be hoarding, bingeing, or diverting the drug, all of which must be addressed.^{9,15}

False-Positive Results

False-positives occur when a drug is detected by UDT but is, in fact, absent. To reduce the possibility of a false-positive result, positive workplace UDT results are evaluated by a medical review officer (MRO) before final interpretation. This physician assesses all of the circumstances that can lead to a positive result to determine if there is a medical reason for it. In the clinical setting, this role is assumed by the ordering provider.

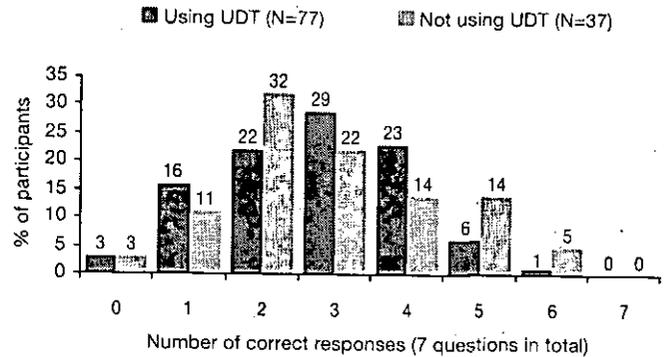
False-positive results can substantially harm patients who are not abusing drugs by placing them under a cloud of unjust suspicion, false accusations of abuse, unjustified cessation of opioid treatment, deterioration of the physician-patient relationship, and/or compromised ability to receive future therapy.^{5,74,75} Immunoassays from different manufacturers have different interference profiles, and laboratories will provide this information when requested.⁷⁸ However, data about false-positive UDT results are often limited to case reports, and not all drugs that cross-react are always included on the immunoassay manufacturer's package insert.^{50,78,79} Examples of drugs previously reported to cause false-positive UDT results with some immunoassays include:

Interfering drug	Immunoassay affected
■ Quinolone antibiotics (eg, levofloxacin, ofloxacin) ^{80,81}	Opiates
■ Antidepressant trazodone ⁸²	Fentanyl
■ Antidepressant venlafaxine ^{79,83,84}	Phencyclidine
■ Atypical antipsychotic quetiapine ⁸⁵	Methadone
■ Antiretroviral efavirenz ⁸⁶	THC
■ Diet pills (eg, clobenzorex, fenproporex) ^{8,40}	Amphetamine
■ Promethazine (for allergies, agitation, nausea, vomiting) ⁷⁸	Amphetamine
■ <i>l</i> -methamphetamine (over-the-counter [OTC] nasal inhaler) ^{9,40}	Amphetamine

Many of the interferences from the drugs listed have been eliminated, but new interferences should be expected to arise as drugs arrive on the market. Physicians can make a valuable contribution within this area by raising the question of false-positives with their laboratory and notifying them of the drugs that a patient is taking.

False-positives due to a prescription or OTC medication cross-reacting with an immunoassay can be avoided by confirming

Figure 5. Physicians' Knowledge Level of UDT by Ordering Status⁷⁵



unexpected results using GC/MS.^{5,78} However, legitimate use of a prescription medication that contains or is metabolized to the target drug can be assessed only by taking an accurate medical history and knowing which medications can account for such results.⁵ Correct interpretation requires a detailed, up-to-date list of prescribed, OTC, and herbal agents that the patient is taking.^{5,40} This should preferably occur before ordering the test, but physicians should conduct a follow-up interview when the patient has an unexpected result.^{5,40} In a primary care study, 21% of confirmed positive UDT results were due to legitimate use of prescription or OTC drugs.⁵ For example, amphetamine and methamphetamine have legitimate medical uses in the treatment of obesity, narcolepsy, and attention deficit/hyperactivity disorder, but can also be diverted from legitimate pharmaceutical sources or manufactured in clandestine laboratories.^{25,40} Medical use of cannabinoids include the orally active synthetic agents dronabinol (Marinol®) and nabilone (Cesamet®), which are both indicated to treat nausea and vomiting associated with cancer chemotherapy.⁸⁷ Dronabinol is also indicated for the treatment of weight loss associated with acquired immune deficiency syndrome. UDT results are likely to be positive after therapy with dronabinol, which is identical to the THC from marijuana, and it is possible that an immunoassay may cross-react with nabilone.^{87,88} The increased availability of cannabinoid-based therapeutics has highlighted the need to identify other biologic markers or metabolites from the mix of cannabinoids in naturally occurring products that will accurately distinguish between ingestion of natural and synthetic cannabinoids.^{88,89} Certain foods can also cause analytically valid results; for example, ingested poppy seeds may cause positive opiate results due to morphine and codeine present on the surface of some seeds. In fact, morphine concentrations as high as 10,000 ng/mL have been found in the urine of volunteers who ingested poppy seed bakery products.⁹⁰ Without an appropriate investigation, this result could be incorrectly interpreted.

remains positive for THC for 1 to 3 days after a single use of marijuana and for 7 days after moderate use—however, this lipophilic metabolite significantly accumulates in fat stores so urine may remain positive for a longer time.⁹⁴ Some studies suggest that this may be up to 30 days in chronic users depending on the quality of the marijuana smoked.⁹⁴ Some benzodiazepines can also take weeks to eliminate from the body depending on the amount and type ingested.^{9,11,25}

Analytic factors that can influence UDT results include the characteristics of the test method used for screening and confirmation (eg, accuracy, sensitivity, specificity), the laboratory's procedures for sample preparation and analysis, and the cutoff concentration used to distinguish positive and negative samples.^{4,7,25,49,94,96} The appearance of an ingested drug or metabolite in urine ends a series of complex events involving absorption, distribution, and metabolism, which can be affected by a number of factors:^{4,7,9,11,25,49,94,96}

- Urine pH
- Urine volume
- Diet
- Urinary frequency
- Body weight
- Presence/absence of malabsorption
- Concurrent medications
- Pharmacokinetic drug properties
- Amount of drug ingested
- Route of administration
- Dosage intervals
- Patient ability to metabolize drug
- Time since ingestion
- State of hydration
- Duration of use
- Disease state

Caveats to Interpretation

As well as having negative consequences for patients, it has been suggested that false accusations of drug abuse or diversion based on misinterpreted UDT results have potential medicolegal ramifications for physicians.⁷⁵ To avoid this, physicians who employ UDT should understand the pharmacology of illicit and prescribed drugs, and work closely with laboratory professionals when ordering and interpreting these tests.^{3,5,75} This includes having accurate knowledge of alternative medical explanations for positive results, reasons why a specimen may be reported as invalid, and the need for confirmatory testing.^{3,75}

Before ordering UDT, ensure that the medical record accurately reflects all medications that the patient is currently taking.⁹ A thorough history provides an opportunity to order more specific tests if the patient's drug of choice or prescribed medication is not detected reliably by a routine panel or if he or she is taking a prescribed or OTC drug that might cross-react with an assay.^{3,9} Problematic results are cues to counsel the patient, tighten treatment boundaries, and possibly refer that individual for drug abuse treatment, but physicians should discuss results with the laboratory and the patient before making major treatment

changes.^{9,40} Concurrent use of illegal drugs is clearly abuse, but a test that fails to detect a prescribed opioid in the urine cannot differentiate whether the patient took the medication early because of uncontrolled pain (pseudoaddiction), to treat psychologic symptoms ("chemical coping"), is addicted, sold some or all of the medication, or whether other factors influenced the results.^{6,9,27,28}

Predicting Dose Compliance

A positive UDT result does not provide enough information on drug use to establish exposure time, dose, and frequency of drug use, nor does it provide enough information to diagnose drug addiction or current impairment.^{9,40} Algorithms are under investigation to help determine whether patients are taking their opioid medication as prescribed by comparing a patient's UDT value to an expected range.^{40,101} However, at this time there is no scientifically validated relationship between the amount of drug taken and the concentration of the drug in urine, and attempts to calculate a normalized value are hampered by a large degree of variability in opioid metabolism and elimination.^{40,101} Even protocols that calculate a normalized value based on patient characteristics and specimen properties (eg, pH, specific gravity, creatinine level) cannot account for the numerous other factors that may influence the absorption, distribution, metabolism, and elimination of a drug.⁴⁰ These include genetic polymorphisms, renal and hepatic function, disease states, drug-drug interactions, drug-food interactions, body surface area and muscle mass, and age.⁴⁰ However, developing methods to help assess compliance with prescribed medications through UDT is an area of intense research.

Consultation With Laboratory Scientists

Physicians who order UDT should frequently consult with laboratory scientists to select appropriate tests, ensure proper results interpretation, and keep informed of changes in the laboratory, such as adoption of new agents or assays.⁵ Physicians should consider UDT results in the context of all the clinical information, and contact the laboratory scientist whenever there is a discrepancy to review the laboratory procedures that were used and clarify test results.⁵ Unfortunately, in a study among family medicine physicians, only 23% indicated that they would consult with the laboratory director when confronted with an abnormal or unexpected UDT result.¹⁰² ■

EMERGING TECHNOLOGIES FOR DRUG TESTING

Urine is the most extensively used specimen for drug testing and remains the standard for drug-use monitoring. It requires minimal preparation for analysis, and many drugs of interest or their primary metabolites concentrate in this matrix.^{9,11} Collecting an adequate volume of urine for analytic purposes is not usually a problem unless the patient is in renal failure or incontinent, although it has been suggested that UDT discriminates against patients who suffer from shy bladder (paruresis), and some patients complain that it is invasive and embarrassing.^{11,51,103} UDT has good sensitivity and specificity for detection of recent drug use, although a very recently ingested drug may not be detected in urine, and the presence of a drug in urine reflects prior exposure only and does not correlate with clinical status.^{11,103}

The major specimens being assessed as alternatives to urine for drug testing are blood, oral fluid, hair, and sweat.

Alternative Specimens

Drugs can be detected in other biologic specimens, including hair, oral fluid, blood, sweat, nails, and semen.²⁵ Of these, the major specimens being assessed as alternatives to urine for drug testing are blood, oral fluid, hair, and sweat.^{9,11} Each biologic specimen offers a unique pattern of information regarding drug use over time and has particular strengths and weaknesses regarding the type of information that may be obtained for each drug class, ease of use, degree of invasiveness, and cost.^{9,25} The window of drug

detection for urine, hair, blood, oral fluid, and sweat are not identical, but the results from each specimen can complement each other (Figure 7).^{3,9,104} Characterization of the disposition of different drug classes in these biologic matrices and the effect of chemical, physiologic, and pharmacologic factors are important for accurate interpretation of results.^{4,105,106} Some drug classes are more difficult to detect than others for a given type of specimen.^{3,11}

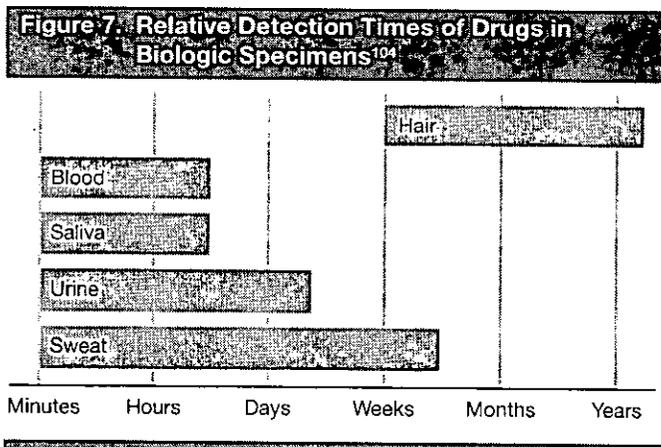
Blood/Serum/Plasma

Low levels of substances can be effectively detected in blood, serum, or plasma and, theoretically, these samples provide the optimal measure for the assessment of an intoxicated patient.¹¹ Their use in the workplace setting is limited because the invasiveness of collection requires a trained individual. This is less of an issue in a pain clinic where skilled personnel are available to properly collect samples. In this setting, blood, serum, or plasma samples may be occasionally useful for an individual who is anuric, but this type of testing is generally more expensive than UDT.^{9,11} As seen in Figure 7, the window of detection for many drugs in this matrix is short and reflects current or very recent drug use.^{9,11} Although the benefits of therapeutic drug monitoring (TDM) using serum drug concentrations is well documented for many drugs—antiepileptics for example—very few studies have been conducted to demonstrate utility of TDM in the management of pain medications.¹⁰⁷

Oral Fluid

Oral fluid testing is increasing in popularity since it overcomes some of the problems of urine—it offers accessible collection in almost any location, less embarrassment, observable conditions, and limited invasiveness.^{4,9,12,68,108,109} Researchers comparing the effectiveness of oral fluid testing with UDT found a similar pattern and frequency of positive drug test results in the general workforce over the same time period.^{9,10} In 2004, the US Department of Health and Human Services (DHHS) proposed developing scientific and technical guidelines, based on the current UDT National Laboratory Certification Program, to include oral fluid analysis in federal workplace drug testing.^{3,4,111}

Oral fluid is composed of saliva mixed with gingival crevicular fluid, buccal and mucosal transudates, cellular debris, bacteria, and residue of ingested products.⁴ Oral fluid specimens reflect circulating drug concentrations because salivary glands are highly perfused, allowing rapid transfer of a drug from blood.⁴ Thus, it can be stated that drugs are detected earlier in saliva than in urine, but for shorter time periods.¹² Oral fluid is generally useful for detecting drugs in the range of less than 1 hour up to 4 hours, but some drugs can be detected for up to 24 hours.^{3,9}



A drug is transferred from blood to saliva primarily by passive diffusion, which depends on chemical properties of the drug, salivary pH, concentration of nonionized drugs, and drug-protein binding (only free nonionized drugs can passively diffuse across biologic membranes; hence, protein-bound drugs are generally present in lower concentrations in oral fluid than in plasma).⁴ Basic drugs (eg, amphetamine and cocaine) tend to accumulate in oral fluid compared to plasma because of the lower pH of saliva, but the dynamic pH of oral fluid can substantially affect their concentration (basal pH of saliva is 6.5, whereas stimulated flow has a pH around 8.0).^{4,9,12}

Oral fluid as a test matrix shows promise for detection of recent drug use.

Collection procedures are not standardized and can affect drug concentrations.¹² Specimens are collected by having the patient expectorate—with or without stimulation—into a clean container, or by using a commercial collection device. Absorption of the drug by the material of a collection device also introduces issues of drug recovery compared with neat oral fluid.^{4,12,51} The sample volume of saliva necessary for laboratory testing is difficult to obtain, and considerably lower drug concentrations compared with urine present an analytic challenge.¹²

Oral fluid as a test matrix shows promise for detection of recent drug use, and a significant body of scientific literature documents aspects such as drug disposition and detection times.^{4,12} However, it has not yet been determined whether adulterants exist that can be safely placed in the mouth to produce false-negative results, and evidence on interference of common compounds present in the mouth, residual drug in the oral cavity, and other issues of manipulation is still lacking.^{4,12,51}

Hair

The disposition of drugs in the body includes incorporation into growing hair.¹¹² Hair may be useful to objectively document past drug use, but it is usually inefficient for clinical testing.^{9,112}

Testing hair can extend the window of detection for a drug to weeks, months, or even years depending on the length of the hair tested.^{3,9,113} However, dose and time relationships for drugs in hair are not clear—some studies support that segmental hair analysis can provide a chronologic record of drug use, but others have found high variability in such results.^{25,114,115}

Several mechanisms for incorporation of drugs into hair have been proposed.¹¹² Drugs diffuse from arterial capillaries near the root into hair matrix cells at the base of hair follicles, but drugs in sweat and sebum on the skin's surface contact hair and contribute to drug incorporation.^{105,112} The ability of hair testing to distinguish drug use from external contamination (eg, drugs in smoke or the environment) remains controversial.^{25,112} Typically, measuring metabolites and washing hair samples in solvents can help prevent false-positive results from external contamination.¹¹²

Darkly pigmented hair has a greater capacity to bind a drug than hair that is light or gray, leading to the claim that hair analysis might have a color or racial bias.^{9,25,114-116} Other disadvantages of hair analysis to validate drug use include irregular growth, labor-intensive sample preparation, low analyte concentrations, and excessive cost.^{25,115,116} Differences in hairstyle lengths may affect ability to analyze hair specimens, and hair treatments such as bleaching, dyeing, and permanent waves can alter drug concentrations in hair.²⁵ However, methods for evading UDT do not affect hair analysis, and collection may be achieved under close supervision.¹¹³

Sweat

Sweat could provide a convenient, less invasive collection method and a longer detection window than urine for most drugs.^{103,105} The window of drug detection for a sweat patch is a cumulative measure of drug use from shortly before the patch is applied until it is removed, which may be from several days to weeks.^{3,9,105} Sweat testing may be most useful to deter future drug use in patients participating in drug abuse treatment programs, but is not ideal to monitor drug use for pain management.^{3,9,105}

Criteria for reporting hair, oral fluid, and sweat-patch specimens as invalid, adulterated, or substituted have yet to be defined.

The mechanisms by which drugs are incorporated into sweat are not fully understood.¹⁰⁶ Drugs primarily passively diffuse from blood to the sweat gland, but also dissolve in sweat on the skin's surface after passing through the stratum corneum.^{103,106} Deposition of drugs in sweat depends on molecular mass, pKa, extent of protein binding, and lipophilicity.¹⁰⁵ Nonionized basic drugs (eg, codeine) in blood diffuse into sweat and become ionized, leading to ion trapping and accumulation in the

lower pH of sweat.¹⁰⁵ Lipophilic drugs may also deposit in sweat from sources other than passive diffusion from blood (eg, adipose depots), so the possibility of residual excretion of drug into sweat should be considered when interpreting test results.^{105,106}

Sources of drug-concentration variability include the site of patch application, intra- and intersubject variability in sweat production, loss or dynamic exchange of drug between the patch and skin, and possible environmental contamination.^{103,105,106} Early sweat patches occluded the skin, causing irritation and altering the skin's steady-state pH.¹⁰³ Although newer nonocclusive patches use a transparent film that allows oxygen, carbon dioxide, and water vapor to escape, researchers have demonstrated low acceptability by patients (only half of applied patches were brought back attached to the skin) and a low sensitivity for detecting illicit opioid use (sweat patches detected one-third of illicit opioid-use instances detected by weekly UDT).¹⁰³

It is premature to replace UDT in clinical settings, despite limitations and inconveniences associated with urine collection and testing.

Alternative Specimens Summary

New diagnostic tests are developed in an attempt to increase clinical utility, accuracy, convenience for the patient and/or clinician, and revenue; or to decrease expense and turnaround time.⁶⁸ Different biologic matrices have varying cutoff concentrations depending on the drug, but criteria for reporting hair, oral fluid, and sweat-patch specimens as invalid, adulterated, or substituted have yet to be defined.³ At present, much of the available knowledge on drug disposition in biologic matrices has been generated from single- or multiple-dose studies, but information is limited in chronic users.⁴ Ethical issues exist in the study of many licit and illicit drugs that preclude their study under conditions that simulate “real-world use,” and relevant information may never be available.⁴ It is premature to replace UDT in clinical settings, despite limitations and inconveniences associated with urine collection and testing.¹⁰³

Testing for Alcohol Abstinence

Some physicians test for alcohol abuse, which can compromise the safety of opioid treatment by accelerating the release of certain sustained-delivery formulations.⁹ More than half of Americans aged 12 years and older reported being current alcohol users in 2006—23% participated in binge drinking at least once and 7% reported heavy drinking in the month prior to the survey.²⁵ Ethanol concentrations in breath parallel those in blood and relate to impairment. Ethanol, however, has a short duration in the body and is generally detected for less than 12 hours following use.¹¹⁷ While ethanol is excreted in urine, this is not the optimal sample for assessing alcohol use.

Alcohol biomarkers can serve as measures for possible alcohol problems in individuals unwilling to accurately self-report their drinking, and as evidence of abstinence in individuals prohibited from drinking.¹¹⁸ A recently available laboratory test is for ethyl glucuronide (EtG), a minor but stable ethanol metabolite that can persist in urine for up to 80 hours, providing an extended window to assess drinking status.¹¹⁸⁻¹²¹ The test is a specific marker for alcohol exposure that may help motivate patients to remain or become abstinent from alcohol, but is not useful to measure reduced alcohol intake.⁴⁰ However, the marker does not distinguish between alcoholic beverage consumption and incidental exposure to alcohol in daily use products such as mouthwash, cough medication, “nonalcoholic” beer, and cleaning products.^{118,121,122} The US DHHS issued the following warning:¹¹⁸

Currently, the use of an EtG test in determining abstinence lacks sufficient proven specificity for use as primary or sole evidence that an individual prohibited from drinking, in a criminal justice or a regulatory compliance context, has truly been drinking. Legal or disciplinary action based solely on a positive EtG, or other test discussed in this Advisory, is inappropriate and scientifically unsupported at this time. These tests should be considered as potential valuable clinical tools, but their use in forensic settings is premature.

While promising, much remains to be learned about this marker and the potential causes of false-positive or -negative EtG results; for example, false-negative EtG results have been documented for individuals due to bacterial urinary tract infections.^{117,123} Other investigators have found that urine samples collected more than 26 hours after alcohol ingestion had false-negative results.¹²⁴ It is not known how disease, ethnicity, gender, time, or other drug use might affect results.^{118,122}

PRACTICE MANAGEMENT

Selecting a Testing Laboratory: Questions to Ask

- How are urine collection kits provided?
 - What is included?
 - Are there any out-of-pocket charges to the clinician?
- How are the samples sent to the laboratory?
 - Is there a preferred courier for specimen shipping?
 - Can routine pickups be scheduled?
 - Who provides and pays for shipping supplies?
 - Who pays for shipping charges?
- What is the normal time frame for results reporting?
 - Can expedited reporting be provided?
- How are results reported?
 - Is there secure Internet access for data transmission?
 - During what hours are laboratory scientists available to consult with and review results?
 - What qualifications do they have?
- Can customized testing panels be ordered?
 - Are there any customized pain management panels?
 - Is a laboratory scientist available for consultation about appropriate tests to order?
 - What kinds of technology are available for initial screening and confirmatory testing?
 - Is confirmatory testing performed in-house?
 - What testing is performed to assess specimen integrity or validity?
 - Under what circumstances?
- Does the laboratory handle billing through third-party insurance carriers?
 - If not, how is billing handled? ■

CASE STUDIES

Case 1

TF is a 35-year-old female with a history of depression, anxiety, migraine, constipation, and chronic low back pain related to multiple motor vehicle accidents. Her medications include baclofen 10 mg 2 to 3 times per day, clonazepam 1 mg 3 times per day, diazepam 5 mg 3 times per day, venlafaxine extended release 75 mg once daily, hydrocodone/acetaminophen (APAP) 7.5/750 mg 2 times per day, hydroxyzine 50 mg at bedtime, propranolol hydrochloride 20 mg daily, and polyethylene glycol 17 g daily.

Immunoassay results showed benzodiazepines in urine as expected, but were also positive for opiates, suggesting codeine, morphine, or heroin use. Confirmation testing with GC/MS revealed the presence of codeine and morphine in addition to the expected hydrocodone and hydromorphone (metabolite of hydrocodone). Further investigation is required to determine the reason for the unauthorized use of nonprescribed opioids.

Case 2

AC, a 52-year-old male, is transferred to a university hospital from a small outside facility in response to a positive urine drug screen for phencyclidine. The history accompanying the emergent urine drug screen indicated that on arrival, the patient was difficult to arouse, with no history or report of violent or unusual behavior. The immunoassay screen obtained at transfer was negative for all classes tested (opiates, barbiturates, cocaine, methadone, benzodiazepines, phencyclidine, amphetamines). When these results were obtained, the admitting team contacted the laboratory toxicologist to determine what could be interfering with testing. Because the history and admission presentation made the ingestion of phencyclidine unlikely, the toxicologist suggested that another drug may have caused a false-positive result. On questioning, an accompanying family member indicated finding an empty bottle of zolpidem that had been filled 2 days earlier. On day 2 of hospitalization, AC admitted to having ingested 8 tablets of 10 mg zolpidem. Subsequent investigation determined that the phencyclidine immunoassay screening method used in the referring facility exhibited significant cross-reactivity with zolpidem. This is an example of cross-reactivity and emphasizes why it is important to communicate with the testing laboratory.

Case 3

JB is a 24-year-old male with a history of low back pain that started after a motocross accident 4 years ago. During that time, he underwent trigger-point and steroid injections and tried a variety of alternative and medication regimens, including opioids, all of which afforded him only partial relief. He continued to experience persistent and intermittent, sharp, shooting pain that worsened his emotional state and lessened his ability to concentrate on work or to enjoy recreational activities. He admitted to once using a friend's methadone, but stated that he obtained little pain relief from doing so. He exhibited no personal history of drug abuse and did not use alcohol or tobacco. At the time of his initial visit, the patient was prescribed only ibuprofen 800 mg 3 to 4 times daily. His stated goal was for pain therapy that would allow him to fully resume the life he had led before the accident.

Most assays used to detect opiates do not reliably detect synthetic/semisynthetic opioids.

JB was administered a urine immunoassay as part of routine screening, which revealed the presence of opiates. The positive opiate immunoassay result suggested that the patient had ingested morphine, codeine, or heroin because most assays used to detect opiates do not reliably detect synthetic/semisynthetic opioids; however, cross-reactivity can occur. A request was made to the laboratory to test specifically for the presence of several common opioids. This GC/MS confirmation testing detected methadone, methadone metabolite, and oxycodone. It appears this patient was ingesting unauthorized, unprescribed opioids. This behavior may be a sign of undertreated pain or could be a form of prescription drug abuse and requires further investigation.

Case 4

MT is a 44-year-old male with a 10-year history of low back pain that started with a series of work-related injuries involving his back and fractures of his right foot, ankle, and scapula. He had significant neck and back pain that he described as sharp, shooting, and, at times, burning. Because he was unable to lift his right arm, bend over, or walk for long distances, he switched his former labor-intensive occupation to the less physical job of part-time building supervisor, but was still unable to work for more than a couple of hours before the pain forced him to lie down. Sleep disturbance, sexual dysfunction, curtailed social activities, and depression followed.

Interventions that included medication, surgeries, counseling, and occupational therapy were only partially helpful. To combat sexual dysfunction, plans were made to slowly wean MT from paroxetine while initiating duloxetine for depression. The patient reported good prior pain relief from oxycodone/APAP, which was therefore started at 10 mg/325 mg 4 times daily, along with ramelteon 8 mg at bedtime to assist with sleep. Though this patient revealed no prior indications of illicit drug abuse, a routine immunoassay drug test revealed the presence of cocaine.

Significant and ongoing life stresses heighten the potential for abuse of illicit drugs.

Significant and ongoing life stresses heighten the potential for abuse of illicit drugs, even in people who appear to demonstrate low risk for abuse, and abnormal UDT results may appear when least expected. Patients can have chronic pain that warrants opioid therapy concurrent with abuse of illicit substances, but comorbid conditions such as depression and drug abuse must be managed simultaneously with pain therapy.

Case 5

DR is a 45-year-old male referred by his PCP for pain management resulting from a job-related injury 3 years ago. As part of the treatment agreement, UDT is performed at the conclusion of the first visit. Immunoassay results are positive for cannabinoids and benzodiazepines. Confirmation testing with GC/MS confirms the presence of THC and a previously prescribed benzodiazepine. When you discuss these results with the patient during a telephone follow-up the next day, he admits to using marijuana regularly, but states that he understands the terms of the agreement and has not used since signing it.

Three days later, he returns to the clinic for physical therapy and counseling. At the conclusion of the visit he is asked to provide another urine sample. He appears stressed about the request but agrees to do so. UDT reveals the presence of the prescribed benzodiazepine, a newly prescribed opioid, and THC. You contact the laboratory to discuss if there is a way to determine whether this result represents new or continued use.

After cessation of marijuana use, cannabinoids are released from the tissue over several days to weeks.

Most laboratories that perform confirmation testing report both the compound detected as well as its concentration. Using these data in conjunction with urinary creatinine concentration can help in interpreting the results. THC has a long half-life, and, in general, cannabinoids are lipid-soluble compounds that are taken up by and stored in adipose tissue. After cessation of marijuana use, cannabinoids are released from the tissue over several days to weeks and excreted into the urine where they are detected by UDT. This means patients who have used marijuana for some time may have positive UDT results for several weeks after stopping. How long this lasts varies and is related to the marijuana's quality and quantity, in addition to the individual's physiology. Studies have shown that most individuals' results are negative within 3 weeks.

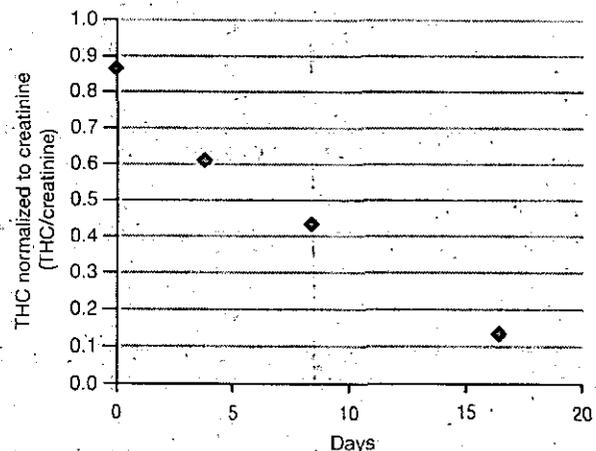
During this time, one can monitor this clearance by following the concentration of THC normalized to the

urinary creatinine. This takes into account varying urine concentration. If the patient is compliant and has not relapsed to or continued marijuana use, normalized levels will steadily decline. Over the next 6 weeks, several urine samples from DR are tested via GC/MS. The concentration of THC is shown below along with the accompanying creatinine:

Visit	THC (ng/mL)	Creatinine (mg/dL)	THC/creatinine
1 (day 0)	97	110	0.88
2 (day 4)	75	121	0.61
3 (day 9)	90	210	0.43
4 (day 17)	15	115	0.13
5 (day 28)	0	122	—
6 (day 40)	0	110	—

There is an initial decline in THC concentration, but on visit 3 (day 9) there is a sharp increase, which could cause one to conclude that DR has resumed marijuana use. However, by normalizing the results to the creatinine excretion, you see this rise was likely the result of a concentrated sample and dehydration. When the normalized values are graphed over time (see figure below), the results show a steady decline. From these data, one should conclude that DR has not relapsed to drug use.

Graph of normalized THC results for DR:



SUMMARY: GUIDELINES FOR TESTING

UDT can be an effective tool in clinical practice for the assessment and ongoing management of patients being considered for or currently managed with opioid analgesics for chronic pain.^{9,40} However, such testing should never be substituted for good diagnostic skills.¹¹

Whether UDT is cost-effective and of clinical value depends upon the ordering physician's interactions with the testing laboratory.

Whether UDT is cost-effective and of clinical value depends upon the ordering physician's interactions with the testing laboratory, so that he or she can:¹¹

- Clarify the purpose of UDT
- Identify a clear testing strategy: why, who, and when to test
- Understand the limits of what is actually being measured
 - Under what circumstances a false-positive result might be reported
 - The probability of cross-reactivity with other substances
 - What confirmatory testing to order
- Understand the terminology the laboratory uses to report its results
- Distinguish between the needs and cutoffs used in workplace testing and clinical settings
- Use strategies to improve analysis and interpretation of results ■

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Instructions for CME Credit

To obtain CME credit for this activity, participants are required to:

1. Read the learning objectives and review the activity in its entirety.
2. Register online at <http://ccoe.umdj.edu/online/activities/09MC07>.
3. Complete the post-test and obtain a passing score of 70% or higher.
4. Complete the activity evaluation.
5. Print a CME credit letter.