SOAPP (Symptom Outcomes and Practice Patterns):
A Survey of Disease and Treatment-Related
Symptoms in Patients with Invasive Cancer of the
Breast, Prostate, Lung or Colon/Rectum

ECOG Investigators: The following forms must be submitted to the ECOG Coordinating Center, FSTRF, 900 Commonwealth Avenue, Boston, MA 02215 (ATTN: DATA).

FORMS SUBMISSION SCHEDULE

NOTE: To ensure accurate and complete logging of forms at the ECOG Coordinating Center, forms should be submitted for each required time period, regardless of whether there is new data to report.

<table>
<thead>
<tr>
<th>BASELINE</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Within One Week After Registration:</strong></td>
<td></td>
</tr>
<tr>
<td>E2Z02 Baseline Data Form (#2430, 12/6/06)</td>
<td></td>
</tr>
<tr>
<td>E2Z02 Clinician On-Study Form (#2431, 12/6/06)</td>
<td></td>
</tr>
<tr>
<td>E2Z02 Patient On-Study Form (#2432, 12/6/06)</td>
<td></td>
</tr>
<tr>
<td>E2Z02 Medication Form (#2433, 12/6/06)</td>
<td></td>
</tr>
<tr>
<td>E2Z02 MDASI-ECOG Form (#2434, 12/6/06)</td>
<td></td>
</tr>
<tr>
<td>E2Z02 Assessment Compliance Form (#2435, 12/6/06)</td>
<td></td>
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</tbody>
</table>

<table>
<thead>
<tr>
<th>FOLLOW-UP</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>28-35 Days After Baseline:</strong></td>
<td></td>
</tr>
<tr>
<td>E2Z02 Clinician Follow-up Form (#2436, 12/6/06)</td>
<td></td>
</tr>
<tr>
<td>E2Z02 Patient Follow-up Form (#2437, 12/6/06)</td>
<td></td>
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<tr>
<td>E2Z02 Medication Form (#2433, 12/6/06)</td>
<td></td>
</tr>
<tr>
<td>E2Z02 MDASI-ECOG Form (#2434, 12/6/06)</td>
<td></td>
</tr>
<tr>
<td>E2Z02 Assessment Compliance Form (#2435, 12/6/06)</td>
<td></td>
</tr>
</tbody>
</table>
## E2Z02 Forms Submission Schedule by Reporting Period

### Reporting Periods While On Study

<table>
<thead>
<tr>
<th>On Study Report Period</th>
<th>Baseline</th>
<th>Follow-Up¹</th>
</tr>
</thead>
<tbody>
<tr>
<td>Forms Required</td>
<td>Baseline Data Form</td>
<td>Clinician Follow-Up Form</td>
</tr>
<tr>
<td></td>
<td>Clinician On-Study Form</td>
<td>Patient Follow-Up Form</td>
</tr>
<tr>
<td></td>
<td>Patient On-Study Form</td>
<td>Medication Form</td>
</tr>
<tr>
<td></td>
<td>Medication Form</td>
<td>MDASI-ECOG Form</td>
</tr>
<tr>
<td></td>
<td>MDASI-ECOG Form</td>
<td>Assessment Compliance Form</td>
</tr>
<tr>
<td></td>
<td>Assessment Compliance Form</td>
<td></td>
</tr>
</tbody>
</table>

¹ Between 28-35 days from Baseline
INSTRUCTIONS: Complete this form and submit original to the ECOG Coordinating Center within one week of registration. Keep a copy for your files.

**Registration Step 1**

**Report period:** [X] Baseline

<table>
<thead>
<tr>
<th>Date(s) Data Amended</th>
<th>M</th>
<th>D</th>
<th>Y</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

**Disease Characteristics**

Primary Site(s) (Place an ‘X’ in the appropriate boxes)

- [ ] Breast
- [ ] Prostate
- [ ] Colorectal
- [ ] Lung

Date of initial pathologic/clinical/radiographic diagnosis

Date of initial diagnosis of metastatic disease (if applicable)

**Disease Status**

Current Status of Disease

- [ ] 1=CR (Complete Disappearance of Lesions)
- [ ] 2=PR (Partial Response)
- [ ] 3=SD (Stable)
- [ ] 4=PD (Progression)

Current Stage of Disease

- [ ] 1=NED (No evidence of disease)
- [ ] 2=Local/regional
- [ ] 3=Metastatic
- [ ] 4=Local/regional and metastatic

Assessment Date

Date(s) Data Amended

- [ ] M
- [ ] D
- [ ] Y

Mark an ‘X’ if data have been amended

(Place an ‘X’ if unknown)

(Mark an ‘X’ if not applicable)

12/6/06
<table>
<thead>
<tr>
<th>Disease Status (cont.)</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Metastatic Site(s):</td>
<td></td>
</tr>
<tr>
<td>Abdominal/visceral</td>
<td>Brain</td>
</tr>
<tr>
<td>Breast</td>
<td>Bone</td>
</tr>
<tr>
<td>Bone marrow</td>
<td>Leptomeningeal or epidural</td>
</tr>
<tr>
<td>Liver</td>
<td>Lung</td>
</tr>
<tr>
<td>Pleuritic</td>
<td>Soft tissue/nodes</td>
</tr>
<tr>
<td>Other</td>
<td>Other visceral, specify</td>
</tr>
</tbody>
</table>

ECOG Performance Status (On date of this evaluation)

- 0 = Fully active, able to carry on all pre-disease performance without restriction (Karnofsky 90-100)
- 1 = Restricted in physically strenuous activity but ambulatory (K 70-80)
- 2 = Ambulatory and capable of all selfcare but unable to carry out any work activities (K 50-60)
- 3 = Capable of only limited selfcare, confined to bed or chair more than 50% of waking hours (K 30-40)
- 4 = Completely disabled (K 10-20)

Weight loss in previous six months

- 1 = <5% of body weight
- 2 = 5 - <10% of body weight
- 3 = 10 - <20% of body weight
- 4 = ≥20% of body weight

Prior Treatment For Cancer

Has the patient had prior chemotherapy/immunotherapy/hormonal therapy?

- 1 = No
- 2 = Yes

If yes:

Total number of prior chemotherapy/immunotherapy/hormonal therapy regimens

- 1 = 1 Regimen
- 2 = 2 Regimens
- 3 = 3 or more Regimens

Prior radiation therapy?

- 01 = No
- 02 = Yes
- 1 = Unknown

Current Treatment For Cancer

Is the patient currently receiving treatment for cancer?

- 1 = No (Follow-up only) (Skip remainder of form)
- 2 = Yes

If yes:

Type of therapy patient is currently receiving

- 1 = Adjuvant
- 2 = Neoadjuvant
- 4 = Recurrent/Non-metastatic
- 5 = Metastatic

12/6/06
Current Treatment For Cancer (cont.)

Current chemotherapy/immunotherapy/hormonal therapy
01 = No, 02 = Yes, -1 = unknown

☐ chemotherapy, single-agent cytotoxic systemic
☐ chemotherapy, multi-agent cytotoxic systemic
☐ chemotherapy, non-cytotoxic (e.g. endostatin, mmpi, TKI)
☐ chemotherapy – not otherwise specified (includes non-systemic chemotherapy)
☐ immunotherapy
☐ hormonal therapy

Current radiation therapy?
01 = No
02 = Yes
-1 = Unknown

Start Dates of Current Treatment

<table>
<thead>
<tr>
<th></th>
<th>M</th>
<th>D</th>
<th>Y</th>
</tr>
</thead>
<tbody>
<tr>
<td>Chemotherapy</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Immunotherapy</td>
<td></td>
<td></td>
<td></td>
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<tr>
<td>Hormonal therapy</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Radiation therapy</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
E2Z02 Clinician On-Study Form

1. Mechanism of Pain
   - 1 = No pain syndrome
   - 2 = Any nociceptive combination of visceral and/or bone or soft tissue pain
   - 3 = Neuropathic pain syndrome with or without any combination of nociceptive pain
   - 4 = Insufficient information to classify

2. Incidental Pain
   - 1 = Absence of incidental pain
   - 2 = Presence of incidental pain
   - 3 = Insufficient information to classify

3. Psychological Distress and Addictive Behavior
   - 1 = Psychological distress and addictive behavior not present
   - 2 = Psychological distress alone present
   - 3 = Addictive behavior alone present
   - 4 = Psychological distress and addictive behavior present
   - 5 = Insufficient information to classify

4. Cognitive Function
   - 1 = No impairment. Patient able to provide accurate present and past pain history unimpaired
   - 2 = Partial impairment. Sufficient impairment to affect patient’s ability to provide accurate present and/or past pain history
   - 3 = Total impairment. Patient unresponsive, delirious or demented to the stage of being unable to provide any present and past pain history
   - 4 = Insufficient information to classify
Section 2

How long has the patient had some form of pain?

[ ] 1 = No current pain problem
[ ] 2 = Less than the past 48 hours
[ ] 3 = Less than the past 1 month
[ ] 4 = More than the past 1 month
[ ] 5 = More than the past 6 months

What treatments or medications are being provided for pain?

(Please code an answer of “01=No”, “02=Yes” or “-1=Unknown” for each of the following treatments)

[ ] Systemic Opioids
[ ] Neuroaxial opioids (epidural or intrathecal)
[ ] Non-opioids
[ ] Nerve block
[ ] Opioid/Non-opioid combination
[ ] Other, specify__________________
[ ] Surgery

The patient has pain due to (Please mark an ‘X’ for all that apply):

[ ] Primary disease (cancer)
[ ] Effects of cancer treatment
[ ] Medical condition unrelated to primary disease
[ ] Psychological causes more than actual nociception
[ ] Other, Specify__________________

Section 3

CONSULTATION: Is patient being referred to another physician or multi-disciplinary team for symptom management?

[ ] 1 = No
[ ] 2 = Yes

If yes, please code the service(s):

[ ] 01 = Pain
[ ] 02 = Palliative Care
[ ] 03 = Combined Pain and Palliative Care
[ ] 04 = Psychiatry
[ ] 05 = Physical Therapy/Occupational Therapy
[ ] 06 = Nutrition
[ ] 07 = Chaplain
[ ] 08 = Wound/Enterostomal
[ ] 09 = Speech Therapy
[ ] 10 = Practitioner of Complementary Therapy (Yoga, massage, aromatherapy, etc.)
[ ] 11 = Other, Specify__________________
[ ] 12 = Radiation Therapy Service

Please indicate the top 3 areas in order of importance that are causing difficulties for this patient as far as you can tell.

[ ] 1st
01 = pain
02 = fatigue
03 = nausea
04 = disturbed sleep
05 = being distressed (upset)
06 = dyspnea
07 = cognitive difficulties
08 = anorexia/cachexia
09 = drowsiness
10 = dry mouth
11 = sad/depressed
12 = vomiting
13 = numbness/tingling
14 = constipation
15 = sore mouth
16 = rash/pruritis
17 = difficulty walking
18 = lack of information
19 = financial problems
20 = family problems
21 = existential worries
22 = spiritual problems

[ ] 2nd
[ ] 3rd
Section 4

Overall, how much do you think this patient is bothered by difficulties related to comorbidities other than cancer (or the primary disease for which you are seeing the patient)?

- 0 = Not at all
- 1 = A little bit
- 2 = Moderately
- 3 = Quite a bit
- 4 = Extremely

Overall, how much do you think this patient is bothered by difficulties related directly to cancer (or the primary disease for which you are seeing the patient)?

- 0 = Not at all
- 1 = A little bit
- 2 = Moderately
- 3 = Quite a bit
- 4 = Extremely

Overall, how much do you think this patient is bothered by difficulties related to treatment of cancer (i.e. chemotherapy or other systemic therapy, radiation therapy, surgery)?

- 0 = Not at all
- 1 = A little bit
- 2 = Moderately
- 3 = Quite a bit
- 4 = Extremely

Overall, how much do you think this patient is bothered by side effects from medications used to treat pain or other symptoms?

- 0 = Not at all
- 1 = A little bit
- 2 = Moderately
- 3 = Quite a bit
- 4 = Extremely

Overall, how much do you think this patient is bothered by weight gain or loss?

- 0 = Not at all
- 1 = A little bit
- 2 = Moderately
- 3 = Quite a bit
- 4 = Extremely

How would you rate this patient’s overall quality of life at this time?

- 1 = Very poor
- 2 = Poor
- 3 = Fair
- 4 = Good
- 5 = Excellent

Relative to other patients with same stage of disease, how would you categorize the degree of difficulty in caring for this patient’s physical/psychological symptoms?

- 1 = Very difficult
- 2 = Difficult
- 3 = Average
- 4 = Easier than average
- 5 = Much easier than average
1. What is your current employment status?
   - 1 = Working, Full-Time
   - 2 = Working, Part-Time
   - 3 = Not in the workforce (e.g., retired, disabled, student, homemaker)

2. Has your employment status changed due to illness?
   - 1 = No
   - 2 = Yes

3. In general, would you say your overall quality of life is:
   - 1 = Excellent
   - 2 = Good
   - 3 = Fair
   - 4 = Poor
   - 5 = Very Poor

4. Have you driven a car within the past 4 weeks?
   - 1 = No
   - 2 = Yes

5. Have you participated in a support group within the past 4 weeks?
   - 1 = No
   - 2 = Yes

6. Have you received individual counseling within the past 4 weeks?
   - 1 = No
   - 2 = Yes

7. Is there any history of depression in yourself?
   - 1 = No
   - 2 = Yes

8. Is there any history of depression in your mother or father?
   - 1 = No
   - 2 = Yes

9. Is there any history of depression in your brother(s) or sister(s):
   - 1 = No
   - 2 = Yes
(continued):

10. Overall, how much are you bothered by difficulties related to health problems other than cancer?

☐ 0=Not at all
    1=A little bit
    2=Moderately
    3=Quite a bit
    4=Extremely

11. Overall, how much are you bothered by difficulties related directly to cancer?

☐ 0=Not at all
    1=A little bit
    2=Moderately
    3=Quite a bit
    4=Extremely

12. Overall, how much are you bothered by difficulties related to the treatment of cancer (i.e. chemotherapy or other systemic therapy, radiation therapy, surgery)?

☐ 0=Not at all
    1=A little bit
    2=Moderately
    3=Quite a bit
    4=Extremely

13. Overall, how much are you bothered by side effects from medications used to treat pain or other symptoms?

☐ 0=Not at all
    1=A little bit
    2=Moderately
    3=Quite a bit
    4=Extremely

14. Did anyone come with you to this office visit?

☐ 1=No
    2=Yes

15. Overall, how much are you bothered by weight gain or loss?

☐ 0=Not at all
    1=A little bit
    2=Moderately
    3=Quite a bit
    4=Extremely
E2Z02 Medication Form

INSTRUCTIONS: Complete and submit this form at baseline, and at follow-up. Please indicate what medications the patient is taking according to the list below. Submit forms to the ECOG Coordinating Center. Keep a copy for your files.

ECOG Protocol Number

ECOG Patient ID

CON_MED DCI Name

Registration Step

Place ID label here

Patient Initials (First, Last)

ECOG Protocol Number

ECOG Patient ID

Participating Group

Participating Protocol Number

Group Patient ID

Institution/Affiliate

Please mark an ‘X’ if data have been amended
(Please circle amended items in red)

Date(s) Data Amended

Report Period

Choose one (8):

Baseline

Follow-Up (28-35 days)

Is patient currently taking medications (this reporting period)?

01 = No (Skip rest of form)

02 = Yes

-1 = Unknown (no contact with patient)

Section 1 - Pain Medications

Agent Code

(Consult list of agents below)

Action Taken with this Agent

(this reporting period)

1 = Initiated at this visit

2 = Discontinued at this visit

3 = Continuing at this visit

This medication was

prescribed by:

1 = Medical-oncology professional

2 = Other oncology professional

3 = Other physician/non-oncology

Usual Dose per

day (mg)

(For opioids only)

LONG ACTING OPIOID TREATMENT

01 = Long acting morphine

02 = Oxycontin

03 = Transdermal Fentanyl

04 = Methadone

05 = Intrathecal pump

IMMEDIATE RELIEF/BREAKTHROUGH OPIOID TREATMENT

06 = Morphine

07 = Oxycodeone

08 = Hydromorphone

09 = Oral Transmucosal fentanyl

10 = Hydrocodeone/acetaminophen

11 = Codeine/acetaminophen

12 = Propoxyphene/acetaminophen

13 = SQ or IV opioids

OTHER TREATMENTS FOR PAIN

14 = Common NSAID

15 = COX-2 inhibitor

17 = Acetaminophen

18 = Muscle relaxant

19 = Herbal or other supplements

20 = Acupuncture referral

21 = Nerve block referral

32 = Corticosteroids

87 = Anticonvulsant treatment for nerve pain

89 = Antidepressant treatment for nerve pain

91 = Topical therapy for pain control

12/6/06
### Section 2 - Other Medications

<table>
<thead>
<tr>
<th>Agent Code</th>
<th>Action Taken with this Agent (this reporting period)</th>
<th>This medication was prescribed by:</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>1 = Initiated at this visit</td>
<td>1 = Medical-oncology professional</td>
</tr>
<tr>
<td></td>
<td>2 = Discontinued at this visit</td>
<td>2 = Other oncology professional</td>
</tr>
<tr>
<td></td>
<td>3 = Continuing at this visit</td>
<td>3 = Other physician/non-oncology</td>
</tr>
</tbody>
</table>

*For an agent not listed, please code 88 for other and list the agent on the line.

**ANTIBACTERIAL ANTIBIOTICS**
- 22 = Prophylactic antibiotics
- 23 = Treatment of current infection

**ANTIFUNGAL AGENTS**
- 24 = Prevention of thrush
- 25 = Treatment of current thrush
- 26 = Treatment of systemic fungal infection

**ANTIEMETICS**
- 27 = 5HT3 antagonist
- 28 = NK-1 antagonist (aprepitant, Emend)
- 29 = Metoclopramide
- 30 = Phenothiazines
- 31 = Cannabinoids
- 32 = Corticosteroids

**BOWEL REGIMEN**
- 33 = Daily bowel regimen to prevent constipation
- 34 = Stool softeners regularly
- 35 = Sena-containing laxative regularly
- 36 = Lactulose or sorbitol as needed

**GASTRIC PROPHYLAXIS**
- 37 = Antacids
- 38 = H2 blocker
- 39 = Proton-pump inhibitor

**GLYCEMIC CONTROL AGENTS**
- 40 = Sulfonylurea
- 41 = Metformin
- 42 = Long-acting insulin
- 43 = Short-acting insulin

**ANTIETHERAPY USE**
- 44 = Serotonin-Reuptake Inhibitor/newer anti-depressant
- 45 = Tricyclic antidepressants
- 46 = Psychostimulants

**ANXIOLYTIC/SEDATIVE HYPNOTIC USE**
- 47 = Long-acting agents (alprazolam, clonazepam, diazepam)
- 48 = Intermediate-acting agents (temazepam, clorazapate)
- 49 = Short-acting agents (lorazepam, midazolam)
- 50 = Non-benzodiazepine (zolipedem, chloral hydrate)

**BONE PROTECTION AGENTS**
- 60 = Bisphosphonates
- 61 = Calcium supplement
- 62 = Vitamin D supplement
- 63 = Angiotensin II inhibitor

**COLONY STIMULATING FACTORS**
- 80 = Erythropoietic agents
- 81 = Thrombopoietic agent
- 82 = G-CSF or GM-CSF
- 83 = Topical ointment for skin rash
- 84 = Oral medication for skin rash
- 85 = Both topical ointment and oral medication for skin rash
- 86 = Keratinocyte CSF (Palifermin)

**TREATMENT OF HOT FLUSHES**
- 68 = Hormonal Agents
- 69 = Antidepressant
- 70 = Vitamin E

**OTHER SYMPTOM AGENTS OR SUPPLEMENTS**
- 71 = Enteral nutrition supplement
- 72 = Parenteral nutrition
- 73 = Supplemental vitamins
- 74 = Herbal supplements
- 75 = Pilocarpine for dry mouth
- 76 = Oral hygiene regimen
- 77 = Glutamine or Gelclair
- 78 = Progestational agents for appetite
- 79 = Anabolic steroid for appetite

---

How many different medications is the patient currently taking?

- [ ] 1 = 0-4
- [ ] 2 = 5-9
- [ ] 3 = 10 or more

---

Investigator Signature  Investigator Signature Date

---

12/6/06
Attached are the follow-up forms you agreed to fill out 28-35 days after the first set of forms were completed.

Please fill out these 2 forms any time between ___/___/_____ and ___/___/_____ (28-35 days after the first set of forms were completed).

We will call you at some time before day 35 to confirm that the forms were completed/mailed or to answer any questions.

Please be sure to place the completed forms in the self-addressed stamped envelope provided.
Part I. How **severe** are your symptoms?

People with cancer frequently have symptoms that are caused by their disease or by their treatment. We ask you to rate how severe the following symptoms have been **in the last 24 hours**. Please fill in the circle below from 0 (symptom has not been present) to 10 (the symptom was as bad as you can imagine it could be) for each item.

<table>
<thead>
<tr>
<th></th>
<th>Not Present</th>
<th>0</th>
<th>1</th>
<th>2</th>
<th>3</th>
<th>4</th>
<th>5</th>
<th>6</th>
<th>7</th>
<th>8</th>
<th>9</th>
<th>10</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Your <strong>pain</strong> at its WORST?</td>
<td>[ ]</td>
<td>X</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>X</td>
</tr>
<tr>
<td>2. Your <strong>fatigue</strong> (tiredness) at its WORST?</td>
<td>[ ]</td>
<td>X</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>X</td>
</tr>
<tr>
<td>3. Your <strong>nausea</strong> at its WORST?</td>
<td>[ ]</td>
<td>X</td>
<td></td>
<td></td>
<td></td>
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<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>X</td>
</tr>
<tr>
<td>4. Your <strong>disturbed sleep</strong> at its WORST?</td>
<td>[ ]</td>
<td>X</td>
<td></td>
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<td></td>
<td></td>
<td></td>
<td>X</td>
</tr>
<tr>
<td>5. Your feelings of being <strong>distressed</strong> (upset) at its WORST?</td>
<td>[ ]</td>
<td>X</td>
<td></td>
<td></td>
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<td></td>
<td></td>
<td></td>
<td>X</td>
</tr>
<tr>
<td>6. Your <strong>shortness of breath</strong> at its WORST?</td>
<td>[ ]</td>
<td>X</td>
<td></td>
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<td></td>
<td></td>
<td></td>
<td>X</td>
</tr>
<tr>
<td>7. Your problem with <strong>remembering</strong> things at its WORST?</td>
<td>[ ]</td>
<td>X</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
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<td></td>
<td></td>
<td></td>
<td>X</td>
</tr>
<tr>
<td>8. Your problem with <strong>lack of appetite</strong> at its WORST?</td>
<td>[ ]</td>
<td>X</td>
<td></td>
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<td></td>
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<td></td>
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<td></td>
<td></td>
<td></td>
<td>X</td>
</tr>
<tr>
<td>9. Your feeling <strong>drowsy</strong> (sleepy) at its WORST?</td>
<td>[ ]</td>
<td>X</td>
<td></td>
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<td></td>
<td></td>
<td></td>
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<td></td>
<td></td>
<td></td>
<td>X</td>
</tr>
<tr>
<td>10. Your having a <strong>dry mouth</strong> at its WORST?</td>
<td>[ ]</td>
<td>X</td>
<td></td>
<td></td>
<td></td>
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<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>X</td>
</tr>
<tr>
<td>11. Your feeling <strong>sad</strong> at its WORST?</td>
<td>[ ]</td>
<td>X</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>X</td>
</tr>
<tr>
<td>12. Your <strong>vomiting</strong> at its WORST?</td>
<td>[ ]</td>
<td>X</td>
<td></td>
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<td></td>
<td>X</td>
</tr>
<tr>
<td>13. Your <strong>numbness or tingling</strong> at its WORST?</td>
<td>[ ]</td>
<td>X</td>
<td></td>
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<td>X</td>
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<tr>
<td>Not Present</td>
<td>0</td>
<td>1</td>
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<td>14. Your diarrhea (loose stools) at its WORST?</td>
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<td>15. Your constipation at its WORST?</td>
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<td>16. Your mouth sores at its WORST?</td>
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<td>17. Your skin rash at its WORST?</td>
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<tr>
<td>18. Your hair loss at its WORST?</td>
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<tr>
<td>19. Your coughing at its WORST?</td>
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</tr>
</tbody>
</table>

**Part II. How have your symptoms interfered with your life?**

Symptoms frequently interfere with how we feel and function. How much have your symptoms interfered with the following items *in the last 24 hours*:

<table>
<thead>
<tr>
<th>Did Not Interfere</th>
<th>0</th>
<th>1</th>
<th>2</th>
<th>3</th>
<th>4</th>
<th>5</th>
<th>6</th>
<th>7</th>
<th>8</th>
<th>9</th>
<th>10</th>
</tr>
</thead>
<tbody>
<tr>
<td>20. General activity?</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
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<tr>
<td>21. Mood?</td>
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<tr>
<td>22. Work (including work around the house)?</td>
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</tr>
<tr>
<td>23. Relations with other people?</td>
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<tr>
<td>24. Walking?</td>
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<tr>
<td>25. Enjoyment of life?</td>
<td></td>
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<td></td>
<td></td>
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</tr>
</tbody>
</table>
Thank you for your participation in E2Z02, “A Survey of Disease and Treatment-Related Symptoms in Patients with Invasive Cancer: Prevalence, Severity, and Treatment”.

Thank you for agreeing to complete the follow-up forms 28-35 days following the first set of forms.

We appreciate your honest answers and trust that they will help us better understand symptoms experienced by cancer patients.
INSTRUCTIONS: Please complete this form according to the forms submission schedule. Submit original to the ECOG Coordinating Center. Keep a copy for your files.

E2Z02 ECOG Protocol Number

ECOG Patient ID

ASMT_COMP DCI Name

Registration Step

Report Period (since start of treatment) Choose one (X):

[ ] Baseline [ ] Follow-Up (28-35 days)

Section I

Assessment Date

If not completed, enter date scheduled per E2Z02 protocol.

Section II - Assessments Not Completed

Were all of the quality of life forms completed for this timepoint?

[ ] 1=no    - Fill out each box of the corresponding column, for each form not completed

[ ] 2=yes   - Skip this section

Patient On-Study Form (Only applicable at Baseline)

Patient Follow-Up Form (Only applicable at Follow-Up)

MDASI-ECOG

Assessment Form No.

2 4 3 2  2 4 3 7  2 4 3 4

Indicate primary reason(s) why form was not completed:

[ ] Patient refusal

[ ] Unable to accommodate disability or language needs

[ ] Patient did not show up in clinic/office

[ ] Staff unavailable

[ ] Patient not given form by staff

[ ] Patient too ill

[ ] Patient expired

[ ] Assessment not required per protocol

[ ] Staff thought patient too ill

[ ] Other

1=no 2=yes 1=no 2=yes 1=no 2=yes

12/6/06
### Section III - Assessments Completed

Fill out the corresponding column for *each* quality of life form that was completed for this time point. Leave a column **blank** if the quality of life form was **not completed**.

<table>
<thead>
<tr>
<th>Was Assessment self-administered?</th>
<th>Patient On-Study Form (Only applicable at Baseline)</th>
<th>Patient Follow-Up Form (Only applicable at Follow-Up)</th>
<th>MDASI-ECOG</th>
</tr>
</thead>
<tbody>
<tr>
<td>1=no - Complete each box in the corresponding column</td>
<td>1=no</td>
<td>1=no</td>
<td>1=no</td>
</tr>
<tr>
<td>2=yes - Skip remaining questions in this section for this form</td>
<td>2=yes</td>
<td>2=yes</td>
<td>2=yes</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>How was the patient assisted?</th>
</tr>
</thead>
<tbody>
<tr>
<td>Were the questions read aloud to patient?</td>
</tr>
<tr>
<td>Did the patient require clarification of questions or instructions?</td>
</tr>
<tr>
<td>Did the patient require other assistance?</td>
</tr>
<tr>
<td>Were the forms completed independently by another person?</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>What was the reason for assistance?</th>
</tr>
</thead>
<tbody>
<tr>
<td>Did the patient have a language difficulty? (questions needed to be translated)</td>
</tr>
<tr>
<td>Specify language:</td>
</tr>
<tr>
<td></td>
</tr>
<tr>
<td>Did the patient have a literacy difficulty? (patient could not read well enough)</td>
</tr>
<tr>
<td>Was the patient disabled?</td>
</tr>
<tr>
<td>Specify disability:</td>
</tr>
<tr>
<td></td>
</tr>
<tr>
<td>Were the forms completed via a telephone interview?</td>
</tr>
<tr>
<td>Other</td>
</tr>
<tr>
<td>Specify other reason:</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Who assisted or completed the Assessment?</th>
</tr>
</thead>
<tbody>
<tr>
<td>Staff</td>
</tr>
<tr>
<td>Family</td>
</tr>
<tr>
<td>Friend</td>
</tr>
<tr>
<td>Other</td>
</tr>
<tr>
<td>Specify other person:</td>
</tr>
</tbody>
</table>
Section 1

Specify which type of clinician is filling out form
- 1=Attending Physician
- 2=Resident or fellow
- 3=Advanced practice nurse or nurse practitioner
- 4=Physician assistant
- 5=Other, specify _______________

Is this clinician the same as at baseline?
- 1=No
- 2=Yes

Disease Status
- 1=Unchanged from prior visit
- 2=New evidence of response (good news)
- 3=New evidence of progression (bad news)

Current treatment for cancer (Include description and start date of treatment)
- 1=Unchanged
- 2=Changed

ECOG Performance Status (On date of this evaluation)
- 0=Fully active, able to carry on all pre-disease performance without restriction (Karnofsky 90-100)
- 1=Restricted in physically strenuous activity but ambulatory (K 70-80)
  - 2=Ambulatory and capable of all selfcare but unable to carry out any work activities (K 50-60)
  - 3=Capable of only limited selfcare, confined to bed or chair more than 50% of waking hours (K 30-40)
- 4=Completely disabled (K 10-20)

Revised Edmonton Staging System (rESS)

The following items are part of a pain classification system called the revised Edmonton Staging System (rESS) that is used with the permission of Dr. Robin Fainsinger.

For each of the following features, code the response that is most appropriate, based on your clinical assessment of the patient.

1. Mechanism of Pain

- 1=No pain syndrome
- 2=Any nociceptive combination of visceral and/or bone or soft tissue pain
- 3=Neuropathic pain syndrome with or without any combination of nociceptive pain
- 4=Insufficient information to classify

Date(s) Data Amended  

Assessment Date

INSTRUCTIONS: Please complete this form according to the forms submission schedule. Submit original to the ECOG Coordinating Center. Keep a copy for your files.
Revised Edmonton Staging System (rESS) (cont.)

2. Incidental Pain

☐ 1=Absence of incidental pain
☐ 2=Presence of incidental pain
☐ 3=Insufficient information to classify

3. Psychological Distress and Addictive Behavior

☐ 1=Psychological distress and addictive behavior not present
☐ 2=Psychological distress alone present
☐ 3=Addictive behavior alone present
☐ 4=Psychological distress and addictive behavior present
☐ 5=Insufficient information to classify

4. Cognitive Function

☐ 1=No impairment. Patient able to provide accurate present and past pain history unimpaired
☐ 2=Partial impairment. Sufficient impairment to affect patient’s ability to provide accurate present and past pain history
☐ 3=Total impairment. Patient unresponsive, delirious or demented to the stage of being unable to provide any present and past pain history
☐ 4=Insufficient information to classify.

Section 2

How long has the patient had some form of pain?

☐ 1=No current pain problem (Skip to Section 3)
☐ 2=Less than the past 48 hours
☐ 3=Less than the past 1 month
☐ 4=More than the past 1 month
☐ 5=More than the past 6 months

The patient has pain due to (Please mark an ‘X’ for all that apply):

☐ Primary disease (cancer)
☐ Effects of cancer treatment
☐ Medical condition unrelated to primary disease
☐ Psychological causes more than actual nociception
☐ Other, Specify_________________________

Section 3

Please indicate in order of importance the top 3 areas that are causing difficulties for this patient as far as you can tell.

1st

☐ 01=pain
☐ 02=fatigue
☐ 03=nausea
☐ 04=disturbed sleep
☐ 05=being distressed (upset)
☐ 06=dyspnea
☐ 07=cognitive difficulties
☐ 08=anorexia/cachexia
☐ 09=drowsiness
☐ 10=dry mouth
☐ 11=sad/depressed

☐ 12=vomiting
☐ 13=numbness/tingling
☐ 14=constipation
☐ 15=sore mouth
☐ 16=rash/pruritis
☐ 17=difficulty walking
☐ 18=lack of information
☐ 19=financial problems
☐ 20=family problems
☐ 21=existential worries
☐ 22=spiritual problems

12/6/06
Overall, how much do you think this patient is bothered by difficulties related to comorbidities other than cancer (or the primary disease for which you are seeing the patient)?

☐ 0=Not at all
☐ 1=A little bit
☐ 2=Moderately
☐ 3=Quite a bit
☐ 4=Extremely

Overall, how much do you think this patient is bothered by difficulties related directly to cancer (or the primary disease for which you are seeing the patient)?

☐ 0=Not at all
☐ 1=A little bit
☐ 2=Moderately
☐ 3=Quite a bit
☐ 4=Extremely

Overall, how much do you think this patient is bothered by difficulties related to the cancer treatment (i.e. chemotherapy or other systemic therapy, radiation therapy, surgery)?

☐ 0=Not at all
☐ 1=A little bit
☐ 2=Moderately
☐ 3=Quite a bit
☐ 4=Extremely

Overall, how much do you think this patient is bothered by side effects from medications being used to treat pain or other symptoms?

☐ 0=Not at all
☐ 1=A little bit
☐ 2=Moderately
☐ 3=Quite a bit
☐ 4=Extremely

How would you rate this patient’s overall quality of life at this time?

☐ 1=Very poor
☐ 2=Poor
☐ 3=Fair
☐ 4=Good
☐ 5=Excellent

Compared to this patient’s previous visit, would you say his/her overall quality of life is?

☐ 1=Much better
☐ 2=Better
☐ 3=Nearly the same
☐ 4=Worse
☐ 5=Much worse

Relative to other patients with progressive/recurrent cancer, how would you categorize the degree of difficulty in caring for this patient’s physical/psychological symptoms?

☐ 1=Very difficult
☐ 2=Difficult
☐ 3=Average
☐ 4=Easier than average
☐ 5=Much easier than average

**Response to Symptom-Directed Treatment**

☐ 1=Progressive symptoms
☐ 2=Stable symptoms
☐ 3=Partial improvement
☐ 4=Complete improvement

**Patient Compliance with Symptom Treatment Recommendation**

☐ 1=Perfect
☐ 2=Acceptable
☐ 3=Poor/Needs improvement
Attached are the follow-up forms you agreed to fill out 28-35 days after the first set of forms were completed.

Please fill out these 2 forms any time between ___/___/_____ and ___/___/_____ (28-35 days after the first set of forms were completed).

We will call you at some time before day 35 to confirm that the forms were completed/mailed or to answer any questions.

Please be sure to place the completed forms in the self-addressed stamped envelope provided.
INSTITUTION INSTRUCTIONS: Have the patient complete this form (in blue or black ink) at the intervals required per protocol and submit original to the ECOG Coordinating Center. Keep a copy for your files.

PATIENT INSTRUCTIONS: The following questions will help the study team understand your health and the influence of symptoms on your quality of life. Please place a number in the box to represent your response to each question.

1. Compared to your previous visit, would you say your overall quality of life is:
   - 1 = Much better
   - 2 = Better
   - 3 = Nearly the same
   - 4 = Worse
   - 5 = Much worse

2. Do you currently drive a car?
   - 1 = No
   - 2 = Yes

3. Do you participate in a support group?
   - 1 = No
   - 2 = Yes

4. Do you receive individual counseling?
   - 1 = No
   - 2 = Yes

5. Overall, how much are you bothered by difficulties related to health problems other than cancer?
   - 0 = Not at all
   - 1 = A little bit
   - 2 = Moderately
   - 3 = Quite a bit
   - 4 = Extremely

6. Overall, how much are you bothered by difficulties related directly to cancer?
   - 0 = Not at all
   - 1 = A little bit
   - 2 = Moderately
   - 3 = Quite a bit
   - 4 = Extremely

7. Overall, how much are you bothered by difficulties related to the treatment of cancer (i.e. chemotherapy or other systemic therapy, radiation therapy, surgery)?
   - 0 = Not at all
   - 1 = A little bit
   - 2 = Moderately
   - 3 = Quite a bit
   - 4 = Extremely

8. Overall, how much are you bothered by side effects from medications being used to treat pain or other symptoms?
   - 0 = Not at all
   - 1 = A little bit
   - 2 = Moderately
   - 3 = Quite a bit
   - 4 = Extremely
Thank you for your participation in E2Z02, “A Survey of Disease and Treatment-Related Symptoms in Patients with Invasive Cancer: Prevalence, Severity, and Treatment”.

Thank you for agreeing to complete the follow-up forms 28-35 days following the first set of forms.

We appreciate your honest answers and trust that they will help us better understand symptoms experienced by cancer patients.
E2Z02 Baseline Data Form

This form is intended to assess the patient’s disease characteristics and any prior treatment the patient may have received for his or her disease.

E2Z02 Clinician On-Study Form

This form is intended to assess the patient’s overall symptoms from the point of view of the clinician during the first visit. It is not expected clinicians/physicians can precisely gauge subjective complaints of patients. Please do not feel threatened by this form. We are not profiling your quality of care.

E2Z02 Patient On-Study Form

This form is intended to assess the patient’s overall symptoms from the point of view of the patient during the first visit.

E2Z02 Medication Form

This form is intended to assess the patient’s prescribed medication, how often it is taken, if it is continuing, who prescribed it and what the intention of the medication was/is.

E2Z02 Clinician Follow-up Form

This form is intended to assess the patient’s overall symptoms from the point of view of the clinician at the follow-up period. It is not expected clinicians/physicians can precisely gauge subjective complaints of patients. Please do not feel threatened by this form. We are not profiling your quality of care.

E2Z02 Patient Follow-up Form

This form is intended to assess the patient’s overall symptoms from the point of view of the patient at the follow-up period.
**Section 1 - Pain Medications**

<table>
<thead>
<tr>
<th>Agent Code</th>
<th>Action Taken with this Agent (this reporting period)</th>
<th>This medication was prescribed by</th>
<th>Usual Dose per day (mg)</th>
</tr>
</thead>
<tbody>
<tr>
<td>01</td>
<td>Initiated at this visit</td>
<td>1=Medical-oncology professional</td>
<td>(For opioids only)</td>
</tr>
<tr>
<td>02</td>
<td>Discontinued at this visit</td>
<td>2=Other oncology professional</td>
<td></td>
</tr>
<tr>
<td>03</td>
<td>Continuing at this visit</td>
<td>3=Other physician/non-oncology</td>
<td></td>
</tr>
</tbody>
</table>

**LONG ACTING OPIOID TREATMENT**
- 01 = Long acting morphine
- 02 = Oxycontin
- 03 = Transdermal Fentanyl
- 04 = Methadone
- 05 = Intrathecal pump

**IMMEDIATE RELIEF/BREAKTHROUGH OPIOID TREATMENT**
- 06 = Morphine
- 07 = Oxycodone
- 08 = Hydromorphone
- 09 = Oral Transmucosal fentanyl
- 10 = Hydrocodone/acetaminophen
- 11 = Codeine/acetaminophen
- 12 = Propoxyphene/acetaminophen
- 13 = SQ or IV opioids

**OTHER TREATMENTS FOR PAIN**
- 14 = Common NSAID
- 15 = COX-2 inhibitor
- 17 = Acetaminophen
- 18 = Muscle relaxant
- 19 = Herbal or other supplements
- 20 = Acupuncture referral
- 21 = Nerve block referral
- 32 = Corticosteroids
- 87 = Anticonvulsant treatment for nerve pain
- 89 = Antidepressant treatment for nerve pain
- 91 = Topical therapy for pain control
### Other Medications

**Action Taken with this Agent**
1. Initiated at this visit
2. Discontinued at this visit
3. Continuing at this visit

**This medication was prescribed by:**
1. Medical-oncology professional
2. Other oncology professional
3. Other physician/non-oncology

**Agent Code** *(Consult list of agents below)*

<table>
<thead>
<tr>
<th>Agent Code</th>
<th>Action Taken with this Agent</th>
<th>This medication was prescribed by</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Initiated at this visit</td>
<td>1. Medical-oncology professional</td>
</tr>
<tr>
<td>2</td>
<td>Discontinued at this visit</td>
<td>2. Other oncology professional</td>
</tr>
<tr>
<td>3</td>
<td>Continuing at this visit</td>
<td>3. Other physician/non-oncology</td>
</tr>
</tbody>
</table>

For an agent not listed, please code 88 for other and list the agent on the line.

**Section 2 - Other Medications**

**ANTIBACTERIAL ANTIBIOTICS**
- 22 = Prophylactic antibiotics
- 23 = Treatment of current infection

**ANTIFUNGAL AGENTS**
- 24 = Prevention of thrush
- 25 = Treatment of current thrush
- 26 = Treatment of systemic fungal infection

**ANTIEMETICS**
- 27 = 5HT3 antagonist
- 28 = NK-1 antagonist (aprepitant, Emend)
- 29 = Metoclopramide
- 30 = Phenothiazines
- 31 = Cannabinoids
- 32 = Corticosteroids

**ANTITUMOR IMMUNOMODULATING AGENTS**
- 33 = Daily bowel regimen to prevent constipation
- 34 = Stool softeners regularly
- 35 = Senna-containing laxative regularly
- 36 = Lactulose or sorbitol as needed

**BOWEL REGIMEN**
- 37 = Antacids
- 38 = H2 blocker
- 39 = Proton-pump inhibitor

**GLYCEMIC CONTROL AGENTS**
- 40 = Sulfonylurea
- 41 = Metformin
- 42 = Long-acting insulin
- 43 = Short-acting insulin

**ANTIDEPRESSANT USE**
- 44 = Serotonin-Reuptake Inhibitor/newer anti-depressant
- 45 = Tricyclic antidepressants
- 46 = Psychostimulants

**ANXIOLYTIC/SEDATIVE HYPNOTIC USE**
- 47 = Long acting agents (alprazolam, clonazepam, diazepam)
- 48 = Intermediate-acting agents (temazepam, clorazepate)
- 49 = Short-acting agents (lorazepam, midazolam)
- 50 = Non-benzodiazepine (zolpidem, chloral hydrate)

**ANTIHYPERLIPIDEMIC AGENTS**
- 51 = HMG-CoA reductase inhibitors
- 52 = Nsaid agents
- 53 = Bezafibrate family
- 54 = Cholesterosis

**ANTI-OXIDANTS**
- 55 = Vitamin C
- 56 = Vitamin E

**ANTICOAGULANTS**
- 51 = Heparin (not including catheter flushes)
- 52 = Low molecular weight heparin
- 53 = Warfarin/Coumadin
- 54 = Aspirin

**ANTIHYPERTENSIVES**
- 55 = B-Blocker
- 56 = Diuretic
- 57 = Calcium-channel blocker
- 58 = Angiotensin II inhibitor
- 59 = ACE inhibitor

**BONE PROTECTION AGENTS**
- 60 = Bisphosphonates
- 61 = Calcium supplement
- 62 = Vitamin D supplement
- 63 = Angiotensin II inhibitor

**BONE-PROTECTING AGENTS**
- 64 = Amifostine
- 65 = Dexrazoxane
- 66 = Oxygen
- 67 = IV Fluids

**TREATMENT OF HOT FLASHES**
- 68 = Hormonal Agents
- 69 = Antidepressant
- 70 = Vitamin E

**OTHER SYMPTOM AGENTS OR SUPPLEMENTS**
- 71 = Enteral nutrition supplement
- 72 = Parenteral nutrition
- 73 = Supplemental vitamins
- 74 = Herbal supplements
- 75 = Pilocarpine for dry mouth
- 76 = Oral hygiene regimen
- 77 = Glutamine or Gelclair
- 78 = Progestational agents for appetite
- 79 = Anabolic steroid for appetite

**ANTI-INFECTION AGENTS**
- 80 = Erythromycin
- 81 = Clarithromycin
- 82 = Azithromycin
- 83 = Levofloxacin
- 84 = Metronidazole

**COLONY STIMULATING FACTORS**
- 80 = Erythropoietic agents
- 81 = Thrombopoietic agent
- 82 = G-CSF or GM-CSF
- 83 = Topical ointment for skin rash
- 84 = Oral medication for skin rash
- 85 = Both topical ointment and oral medication for skin rash
- 86 = Keratinocyte CSF (Palifermin)

**How many different medications is the patient currently taking?**
1. 0-4
2. 5-9
3. 10 or more