Communication of Critical Values: An Update
PROCEDURE TITLE:
Communication of Critical Values

UNIFIED DEPARTMENTAL POLICY NUMBER:

PURPOSE:
To implement standard process for reporting critical values

DEFINITIONS:
critical value = any anatomic pathology result with potential to negatively impact patient care if not communicated in an urgent and timely fashion
significant = potential to impact patient management

STANDARDS:
JCAHO National Patient Safety Goals 2006
(http://www.jointcommission.org/PatientSafety/NationalPatientSafetyGoals/)
CAP accreditation checklist (ANP.12175, October 2005).

PROCEDURE:

<table>
<thead>
<tr>
<th>Step</th>
<th>Action</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Identify critical values using the attached list.</td>
</tr>
<tr>
<td>2</td>
<td>Identify the responsible licensed caregiver from the pathology report or CareWeb.</td>
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<td>3</td>
<td>In collaboration with the resident or fellow who shares responsibility for the case, communicate the critical value to the identified caregiver using a communication method that allows for confirmation of message receipt.</td>
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<td>4</td>
<td>Affirm the recipient’s understanding of the critical value and its clinical impact.</td>
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<td>5</td>
<td>Document the person to whom the information was conveyed, the date and the time of communication in a Comment on the pathology report.</td>
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<td>6</td>
<td>If unable to contact responsible caregiver, contact the caregiver’s secretary, administrative assistant or other member of the care team to devise communication strategy to convey clinical information to the appropriate clinician.</td>
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<tr>
<td>7</td>
<td>If deemed appropriate, send e-mail to responsible caregiver identifying affected patient by name and registration number and summarizing critical value copying your own secretary/administrative assistant on the note. Request response to confirm receipt.</td>
</tr>
<tr>
<td>8</td>
<td>Your secretary/administrative assistant will follow-up daily with e-mail recipient or recipient’s secretary/administrative assistant until receipt of communication is confirmed.</td>
</tr>
<tr>
<td>9</td>
<td>Confirmation of e-mail communication will be documented in PathNet</td>
</tr>
</tbody>
</table>
Case 1

An Amended Diagnosis

- 61-year old man referred for evaluation and care of rectal carcinoma
- endoscopic biopsy of rectal mass
- original report prematurely verified on a Friday
Case 1
Original Diagnosis - Friday

HISTORY:
Operative Procedure: Lower EUS. Indications: Pre-treatment staging for rectal adenocarcinoma. Impression: A fungating, near circumferential, rectal mass consistent with known history of rectal adenocarcinoma. This is stage T3 N0. No lymph nodes are seen during endosonograph examination of sigmoid colon.

GROSS:
1. Rectal mass 8 cm
Multiple, more than fifteen, soft tissue biops range from 0.1 to 0.4 cm. (ns)

MICROSCOPIC DIAGNOSIS:
1. Rectum, biopsy: Fragments of adenomatous epithelium. See COMMENT.

COMMENT:

We note the presence of a mass clinically, and the history of rectal adenocarcinoma. While this biopsy is not diagnostic of an invasive adenocarcinoma, it is compatible with the surface of such a lesion.
Case 1
An Amended Diagnosis

• 61-year old man referred for evaluation and care of rectal carcinoma
• endoscopic biopsy of rectal mass
• original report prematurely verified on a Friday
• an amended diagnosis was released on Monday . . .
Case 1
Amended Diagnosis - Monday

MICROSCOPIC:
AMENDED REPORT TO CORRECT THE DIAGNOSIS:

The original report was verified inadvertently and is inaccurate. The previous diagnosis should be disregarded and replaced by the diagnosis below.

MICROSCOPIC DIAGNOSIS:
NOTE: PLEASE DISREGARD PREVIOUS REPORT.

1. Rectal mass, biopsy: Adenocarcinoma.

Dr.  notified of the above result or
Case 1

An Amended Diagnosis

• 61-year old man referred for evaluation and care of rectal carcinoma
• endoscopic biopsy of rectal mass
• original report prematurely verified on a Friday
• an amended diagnosis was released on Monday and the clinician was called
CRITICAL VALUE – SURGICAL PATHOLOGY

• any significant or unexpected diagnosis of malignancy (or vice versa) for which no equally timely and effective communication method (e.g. daily patient-based interaction with clinical colleagues) exists
• any significant disagreement with outside interpretation of TS cases for which no equally timely and effective communication method (e.g. daily patient-based interaction with clinical colleagues) exists
• any significant difference in final versus frozen section diagnosis
• any amended report reflecting a significant change in diagnosis
• discovery of clinically significant infections
• unexpected absence of chorionic villi in uterine curettings
• any findings likely to reflect either 1) unrecognized perforation of an organ (e.g. fat in endometrial curettage or endoscopic polypectomy specimen), or 2) unintended surgical consequences or misidentification of a specimen (e.g. ureter in specimen submitted as fallopian tube)
• suspicion of wrong-site surgery
• biopsies from transplant patients showing either rejection or graft-versus-host disease
• crescents in kidney biopsies
• evidence of an acute necrotizing vasculitic syndrome
Case 1
An Amended Diagnosis
# Case 1

**Original Diagnosis - Monday**

<table>
<thead>
<tr>
<th>More</th>
<th>Condensed</th>
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**SP FINAL REPORT**

**Source:**

**HISTORY:**
Operative Procedure: Lower EUS. Indications: Pre-treatment staging for rectal adenocarcinoma. Impression: A fungating, near circumferential, rectal mass consistent with known history of rectal adenocarcinoma. This is stage T3 N0. No lymph nodes are seen during endosonograph examination of sigmoid colon.

**GROSS:**
1. "Rectal mass 8cm"
   - Multiple, more than fifteen, soft tissue biops range from 0.1 to 0.4 cm. (ms)
   - DF

**VP: ABS**

**MICROSCOPIC DIAGNOSIS:**
1. Rectum, biopsy: Fragments of adenomatous epithelium. See COMMENT.

**COMMENT:**

We note the presence of a mass clinically, and the history of rectal adenocarcinoma. While this biopsy is not diagnostic of an invasive adenocarcinoma, it is compatible with the surface of such a lesion.
Amended diagnoses with the potential to change patient management require direct faculty-to-faculty contact with clinician.
Case 2
New Diagnosis of Malignancy

- 41-year-old man with history of lupus
- referred to Ypsilanti Health Center for evaluation of severe chronic low back and leg pain
  14 years status post diskectomy (x 2)
- right inguinal canal mass on exam
  US: multiple enlarged lymph nodes
Case 2
New Diagnosis of Malignancy

- referred to radiology for CT-guided needle biopsy
- needle bx (IF case) showed classical Hodgkin lymphoma

What, if anything, would you do beyond verifying report in PathNet?
Case 2

New Diagnosis of Malignancy

4 responses (all faculty)
3 – contact (call) clinician
1 – transfer to hemepath

What, if anything, would you do beyond verifying report in PathNet?
Case 2

New Diagnosis of Malignancy

Red flags?

- follow-up appointment in 4 weeks with primary provider
- hand-off from primary provider to proceduralist (radiology – CT guided needle biopsy) and back again
- most recent note implied benign diagnoses were favored
CRITICAL VALUE – SURGICAL PATHOLOGY

- any significant or unexpected diagnosis of malignancy (or vice versa) for which no equally timely and effective communication method (e.g. daily patient-based interaction with clinical colleagues) exists
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- any significant difference in final versus frozen section diagnosis
- any amended report reflecting a significant change in diagnosis
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- unexpected absence of chorionic villi in uterine curettings
- any findings likely to reflect either 1) unrecognized perforation of an organ (e.g. fat in endometrial curettage or endoscopic polypectomy specimen), or 2) unintended surgical consequences or misidentification of a specimen (e.g. ureter in specimen submitted as fallopian tube)
- suspicion of wrong-site surgery
- biopsies from transplant patients showing either rejection or graft-versus-host disease
- crescents in kidney biopsies
- evidence of an acute necrotizing vasculitic syndrome
Case 2
New Diagnosis of Malignancy

**Action taken**

- provider’s pager being covered by another according to *Paging Search Page*
- email with request for confirmation of receipt (cc to Administrative Assistant)

“Thanks for contacting me, I will see him in followup. Linda, can we get this patient into hematology/oncology ASAP for evaluation with new diagnosis of Hodgkin's lymphoma? Thanks to all,”
Case 2
New Diagnosis of Malignancy

Critical Values Alerts

When in doubt, check out EMR in CareWeb.
(e.g. malignancy a relative surprise?
hand-off from primary provider to proceduralist?
timely follow-up appointment?)
Case 3
New Diagnosis of Malignancy

- 68-year-old woman underwent screening colonoscopy ("average risk screening")
- three polyps
  - cecum – sessile, 5 mm
  - ascending – sessile, 4 mm
  - sigmoid – pedunculated, 15 mm

Recommendation
✓ “await pathology results”
✓ “return to primary care provider in 1 year”
Case 3

New Diagnosis of Malignancy

HISTORY:
Indications: Average risk screening for malignant neoplasm in the colon.
Endoscopic impression: Non-thrombosed external hemorrhoids. One 8 mm polyp in the cecum, excised and retrieved. One 4 mm polyp in the ascending colon, excised and retrieved. One 15 mm polyp in the sigmoid colon, excised and retrieved. Please see colonoscopy report.

ENDOSCOPIC:
1. "Colon cecum"
   A 0.3 cm soft tissue polyp. [1ns]
2. "Colon ascending"
   A 0.2 cm soft tissue polyp. [1ns]
3. "Pedunculated sigmoid polyp" Received in formalin is a 1.5 x 1.0 cm tan-brown pedunculated polyp. Biopsied. [2ns]

EX5

DFF: AMX 09/19/06

MICROSCOPIC DIAGNOSIS:
Case 3
New Diagnosis of Malignancy

SEP 2006
new diagnosis of adca in colon polyp
endometrial mass discovered in course of evaluation for PMB
husband dies

OCT 2006
endometrial adca, FIGO grade 2

NOV 2006
TAH-BSO (stage IC endometrial adca; stage IA ovarian ca)
Case 3
New Diagnosis of Malignancy

JAN 2007  radiation therapy
APR 2007  multiple bilateral lung nodules on CT
MAY 2007  chemotherapy (3 cycles)
JUL 2007  lung nodules stable on CT
SEP 2007  follow-up visit with OB-gyn
Case 3
New Diagnosis of Malignancy

SEPTEMBER 25, 2007

On further review of her records, we talked about colonoscopy that she had had previously in September. I reviewed those colonoscopy results and that was performed on September 14, 2006, by Dr. ______ . . . Unfortunately, I had not seen these results previously and I looked through other documented reports of her health care and I have not seen where this has been addressed. I did disclose those results to Mrs. ______ and recommended that we have her visit with a colorectal surgeon as soon as possible.
Case 3

New Diagnosis of Malignancy

- repeat colonoscopy October 31, 2007
- findings
  granularity in recto-sigmoid c/w radiation ascending – sessile, 4 mm
  sigmoid – sessile, 7 mm

Recommendation

✓ “await pathology results”
✓ “discharge patient to home (ambulatory)”
ANATOMIC PATHOLOGY
U. Mich Critical Values Alerts Policy and Process

closing the loop on communication of critical values

critical alert values defined

definitions/policy endorsed by ECCA

critical alert values urgently communicated

report reconciled against EMR

daily report to signing faculty

daily report to service director
TOTAL REPORTED "EVENTS"

# requiring action
The diagram shows a line graph representing the number of reported events (per day) from January 11, 2007, to October 18, 2007. The y-axis indicates the number of reported events, ranging from -20 to 50. The x-axis represents the dates, marked with specific days.

Key indicators on the graph include:
- **Avg = 13.1**
- **UCL = 32.7** (Upper Control Limit)
- **LCL = -6.5** (Lower Control Limit)

The data points fluctuate around the average, with some days showing significantly higher or lower reported events compared to others.
Critical Values Alerts – Conclusions

- Critical values alerts policy can prevent sentinel events
- Trend toward increasing policy compliance
- Unanticipated communication gaps persist in our complex medical practice