AORN Guideline for Specimen Management
Evidence Table

REFERENCE #	CITATION	EVIDENCE TYPE	SAMPLE SIZE/ POPULATION	INTERVENTION(S)	CONTROL/ COMPARISON	OUTCOME MEASURE(S)	CONCLUSION(S)	CONSENSUS SCORE
1	Steelman VM, Williams TL, Szekendi MK, Halverson AL, Dintzis SM, Pavkovic S. Surgical specimen management: A descriptive study of 648 adverse events and near misses. Arch Pathol Lab Med. 2016;140(12):1390-1396.	Nonexperimental	648 surgical specimens	n/a	n/a	Specimen errors by category	Categories with the most specimen errors included labeling 49%, transportation and storage 38%, collection 24%. Recommendations were made for error prevention.	IIIA
2	Makary MA, Epstein J, Pronovost PJ, Millman EA, Hartmann EC, Freischlag JA. Surgical specimen identification errors: A new measure of quality in surgical care. Surgery. 2007;141(4):450-455. doi: 10.1016/j.surg.2006.08.018.	Nonexperimental	21,351 surgical specimens	n/a	n/a	Rate of specimen errors	The rate of specimen errors from outpatient clinics and the OR was 0.43% or 182 errors a year.	IIIA
3	Bixenstine PJ, Zarbo RJ, Holzmueller CG, et al. Developing and pilot testing practical measures of preanalytic surgical specimen identification defects. Am J Med Qual. 2013;28(4):308-314. doi: https://dx.doi.org/10.1177/1062860612469824.	Nonexperimental	Multiple facility specimen error data reported median rated including, 523 in pathology cases, 654 on containers, and 457 in requisitions for 3 months.	n/a	n/a	Preanalytical specimen errors	The average rate of error was 2.9%. Errors involving containers was 1.2% and errors involving requisition forms was 2.3%.	IIIB
4	Zervakis Brent MA. OR specimen labeling. AORN J. 2016;103(2):164-176. http://search.ebscohost.com/login.aspx?direct=true&db=ccm&AN=112741843&site=ehost-live&scope=site. doi: 10.1016/j.aorn.2015.12.018.	Organizational Experience	An average of 500 surgical specimens sent to the pathology department each month.	n/a	n/a	n/a	The FMEA analysis and subsequent process improvements reduced specimen errors by 60%.	VB
5	Cooper K. Errors and error rates in surgical pathology: An association of directors of anatomic and surgical pathology survey. Arch Pathol Lab Med. 2006;130(5):607-609. http://rpauthor.aorn.org/specimens/Shared%20Documents/Full%20Text%20References/Cooper.pdf. doi: 2.	Nonexperimental	Survey of 41 laboratories from the Association of Directors of Anatomic and Surgical Pathology Council.	n/a	n/a	Definitions and perceptions of pathology errors and frequency rate of errors.	Standardization and monitoring is needed.	IIIC
6	Novis DA. Detecting and preventing the occurrence of errors in the practices of laboratory medicine and anatomic pathology: 15 years' experience with the college of american pathologists' Q-PROBES and Q-TRACKS programs. Clin Lab Med. 2004;24(4):965-978. http://rpauthor.aorn.org/specimens/Shared%20Documents/Full%20Text%20References/Novis.pdf. doi: 10.1016/j.cll.2004.09.001.	Expert Opinion	n/a	n/a	n/a	n/a	Discusses literature related to errors of identification (eg, specimen, patient) and suggests best practices.	VB
7	Valenstein PN, Sirota RL. Identification errors in pathology and laboratory medicine. Clin Lab Med. 2004;24(4):979-96, vii. http://rpauthor.aorn.org/specimens/Shared%20Documents/Full%20Text%20References/Valenstein2004.pdf. doi: 10.1016/j.cll.2004.05.013.	Expert Opinion	n/a	n/a	n/a	n/a	Reviews information regarding specimen and patient identification errors and potential solutions.	VA
8	Lost surgical specimens, lost opportunities. Penn Patient Saf Advis. 2005;2(3):1-5.	Expert Opinion	n/a	n/a	n/a	n/a	Discusses problems associated with specimen errors and potential solutions.	VA
9	Ask HRC: Best practices for specimen handling. ECRI Institute; 2017.	Expert Opinion	n/a	n/a	n/a	n/a	Discusses errors in specimen handling and makes recommendations to prevent or minimize errors.	VA

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10	Nakhleh RE, Idowu MO, Souers RJ, Meier FA, Bekeris LG. Mislabeling of cases, specimens, blocks, and slides: A college of american pathologists study of 136 institutions. Arch Pathol Lab Med. 2011;135(8):969-974.	Nonexperimental	1811 mislabeling events from 136 organizations	n/a	n/a	Mislabeled cases, specimens, blocks, and slides	Rates of mislabeled specimens were 0.1%. 20.9% of errors occurred before accessioning.	IIIB
11	D'Angelo R, Mejabi O. Getting it right for patient safety: Specimen collection process improvement from operating room to pathology. *Am J Clin Pathol* . 2016;146(1):8-17.	Organizational Experience	Average of 800 specimens and 700 requisition orders per month for 21 months.	n/a	n/a	n/a	Improved the baseline specimen defect rate by 89% by creating standard work for specimen management.	VA
12	Dock B. Improving the accuracy of specimen labeling. Clin Lab Sci. 2005;18(4):210-212.	Organizational Experience	Not reported.	n/a	n/a	n/a	Use of FMEA processes reduced specimen management errors by 75%.	VB
13	Patient identification errors. West Conshohocken, PA: ECRI Institute; 2016Health Technology Assessment Information Service: Special Report.	Literature Review	n/a	n/a	n/a	n/a	Literature review of patient identification errors in the clinical setting.	VA
14	They Don't make the cut: Lost, mislabeled, and unsuitable surgical specimens. ECRI Institute; 2017. Event Reporting & Analysis - Alerts.	Expert Opinion	n/a	n/a	n/a	n/a	Discusses problems in specimen errors and makes recommendations for handling.	VA
15	Rees S, Stevens L, Mikelsons D, Quam E, Darcy T. Reducing specimen identification errors. J Nurs Care Qual. 2012;27(3):253-257.	Organizational Experience	Started with 197 Specimen identification errors.	n/a	n/a	n/a	After tracking, determining root cause, and implementing process changes involving printers on units the rate of specimen identification errors decreased.	VB
16	Where do most lab errors occur? not the lab. West Conshohocken, PA: ECRI Institute; 2012PSO Monthly Brief.	Expert Opinion	n/a	n/a	n/a	n/a	Discussion about specimen errors, frequency, and phase.	VB
17	42 CFR 493 laboratory requirements. 10-1-17 ed. Office of the Federal Register National Archives and Records Administration; 2017; No. 5.	Regulatory	n/a	n/a	n/a	n/a	Regulatory requirements of laboratories.	n/a
18	Johnstone EM, Burlingame BL, Conner R. Guideline for a safe environment of care. In: Conner R, ed. *Guidelines for perioperative practice.* Denver, CO: AORN; 2020.	Guideline	n/a	n/a	n/a	n/a	Provides recommendations on safety in the perioperative environment.	IVA
19	Cahn JA. Guideline for autologous tissue management. In: Wood A, ed. Guidelines for perioperative practice. Denver, CO: AORN; 2020.	Guideline	n/a	n/a	n/a	n/a	Provides recommendations for autologous tissue handling in perioperative practice.	IVA
20	Burlingame B, Conner R. Guideline for radiation safety. In: Conner R, ed. Guidelines for perioperative practice. Denver, CO: AORN; 2020.	Guideline	n/a	n/a	n/a	n/a	Provides recommendations for radiation safety in the perioperative environment.	IVA

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21	Nemeth SA, Lawrence N. Site identification challenges in dermatologic surgery: A physician survey. J Am Acad Dermatol. 2012;67(2):262-268.	Nonexperimental	325 survey responses from dermatologic physicians.	n/a	n/a	Rate of site identification problems and potential solutions.	Researchers found that 71% of surgeons have patients that have problems identifying the site more than 5% of the time. Concluded that high quality photography with a clear label and anatomic positions may reduce the risk of wrong-site surgery.	IIIB
22	Rossy KM, Lawrence N. Difficulty with surgical site identification: What role does it play in dermatology? J Am Acad Dermatol. 2012;67(2):257-261.	Nonexperimental	333 Mohs lesions from 329 patients.	n/a	n/a	How frequently problems with site identification occur and contributing factors.	The rate of site identification difficulty was 9%. The likelihood for difficulty with site identification increased if the lesion was not visible to the patient.	IIIB
23	McGinness J, Goldstein G. The value of preoperative biopsy-site photography for identifying cutaneous lesions. Dermatol Surg. 2010;36(2):194-197.	Nonexperimental	271 Mohs procedure sites.	n/a	n/a	How often patients and surgeons identified the correct surgery site.	Incorrect site identification occurred 16.6% of the time by patients and 5.9% of the time by surgeons. Both the surgeon and patient incorrectly identified the same surgical site 4.4% of the time. Researchers concluded that photographs of the lesions should be used in site identification.	IIIB
24	Ke M, Moul D, Camouse M, et al. Where is it? the utility of biopsy-site photography. Dermatol Surg. 2010;36(2):198-202.	Nonexperimental	34 Mohs procedure sites.	n/a	n/a	Rate of incorrect biopsy site identification.	The patient and dermatologist together incorrectly identified the same biopsy site 12% of the time. The patient alone incorrectly identified the biopsy site 29% of the time. Recommended the use of photography for correct site identification.	IIIC
25	Fearon MC, Spruce L, Wood A, Conner R. Guideline for team communication. In: Conner R, ed. *Guideli*	Guideline	n/a	n/a	n/a	n/a	Provides recommendations on team communication in the perioperative environment.	IVA
26	Sandbank S, Klein D, Westreich M, Shalom A. The loss of pathological specimens: Incidence and causes. Dermatol Surg. 2010;36(7):1084-1086.	Organizational Experience	4,400 biopsy specimens sent to pathology.	n/a	n/a	n/a	Five specimens were found missing from the 4,400 sent to pathology. Of the five specimens, two were retrieved and one was lost in pathology. The remaining two were lost due to not placing the specimen in the container immediately.	VB

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27	Martis WR, Hannam JA, Lee T, Merry AF, Mitchell SJ. Improved compliance with the world health organization surgical safety checklist is associated with reduced surgical specimen labelling errors. *N Z Med J* . 2016;129(1441):63-67.	Organizational Experience	9,825 surgical specimens.	n/a	n/a	n/a	Improved use of the WHO Safe Surgery Checklist procedural debrief section significantly reduced the rate of specimen errors after initiation of the project.	VA
28	World Health Organization. Implementation manual WHO surgical safety checklist 2009: Safe surgery saves lives. France: World Health Organization; 2009:16. http://apps.who.int/iris/bitstream/10665/44186/1/9789241598590_eng.pdf. Accessed 1/6/2017.	Guideline	n/a	n/a	n/a	n/a	Guideline for using WHO Safe Surgical Checklist.	IVA
29	Makary MA, Holzmueller CG, Sexton JB, et al. Operating room debriefings. Jt Comm J Qual Patient Saf. 2006;32(7):407-10, 357. http://rpauthor.aorn.org/specimens/Shared%20Documents/Full%20Text%20References/Makary_debriefings.pdf.	Expert Opinion	n/a	n/a	n/a	n/a	Discussion of items that may be included during OR debrief sessions.	VB
30	Nakhleh RE, Myers JL, Allen TC, et al. Consensus statement on effective communication of urgent diagnoses and significant, unexpected diagnoses in surgical pathology and cytopathology: From the college of american pathologists and association of directors of anatomic and surgical pathology. Arch Pathol Lab Med. 2012;136(2):148-154.	Consensus	n/a	n/a	n/a	n/a	Consensus document reviewing communication of urgent and significant, unexpected diagnoses from the pathology department.	IVA
31	Lott R, Tunnicliffe J, Sheppard E, et al, eds. Pre-microscopic examination specimen handling guidelines in the surgical pathology laboratory. 8.0th ed. College of American Pathologists; 2018.	Guideline	n/a	n/a	n/a	n/a	Discussion of recommendations for specimen handing from the College of American Pathologists and the National Society for Histotechnology.	IVB
32	Cahn JA, Wood A. Guideline for sterile technique. In: Wood A, ed. *Guidelines for perioperative practice.* Denver, CO: AORN; 2020.	Guideline	n/a	n/a	n/a	n/a	Provides recommendations on the use of sterile technique in the perioperative environment.	IVA
34	Siegel, JD, Rhinehart, E., Jackson, M., Chiarello, L. and the Healthcare Infection Control Practices Advisory Committee. 2007 Guidelines for Isolation Precautions: Preventing Transmission of Infectious Agents in Healthcare Settings 2007	Guideline	n/a	n/a	n/a	n/a	Makes recommendations for isolation precautions for prevention of disease.	IVA
35	Wood A. Guideline for transmission-based precautions. In: Wood A, ed. Guidelines for perioperative practice. Denver, CO: AORN; 2020.	Guideline	n/a	n/a	n/a	n/a	Provides recommendations for the use of transmission-based precautions in the perioperative environment.	IVA
36	Bussolati G, Annaratone L, Maletta F. The pre-analytical phase in surgical pathology. *Recent Results Cancer Res* . 2015;199:1-13.	Expert Opinion	n/a	n/a	n/a	n/a	Due to changes in specimen testing for genetic and biological markers, there may be changes in how specimens are handled in the preanalytical phases, including the use of vacuum sealing and cooling.	VB

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37	Comanescu M, Annaratone L, D'Armento G, Cardos G, Sapino A, Bussolati G. Critical steps in tissue processing in histopathology. *Recent Pat DNA Gene Seq* . 2012;6(1):22-32.	Expert Opinion	n/a	n/a	n/a	n/a	Discusses the advantages of vacuum sealed and cooled specimens.	VB
38	Francis DL, Prabhakar S, Sanderson SO. A quality initiative to decrease pathology specimen-labeling errors using radiofrequency identification in a high-volume endoscopy center. Am J Gastroenterol. 2009;104(4):972-975. doi: 10.1038/ajg.2008.170; 10.1038/ajg.2008.170.	Nonexperimental	8,231 pre-intervention and 8,539 post-intervention gastrointestinal endoscopic specimens.	n/a	n/a	rate of errors	The introduction of the RFID system in the specimen bottles, the paperless requisition forms, and the confirmation of the correct patient and site by two people significantly reduced the risk of every type of error in the article.	IIIB
39	Snyder SR, Favoretto AM, Derzon JH, et al. Effectiveness of barcoding for reducing patient specimen and laboratory testing identification errors: A laboratory medicine best practices systematic review and meta-analysis. Clin Biochem. 2012;45(13-14):988-998.	Systematic Review w/ Meta-Analysis	n/a	n/a	n/a	n/a	The review recommended bar coding as an effective intervention for reducing the risk of specimen identification errors.	IIIB
40	29 CFR 1910.1030: Hazardous substances. bloodborne pathogens. 7-1-17 ed. Office of the Federal Register National Archives and Records Administration; 2019; No. 6.	Regulatory	n/a	n/a	n/a	n/a	OSHA Bloodborne Pathogen Standard.	n/a
45	Annaratone L, Marchio C, Russo R, et al. A collection of primary tissue cultures of tumors from vacuum packed and cooled surgical specimens: A feasibility study. *PloS one* . 2013;8(9):e75193-e75193.	Nonexperimental	52 Surgical specimens.	n/a	n/a	Cell viability.	Cell viability was affected by the length of the surgery and the length of time the specimen had been vacuum packed and cooled. Use of vacuum sealing and refrigeration (4° C) cause a significant rapid decrease in temperature compared with vacuum sealing at room temperature.	IIIB
46	Saliceti R, Nicodemo E, Giannini A, Cortese A. Health technology assessment: Introducing a vacuum-based preservation system for biological materials in the anatomic pathology workflow. *Pathologica* . 2016;108(1):20-27.	Organizational Experience	Not reported	n/a	n/a	n/a	This article used a Health Technology Assessment process to review the literature and inform a decision about use of vacuum sealing technology for surgical specimens.	VA
47	Zarbo RJ. Histologic validation of vacuum sealed, formalin-free tissue preservation, and transport system. *Recent Results Cancer Res* . 2015;199:15-26.	Organizational Experience	Different specimen levels reported within multiple phases	n/a	n/a	n/a	Discussion of the benefits of vacuum sealing of specimens.	VA
48	Di Novi C, Minniti D, Barbaro S, Zampirolo MG, Cimino A, Bussolati G. Vacuum-based preservation of surgical specimens: An environmentally-safe step towards a formalin-free hospital. *Sci Total Environ* . 2010;408(16):3092-3095.	Organizational Experience	Two surveys, the first included 118 and second included 86 of OR and pathology department personnel.	n/a	n/a	n/a	Staff were satisfied with the new vacuum sealing specimen procedure. The new procedure decreased formalin use and the potential for exposure.	VB

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49	Dammrich ME, Kreipe HH. Standardized processing of native tissue in breast pathology. *Recent Results Cancer Res* . 2015;199:45-53.	Expert Opinion	n/a	n/a	n/a	n/a	Discusses the potential for vacuum-sealing of breast specimens without formalin and use of refrigerated storage instead of formalin fixation.	VC
50	*Recommended practices for safety and health programs.* Occupational Safety and Health Administration; 2016.	Guideline	n/a	n/a	n/a	n/a	Recommended practices for health and safety specifically regarding the OSHA Hierarchy of Controls	IVA
52	29 CFR 1910.1048: Hazardous substances. formaldehyde. 7-1-17 ed. Office of the Federal Register National Archives and Records Administration; 2017; No. 6.	Regulatory	n/a	n/a	n/a	n/a	OSHA Formaldehyde standard contains regulations on formaldehyde.	n/a
53	Bell WC, Young ES, Billings PE, Grizzle WE. The efficient operation of the surgical pathology gross room. *Biotechnic & Histochemistry* . 2008;83(2):71-82.	Expert Opinion	n/a	n/a	n/a	n/a	Discusses multiple recommendations for specimen management.	VB
54	Trask L, Tournas E. Barcode specimen collection improves patient safety. Mlo: Medical Laboratory Observer. 2012;44(4):42. http://rpauthor.aorn.org/specimens/Shared%20Documents/Full%20Text%20References/Trask.pdf.	Expert Opinion	n/a	n/a	n/a	n/a	Discussion of how bar coding of specimens helped decrease specimen labeling errors after implementation.	VB
55	Granata J. Getting a handle on specimen mislabeling. J Emerg Nurs. 2011;37(2):167-168. http://rpauthor.aorn.org/specimens/Shared%20Documents/Full%20Text%20References/Granata.pdf. doi: 10.1016/j.jen.2010.11.004; 10.1016/j.jen.2010.11.004.	Expert Opinion	n/a	n/a	n/a	n/a	Discussion of implementation of bar coding technology and process problems that were corrected.	VC
56	Hill PM, Mareiniss D, Murphy P, et al. Significant reduction of laboratory specimen labeling errors by implementation of an electronic ordering system paired with a bar-code specimen labeling process. Ann Emerg Med. 2010;56(6):630-636.	Nonexperimental	Specimen errors.	n/a	n/a	Rates of specimen errors pre and post intervention.	The rate of specimen errors decreased by 0.31% post intervention with use of a electronic order entry and a bar-coded specimen labeling system.	IIIB
57	Colard D. Reduction of patient identification errors using technology. Point of Care. 2005;4(1):61-63.	Organizational Experience	12,000 point of care glucose patient tests per month.	n/a	n/a	n/a	Rate of unidentified tests decreased to almost none after implementation of a bar coded patient identifying system and wrist band changes.	VB
58	Bostwick DG. Radiofrequency identification specimen tracking in anatomical pathology: Pilot study of 1067 consecutive prostate biopsies. Ann Diagn Pathol. 2013;17(5):391-402.	Organizational Experience	1067 prostate biopsy specimens.	n/a	n/a	n/a	Discussion of implementation of RFID technology in a pathology department.	VA
59	Radio frequency identification (RFID). https://www.fda.gov/radiation-emitting-products/electromagnetic-compatibility-emc/radio-frequency-identification-rfid. Updated Content current as of: 09/17/2018. Accessed 5/26, 2020.	Expert Opinion	n/a	n/a	n/a	n/a	Guidance from the FDA on use of RFID in health care settings.	VA
60	ANSI/HIBC 4.0: The health industry supplier standard for RFID product identification . American National Standards Institute, Health Industry Business Communications Council; 2009.	Guideline	n/a	n/a	n/a	n/a	Discusses standards for RFID products for health industry suppliers.	IVB

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62	Yaziji H, Taylor C, MA MD, et al. Consensus recommendations on estrogen receptor testing in breast cancer by immunohistochemistry. *Appl Immunohistochem Molecul Morphol* . 2008;16(6):513-520.	Consensus	n/a	n/a	n/a	n/a	Includes recommendations for breast tissue specimen handling to preserve the tissue for consistency and accuracy of results for estrogen receptor testing.	IVB
65	OSHA Fact Sheet: Formaldehyde 2011	Regulatory	n/a	n/a	n/a	n/a	Describes OSHA regulations on formaldehyde and defines the difference between formaldehyde and formalin.	n/a
66	Formaldehyde, 2-butoxyethanol and 1-tert-butoxypropan-2-ol. Lyon, France: World Health Organization: International Agency for Research on Cancer; 2006IARC Monographs on the Evaluation of Carcinogenic Risks to Humans; No. 88.	Consensus	n/a	n/a	n/a	n/a	Consensus document based on synthesized evidence stating that formaldehyde is considered carcinogenic to humans.	IVA
67	Buesa RJ. Histology without formalin? *Ann Diagn Pathol* . 2008;12(6):387-396. doi: 10.1016/j.anndiagpath.2008.07.004.	Expert Opinion	n/a	n/a	n/a	n/a	Excellent summary of the background of formalin, its use, potential alternatives, and solutions to using less formalin.	VA
72	Modifications to the HIPAA privacy, security, enforcement, and breach notification rules under the health information technology for economic and clinical health act and the genetic information nondiscrimination act; other modifications to the HIPAA rules . Fed Regist. 2013;78(17 Part 2):5566-5702.	Regulatory	n/a	n/a	n/a	n/a	HIPAA regulations	n/a
73	Standards of perioperative nursing. Denver, CO: AORN, Inc; 2015.	Consensus	n/a	n/a	n/a	n/a	Perioperative nursing standards. Including protecting confidentiality and patient privacy.	IVB
74	40 CFR 260- hazardous waste system: General. 7-1-12 ed. U.S. Government Publishing Office; 2012; No. 27.	Regulatory	n/a	n/a	n/a	n/a	Regulations for hazardous waste.	n/a
75	Safety data sheet: Formalin, buffered, 10%. Revision Date 13-Apr-2018 ed. ThermoFisher Scientific; 2011.	Expert Opinion	n/a	n/a	n/a	n/a	Provides safety information on the use of 10% Formalin.	VA
77	Li JK, Shah BA. Survey on imaging management and handling of breast surgical specimens by radiologists. *Journal of the American College of Radiology* . 2014;11(9):890-893.	Nonexperimental	354 survey responses. Response rate 14.6%	n/a	n/a	Process for radiological imaging of breast specimens.	There is considerable variability in practice but most survey respondents agree that a standard process is necessary.	IIIB
78	Allison KH, Hammond ME, Dowsett M, et al. Estrogen and progesterone receptor testing in breast cancer: ASCO/CAP guideline update. *JCO* . 2020:JCO.19.02309.	Guideline	n/a	n/a	n/a	n/a	States that time of removal, time placed in fixative and cold ischemia time should be recorded, and that the time from specimen acquisition to fixation should be as short as possible.	IVB

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79	Wolff AC, Hammond ME, Allison KH, et al. Human epidermal growth factor receptor 2 testing in breast cancer: American society of clinical Oncology/College of american pathologists clinical practice guideline focused update. *Arch Pathol Lab Med* . 2018;142(11):1364-1382.	Guideline	n/a	n/a	n/a	n/a	States that fixation times should be recorded and that the specimens should be fixated as soon as possible after initial gross inspection.	IVB
80	Baltuonyte A, Ruparelia V, Shah BA. In the clinic. surgical breast tissue specimen handling and transportation in radiology. *Radiol Technol* . 2016;87(5):564-568.	Organizational Experience	Not reported.	n/a	n/a	n/a	An interdisciplinary standard process for breast specimen containment for transportation between surgery, radiology, and pathology is important.	VB
82	Hicks DG, Boyce BF. The challenge and importance of standardizing pre-analytical variables in surgical pathology specimens for clinical care and translational research. *Biotech Histochem* . 2012;87(1):14-17.	Expert Opinion	n/a	n/a	n/a	n/a	Discussion of the need for standardization in the handling of surgical specimens. Also discusses some quality improvements made at one facility.	VB
83	Hicks DG, Kushner L, McCarthy K. Breast cancer predictive factor testing: The challenges and importance of standardizing tissue handling. *J Natl Cancer Inst Monogr* . 2011;2011(42):43-45.	Expert Opinion	n/a	n/a	n/a	n/a	Discussion of the need for standardization in the handling of surgical specimens. Also discusses some quality improvements made at one facility including how it is feasible for breast cancer specimens to get to the pathology department in one hour.	VB
84	Balch, C. M. Reexamining our routines of handing surgical tissue in the operating room 2011	Expert Opinion	n/a	n/a	n/a	n/a	Discussion of how to examine facility procedures in an attempt to standardized specimen quality for biological marker and gene assay testing in cancer specimens.	VB
85	Hewitt SM, Lewis FA, Cao Y, et al. Tissue handling and specimen preparation in surgical pathology: Issues concerning the recovery of nucleic acids from formalin-fixed, paraffin-embedded tissue. *Arch Pathol Lab Med* . 2008;132(12):1929-1935.	Expert Opinion	n/a	n/a	n/a	n/a	Discusses potential changes to the tissue handling process to facilitate obtaining quality biological markers from surgical specimens.	VB

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88	Portier, B. P., Wang, Z., Downs-Kelly, E., et al. Delay to formalin fixation 'cold ischemia time': effect on ERBB2 detection by in-situ hybridization and immunohistochemistry. Modern Pathology. 2013;26(1):1-9.	Nonexperimental	84 core specimens of invasive breast carcinoma.	n/a	n/a	Cold ischemia time compared to estrogen receptor testing using Fluorescence in-situ hybridization (FISH), immunochemistry assay (IHC), and Inform HER2® dual in-situ hybridization.	Cold ischemia time up to 4 hours does not alter detection of Erb-B2 Receptor Tyrosine Kinase 2P (ERBB2) also known as HER2. These study results are in disagreement with the less than one hour cold ischemia time recommended by the American Society of Clinical Oncology/College of American Pathologists (ASCO/CAP).	IIIB
90	Arima N, Nishimura R, Osako T, et al. The importance of tissue handling of surgically removed breast cancer for an accurate assessment of the ki-67 index. *J Clin Pathol* . 2016;69(3):255-259.	Nonexperimental	28 samples for study on time of fixation.	n/a	n/a	Ki-67 index compared between type of fixative, time of fixation (in pathology), and timing of cutting into the tumor.	Several hours of cold ischemia time may not have serious effects on ER, PgR, HER2, and Ki-67. Recommend following the ASCO/CAP guidelines that state breast specimens should be fixed (in pathology) as soon as possible.	IIIB
91	Li X, Deavers MT, Guo M, et al. The effect of prolonged cold ischemia time on estrogen receptor immunohistochemistry in breast cancer. *Mod Pathol* . 2013;26(1):71-78.	Nonexperimental	97 patients with paired breast tumor core biopsy specimens and resection specimens.	n/a	n/a	Estrogen receptors compared against cold ischemia time.	The estrogen receptors in the biopsy specimens and resection specimens were not significantly associated with the time of cold ischemia. Cold ischemia time up to 4 hours in the researcher's institution has minimal impact on estrogen receptor markers.	IIIB
92	Arber D. Effect of prolonged formalin fixation on the immunohistochemical reactivity of breast markers. *Appl Immunohistochem Molecul Morphol* . 2002;10(2):183-186.	Nonexperimental	33 infiltrating breast carcinomas.	n/a	n/a	Grading of immunochemistry stains for estrogen receptors, progesterone receptors and c-erb-b2 .	Fixation in 10% NBF allows for immunoreactions with antigen retrieval after several days and c-erb-B2 immunoreactivity for up to 20 days, and Estrogen and progesterone reactivity for up to 57 days.	IIIB

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93	Tevis SE, Neuman HB, Mittendorf EA, et al. Multidisciplinary intraoperative assessment of breast specimens reduces number of positive margins. *Ann Surg Oncol* . 2018;25(10):2932-2938.	Nonexperimental	100 surveys completed by surgeons that had performed breast surgery and reviewed radiographs.	n/a	n/a	Rate of positive or close margins.	The surgeon reviewing the radiograph alone did not reduce the rate of positive or close margins compared to the standard practice. Best practice is intraoperative evaluation by an interdisciplinary team which increased the additional margins reducing the rate of reoperations for positive margins.	IIIB
94	10 CFR 20 standards for protection against radiation. 1-1-19 ed. Office of the Federal Register National Archives and Records Administration; 2019; No. 1.	Regulatory	n/a	n/a	n/a	n/a	Radiation protection regulations.	n/a
95	10 CFR 35: Medical use of byproduct material. 1-1-19 ed. Office of the Federal Register National Archives and Records Administration; 2019; No. 1.	Regulatory	n/a	n/a	n/a	n/a	Regulations on use of byproduct material.	n/a
96	Goudreau S.H., Joseph J.P., Seiler SJ. Preoperative radioactive seed localization for nonpalpable breast lesions: Technique, pitfalls, and solutions. Radiographics. 2015;35(5):1319-1334. Accessed 20160726; 20160726. doi: http://dx.doi.org/10.1148/rg.2015140293.	Organizational Experience	Not reported.	n/a	n/a	n/a	Discusses the use of radioactive seed localization, errors, and makes recommendations for practice.	VB
97	NRC: Iodine-125 and palladium-103 low dose rate brachytherapy seeds used for localization of non-palpable lesions. http://www.nrc.gov/materials/miau/med-use-toolkit/seed-localization.html. Updated 2017. Accessed 11/13, 2019.	Regulatory	n/a	n/a	n/a	n/a	Discussion of regulations for use of radioactive seeds for localization procedures.	n/a
98	Graham RPD, Jakub JW, Brunette JJ, Reynolds C. Handling of radioactive seed localization breast specimens in the pathology laboratory. Am J Surg Pathol. 2012;36(11):1718-23.	Organizational Experience	Not reported.	n/a	n/a	n/a	Discusses the process for handling of radioactive seed specimens.	VB
99	Renshaw AA, Kish R, Gould EW. Increasing radiation from sentinel node specimens in pathology over time. Am J Clin Pathol. 2010;134(2):299-302.	Nonexperimental	2,902 sentinel nodes and resected specimens.	n/a	n/a	Level of radiation.	The levels of radiation were increasing over time. Discusses radiation limits, timing of specimens received in pathology, and quality monitoring.	IIIB
101	Fitzgibbons PL, LiVolsi VA. Recommendations for handling radioactive specimens obtained by sentinel lymphadenectomy. surgical pathology committee of the college of american pathologists, and the association of directors of anatomic and surgical pathology. Am J Surg Pathol. 2000;24(11):1549-51.	Guideline	n/a	n/a	n/a	n/a	Provides recommendations on handling of radioactive specimens.	IVB
102	Michel R, Hofer C. Radiation safety precautions for sentinel lymph node procedures. Health Phys. 2004;86(2):S35-7.	Expert Opinion	n/a	n/a	n/a	n/a	Discusses the literature and proposes recommendations for safe specimen handling, policy and procedure requirements, and education.	VB

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103	Coventry BJ, Collins PJ, Kollias J, Bochner M, Rodgers N4 Gill PG, Chatterton BE and Farshid G. Ensuring radiation safety to staff in lymphatic tracing and sentinel lymph node biopsy surgery – some recommendations. J Nucl Med Radiat Ther. 2012:1-5. Accessed 1/2/2014. doi: 10.4172/2155-9619.S2-008.	Nonexperimental	Whole body exposure measurements, surgeon extremity exposure measurements, and specimen courier measurements were 36, 24, and 19, respectively.	n/a	n/a	Radiation dosimetry measurements.	Whole body exposure is negligible for surgeons and couriers. Extremity exposures for surgeons is low risk compared to international expires limits. Researchers make recommendations for practice.	IIIC
104	Law M, Chow LWC, Kwong A, Lam CK. Sentinel lymph node technique for breast cancer: Radiation safety issues. Semin Oncol. 2004;31(3):298-303.	Organizational Experience	Not reported. Measured surgeon, assistant, and scrub person radiation exposure during sentinel lymph node procedures.	n/a	n/a	n/a	Discusses radiation doses received by the sterile personnel. Doses were low, use of lead shielding is optional. Surgeons could perform up to 2000 procedures before reaching a occupational limit.	VB
105	Dessauvagie BF, Frost FA, Sterrett GF, et al. Handling of radioactive seed localisation breast specimens in the histopathology laboratory: The western australian experience. Pathology. 2015;47(1):21-26. doi: https://dx.doi.org/10.1097/PAT.0000000000000197.	Expert Opinion	n/a	n/a	n/a	n/a	Discusses the process for specimen handling of radioactive seeds during intraoperative and postoperative areas including the pathology department.	VB
106	Garner HW, Bestic JM, Peterson JJ, Attia S, Wessell DE. Preoperative radioactive seed localization of nonpalpable soft tissue masses: An established localization technique with a new application. Skeletal Radiol. 2017;46(2):209-216. doi: https://dx.doi.org/10.1007/s00256-016-2529-x.	Nonexperimental	10 nonpalpable soft tissue mass patients.	n/a	n/a	Satisfaction survey.	The use of radioactive seeds for surgical intervention to nonpalpable masses had high patient and surgeon satisfaction. Discusses how seeds were used.	IIIC
107	Sung JS, King V, Thornton CM, et al. Safety and efficacy of radioactive seed localization with I-125 prior to lumpectomy and/or excisional biopsy. Eur J Radiol. 2013;82(9):1453-1457. http://search.ebscohost.com/login.aspx?direct=true&db=ccm&AN=104085341&site=ehost-live&scope=site. doi: 10.1016/j.ejrad.2013.04.008.	Nonexperimental	356 women undergoing seed and/or wire localization procedures.	n/a	n/a	Safety and efficacy of radioactive seed localization procedures.	Researchers concluded that the procedure is safe and effective. Reported two adverse events. One seed was lost during dissection in the axilla. The second reported event was a marker clip that was dislodged during seed placement.	IIIB
108	Pavlicek W, Walton HA, Karstaedt PJ, Gray RJ. Radiation safety with use of I-125 seeds for localization of nonpalpable breast lesions. Acad Radiol. 2006;13(7):909-915.	Organizational Experience	More than 300 seed localization procedures.	n/a	n/a	n/a	Discusses the process of radioactive seed handling throughout all phases from receiving the seed to when the seed is placed in decay storage after pathological assessment.	VB
109	10 CFR 71.5: Transportation of licensed material. 1-1-19 ed. Office of the Federal Register National Archives and Records Administration; 2019; No. 2.	Regulatory	n/a	n/a	n/a	n/a	Regulations on transporting hazardous material.	n/a

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110	10 CFR 30.41: Transfer of byproduct material. 1-1-19 ed. Office of the Federal Register National Archives and Records Administration; 2019; No. 1.	Regulatory	n/a	n/a	n/a	n/a	Regulations on transferring hazardous material.	n/a
111	Johnstone EM, Conner R. Guideline for medical device and product evaluation. In: Conner R, ed. *Guidelines for perioperative practice.* Denver, CO: AORN; 2020.	Guideline	n/a	n/a	n/a	n/a	Provides recommendation on product evaluation in the perioperative environment.	IVA
112	21 CFR 821: Medical device tracking requirements. 4-1-19 ed. Office of the Federal Register National Archives and Records Administration; 2019; No. 8.	Regulatory	n/a	n/a	n/a	n/a	Regulations on medical device tracking.	n/a
113	Medical device tracking; guidance for industry and FDA staff. "Content current as of: 06/28/2018" ed. U. S. Food & Drug Administration, Issued by Center for Devices and Radiological Health; 2014.	Expert Opinion	n/a	n/a	n/a	n/a	Update of 2010 document guiding industry and final distributors on medical device tracking.	VA
114	21 CFR 803 subpart C: User facility reporting requirements. 4-1-19 ed. Office of the Federal Register National Archives and Records Administration; 2019.	Regulatory	n/a	n/a	n/a	n/a	Regulations on reporting requirements of user facilities for medical devices.	n/a
115	Medical device reporting (MDR): How to report medical device problems. Medical Device Reporting Web site. https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems. Updated 2019. Accessed 11/13, 2019.	Expert Opinion	n/a	n/a	n/a	n/a	FDA instructions on reporting death or serious injuries for medical devices.	VA
116	MedWatch: The FDA safety information and adverse event reporting program. https://www.fda.gov/safety/medwatch-fda-safety-information-and-adverse-event-reporting-program. Updated 2019. Accessed 11/13, 2019.	Expert Opinion	n/a	n/a	n/a	n/a	FDA information on MedWatch program.	VA
117	Unique device identification system. Federal Register; 2013; No. 78.	Regulatory	n/a	n/a	n/a	n/a	Regulations regarding unique device identifiers.	n/a
118	Burlingame BL, Maxwell-Downing D. Clinical issues-november 2015. AORN Journal. 2015;102(5):536-544. [2019].	Expert Opinion	n/a	n/a	n/a	n/a	Discusses unique device identifier (UDI) information.	VA
119	Policy on surgical specimens to be submitted to pathology for examination. appendix M. College of American Pathologists; 2007.	Position Statement	n/a	n/a	n/a	n/a	College of American Pathologists policy on surgical specimen submission.	IVB
120	Davidovitch RI, Temkin S, Weinstein BS, Singh JR, Egol KA. Utility of pathologic evaluation following removal of explanted orthopaedic internal fixation hardware. Bulletin of the NYU Hospital for Joint Diseases. 2010;68(1):18-21. [IIIC].	Nonexperimental	46 patients that had hardware removal procedures.	n/a	n/a	Results of pathology reports and cost of examination.	The results of the pathology reports consisted mostly of the word "hardware". The researchers estimated that the cost per year to the healthcare system in the US may be $9.8 million dollars.	IIIC
121	Forensic evidence collection in the emergency care setting. Schaumburg, IL: Emergency Nurses AssociationPosition Statement.	Position Statement	n/a	n/a	n/a	n/a	Recommendations on forensic evidence for emergency department nurses.	IVB
122	Foresman-Capuzzi J. CSI & U: Collection and preservation of evidence in the emergency department. Journal of Emergency Nursing. 2014;40(3):229-236.	Expert Opinion	n/a	n/a	n/a	n/a	Discussion of forensic evidence collection, documentation, and chain of custody.	VA
123	Peel M. Opportunities to preserve forensic evidence in emergency departments. Emerg Nurse. 2016;24(7):20-26.	Expert Opinion	n/a	n/a	n/a	n/a	Discussion of forensic evidence handling.	VC

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124	Byrne-Dugan CJ, Cederroth TA, Deshpande A, Remick DG. The processing of surgical specimens with forensic evidence: Lessons learned from the boston marathon bombings. Arch Pathol Lab Med. 2015;139(8):1024-1027.	Expert Opinion	n/a	n/a	n/a	n/a	Designed a protocol for care of forensic specimens for the pathology department based on a collaborative process with three facilities in Boston, the FBI, and the Chief Medical Examiner of Massachusetts.	VA
125	Evans MM, Stagner PA, Rooms R. Maintaining the chain of custody--evidence handling in forensic cases. AORN J. 2003;78(4):563-569.	Expert Opinion	n/a	n/a	n/a	n/a	Discusses recommendations for handling potential forensic evidence.	VA
126	Wick JM. Don't destroy the evidence! AORN Journal. 2000;72(5):805-827.	Expert Opinion	n/a	n/a	n/a	n/a	Discusses handling of forensic evidence.	VB
127	Porteous J. Don't tip the scales! care for patients involved in a police investigation. Can Oper Room Nurs J. 2005;23(3):12-4, 16.	Expert Opinion	n/a	n/a	n/a	n/a	Provides recommendations for forensic evidence management during the perioperative phases.	VA
128	Recommended equipment for obtaining forensic samples from complainants and suspects. Faculty of Forensic & Legal Medicine; 2019.	Guideline	n/a	n/a	n/a	n/a	Recommendations on equipment needed for obtaining forensic specimens.	IVB
129	Recommendations for the collection of forensic specimens from complainants and suspects. Faculty of Forensic & Legal Medicine; 2020.	Guideline	n/a	n/a	n/a	n/a	Recommendations on forensic specimen collection.	IVB
130	Koehler SA. Firearm evidence and the roles of the ER nurse and forensic nurse. Journal of forensic nursing. 2009;5(1):46-48.	Expert Opinion	n/a	n/a	n/a	n/a	Describes handling, documentation, and chain of custody for clothing that may be forensic evidence.	VC
131	Carrigan M, Collington P, Tyndall J. Forensic perioperative nursing. advocates for justice. Can Oper Room Nurs J. 2000;18(4):12-16.	Expert Opinion	n/a	n/a	n/a	n/a	Discusses considerations for handling of forensic evidence.	VA
132	Labelling forensic samples. Faculty of Forensic & Legal Medicine; 2019.	Guideline	n/a	n/a	n/a	n/a	Recommendations on forensic specimen labeling.	IVB
133	Baergen RN, Thaker HM, Heller DS. Placental release or disposal? experiences of perinatal pathologists. Pediatr Dev Pathol. 2013;16(5):327-330.	Nonexperimental	36 survey responses.	n/a	n/a	If placentas were allowed to be released and if so under what circumstances.	Survey found most institutions did not release placentas but those that did generally had paperwork to complete. Researchers made recommendations for placental release.	IIIC
134	Helsel DG, Mochel M. Afterbirths in the afterlife: Cultural meaning of placental disposal in a hmong american community. J Transcult Nurs. 2002;13(4):282-286.	Qualitative	94 interviews.	n/a	n/a	Belief in traditional cultural methods of placental burial.	Most individuals that identified as annamist were 36 years old or above and believed that the placenta should be buried at home. However, only 11.7% of those with hospital births asked for the placenta and only 5 were given the placenta.	IIIB

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135	WHO infection control guidelines for transmissible spongiform encephalopathies: Report of a WHO consultation geneva, switzerland, 23-26 march 1999. ; [2000]; No. WHO/CDS/CSR/APH/2000.3.	Guideline	n/a	n/a	n/a	n/a	Recommendations for care of patients with TSE (CJD).	IVA
136	Pizzella N, Kurec A. The proper handling of CJD-infected patient samples in the pathology laboratory. MLO. 2018;50(5):40-42. http://search.ebscohost.com/login.aspx?direct=true&db=ccm&AN=129341093&site=ehost-live&scope=site.	Expert Opinion	n/a	n/a	n/a	n/a	Discusses precautions for handling of CJD specimens in the pathology department.	VA
137	Karasin M. Special needs populations: Perioperative care of the patient with creutzfeldt-jakob disease. AORN J. 2014;100(4):391-410. http://search.ebscohost.com/login.aspx?direct=true&db=ccm&AN=103895025&site=ehost-live&scope=site. doi: 10.1016/j.aorn.2014.06.018.	Expert Opinion	n/a	n/a	n/a	n/a	Discusses perioperative considerations for care of patients with CJD.	VA
138	Alcalde-Cabero E, Almazán-Isla J, Brandel JP, et al. Health professions and risk of sporadic Creutzfeldt–Jakob disease, 1965 to 2010. Eurosurveillance. 2012;17(15):20144. doi: https://doi.org/10.2807/ese.17.15.20144-en.	Literature Review	n/a	n/a	n/a	n/a	Health care personnel are not at greater risk for sCJD than the rest of the population.	VA
139	Giarrizzo-Wilson S, Conner R. Guideline for patient information management. In: Conner R, ed. Guidelines for perioperative practice. Denver, CO: AORN; 2020.	Guideline	n/a	n/a	n/a	n/a	Provides recommendations on information management in the perioperative setting.	IVA
140	Liebmann R, Varma M, eds. Best practice recommendations: Histopathology and cytopathology of limited or no clinical value. 3rd ed. London: Royal College of Pathologists; 2019.	Guideline	n/a	n/a	n/a	n/a	Discusses when placentas may be sent and testing or exclusion of tissue by type.	IVB
141	Damjanov I, Vranic S, Skenderi F. Does everything a surgeon takes out have to be seen by a pathologist? A review of the current pathology practice. Virchows Arch. 2016;468(1):69-74. doi: https://dx.doi.org/10.1007/s00428-015-1801-0.	Expert Opinion	n/a	n/a	n/a	n/a	Review of evidence and recommendations for determining what should be sent to pathology and for what level of examination.	VB
142	Fisher M, Alba B, Bhuiya T, Kasabian AK, Thorne CH, Tanna N. Routine pathologic evaluation of plastic surgery specimens: Are we wasting time and money?. Plast Reconstr Surg. 2018;141(3):812-816. doi: https://dx.doi.org/10.1097/PRS.0000000000004129.	Nonexperimental	759 plastic surgery specimens.	n/a	n/a	Clinically significant findings during pathology examination.	There was no clinically significant findings from the specimens. One specimen had a seborrheic keratosis on breast skin. The annual cost was $430,095. Recommended only sending plastic surgery specimens when there is history or clinical suspicion to do so.	IIIA
143	Bizzell JG, Richter GT, Bower CM, Woods GL, Nolder AR. Routine pathologic examination of tonsillectomy specimens: A 10-year experience at a tertiary care children's hospital. Int J Pediatr Otorhinolaryngol. 2017;102:86-89. doi: https://dx.doi.org/10.1016/j.ijporl.2017.09.012.	Nonexperimental	8807 paired tonsil specimens.	n/a	n/a	Results of pathology reports.	Microscopic analysis of tonsil specimens is unlikely to identify abnormal pathology. Neither gross or microscopic pathological examination is needed on a routine basis.	IIIA
144	Teraphongphom N., Kong C.S., Warram J.M., Rosenthal EL. Specimen mapping in head and neck cancer using fluorescence imaging. Laryngoscope Investigative Otolaryngology. 2017;2(6):447-452. doi: http://dx.doi.org/10.1002/lio2.84.	Expert Opinion	n/a	n/a	n/a	n/a	Discussion of use of intraoperative specimen fluorescence.	VA

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145	Meier FA, Varney RC, Zarbo RJ. Study of amended reports to evaluate and improve surgical pathology processes. Adv Anat Pathol. 2011;18(5):406-413. doi: 10.1097/PAP.0b013e318229bf20; 10.1097/PAP.0b013e318229bf20.	Organizational Experience	1429 amended pathology reports.	n/a	n/a	n/a	Total amended report rates initially increased and then subsequently decreased each year of the study. Authors create a taxonomy for classifying amended report defects.	VA
146	Gillio-Meina C, Zielke HR, Fraser DD. Translational research in pediatrics IV: Solid tissue collection and processing. Pediatrics. 2016;137(1). doi: https://dx.doi.org/10.1542/peds.2015-0490.	Expert Opinion	n/a	n/a	n/a	n/a	This expert opinion article reviews ethical standards related to tissue specimens for research purposes, handling, storage, and processing.	VB
147	Harrison BT, Dillon DA, Richardson AL, Brock JE, Guidi AJ, Lester SC. Quality assurance in breast pathology: Lessons learned from a review of amended reports. Arch Pathol Lab Med. 2017;141(2):260-266. doi: https://dx.doi.org/10.5858/arpa.2016-0018-OA.	Nonexperimental	12,228 breast pathology reports.	n/a	n/a	Rate of amended reports.	The rate of amended reports was 0.99%. The rate of amended pathology reports may be one indicator of error rates and types.	IIIA
148	Volmar KE, Idowu MO, Hunt JL, Souers RJ, Meier FA, Nakhleh RE. Surgical pathology report defects: A college of american pathologists Q-probes study of 73 institutions. Arch Pathol Lab Med. 2014;138(5):602-612. doi: https://dx.doi.org/10.5858/arpa.2013-0099-CP.	Nonexperimental	73 institutions reported 1688 defects in pathology reports out of 360,218 cases.	n/a	n/a	Rate and type of defects.	Misidentification defects made up 11.8% of all defect types. These included wrong patient, wrong site, wrong tissue, and wrong laterality.	IIIA