Frozen-Section Checklist Implementation Improves Quality and Patient Safety

Yigu Chen, MPH,[1] Kevin R. Anderson, MD, PhD,[1] Jia Xu, MD,[1] Jeffrey D. Goldsmith, MD,[1,2] and Yael K. Heher, MD, MPH[1]

From the [1]Beth Israel Deaconess Medical Center, Pathology, Boston, MA; and [2]Boston Children's Hospital, Pathology, Boston, MA.

Key Words: Intraoperative consultation; Frozen section; Quality improvement; Patient safety; Safety

Am J Clin Pathol June 2019;151:607-612

DOI: 10.1093/AJCP/AQZ009

ABSTRACT

Objectives: *An intraoperative consultation (IOC) checklist was developed and implemented aimed at standardizing slide labeling and monitoring metrics central to quality and safety in surgical pathology.*

Design: *Data were collected for all IOC cases over a 9-month period. Slide labeling defect rates and IOC turnaround time (TAT) were recorded and compared for the pre- and postimplementation periods.*

Results: *In total, 839 IOC cases were analyzed. Preintervention slide labeling showed that 85% of cases contained at least one defect (n = 565). Postintervention data revealed that 27% of cases contained at least one defect (n = 274). The improvement was statistically significant (*P < *.001). Mean TAT was 21.6 minutes preintervention vs 23.2 minutes postintervention, and the change was insignificant (*P = *.071).*

Conclusions: *The implementation of a standardized IOC reduced slide labeling error. This improvement did not affect mean TAT and may have the increased quality of IOC TAT data reporting. Other metrics affecting patient safety and quality were monitored and standardized.*

Intraoperative consultation (IOC) is an integral part of surgical pathology and surgical patient care, providing critical real-time information to help guide intraoperative clinical decision making. As a result of the IOC's significant impact on patient care, the College of American Pathologists (CAP) laboratory accreditation program mandates correlation between frozen-section and final diagnoses to ensure the quality of IOC service.[1] Monitoring IOC diagnostic discrepancies is also recommended by the Association of Directors of Anatomic and Surgical Pathology as a key analytic quality indicator.[2] Extensive research on the accuracy of IOC diagnosis has been published to identify analytic issues and to improve diagnostic performance.[3-5] However, little or no attention has been paid to the preanalytic and nondiagnostic process vulnerabilities in the frozen-section laboratory. Time pressure is built into the IOC process, with the pathology team attempting to provide a diagnosis as quickly as possible to the surgical team while the patient is under anesthesia. Considerations of diagnostic speed can lead to process shortcuts and workarounds, with subsequent patient safety risk, including labeling errors and mix-ups. Although appropriate slide labeling is universally recognized as an essential part of laboratory workflow, IOC practices vary considerably between institutions and are an underreported source of error and near misses. Busy operating rooms may have dozens of IOC requests per day, and with centralized, manual case processing, vulnerability for specimen mix-ups should remain a major concern for anatomic pathology leadership.

In our institution, a labeling error involving the serious misdiagnosis of a patient with a brain biopsy to rule out metastatic adenocarcinoma led us to examine

and redesign our IOC workflow. We chose to use a design and implement a validated patient safety tool: the checklist.

In the 1930s, the Boeing Corporation introduced checklists to the aviation industry to aid pilots when performing step-by-step safety checks for takeoff, flight, landing, and taxiing.[6] Since then, checklists have been widely adopted by high-reliability organizations in aviation, aerospace, and nuclear power industries to prevent failures.[7] But the benefits of using the checklist as a safety tool in health care remained unknown until Peter Pronovost devised a short checklist for central line insertion, and its implementation led to a significant decrease in infection rate.[8] The concept was gradually accepted by the medical community, particularly after the landmark publication of the *WHO Safe Surgical Checklist* and *Checklist Manifesto* by Harvard surgeon and public health advocate Atul Gawande.[9] In recent years, applications of the checklist in a variety of clinical settings, primarily the operating room and procedure areas, have shown systematic improvement in preventing error, increasing reliability, and improving patient safety.[10,11]

In our study, using input from various pathology, surgery, nursing, and administrative stakeholders, we were able to design and implement a custom checklist that was built into the IOC pathologist workflow. The checklist was aimed at standardizing IOC workflow with a focus on reliable and reproducible quality and patient safety.

Materials and Methods

To demonstrate the benefits of adopting a checklist in the frozen-section laboratory and to evaluate the effectiveness of its implementation, we conducted a retrospective study of preintervention (6 months) and postintervention (3 months) periods at Beth Israel Deaconess Medical Center, Boston, MA, a teaching hospital of Harvard Medical School.

The IOC Checklist

The IOC checklist began as a preprinted sticker that could be easily be applied to the pathology requisition. It evolved into being electronically embedded into the requisition itself. The checklist was designed as a cognitive aid to prompt standardized IOC workflow and performance necessary checks for pathologists and trainees. Thirteen items were listed under the "frozen-section room" section of the checklist; key parameters included time specimen received, standardized slide labeling, diagnosis, who accepted the diagnosis (surgeon, nurse, etc), was a read back attained (yes/no), and time results communicated. Additional parameters such as billing codes, information on if a consultation with a second pathologist was obtained (yes/no), and if the case was appropriate for future teaching conferences (yes/no) were also captured by the checklist **Figure 1**. To better incorporate the IOC diagnostic discrepancy metrics into the existing sign-out workflow, "permanent diagnosis" parameters were also added onto the checklist to be completed later by the pathologist signing out the case.

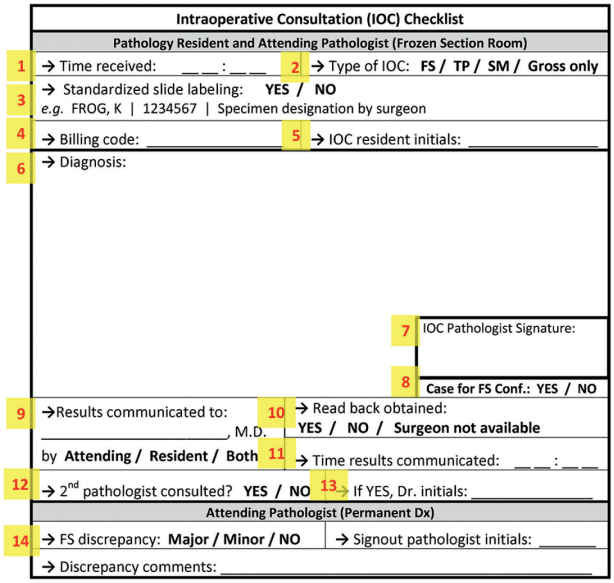

Figure 1 Frozen-section checklist. 1. Time specimen received from the operating room. 2. Type of consultation performed. FS, frozen section; Gross only, gross-only evaluation; SM, smear; TP, touch preparation. 3. Indicates whether or not all three indicators for correct slide labeling were present, with an example of correct labeling shown. 4. Billing code designated. 5. Initials of trainee performing intraoperative consultation (IOC). 6. Narrative diagnosis entered. 7. IOC attending pathologist identification. 8. Flags a case of teaching interest for presentation at a specialized monthly frozen-section educational conference for trainees and attending pathologists. 9. Identification of provider name accepting results (surgeon, trainee, nurse). 10. Documents "read back" per Joint Commission requirements.[12] 11. Time diagnosis rendered and communicated to surgical team. 12. Indicates if a second pathologist was consulted. 13. Identifies the consultant. 14. To be completed by permanent sign-out pathologist, indicates the presence or absence of an IOC-permanent diagnostic discrepancy and grades the severity of the discrepancy if present, per College of American Pathologists requirement.

DOI: 10.1093/ajcp/aqz009

Study Material

Surgical cases with IOC consultations at our institution for a 6-month period (March 2015 to August 2015) before the intervention were reviewed. Cases were obtained retrospectively by performing a query search in the SoftPath (laboratory information system) database. Only IOC cases with microscopic IOC frozen-section slides were used in the study; gross examination-only cases were excluded. This yielded a total of 565 qualified surgical cases, and these were designated as the preintervention cohort. Postintervention cases were obtained in the same manner for a 3-month period (mid-October 2015 to mid-January 2016), allowing for an implementation transitional "grace" period where cases were excluded (September 2015). In total, 274 postintervention cases were included in the study.

Metrics and Statistics

To assess how the IOC checklist affected frozen-section labeling practice, slides were retrieved and manually reviewed for the study. Defect rates on labels were compared before and after the intervention. Per our institution's policy, three required identifiers on the slides were patient name, patient medical record number (MRN), and specimen designation (ie, site and laterality if applicable). These were recorded as present or absent for each case. Partial completion, such as patient initials only or the last four digits of the MRN, was marked as defective. If a case contained multiple frozen-section slides, all parameters must have been present on all slides for the case to be considered correctly labeled.

IOC turnaround time (TAT) was studied as a balancing measure to determine if the new checklist caused significant process delays. TAT data for preintervention cases were previously self-reported in minutes on separate worksheets in the frozen-section room. Postintervention TAT data were collected via the checklist by calculating the difference in minutes between time "specimen received" (box 1) and time "result communicated" (box 11).

The χ^2 test and t tests were performed in SAS 9.3 (SAS Institute) to analyze pre- and postintervention data. The difference was considered statistically significant when $P < .05$.

Results

Labeling Accuracy

Prior to implementation of the IOC checklist, we found that the majority (85%, 481) of frozen-section cases had slides that had defects in at least one patient identifier Table 1, including 84% (472) missing the specimen location designation, 39% (218) missing the patient MRN, and 23% (130) missing the patient's name. Following IOC checklist implementation, labeling defect rates significantly improved. The percentage of cases having slides missing at least one patient identifier sharply dropped from 89% in October to 17% in November during the period of implementation and continued to decrease to 2% in December 2015 and January 2016 Figure 2. Overall, 27% (74) of postintervention cases had slides missing at least one patient identifier, including 24% (65) missing the specimen location designation, 15% (41) missing the patient's MRN, and 8% (23) missing the patient's name. Implementation of an IOC checklist resulted in the reduction of labeling defects for cases missing at least one identifier, cases missing specimen location designation, cases missing the patient's MRN, and cases missing the patient's name by 68%, 71%, 62%, and 65%, respectively, which were all statistically significant reductions in defects ($P < .001$).

TAT

We were able to obtain TAT data for 521 preintervention cases from the previous frozen-section worksheets.

Table 1

Intraoperative Consultation Labeling Defect Rates and Turnaround Time Before and After Checklist Implementation

Quality Metric	Preintervention (6 Months)	Postintervention (3 Months)	Defect Reduction, %	*P* Value
Slide labeling, No. (%) of defects	n = 565	n = 274		
Patient name	130 (23)	23 (8)	65	<.001[a]
MRN	218 (39)	41 (15)	62	<.001[a]
Specimen designation	472 (84)	65 (24)	71	<.001[a]
Missing at least one identifier	481 (85)	74 (27)	68	<.001[a]
	n = 521	n = 204		
TAT mean, min	21.6	23.2		.071[b]
TAT of 15 or 20 minutes, %	55	35		.024[b]

MRN, medical record number; TAT, turnaround time.
[a]χ^2 test at significance level $\alpha = .05$.
[b]Two-tailed t test at significance level $\alpha = .05$.

DOI: 10.1093/ajcp/aqz009

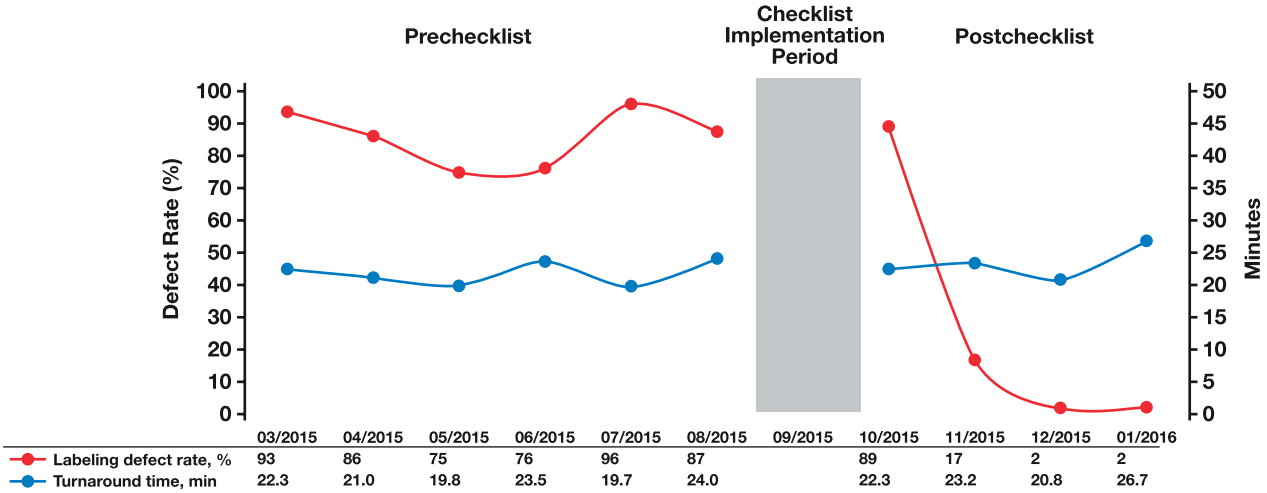

Figure 2 Intraoperative consultation labeling defect rates and turnaround time by month.

IOCs were self-reported as taking an average of 21.6 minutes before checklist implementation, interestingly, with 55% of the cases self-reported as an exact TAT of either 15 or 20 minutes. TAT data were examined for 204 postintervention cases. Average TAT per case was approximately 1.6 minutes longer compared with the preintervention period, but the difference was not statistically significant ($P = .071$). Percentage of reported TATs of either exactly 15 or 20 minutes was decreased to 35% during the postintervention period, and TAT data were more normally distributed (Table 1).

Discussion

Specimen labeling errors are a longstanding and serious patient safety concern in pathology laboratories.[13] Incorrect labeling can result in inappropriate treatment due to diagnostic mix-ups and/or cause significant inconvenience and emotional harm to patients and families.

Complex measures and barcoding technologies have been developed to improve labeling accuracy in laboratories.[14] However, unlike most clinical laboratories where barcoding and on-demand label-printing technologies may potentially serve as "silver bullets" for specimen labeling problems, challenges remain in the highly manual frozen-section laboratory.

First, it is not uncommon for intraoperative consultation specimens to arrive in the frozen-section laboratory with only paper requisitions rather than electronic orders. Second, specimens typically have not yet been accessioned into pathology laboratory information systems when received for IOC, making pathology barcode labeling challenging. Third, the natural time pressure built into the intraoperative consultation service creates hurried labeling practices vulnerable to error and safety events. Finally, the complexity, highly manual nature, and necessity for verbal information handoffs in the frozen-section laboratory make IOC error prone. The pathology team may deviate from their normal procedures due to distraction, interruption, or other challenges particular to the case, leading to potential error and safety events.

The frozen-section laboratory environment is similar to airplane cockpits where pilots must perform difficult tasks while handling multichannel, multilevel communication. An IOC checklist derived from the idea of a preflight checklist was chosen in this study to address these shared challenges. Checklist implementation has proven effective in mitigating patient safety risks, specifically labeling error in our laboratory. We experienced a statistically significant decrease in the number of slide labeling defects, with an overall 68% reduction in cases that were defective in at least one form of slide labeling (Figure 2).

Checklist design and effectiveness was carefully considered by integration into the existing IOC workflow. Checklist item order layout followed typical IOC workflow, including specimen receipt, specimen workup, slide labeling, diagnosis rendering, and results communication. Checklist items served as a reminder to users of each essential step, a process known as "prospective memory."[15] Prospective memory is the ability to plan, retain, and retrieve an intention to act as planned.[16] Forgetting to carry out an action as planned is a failure of prospective memory. For example, a pathology trainee has the intention to label the slides as soon as the IOC specimen arrives, but he or she is called into another operating room by the surgical team for an inquiry and may forget to label the slide when returning to the frozen-section laboratory. Errors such as these are not infrequent. However,

DOI: 10.1093/ajcp/aqz009

the checklist can be a valuable safeguard against these prospective memory slips. It provides users with a second chance to identify and rectify glitches in real time. If "box 3" on the IOC checklist is left unchecked, a visual prompt exists as an empty field. An example of correct slide labeling is present on the checklist itself to facilitate and encourage correct labeling format. In addition, checklists increase accountability and improve sense of ownership during the IOC process by mandating a single user to fill out and initial the checklist.

The standardized IOC checklist improved fidelity of slide labeling in our frozen-section laboratory, but it also enabled integration of other quality and patient safety metrics into the IOC process Table 2. TAT was more accurately captured by calculating the time difference between specimen receipt and result reporting, a safe results read-back policy was implemented and monitored, cases for teaching conferences were prospectively identified, and documentation of IOC-permanent diagnostic discrepancies was captured. Data abstracted from the checklist are tabulated into a quality performance dashboard and reviewed on a quarterly basis by medical directors, managers, technologists, and laboratory leadership Figure 3.[17]

Our results indicate the addition of a standardized checklist to the IOC workflow did not cause significant delay in the IOC process. While postintervention TAT (23.2 minutes) was slightly longer than preintervention TAT (21.6 minutes), the difference was not statistically significant. We did, however, notice an interesting pattern of self-reported TAT. Before checklist implementation, 55% of pathologists self-reported a TAT of exactly 15 or 20 minutes, likely an estimation of true TAT. Prior studies have shown a bias for reporting numbers on common delineations, such as pathologic measurements on 0.5-cm increments or rounding birth weights by common intervals.[18-20] During our preintervention phase, a self-reported TAT estimation was collected as an absolute number. During the postintervention phase, the time of specimen receipt was recorded, and the time the diagnosis was rendered was recorded; TAT was then calculated post hoc by a separate party during data abstraction. The percentage of pathologists who self-reported an exact TAT of 15 or 20 minutes decreased to 35% with a more normal distribution, suggesting increased reporting accuracy of true TAT. Prior to 2011, the CAP mandated monitoring of IOC TAT with a recommended target of 20 minutes for simple cases.[1] Since that time, monitoring of IOC TAT is no longer mandated, and no specific TAT target exists. At our institution, we continue to monitor IOC TAT as an internally mandated quality metric, with a focus on trends rather than specific TAT targets. Different variables can affect optimal and realistic TAT such as case complexity and pathologist travel time to the operating room site. An understanding of true TAT performance, monitoring of upward trends, and feedback from surgical colleagues are all central to successful overall pathology quality programs.

Although the IOC checklist improved labeling accuracy, it did not eliminate all labeling defects. We allowed a 1-month transition time period for checklist education and implementation, but following this period the compliance rate for checklist utilization did not reach 100%. Unlike pilots who view checklists as part of routine daily work, trained to integrate them from flight school throughout their careers, physicians are still unaccustomed to standard work and checklists. Compliance rates as associated with organizational and local cultures of patient safety have been previously described.[21] A robust patient safety culture takes time and requires leadership commitment, frontline engagement, and effective tools. Positive outcomes can be expected only over a longer rather than a shorter time period, with repeated, thoughtful, and data-driven interventions.[22] Moreover, the checklist itself was not designed to serve as a "hard stop" to prevent all types of error. Checklists have limited impact unless they are coupled with safety culture and widespread adoption and compliance.[23]

In summary, our innovative IOC standardized checklist focused on addressing preanalytic and nondiagnostic patient safety events in the IOC workflow. Implementation of the IOC checklist significantly reduced the rate of slide

Table 2
Integrated Quality and Patient Safety Goals in the IOC Checklist

Checklist Items	Quality and Patient Safety Goals
1, 11	Track and monitor TAT for IOC service
3, 5	Improve labeling accuracy, increase accountability
2, 4	Streamline workflow by replacing and eliminating duplicate or existing administrative paperwork
8	Flag challenging cases for teaching
9, 10	Improve result communication/hand-offs between pathology and surgical team
14	Track and monitor IOC diagnostic discrepancies

IOC, intraoperative consultation; TAT, turnaround time.

DOI: 10.1093/ajcp/aqz009

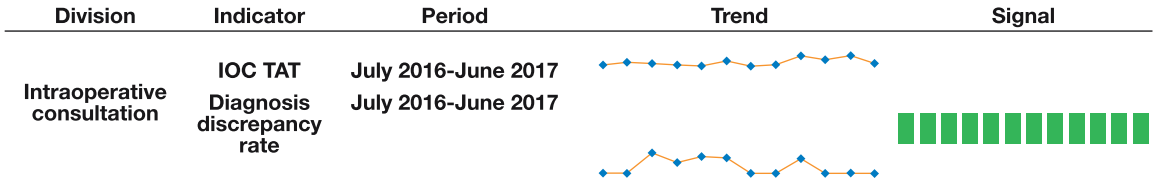

Figure 3 Intraoperative consultation (IOC) dashboard quality metrics monitored by trend lines and/or signals. Sparklines are created to monitor trends over time and to identify significant deviations in the process. If the quality metric has a predetermined benchmark, the signal light remains green when target is met; otherwise, it turns red. TAT, turnaround time.

labeling defects in our laboratory, did not adversely affect TAT, and may have improved TAT reporting accuracy. Checklist implementation is a significant step in a greater effort to adopt a culture of safety and allows laboratory leadership to reliably collect additional meaningful quality metrics associated with an overall quality management plan.

Corresponding author: Yael K. Heher, MD, MPH; ykheher@bidmc.harvard.edu.

References

1. Carter D. Regulatory compliance. In: Nakhleh RE, Fitzgibbons PL, eds. *Quality Management in Anatomic Pathology*. Northfield, IL: College of American Pathology; 2005:9-31.
2. Association of Directors of Anatomic and Surgical Pathology. Recommendations for quality assurance and improvement in surgical and autopsy pathology. *Hum Pathol.* 2006;37:985-988.
3. Liu S, Wang R, Zhang Y, et al. Precise diagnosis of intraoperative frozen section is an effective method to guide resection strategy for peripheral small-sized lung adenocarcinoma. *J Clin Oncol.* 2016;34:307-313.
4. Sams SB, Wisell JA. Discordance between intraoperative consultation by frozen section and final diagnosis. *Int J Surg Pathol.* 2017;25:41-50.
5. Poling JS, Tsangaris TN, Argani P, et al. Frozen section evaluation of breast carcinoma sentinel lymph nodes: a retrospective review of 1,940 cases. *Breast Cancer Res Treat.* 2014;148:355-361.
6. Higgins WY, Boorman DJ. *Checklists to Enhance Safety*. https://www.boeing.com/features/innovation-quarterly/dec2016/feature-technology-checklist.page. Accessed May 5, 2018.
7. Thomassen Ø, Espeland A, Søfteland E, et al. Implementation of checklists in health care; learning from high-reliability organisations. *Scand J Trauma Resusc Emerg Med.* 2011;19:53.
8. Pronovost P, Needham D, Berenholtz S, et al. An intervention to decrease catheter-related bloodstream infections in the ICU. *N Engl J Med.* 2006;355:2725-2732.
9. Haynes AB, Weiser TG, Berry WR, et al; Safe Surgery Saves Lives Study Group. A surgical safety checklist to reduce morbidity and mortality in a global population. *N Engl J Med.* 2009;360:491-499.
10. Sibbald M, de Bruin AB, van Merrienboer JJ. Checklists improve experts' diagnostic decisions. *Med Educ.* 2013;47:301-308.
11. Ely JW, Graber ML, Croskerry P. Checklists to reduce diagnostic errors. *Acad Med.* 2011;86:307-313.
12. Joint Commission of Accreditation of Healthcare Organizations. National patient safety goals. https://www.jointcommission.org/standards_information/npsgs.aspx. Accessed November 23, 2018.
13. Layfield LJ, Anderson GM. Specimen labeling errors in surgical pathology: an 18-month experience. *Am J Clin Pathol.* 2010;134:466-470.
14. 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;45:988-998.
15. Dieckmann P, Reddersen S, Wehner T, et al. Prospective memory failures as an unexplored threat to patient safety: results from a pilot study using patient simulators to investigate the missed execution of intentions. *Ergonomics.* 2006;49:526-543.
16. Walter S, Meier B. How important is importance for prospective memory? A review. *Front Psychol.* 2014;5:657.
17. Heher YK, Chen Y, VanderLaan PA. Measuring and assuring quality performance in cytology: a toolkit. *Cancer Cytopathol.* 2017;125:502-507.
18. Abner AL, Collins L, Peiro G, et al. Correlation of tumor size and axillary lymph node involvement with prognosis in patients with T1 breast carcinoma. *Cancer.* 1998;83:2502-2508.
19. Anderson KR, Heidinger BH, Chen Y, et al. Measurement bias of gross pathologic compared with radiologic tumor size of resected lung adenocarcinomas: implications for the T-stage revisions in the eighth edition of the American Joint Committee on Cancer staging manual. *Am J Clin Pathol.* 2017;147:641-648.
20. Emmerson AJ, Roberts SA. Rounding of birth weights in a neonatal intensive care unit over 20 years: an analysis of a large cohort study. *BMJ Open.* 2013;3:e003650.
21. Asefzadeh S, Rafiei S, Karimi M. Variation in compliance with safe surgery checklist in hospitals with different levels of patient safety culture [published online December 6, 2017]. *Int J Healthc Manag.*
22. Cohen MM, Eustis MA, Gribbins RE. Changing the culture of patient safety: leadership's role in health care quality improvement. *Jt Comm J Qual Saf.* 2003;29:329-335.
23. Bosk CL, Dixon-Woods M, Goeschel CA, et al. Reality check for checklists. *Lancet.* 2009;374:444-445.

DOI: 10.1093/ajcp/aqz009

HOLOGIC®

First and Only FDA Cleared
Digital Cytology System

Genius™ Cervical AI

Genius™ Review Station

Genius™ Digital Imager

Empower Your Genius With Ours

Make a Greater Impact on Cervical Cancer
with the Advanced Technology of the
Genius™ Digital Diagnostics System

Click or Scan
to discover more

genius™
DIGITAL DIAGNOSTICS