VOLUME 31 | SUPPLEMENT 2 | MARCH 2018

MODERN PATHOLOGY

USCAP 2018

ABSTRACTS

QUALITY ASSURANCE

(2129-2228)

107TH ANNUAL MEETING

GEARED TO LEARN

MARCH 17-23, 2018

Vancouver Convention Centre
Vancouver, BC, Canada

Published by
SPRINGER NATURE
www.ModernPathology.org

USCAP
Creating a Better Pathologist
AN OFFICIAL JOURNAL OF THE UNITED STATES AND CANADIAN ACADEMY OF PATHOLOGY

EDUCATION COMMITTEE

Jason L. Hornick, Chair
Rhonda Yantiss, Chair, Abstract Review Board and Assignment Committee
Laura W. Lamps, Chair, CME Subcommittee
Steven D. Billings, Chair, Interactive Microscopy
Shree G. Sharma, Chair, Informatics Subcommittee
Raja R. Seethala, Short Course Coordinator
Ilan Weinreb, Chair, Subcommittee for Unique Live Course Offerings
David B. Kaminsky, Executive Vice President (Ex-Officio)
Aleodor (Doru) Andea
Zubair Baloch
Olca Basturk
Gregory R. Bean, Pathologist-in-Training
Daniel J. Brat
Amy Chadburn
Ashley M. Cimino-Mathews
James R. Cook
Carol F. Farver
Meera R. Hameed
Michelle S. Hirsch
Anna Marie Mulligan
Rish Pai
Vinita Parkash
Anil Parwani
Deepa Patil
Lakshmi Priya Kunju
John D. Reith
Raja R. Seethala
Kwun Wah Wen, Pathologist-in-Training

ABSTRACT REVIEW BOARD

Narasimhan Agaram
Christina Arnold
Dan Berney
Ritu Bhalla
Parul Bhargava
Justin Bishop
Jennifer Black
Thomas Brenn
Fadi Brimo
Natalia Buza
Yingbei Chen
Benjamin Chen
Rebecca Chernock
Andres Chiesa-Vottero
James Conner
Claudiu Cotta
Tim D'Alfonso
Leona Doyle
Daniel Dye
Andrew Evans
Alton Farris
Dennis Firchau
Ann Folkins
Karen Fritchie
Karuna Garg
James Gill
Anthony Gill
Ryan Gill
Tamara Giorgadze
Raul Gonzalez
Anuradha Gopalan
Jennifer Gordetsky
Ilyssa Gordon
Alejandro Gru
Mamta Gupta
Omar Habeeb
Marc Halushka
Krisztina Hanley
Douglas Hartman
Yael Heher
Walter Henricks
John Higgins
Jason Hornick
Mojgan Hosseini
David Hwang
Michael Idowu
Peter Illei
Kristin Jensen
Vickie Jo
Kirk Jones
Chia-Sui Kao
Ashraf Khan
Michael Kluk
Kristine Konopka
Gregor Krings
Asangi Kumarapeli
Frank Kuo
Alvaro Laga
Robin LeGallo
Melinda Lerwill
Rebecca Levy
Zaibo Li
Yen-Chun Liu
Tamara Lotan
Joe Maleszewski
Adrian Marino-Enriquez
Jonathan Marotti
Jerri McLemore
David Meredith
Dylan Miller
Roberto Miranda
Elizabeth Morgan
Juan-Miguel Mosquera
Atis Muehlenbachs
Raouf Nakhleh
Ericka Olgaard
Horatiu Olteanu
Kay Park
Rajiv Patel
Yan Peng
David Pisapia
Jenny Pogoriler
Alexi Polydorides
Sonam Prakash
Manju Prasad
Bobbi Pritt
Peter Pytel
Charles Quick
Joseph Rabban
Raga Ramachandran
Preetha Ramalingam
Priya Rao
Vijaya Reddy
Robyn Reed
Michelle Reid
Natasha Rekhtman
Michael Rivera
Mike Roh
Marianna Ruzinova
Peter Sadow
Safia Salaria
Steven Salvatore
Souzan Sanati
Sandro Santagata
Anjali Saqi
Frank Schneider
Michael Seidman
Shree Sharma
Jeanne Shen
Steven Shen
Jiaqi Shi
Wun-Ju Shieh
Konstantin Shilo
Steven Smith
Lauren Smith
Aliyah Sohani
Heather Stevenson-Lerner
Khin Thway
Evi Vakiani
Sonal Varma
Marina Vivero
Yihong Wang
Christopher Weber
Olga Weinberg
Astrid Weins
Maria Westerhoff
Sean Williamson
Laura Wood
Wei Xin
Mina Xu
Rhonda Yantiss
Akihiko Yoshida
Xuefeng Zhang
Debra Zynger

To cite abstracts in this publication, please use the following format: **Author A, Author B, Author C, et al. Abstract title (abs#).** ***Modern Pathology*** **2018; 31 (suppl 2): page#**

2129 A Comparison of Two Progesterone Receptor Antibodies: Utilizing Oncotype Dx Results to Monitor Quality

Indu Agarwal[1], *Robert Goldschmidt*[1], *William Watkin*[1], *Megan E Sullivan*[1] [1]NorthShore University Health System, Evanston, IL

Background: There are multiple progesterone receptor (PR) antibodies available for clinical use. Currently, there is no standard recommendation as to which antibody to use for breast prognostic immunohistochemistry (IHC) and the decision is made on an institutional level. In this retrospective analysis, we compare our experience with the Dako PR antibody (PgR 1294) and the FDA approved Ventana PR antibody (PgR 1E2).

Design: After using the Dako antibody (Ab) for many years, the decision was made to transition to Ventana as we were already using the FDA approved Abs for estrogen receptor (ER) and HER2 testing. After validation studies were completed as per protocol, the change was implemented on 5/12/17. In our quality review, a number of ER negative/PR positive cases were noted prompting re-evaluation. In our analysis, we 1) re-stained the discordant cases with both Abs and 2) compared the PR IHC results with both antibodies to the PR results reported in the Oncotype Dx report (when available).

Results: 127 invasive breast cancers were stained using the Ventana Ab from 5/12/17 to 7/26/17. Of these, 8 (6.3%) were ER negative/PR positive. With the Dako Ab (1/1/2017 to 5/11/2017), we had 3 out of 248 (1%) with this result. We repeated testing on the 8 cases with both Abs. The Ventana Ab had inconsistent results on repeat testing: 4 remained positive while 4 were negative and the negative cases often had focal weak nuclear staining (<1%). On re-testing with the Dako Ab, 7/8 cases were negative. Only one case was positive on repeat testing and with both Abs. During the same time period, 15 Ventana cases and 54 Dako cases were sent for Oncotype testing. The PR results differed between the IHC and Oncotype in 27% of the Ventana cases compared with 7% of the Dako cases (Table 1).

Comparison of PR Results: IHC / Oncotype

	Neg/Neg	Neg/Pos	Pos/Neg	Pos/Pos
Dako PR	8 (15%)	0	4 (7%)	42 (78%)
Ventana PR	1 (7%)	0	4 (27%)	10 (67%)

Conclusions: Besides monitoring IHC quality by looking for unusual results like ER negative/PR positive breast cancers, ancillary methods like Oncotype can be helpful in detecting possible IHC problems. While neither Ab yielded "false negative" (IHC negative / Oncotype positive) PR results, the "false positive" rate was more than 3x greater with the Ventana Ab. Even low level variation in staining is problematic with a 1% cut-off separating a PR positive from a PR negative tumor. Tumors that would be classified as PR negative with one Ab would be classified as PR positive with another, possibly changing the treatment paradigm and causing confusion for both the patients and clinicians.

2130 Dynamic Telepathology for Rapid Adequacy Assessment of Cytology Specimens Saves Valuable Time for the Cytopathologist: An Institutional Experience

Shweta Agarwal[1], *Jill Grochowski*[1], *Elham Khanafshar*[1]. [1]University of California, San Francisco, San Francisco, CA

Background: The demand for rapid on-site evaluation (ROSE) of fine-needle aspirations in large medical centers has dramatically increased in recent times. Although benefits include higher adequacy rates, fewer passes and appropriate triage; it costs cytopathologist valuable time (travelling to multiple physical locations for the procedures) and affects other clinical and administrative duties. This study aimed at evaluating efficacy of dynamic telepathology in ROSE with onsite cytotechnologist and remote pathologist

Design: Telepathology (Cisco Jabber ™ Video for Telepresence/ Jabber ®Video) was implemented in June 2016 for remote ROSE of FNAs done by interventional radiologists after a validation and cytotechnologist training phase with 20 real cases. Images were captured via Luminera Infinity HD camera connected to on-site microscope. 1207 FNAs were evaluated for adequacy using telepathology (06/2016-09/2017) where a cytotechnologist went onsite, prepared and streamed slides on Jabber® video; simultaneously communicating with remote pathologist over a secure network. Adequacy and further steps (additional passes, triaging the specimens etc.) were guided by pathologist on individual case basis. Data on adequacy of each sample, preliminary diagnosis (if available) & time spent by pathologist on phone were recorded. Average time for diagnosis was recorded and compared to cases done onsite (n=824). Also, time spent by cytotechnologist (from going onsite, preparing slides, telepathology with pathologist to coming back to his/her seat) was recorded in 306 cases

Results: There was 99% agreement between remote ROSE and final diagnoses. 10/1207 cases were discordant (reasons are listed in Figure 1). Average time saved for the pathologist was 21 minutes (total cytotechnologist time minus total phone time used to make adequacy assessment in 306 cases). Average time for diagnosis of cases assessed onsite vs remotely was comparable (2.40 minutes vs 3.13 minutes respectively). Average time for pathologist on phone with cytotechnologist was ~20 minutes which included the wait time while FNA passes were being performed, and cytotechnologist prepared smears. During this time, the remote pathologist could sign out other cases and attend to clinical/administrative duties

Figure 1: Comparison of agreement between remote adequacy and final diagnosis for various organ systems.

Major Organ systems	Number of cases (n)	Agreement (n)	Disagreement (n)	Reason for disagreement
Thyroid	437	437	0	Not applicable
Lymph Node	224	223	1	Scant cellularity
Liver	97	95	2	Scant cellularity, diagnosis on flow collected during FNA
Parathyroid	21	20	1	Scant cellularity
Soft Tissue / Bone	71	69	2	Scant cellularity, diagnosis made on cell block
Kidney / Renal	9	8	1	Scant cellularity, diagnosis on flow collected during FNA
Pancreas/Ampulla	8	8	0	Not applicable
Lung/Pleura	155	152	3	2/3 cases: Scant cellularity, diagnosis made on cell block. 1/3 cases: Small cells resembling lymphocytes on ROSE, neuroendocrine tumor on final diagnosis.
Others	185	185	0	Not applicable
Total	1207	1197	10	Not applicable

Conclusions: Our data indicates that use of telepathology for ROSE of FNAs performed at remote sites can make a considerable impact on saving valuable clinical time for pathologist without compromising adequacy or time taken to make the diagnosis

2131 Role of UroVysion for Detecting Urothelial Carcinoma in Atypical Urine Cytology

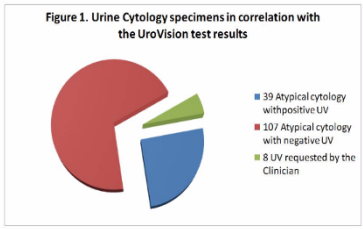
Lubna Alattia[1], *Cynthia Zhao*[1]. [1]LSU Health Shreveport, Shreveport, LA

Background: Urine cytology has been used for screening bladder cancer but has been limited by its low sensitivity, especially for low grade lesions. UroVysion (UV) is a US Food and Drug Administration-approved multiprobe fluorescence in situ hybridization (FISH) assay that detects common chromosome abnormalities in bladder cancers. The assay is designed to detect aneuploidy for chromosomes 3, 7, 17 and loss of 9p21 locus in urine samples. Validation studies demonstrate that the sensitivity of the UV test ranges from 50-89% and specificity from 29-89%.

Design: The data base Copath at our institution was searched for cases sent for UV from January 2015 to December 2016. There are 152 urine specimens that match our study criteria included in the study. 39 cases had surgical resection specimens and 17 cases had subsequent urine cytology. These results were compared with both the cytologic diagnoses and the UV results for the same patient.

Results: The study population included 152 urine specimens. 143 cases were diagnosed as atypical or atypical-suspicious for urothelial carcinoma; 8 cases were diagnosed benign and the UV was requested by the clinician; one case of UV was requested directly without cytology examination. The UV results divided into main two categories either positive or negative. Of those 39 positive UV results, 18 were negative in surgical specimens; 5 were later revealed low grade papillary; 6 were high-grade papillary; 6 were carcinoma in-situ (CIS); 3 were invasive carcinoma; and one was non-urothelial genitourinary carcinoma. The 116 cases with negative UV results show negative for dysplasia (30), lost fellow up (77), low grade papillary (4), high grade papillary (3), CIS (1), none invasive carcinoma (0), and non-urothelial carcinoma (1). The sensitivity for UV test ranges 50-100%, specificity 75-78%, PPV 3-15% and NPV 97-100%. The low grade tumor detection rate is 13% (5/39) in UV positive samples vs 3% (4/116) in UV negative specimens.

Follow up results	Positive UroVysion Results	Negative UroVysion Results
Negative or lost fellow-up	18	107 (30 confirmed by repeated cytology or surgical Bx)
Low-grade papillary carcinoma	5	4
High-grade papillary carcinoma	6	3
Flat carcinoma in-situ	6	1
Invasive carcinoma	3	0
Non urothelial GU carcinoma	1 (Urethra mucinous adenoCA)	1 (prostatic adenoCa)
Total	39	116



Conclusions: In general, our data demonstrate almost equal sensitivity and significantly better specificity compared with the validation studies. The UV sensitivity in detecting urothelial carcinoma was significantly higher than the cytology alone. A negative UV result does not completely rule out a high-grade urothelial carcinoma, CIS and non-urothelial genitourinary carcinoma in the presence of atypical or suspicious urine cytology, but it rules out invasive urothelial carcinoma. It is well known that urine cytology is best in detecting high grade carcinoma.

2132 Do All Granulomas Require Reflex Staining for Mycobacteria and Fungi? A Retrospective Analysis

Caitlin Alexander[1], *Ashley Cimino-Mathews*[1], *Lisa Rooper*[1]. [1]Johns Hopkins University, Baltimore, MD

Background: Granulomas are often identified in surgical pathologic specimens as both targeted lesions and incidental findings. While important to exclude mycobacterial and fungal infection in these cases, common stains such as Kinyoun/Acid Fast Bacilli (AFB) and Grocott Methenamine Silver (GMS) have limited sensitivity for organisms. Moreover, although these stains increase pathology costs and workload, the value of ordering them on every granuloma regardless of histologic appearance or clinical scenario is not well established. This study aims to systematically evaluate the clinical and histologic features of granulomas in hopes of identifying situations where AFB and GMS staining can be safely deferred.

Design: All available cases that demonstrated granulomas and had AFB and GMS stains performed between January 2016 and June 2017 were identified from the surgical pathology archives of a large academic medical center. The original AFB and GMS slides were reviewed for mycobacteria and fungi, and histologic features of the granulomas were tabulated.

Results: 146 cases were reviewed representing 17 different anatomic sites, most frequently including lung (30%), lymph node (24%), soft tissue/serosa (9%), and small intestine/colon (9%). Granulomas were targeted in 81 cases (55%) and found incidentally in 65 cases (45%). There were 92 non-necrotizing (63%), 43 necrotizing (29%), 7 hyalinized (5%), and 4 purulent (3%) granulomas; 89 (61%) were small in size while 57 (39%) were large. Infectious organisms were identified in 10 cases overall (7%), including 2 positive for AFB (1%) and 8 positive for GMS (6%); 9 of these cases were from the lung (6%) and 1 from soft tissue (1%). All 10 granulomas (100%) with positive stains were both necrotizing and large in size. AFB and GMS stains were negative in 90 granuloma cases (61%) that had 2-3 of the following features: small size, non-necrotizing pattern, and incidental discovery.

Conclusions: Positive results on AFB and GMS stains are relatively rare in this series and are primarily associated with large, necrotizing granulomas in the lung. While clinical suspicion for infection or concerning histologic features may require staining in some cases, there is limited yield from reflex staining of all granulomas. A triage system that defers staining in cases that had 2-3 of the features small size, non-necrotizing pattern, and incidental discovery could significantly limit stain use in low-risk patients, leading to both cost and labor savings.

2133 Destaining-Restaining Immunostudies Combined With Whole-Slide Scanning: A Helpful Tool in Dermatopathology

Sri Krishna Chaitanya Arudra[1], *Doina Ivan*[1], *Wei-Shen Chen*[1], *Priyadharsini Nagarajan*[1], *Phyu P Aung*[1], *Jonathan Curry*[1], *Victor A Ortega*[1], *Carlos Torres-Cabala*[1], *Michael Tetzlaff*[1], *Victor Prieto*[1]. [1]The University of Texas MD Anderson Cancer Center, Houston, TX

Background: Rendering accurate pathologic diagnoses is crucial in patient management. However, we are sometimes limited by the lack of availability of additional sections or of the area of interest when new slides are used for immunostudies. In such occasions, at our institution, we employ a protocol to ensure that the area of interest is available in the immunoslides. The slides used include the original hematoxylin and eosin stained slides, negative controls of immunostudies or other immunoslides with negative results. These slides are digitally scanned and then destained and the desired immunostudies performed according to a standard protocol. We present our experience with this method applied to dermatopathology.

Design: A PowerPath® search was conducted from January 2016 to June 2017 to include all immuno requests containing special notes in the instruction field. All cases in which the destain-restain protocol was used were reviewed and tabulated.

Results: A total of 399 cases included special notes in the instructions field. Of those, 73 cases had been processed using destain - restain protocol. 63 (86%) were melanocytic and 10 (14%) were non melanocytic. In the former, the protocol was employed to: 1) confirm the diagnosis of melanoma (24 cases); 2) determine sentinel lymph node positivity (18 cases); 3) determine non-sentinel lymph node positivity (6 cases); 4) determine the presence of lymphovascular space invasion (7 cases); 5) confirm or rule out the presence of mitotic figures (4 cases); 6) determine accurate Breslow thickness (2 cases); 7) determine margin status (1); and 8) determine perineural invasion (1 case). The majority of questions in the 10 non-melanocytic cases were to confirm or rule out carcinoma (especially breast carcinoma in dermis or vascular spaces). In 72 out of 73 cases (99% of cases) the method provided enough information to answer the question asked.

Types of Cases	Antibodies That Were Amenable to our Destaining-Restaining Protocol
Melanocytic	Pan Melanoma 2 Cocktail (HMB-45 & Tyrosinase), PHH3 & MART-1 Cocktail, Ki-67, PHH3, SOX-10, CD68 (KP-1), ERG, D2-40, CD31, S-100, CD163
Non-Melanocytic	EBER, Cytokeratin Cocktail (AE1/AE3, MNF116, Zym5.2, and Cam5.2), Adipophilin, CD30, Cytokeratin 20, Cytokeratin Cam 5.2, Cytokeratin 7, CD1a, CD4, CD3

Conclusions: Destaining - restaining immunohistochemical protocol is very useful in cases when no additional slides are available or when the area of interest is only present in a previously processed slide. If such protocol is used, we recommend whole-slide scanning of the selected slide (s) in order to keep a record of the original morphology.

2134 One Large Tertiary-Referral Cancer Centers Institutional Experience with the Accuracy of Combined Intraoperative Radiologic and Gross Margin Assessment and Resultant Re-excision Rates in Breast Cancer Surgery

Eva Bashover[1], *Qiong Gan*[2], *Maria Del Valle Estopinal*[3], *Alejandro Contreras*[4]. [1]MD Anderson Fellow, Houston, TX, [2]Dewalt, TX, [3]Upstate Medical University, Syracuse, NY, [4]MD Anderson Cancer Center, Houston, TX

Background: At our institution, breast specimens removed for breast cancer are evaluated using a combined intraoperative radiographic and gross assessment technique (IOA) for assessment of margin adequacy. Our objective with the current study was to analyze the accuracy of this IOA method by correlation with histology of margins on final pathology reports and to compare rates of additional intraoperative margin procurement and re-excision frequencies.

Design: MD Anderson Cancer Centers electronic medical record was reviewed during a one month period and cases with IOA assessment of margins in breast cancer specimens were included. A total of 130 cases were identified and all the patients were female with an age range of 30-86 years (mean 57.1). Cases were divided into 6 scenarios. False positive (FP) was positive on IOA with corresponding permanent negative margin, while false negative (FN) was negative on IOA and corresponding permanent margin that was positive. True positive (TP) scenarios included positive, close, or some equivalent term on IOA with corresponding permanent margins positive. True negative (TN) was defined as a negative diagnosis on both IOA and permanent margin diagnosis. Close margin close (CMC) scenarios included an IOA diagnosis of either a positive, close, or equivalent term with corresponding permanent margin 1 mm or less from carcinoma. Close margin far (CMF) was defined as an IOA designation of a margin as close or an equivalent term and permanent greater than 1 mm from tumor.

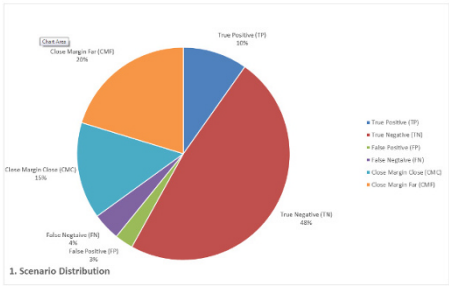
Results: One hundred and forty three scenarios were generated. There was a total of 4 FP (2.8%), 6 FN (4.2%), 14 TP (9.8%), 69 TN (48.3%), 21 CMC (14.7%), and 29 CMF (20.3%) scenarios. There was a total of 10 overall discordant category scenarios (7.0%), 83 overall concordant category scenarios (58.0%), and 50 scenarios in the special close margin category (35.0%). There were a total of 5 cases where re-excision was performed involving 8 scenarios. Cases that received neoadjuvant chemotherapy were more likely to have discordant margins.

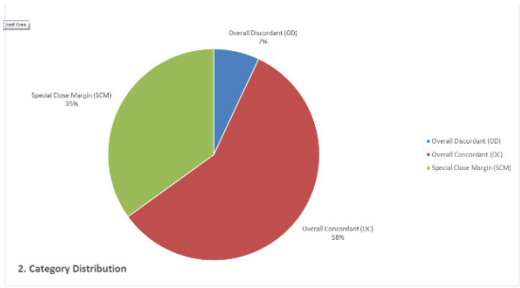
Additional Margins and Re-excisions						
	False Positive (FP), N=4	False Negative (FN), N=6	True Positive (TP), N=14	True Negative (TN), N=69	Close Margin Close (CMC), N=21	Close Margin Far (CMF), N=29
Additional Margins Taken	3/4, 75%	0[a]/6, 0%	10/14, 71.4%	9/69, 13.0%	18/21, 85.7%	24/29, 82.8%
Tumor in Additional Margin	1/4, 25%	0[a]/6, 0%	4/14, 28.6%	0/69, 0%	4/21, 19.0%	3/29, 10.3%
Tumor at new margin	0/4, 0%	0/6, 0%	1/14, 7.1%	0/69, 0%	0/21, 0%	0/29, 0%
Re-excision	0/4, 0%	3[b]/6, 50%	2[b, c]/14, 14.3%	1/69, 1.4%	1[c]/21, 4.8%	1[c]/29, 3.4%

[a] Two cases were excluded due to the fact that the additional margins taken were not the FN margins, but other margins that correlated with other scenario categories (TP and CMC respectively).

[b] Includes one specimen with FN and TP scenarios.

[c] Includes one specimen with TP, CMC, and CMF scenarios.





Conclusions: Utilizing IOA to assess margin status was found to correlate well with final histologic examination, with an accuracy of 89.2%, sensitivity of 70%, specificity of 94.5%, negative predictive value of 92%, and positive predictive value of 77.8%. Additional margins were taken in 43.1% of case, and a total of 3.8% cases had a re-excision at a later date. Margin discrepancy contributed to re-excision in a total of 2.3% of cases.

2135 The Rapidly Growing Role of Pathology in Clinical Trials at a Major Cancer Center

Umeshkumar Bhanot[1], *Jordana Ray-Kirton*[1], *Guray Akturk*[1], *Peter A Ruh*[1], *Aziza Hamrokulova*[1], *Joachim Silbe*[1r], *Michael H Roehrl*[1].
[1]Memorial Sloan Kettering Cancer Center, New York, NY

Background: Clinical trials are vital to the advancement of personalized cancer therapy. Pathology has undergone a rapid evolution to becoming an active player in this space. Our new Precision Pathology Biobanking Center (PPBC) is a central hub for clinical trial and drug development engagement through the discipline of pathology.

Design: The PPBC is the central hub for tissue based clinical trial support at MSKCC. It is actively engaged in planning, project development, pre-screening for tissue adequacy, and providing estimates for tumor content and matched normal tissue for clinical trials and translational research. Additionally, the PPBC also helps devise strategies for tumor enrichment using techniques like LCM. Between Jan. 2017-Jun. 2017, the PPBC processed nearly 600 clinical trial requests. We analyzed this data, and the key findings are being presented.

Results: From Jan. 2017 to Jun. 2017, the PPBC Histology Lab processed 586 tissue-based clinical trial requests. This entailed retrieval, pathologic review, and processing of 983 cases. The most frequent clinical trial requests were for solid tumors NOS (112); lymphoma (66); breast cancer (44); gastroesophageal cancer (38); and lung cancer (29). Of these, the distribution of cases according to the phase of clinical trial was: Phase I (132); Phase II (132); Phase I/II (100) and Phase 3 (100). The typical turnaround time for completion is between 2-5 week days.

Although most of the trials were therapeutic, over 30 were biospecimen research protocols and more than 20 were primarily diagnostic. Another category of trials supported by the PPBC are pilot trials (therapeutic and diagnostic). Most current clinical trials were for advanced and metastatic cancers for which often only small biopsies are available.

Conclusions: The PPBC plays a pivotal role in driving a large and diverse array of tissue based clinical trials at MSKCC. In our experience, advanced solid tumors, lymphomas, breast cancer and gastroesophageal cancers were the top four disease categories of clinical trials. Most requests fell under Phase I and Phase II studies indicating that frequently first-in-man therapeutic options were being offered to patients. It is evident that Pathology as a discipline is now rapidly evolving into a true theranostic medical specialty with direct drug-development relevance, providing new and exciting growth opportunities for our discipline.

2136 The Precision Pathology Biobanking Center (PPBC) Experience at International IBBL Biobank Proficiency Testing

Umeshkumar Bhanot[1], *Jessica Kenney*[1], *Emily Lin*[1], *Michael H Roehrl*[1].
[1]Memorial Sloan Kettering Cancer Center, New York, NY

Background: Modern biobanks play a key role in clinical trials, translational research, biomarker discovery, and validation of novel molecular diagnostic tests. Therefore, biobanks involved in collecting, processing, storage, and redistribution of biospecimens need to develop and adhere to a set of standard operating procedures (SOPs) to maintain and distribute tissues and other biospecimens of the highest quality. This will ensure that researchers receive samples of best quality with minimal impact of any pre-analytic variables for their experiments. Proficiency Testing (PT), long a staple of routine clinical labs, goes a long way to ensure accuracy and reproducibility of results. Similarly, research biobanks should increasingly implement and maintain internal quality control measures and also participate in rigorous PT programs conducted by external agencies. The PPBC participated in the annual international IBBL PT program in late 2016. Our experience is presented.

Design: The newly established Precision Pathology Biobanking Center (PPBC) laboratory at MSKCC participated in the IBBL Proficiency Testing (PT) program. Altogether, the lab participated in thirteen different biobanking testing schemes offered, involving DNA and RNA extraction from frozen & FFPE tissues and whole blood, DNA and RNA quantification and purity assessment, cell viability, PBMC isolation, and tissue histology.

Results: Analysis of PT data received in 2017 showed that the results submitted by the PPBC were either "accurate" or "satisfactory" on all schemes. Further, in depth analysis of all the testing parameters revealed that the results submitted by PPBC lab were on par with or exceeded other participating labs on the IBBL PT program and largely performed at a very high standard. However, on two testing schemes a portion of the results were found to be borderline and provided important procedural improvement feedback for the lab.

Conclusions: Participation in the IBBL PT program proved to be an invaluable experience for the PPBC. The detailed report and analysis on all the results submitted were very useful and reassuring. All research-active biobanks, especially those like our PPBC, that are deeply engaged in many ongoing clinical trials and phase I/II drug and theranostic test development with academic and pharma partners, stand to greatly benefit from participation in international biobanking PT programs.

2137 Electronic Synoptic Pathology Cancer Reporting: Think Global, Act Local

Roger Bjugn[1], *Bettina Casati*[1], *Tor J Eide*[1]. [1]Oslo University Hospital, Oslo, Norway

Background: Synoptic pathology cancer reporting is superior to narrative reporting with respect to the completeness of pathology reports. Electronic synoptic reporting using discrete data elements offers the additional value of rapid data transfer between pathology laboratories and cancer registries. In 2003, a national project on electronic synoptic reporting was started in Norway, and one module for colorectal carcinomas was developed. However, the project had to be closed down due to lack of long-term funding. In October 2014, one pathology department took a new initiative, and we report our experiences here.

Design: The initiative was organized as a project with a staff pathologist with formal project management training as project

manager. An initial analysis identified the following elements as a framework for the project:

- *The World Health Organization (WHO) Classification of Tumors*
- *The Union for International Cancer Control (UICC) TNM Classification of Malignant Tumours*
- *Accreditation in accordance with the standard ISO 15189:2012 Medical laboratories* (www.iso.org)
- *Norwegian national standards for e-health*
- *Compatibility with the hospital's electronic quality management system*
- *The document "Appraisal of Guidelines for Research & Evaluation II"* (www.agreetrust.org)

While the primary goal was to integrate synoptic cancer reporting tools into the laboratory information management system used, a secondary goal was to evaluate resources (particularly time) being spent in the various project phases.

Results: Three electronic cancer reporting tools have been developed and approved so far. Time spent up to implementation was quite similar to the former national project. However, implementation has been significantly delayed (Table 1) due to slow follow-up by the regional IT-service provider the hospital is required to use.

Table 1 Time spent in various project phases

Project Phase		Local Project (2014-2017) (3 synoptic reporting tools)	National Project (2003-2006) (1 synoptic reporting tool)
1.	Initiation	1 month	2 months
2.	Planning	3 months	4 months
3.	Execution	Development: 22 months[1] Implementation: Ongoing (> 8 months)	Development: 16 months Implementation: 2 months
4.	Monitoring and Controlling	-	1 month
5.	Closing	-	<1 month

[1]Including a 6 months delay caused by the hospital's IT-service provider

Conclusions: Development of electronic synoptic pathology cancer reporting tools, based on international classification systems and standards, can be successfully undertaken as a local endeavor. However, a careful stakeholder analysis must be undertaken not to be hampered by unforeseen organizational issues.

2138 Change in Laboratory Practice Can Effectively Decrease the Rate of Tissue Floaters and Contaminants

Margaret Black[1], *Gabriel Acosta-Gonzalez*[1], *Mark Ettel*[2], *Dana Warfield*[1], *Audrey Pagan*[1], *Ruliang Xu*[1], *Aylin Simsir*[1]. [1]New York University Langone Medical Center, Long Island City, NY, [2]University of Michigan, Ann Arbor, MI

Background: In surgical pathology, accurate diagnosis may be compromised by tissue floaters and contaminants on glass slides, which may have adverse effects on patient safety. Tissue processing and slide preparation are two major potential sources of error that can be controlled by improved laboratory practice.

Design: The rate of tissue floaters/contaminants was evaluated before and after implementing better laboratory practice. In phase 1, the rate of tissue floaters/contaminants on glass slides prepared at a single histology laboratory was assessed by reviewing all biopsy slides from three different days. Each slide was assessed for extraneous tissue by two pathologists. Floaters/contaminants were defined as any tissue on a slide that was of a different histologic type than the specimen and at least 2 cells in size with at least one preserved nucleus. Floaters/contaminants also included tissue of the same histologic type as the biopsy that were morphologically distinct, present on a different plane, near the edge of the slide, or only on one level. Single anucleated squamous cells were not included. In phase 2, the laboratory instituted the following changes: 1) changing water in the water bath 2-3 times every shift, 2) cleaning water bath with germicidal wipe at completion of each shift, 3) increasing water pressure in the stainer, and 4) immediately changing staining solutions once sediments became visible. After these changes, the rate of tissue floaters/contaminants was assessed on two separate days in the same way as in phase 1.

Results: Of 1616 slides examined in phase 1, 131 slides had a floater or contaminant (8.11%). The contamination rate on three separate days was 5.30% (26/491 slides), 5.64% (32/567 slides), and 13.08% (73/558 slides). Of 349 total biopsy cases, the contaminants in 2 cases were potentially malignant material (0.57%). After changes were instituted in phase 2, the contamination rate on two separate days was 2.88% (12/416 slides) and 5.54% (27/487 slides), with an overall rate of 4.32% (39/903 slides). Of 190 total biopsy cases in phase 2, contaminants in 2 cases were potentially malignant material (1.05%). The overall decrease in contamination rate between phases was statistically significant (p=0.0001).

Conclusions: Floaters and contamination are not unusual in daily practice, with a rate ranging from 3 - 13% of cases, and may impose risk of inaccurate diagnosis. Institution of better laboratory practices significantly decreases the rate of floaters and contamination.

2139 Is the Rate of Frozen Section Discordance Affected by Subspecialty Sign Out?

Joseph H Blitman[1], *Brandon Buscaglia*[1], *Christa Whitney-Miller*[1], *David Hicks*[1], *Aaron Huber*[1]. [1]University of Rochester Medical Center, Rochester, NY

Background: Monitoring frozen section (FS) and final permanent section (PS) correlation is a valuable quality assurance metric in surgical pathology. Discordant FS and PS results may alter clinical management or care of the patient. In July 2015, our department implemented full subspecialty sign out (SSSO) while maintaining general sign out of frozen sections. The discordant FSs, at our institution, are categorized as minor if there is little or no perceived or actual clinical significance and major if there is major or potentially major clinical significance, which is determined by the final sign out pathologist. We sought to determine if the SSSO model has adversely impacted our FS and PS discordance rate.

Design: We retrospectively evaluated the discordance rates (DRs) before (January 2012-June 2015) and after (July 2015-Present) SSSO. The monthly intraoperative consultation FS and PS correlation data were analyzed from January 2012 to July 2017. The DRs were compared for minor, major and combined disagreements (minor + major) before and after SSSO using the student's t-test.

Results: There were 6,528 total frozen sections with 2,472 after SSSO and 4,056 prior to SSSO, of which 120 had minor disagreements (65 prior to SSSO and 55 after SSSO) and 37 had major disagreements (26 prior to SSSO and 11 after SSSO). The average combined DRs per month; pre and post SSSO were 2.167 and 2.64, respectively. The difference was not statistically significant for the minor (p=0.0517), major (p=0.669) or combined (p=0.212) disagreements; however, the minor disagreements approached statistical significance.

	Avg. Minor Disagreement	Avg. Major Disagreement	Avg. Combined Disagreement
2012-2015	1.55	0.619	2.167
2015-2017	2.2	0.44	2.64
p value	0.0517	0.669	0.212

	Minor Disagreement	Major Disagreement
2012-2015	65	26
2015-2017	55	11

Conclusions: The data shows that SSSO, at this institution, does not appear to adversely affect FS discordance rates, but is close to statistical significance which may warrant further studies. Although our data suggest that SSSO can be undertaken with no impact on FS accuracy, each institution is different and keeping competent with frozen section diagnosis in a SSSO model may be challenging.

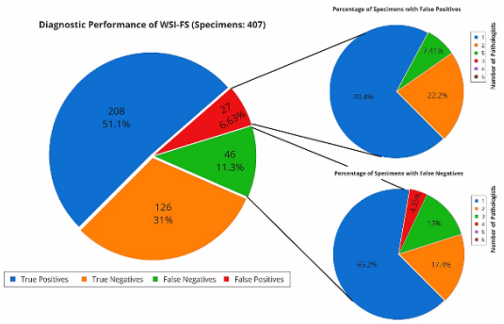
2140 A Systematic Root Cause Analysis of Diagnostic Discordance Among Whole Slide Image-Frozen Section Slides (WSI-FS)

Adriana Borys[1], *Dariusz Borys*[2], *Ewa Borys*[3], *Xianzhong Ding*[4], *Vijayalakshmi Ananthanarayanan*[5], *Swati Mehrotra*[6], *Maria Picken*[7], *Vamsi Parimi (Parini)*[8]. [1]New York University, New York, NY, [2]Loyola University Medical Center, Maywood, IL, [3]Loyola University Chicago, Maywood, Illinois, [4]Loyola University Medical Center, [5]LUMC, Maywood, IL, [6]Loyola University Medical Center, [7]Loyola Univ. Med. Ctr., Maywood, IL, [8]New York University, New York, NY

Background: The adaptation of primary diagnostic digital pathology based on Whole Slide Imaging (WSI) is on the rise. We present our systematically examined surgical pathology diagnostic discordant data from two large independent retrospective study sets for the intra-operative consultation of squamous cell carcinoma (SCC) and adenocarcinoma (ADC).

Design: Six surgical pathologists specializing in neuropathology, head, neck & thorax pathology, bone and soft tissue pathology, genitourinary pathology and gastrointestinal pathology independently evaluated 108 WSI-FS SCC cases (246 specimens and 463 glass microscope slides-GS) and 110 WSI-FS ADC cases (172 specimens and 395 GS) necessary to make a final binary diagnosis (presence or absence of SCC or ADC). No clinical or prior diagnostic information (age, sex, clinical history, location, presence or absence of tumor) were provided to the pathologist in aiding diagnosis. Pathologists reviewed the WSI-FS cases, without the knowledge of primary pathologist's readout on GS-FS. The discordant data is reviewed in an all pathology consensus meeting and classified based on the degree of discrepant diagnosis between observers (inter-observer discrepancy WSI-FS) and in between GS-FS and WSI- FS.

Results: Inter-observer agreement between G-FS and WSI-FS ranged from 84-93% (SCC) and 90-96% (ADC) respectively. The true positive, true negative, false negative and false positive diagnosis on WSI-FS was 51.1% and 31%, 11.3% and 6.6% respectively. The sensitivity, specificity, positive likelihood ratio, negative likelihood ratio are 81.89% (95% CI: 76.59% to 86.43%), 82.35% (95% CI: 75.37% to 88.04%), 4.64 (95% CI: 3.28 to 6.57) and 0.22 (95% CI: 0.17 to 0.29) respectively. Of the 73 discrepant specimens, 10 were discrepant by more than 50% of the participant reviewers (≥3 pathologists) that was principally attributed to WSI methodology (2.4%). The primary reason is the failure to notice a clinically significant finding on WSI-FS.



Conclusions: The diagnostic discordance of WSI-FS is primarily attributed to inter-observer variability rather than due to the review methodology. High quality frozen section slides are essential for WSI-FS interpretation. Surgical pathologists should understand the strengths and limitations for primary diagnostic WSI-FS. We attempted to classify discordances based on the extent of disagreement, listed areas of concern and suggested graded recommendations to reduce diagnostic discordance.

2141 A Retrospective Review of Prostate Biopsies Sent for Oncotype Dx Testing from a Large Tertiary Care Academic Center: Is This Test Appropriately Utilized?

Miguel D Cantu[1], *Theresa Scognamiglio*[2], *Brian Robinson*[3], *Hiral McCarthy*[4], *Francesca Khani*[3]. [1]New York Presbyterian Weill Cornell, New York, NY, [2]New York Presbyterian Hosp, New York, NY, [3]Weill Cornell Medicine, New York, NY, [4]New York Presbyterian Hospital

Background: The Oncotype Dx Genomic Prostate Score (GPS) Assay is a commercially available assay from Genomic Health (GH) designed for patients diagnosed with clinically low-risk prostate cancer (PCa) to help guide treatment. GH has prospective data that the assay can predict death and metastasis at 10 years, tumor behavior, and act as an independent predictor of adverse pathology. We sought to retrospectively investigate the use of this test in practice and assess its role in clinical management at our large tertiary care academic center.

Design: All Oncotype Dx reports received on prostate biopsies sent from our institution to GH from 2015 to present were reviewed. Changes to the patient's NCCN risk group (very low risk [VLR], low risk [LR], or intermediate [INTR]) as a result of the addition of the GPS were recorded. Disease management decisions were also obtained.

Results: A total of 114 men had Oncotype Dx testing, of which 108 had sufficient tissue for the assay. On biopsy, 64% (69/108) had Grade Group 1 PCa and 36% (39/108) had Grade Group 2 PCa. By NCCN guidelines alone, 24% (26/108) were VLR, 31% (33/108) were LR, and 45% (49/108) were INTR. After addition of GPS to the NCCN risk group, 20% (22/108) changed risk groups. None (0/26) of the VLR group changed to a higher risk group, 36% (13/33) of the LR group changed groups (9 to VLR, 4 to INTR), and 20% (10/49) of the INTR group became LR. Treatment information was available in 93 men. Of the VLR men by GPS+NCCN, 16% (5/31) were treated by radical prostatectomy (RP) or XRT and 70% (22/31) did active surveillance (AS). 3/5 VLR men who were treated had been LR by NCCN alone. Of the INTR men by GPS+NCCN, 33% (14/43) were on AS, 47% (20/43) had RP or XRT, and 9% (4/43) had focal therapy. Of the 4 men who changed from LR to INTR by the addition of GPS to NCCN, 2 were definitively treated and 2 did AS.

Conclusions: Nearly half of the GPS assays at our institution were requested on patients who were INTR by NCCN guidelines, suggesting that the test is being overutilized, as GH recommends the test for low risk PCa. The GPS assay did not change the risk group for the majority of men. While the test may provide further reassurance about management decisions, at a price of $4520 per test, the cost-effectiveness is questionable. Furthermore, in patients whose risk group changed after the GPS assay, subsequent treatment decisions in several cases did not appear to reflect the additional data provided by the test.

2142 The Value of Random Respiratory Mucosal Biopsies in Patients with Non-Specific Respiratory Symptoms: A Retrospective Analysis

Carla Caruso[1], *Negar Rassaei*[1]. [1]MS Hershey Medical Center, Hershey, PA

Background: Approximately 40% of the outpatient pulmonary visits are associated with upper tract respiratory symptoms (e.i chronic cough, dyspnea, lymphadenopathies, among others). Algorithms for the evaluation of these symptoms have been developed, and flexible bronchoscopy with biopsy has been clinically indicated after common diseases have been excluded. There are currently limited studies in the literature regarding diagnostic yield of histopathologic evaluation of random respiratory mucosal biopsies. With this study, we aim to determine the usefulness of random mucosal biopsy as a tool in the workup of non-specific respiratory symptoms.

Design: Retrospective review (2012-2017) of surgical cases and associated cytology specimens (bronchioalveolar lavage - BAL and fine needle aspirations -FNA), and radiology reports of patient evaluated by bronchoscopy with random mucosal biopsy without prior significant clinical history. Eighty-six cases were identified. Two cases were excluded since they had prior diagnosis of non-small cell adenocarcinoma. The findings were classified as: no pathological alterations (NPA), granulomas, chronic inflammation (mild and moderate), tumor, fibrosis, squamous metaplasia, and squamous metaplasia with chronic inflammation.

Results: 52 cases were females (mean age 53), and 32 males (mean age 48). Fifty-one of eighty four cases had chronic inflammation (only 36 cases had associated BAL and the results were concordant); 9/84 non-necrotizing granulomas (NNG) with concordant BAL and FNA results; 8/84 squamous metaplasia; 6/84 squamous metaplasia and chronic inflammation, 1/84 fibrosis and 1/84 tumor (metastasis). On imaging, the cases diagnosed with NNG displayed mild to moderate mediastinal adenopathy. The cases diagnosed with metastasis demonstrated a suspicious nodule. The imaging did not show any specific radiologic findings on the rest of the cases.

Conclusions: Our data shows that compared to radiology and cytology, histology showed significant findings in limited number of cases (granulomas in less than 1% of cases) and essentially did not yield a specific histological diagnosis in the majority of cases. Thus, meticulous clinical-radiologic correlation could contribute to decrease the unnecessary exposure of patients to invasive procedures and its possible adverse effects, and improve the hospital resources utilization. One of our future directions is to increase the number of cases and compare our results with data from other institutions.

2143 Clinical Value in Submitting Additional Sections in Grossly Normal and Abnormal Appendectomy Specimens

Jason Chen[1], *Vijayalakshni Padmanabhan*[1], *Shilpa Jain*[1]. [1]Baylor College of Medicine, Houston, TX

Background: Current grossing protocol for appendectomy includes sampling the base (margin), mid-section, and longitudinally bisected tip. This study examines the utility of additional sections based on clinical impression, gross examination and/or preliminary microscopic evaluation.

Design: After obtaining IRB approval, the laboratory information system was searched (2010-2017) for all appendectomy specimens. The cases with additional sections or complete submission were included in this study. These appendices were divided into appendectomy-only specimen (Group 1) and appendectomy performed as a part of a larger abdominal surgery (Group 2). Patient demographics, clinical history, gross examination, and final diagnosis were recorded.

Results: Two hundred seventy-two of 2,913 (9.3%) appendectomy specimens had either additional sections or entire submission for microscopic examination. The appendectomy specimens were divided into grossly normal or abnormal based on perforation, exudates, dilated lumen, mucin, or any lesion grossly. Statistical analysis with Fisher's exact test was performed. The inflammatory/

reactive conditions in Group1 showed a significantly higher incidence (p<0.0001) in the grossly abnormal appendix (55%, 109/197) when compared to the grossly normal appendix (23%, 46/197). However, Group 2 showed no significant difference (p=0.07) in incidence rate of inflammatory/reactive conditions (Grossly normal = 19%, grossly abnormal = 16%). The incidence of primary neoplasm was higher in grossly abnormal appendix (2%, 5/197) compared to the grossly normal appendix (0.5%, 1/197) in Group 1 while in Group 2 the incidence was similar. There is no statistically significant difference (p >0.05) in incidence rate of metastatic disease in Group 2 between grossly normal (6%, 5/75) and grossly abnormal appendix (8%, 6/75). See Table 1-2.

FOR TABLE DATA, SEE PAGE 799, FIG. 2143

Conclusions: The grossly abnormal appendix specimens showed higher percentages of primary neoplasm and inflammatory benign findings in comparison to grossly normal appendix in simple appendectomy specimen; hence the gross evaluation of the specimen is a key indication of submitting extra sections. In the evidence of metastatic diseases can be found in grossly normal appendix at a rate comparable to grossly abnormal appendix, a recommendation of submitting additional sections or entire appendix in multi part abdominal surgery is warranted.

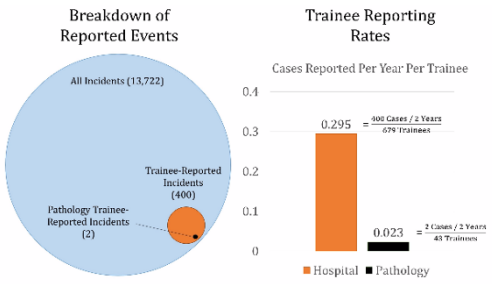
2144 Do Pathology Trainees Report Fewer Incidents Than their Peers? A Review of 13,722 incidents

Yigu Chen[1], *Benjamin E Yarsky*[1], *Richard Haspel*[2], *Yael Kushner Heher*[1]. [1]Beth Israel Deaconess Medical Center, Boston, MA, [2]Harvard, Boston, MA

Background: Patient safety incident reporting is one of the cornerstones of improving hospital healthcare quality. The Accreditation Council for Graduate Medical Education (ACGME) recently increased its educational requirements for quality improvement and patient safety. The ACGME has specifically mandated, via its Milestones framework, trainee education and active participation in incident recognition, reporting, and root cause analysis. Despite this, published data do not exist on the frequency of pathology trainees reporting patient care issues as compared with their peers. We undertook a study to assess our trainees' performance on error reporting and to understand the potential gap between trainees in Pathology and other medical specialties.

Design: We performed a retrospective analysis of 13,722 adverse events submitted to the Beth Israel Deaconess Medical Center hospital incident reporting system between January 2015 and December 2016. We reviewed and identified cases reported by trainees including residents and fellows using data contained within the incident reporting system and information provided by the Office of Graduate Medical Education. To adjust for the effect of residency program size, we then compared the average number of incidents reported per trainee per year in Pathology to the hospital average.

Results: Of the 13,722 incidents analyzed, 400 cases were submitted by trainees hospital-wide. 2 reports (0.5%) were entered by Pathology residents or fellows during the study period. Trainees from other departments submitted 398 reports (99.5%) during the study period. Our institution had an average of 679 trainees at any given time during this 2-year study period, and 43 of them were Pathology trainees. The average number of incidents reported by Pathology trainees is 0.023 cases per trainee per year. This represents a greater than ten-fold difference from the hospital average, which is 0.295 cases per trainee per year.



Conclusions: Despite regulatory requirements and the potential for learning and quality improvement, our pathology trainees lag far behind their colleagues with regards to incident reporting rates. Our trainees report incidents one tenth as often as other types of residents and fellows. The root cause of this is unclear, and needs to be investigated further. Further studies are needed to determine if there is a link between program-specific quality and patient safety curricula and training programs with higher reporting rates.

2145 Pathology Report of Nonneoplastic Nephrectomized Renal Parenchyma: A Revisit

Bo Chen[1], *Isam-Eldin Eltoum*[1], *Huma Fatima*[1]. [1]University of Alabama at Birmingham, Birmingham, AL,

Background: Nonneoplastic diseases in tumor nephrectomy specimens have significant implications for patient outcomes, however, they are often neglected in pathology reports. The objective of this study is to compare adherence to the College of American Pathologists (CAP) guideline for reporting nonneoplastic diseases in tumor nephrectomy specimens, and assess the quality improvement in reporting rate before and after adopting CAP synoptic protocol, and the trend over 5 years time in a single institution.

Design: This is a retrospective review of all tumor nephrectomy pathology reports for the years 2009, 2011, and 2016 in our department. Years 2009 and 2011 represent one-year before and after the CAP guideline starting to require the evaluation of nonneoplastic renal parenchyma from 2010. Year 2016 was chosen to assess a trend of change over 5 years after adopting the CAP guideline to report nonneoplastic changes.

Results: Total 147 pathology reports for 90 radical nephrectomy (RN) and 57 partial nephrectomy (PN) specimens were retrieved in 2009; 109 reports for 55 RN and 54 PN specimens in 2011, and 141 reports for 95 RN and 46 PN specimens in 2016. The distribution of primary neoplastic diagnosis are not significantly different among the 3 years. Before CAP guideline, 21.09% of the reports (31/147) had described at least one of the 6 elements listed in "Nonneoplastic Findings" section in the CAP protocol in 2009; this rate increased to 30.28% (33/109) in 2011 (p=0.09 compared to 2009). In 2016, this rate had significantly improved to 68.79% (97/141; p<0.001 compared to 2009 or 2011, Table 1). Among 9 pathologists signed out more than 10 cases in the 3 years, the pathologists who had completed their training recently are more adherent to report these findings (Pathologists F and G in Table 1). Interestingly, the two pathologists involved in all 3 years have a similar improvement in rate of reporting (Pathologists H and I in Table 1).

Table 1: Rate of adherence to CAP guideline for reporting nonneoplastic findings among 9 pathologists in the years 2009, 2011, and 2016.

Pathologists	2009	2011	2016
A	2/11 (18.0%)	N/A	N/A
B	4/11 (36.36%)	N/A	N/A
C	12/22 (54.54%)	N/A	N/A
D	2/35 (5.71%)	1/4 (25%)	N/A
E	7/24 (29.17%)	10/22 (45.45%)	N/A
F	N/A	N/A	35/44 (79.55%)
G	N/A	N/A	37/58 (63.79%)
H	0/14 (0%)	6/22 (27.27%)	8/14 (57.14%)
I	1/10 (10%)	15/58 (25.86%)	9/14 (64.29%)
Total	31/147 (21.09%)	33/109 (30.28%)	97/141 (68.79%)

Conclusions: Five years after adopting CAP synoptic report protocol, there is a significant improvement in adherence to report nonneoplastic findings for the tumor nephrectomy specimens in our institution but not to the ideal level. The accuracy of histological evaluation of each elemnents listed in the "Nonneoplastic Findings" section will be furtherly studied.

2146 What Can We Learn from No-Harm Events and Near Misses in Pathology? A Review of 244 Cases

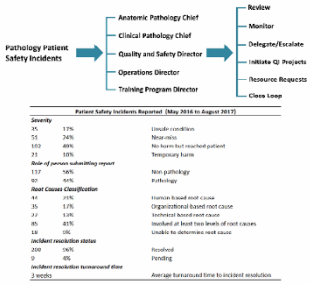
Yigu Chen[1], *Gina McCormack*[1], *Yael Kushner Heher*[1]. [1]Beth Israel Deaconess Medical Center, Boston, MA

Background: Harmful pathology errors typically undergo systematic review for root causes in order to seek out opportunities for improvement. However, non-harmful events including minor errors, near misses, and unsafe conditions are far more frequent and undergo minimal to no systematic review. Harmful errors and near misses often share root causes and the difference between the two can be due to chance alone. Despite this, non-harmful events and near misses rarely get reported and do not undergo review. If studied, these events offer an opportunity for learning and risk reduction for pathologists before serious patient harm occurs.

Design: A hospital-wide Outlook mailbox was created to solicit information on non-harmful and near miss laboratory incidents not submitted to the hospital incident reporting system. A multidisciplinary team was established including quality, operations, clinical, and educational leadership to review and manage incidents weekly. Incidents were classified using the Eindhoven error classification model by severity, error type, laboratory testing phase, and root cause. A VBA-programed Excel spreadsheet dashboard served as a hub for documentation and to track resolution progress. Rate and turnaround time of incident resolution was monitored.

Results: 244 incidents were reported hospital-wide from May 2016 to August 2017. 35 incidents were excluded as they were not considered patient safety incidents following review. 188 (90%) cases were classified as unsafe conditions, near-misses, or no-harm

incidents. 21 (10%) cases caused temporary harm. 117 (56%) were reported by non-pathology personnel and 92 (44%) cases were reported by pathology personnel. Using the Eindhoven error classification model, we found that 44 (23%) of incidents were caused by human error. The remainder of the incidents involved at least one technical and/or one organizational level root cause. In response to these findings, we have initiated 32 changes in procedures, workflows, and information systems to prevent similar incidents from recurring. By August 2017, 200 (96%) cases were investigated and resolved with an average turnaround time to incident resolution of 3 weeks.



Conclusions: Non-harmful pathology errors and near misses offer critical opportunities for risk reduction and learning. By establishing a user-friendly reporting mechanism and regular local review and tracking, we were able to understand and address systems vulnerabilities before patient harm ensued.

2147 A Proposal for Standardized Sampling of Reduction Mammoplasty Specimens

Elizaveta Chernetsova[1], *Sergey Pyatibrat*[2], *Susan Robertson*[2], *Zuzana Kos*[3]. [1]University of Ottawa, Ottawa, ON, [2]The Ottawa Hospital, Ottawa, ON, [3]Kanata, ON

Background: Reduction mammoplasty specimens (RMS) usually consist of multiple, unoriented fragments of fibroadipose breast tissue. To date, there are no standardized protocols for handling these types of specimens. At the same time, the incidence of clinically important pathologic findings (CIPF) have been reported in a wide range varying from 0.06% to 12.8%. The goals of our study are to report the incidence of CIPF at our institution, to evaluate the initial approach to tissue sampling, and how to conduct consecutive sampling in RMS when CIPF were identified.

Design: Recent quality initiatives carried out at our institution resulted in a change in RMS protocol prompting prospective data collection. We accumulated data over a four-year period (1/1/2012-12/31/2016). Only patients with no prior history of breast pathology or genetic risk factors were included in this study. All patients were divided into two groups at the time of specimen accessioning. Women in Group A (<40) had 2 sections per side submitted for histologic evaluation while women in Group B (≥40) had 4 sections per side submitted for histologic evaluation. Retrospectively we collected data on the number of blocks submitted after initial CIPF were identified in the index blocks, as well as the pathology that triggered the submission of additional tissue.

Results: 1383 RMS were evaluated during our study period. In the original quality initiative, CIPF were detected in 2.1% (8/375) of patients compare to the current incidence of 3.6% (Table 1).

There is a statistically significant difference in the incidence of CIPF in Groups A and B (chi-square statistics is 18.46, at $p<0.01$).

Submission of 2 additional sections prompted detection of CIPF in 11 (24%) RMS in Group B. On average 13 additional sections were submitted after initial CIPF were identified in Group B. An upgrade in the diagnosis after submission of additional blocks was made in 9 cases. It was found on average in block 11 (6-23). Submission of 10 additional sections would detect only 44% of the potential upgrade in CIPF while submission of 20 additional sections would detect 89% of the potential upgrade in CIPF.

Table 1

Age group	%	Mean age ± SD	All CIPF* (%)	ALH (N/ age±SD)	ADH (N/ age±SD)	LCIS (N/ age±SD)	DCIS (N/ age±SD)	Invasive Carcinoma (N/ age±SD)
Patients younger than 40 (541)	39	29±7	5(1%)	2/37±0	1/28	1/33	1/31	0
Patients 40 and older (842)	61	53±8	45(5%)	16/52±7	13/53±8	7/50±4	6/55±11	3/55±8
Total (1383)	100	44±14	50(3.6%)	18/50±8	14/52±10	8/48±7	7/51±14	3/55±8

* CIPF include ALH, ADH, LCIS, DCIS and Invasive Carcinoma categories. An upgrade was defined as a change in a diagnostic category with an increase in relative risk of breast cancer.

Conclusions: Based on our study, we recommend the following algorithm for RMS:

- Patients <40 years: gross evaluation and submission of 2 sections per side.

- Patients ≥40 years: gross examination and submission of 4 sections per side.

- When CIPF are detected in initial sections, an additional 20 sections (2 sections per cassette) should be submitted.

2148 A Comparison of Diagnostic Usefulness and Workload Impact Using Endoscopic Ultrasound Fine Needle Aspiration Cytology (EUS-FNAC) Versus Endoscopic Ultrasound Fine Needle Biopsy (EUS-FNB) for Solid Non-Cystic Lesions

Chun Yuen Chow[1], *Tiing Leong Ang*[1], *Boon Eu Andrew Kwek*[1], *Thurairajah Prem Harichander*[1], *Khin Yu Lwin*[1], *Lai Mun Wang*[1]. [1]Changi General Hospital, Singapore

Background: Endoscopic ultrasound fine needle aspiration cytology (FNAC) is an invaluable tool for investigating lesions within upper gastrointestinal tract, pancreas and lymph nodes around the region. Endoscopic ultrasound fine needle biopsy (FNB) is a relatively novel technique that allows tissue acquisition in the same setting for histological tissue architecture assessment. We aim to compare the diagnostic usefulness of FNB with FNAC for solid lesions and to assess the workload impact by each technique.

Design: Using endoscopy database, cases with both cytology and biopsy performed simultaneously using FNAC and FNB by 19G and 19G procore needles from January 2015 to March 2017 were selected. Slides and reports were reviewed to assess adequacy for diagnosis and additional tests. The number of slides generated by FNAC and FNB and quality of the cell block were recorded.

Results: 50 cases were identified [M:F 23:27; mean age 64 (range 34 to 104)]. 24 specimens were from gastric mass, 12 pancreatic lesion, 5 lymph node, 2 paraoesophageal mass, 2 liver mass and 1 each from perigastric, duodenal and retroperitoneal masses, and ampullary and adrenal lesions. 9 cases were non-diagnostic for both FNAC and FNB. 4 cases that were non-diagnostic on FNAC, were diagnostic on FNB. Only 1 case non-diagnostic with FNB, was diagnostic on FNAC (non-diagnostic rate FNAC 26%, FNB 20%). In 18 cases FNB diagnosis was deemed superior because histology architecture and immunohistochemistry was possible to improve diagnostic reporting (TABLE A). Both FNAC and FNB were interpreted as equally diagnostic in 18 cases FNAC generated 357 slides in total (range 4-16; mean 7.1; median 6). 63% of 54 cellblock slides generated from 46 FNAC cases were inadequate for immunohistochemistry. FNB had 50 slides (surface area 12 to 594 mm^2).The calculated time to screen one FNAC case on average is 34.27 min (based on 8-hour working day for a maximum of 100 slides/ day) versus 1 slide per FNB case at 4.8 min.

TABLE A: 18 cases that EUS-FNB provided better diagnosis than EUS-FNAC

Specimen	EUS-FNAC Report	EUS-FNB Report	Reasons
Gastric mass	Spindle cell lesion	Gastrointestinal stromal tumour	Cellblock is acellular. IHC on biopsy.
Gastric nodule	Suggestive of pancreatic heterotopia	Consistent with pancreatic heterotopia	IHC on biopsy.
Gastric mass	Suggestive of spindle cell lesion	Gastrointestinal stromal tumour	Cellblock is insufficient. IHC on biopsy.
Gastric mass	Spindle cell lesion	Gastrointestinal stromal tumour	Cellblock is insufficient. IHC on biopsy.
Gastric mass	Spindle cell lesion	Gastrointestinal stromal tumour	Cellblock is acellular. IHC on biopsy.
Gastric mass	Spindle cell lesion	Gastrointestinal stromal tumour	Cellblock is acellular. IHC on biopsy
Gastric mass	Spindle cell lesion	Gastrointestinal stromal tumour	Cellblock is insufficient. IHC on biopsy.
Paraoesophageal mass	Spindle cell lesion	Gastrointestinal stromal tumour	IHC on biopsy.
Pancreatic mass	Suggestive of solid pseudo-papillary tumour	Solid pseudo-papillary tumour	Cellblock is insufficient. IHC on biopsy.
Pancreatic mass	Suggestive of solid pseudo-papillary tumour	Solid pseudo-papillary tumour	Cellblock is insufficient. IHC on biopsy.
Ampullary lesion	Atypical small bowel epithelial cells	High grade dysplasia, suspicious for invasion	Histological architecture allows definite diagnosis of dysplasia and raising the suspicion of invasion.
Pancreatic mass	Mucin producing neoplasm, consistent with intraductal papillary mucinous neoplasm (IPMN).	Adenocarcinoma with intraductal papillary mucinous neoplasm (IPMN)	Histological architecture allow confident diagnosis when the predominant part of the tumour is IPMN and the invasive component is small.
Para-aortic lymph node	Lymph node aspirate	Lymph node aspirate, reactive	Biopsy material allows architectural assessment and IHC can was done to exclude lymphoma
Abdominal lymph node	Positive for tumour cells	Positive for metastatic hepatocellular carcinoma	Cell block is insufficient. IHC performed on biopsy.
Mediastinal lymph node	Non-small cell carcinoma, favour squamous cell carcinoma	Moderately differentiated squamous cell carcinoma	Confirmatory IHC performed on biopsy.
Hilar lymph node	Features consistent with reactive lymph node	Reactive lymph node	Biopsy material allows architectural assessment and IHC to be performed to exclude malignancy.
Retroperitonal mass	Spindle cell neoplasm	Gastrointestinal stromal tumour	Cellblock is insufficient. IHC on biopsy.
Adrenal gland lesion	Constituent cells from adrenal gland	Adrenal gland tissue	Biopsy material allows architectural assessment and IHC to be performed to exclude metastatic tumour from other site.

Conclusions: Diagnostic yield from FNB was better and more consistent in providing adequate material for immunohistochemical studies that permit improved diagnostic reporting. The workload impact by FNAC was significantly greater and also generated much wastage reflected by the high number of inadequate FNAC cellblocks that have no added value. FNB for solid lesions is therefore superior in terms of its usefulness to allow better quality and confident diagnostic reporting and improve laboratory efficiency by reducing waste.

2149 Cytologic Smears Improve Accuracy of Frozen Sections on Ovarian Tumors in the Community Practice Settings

Adela Cimic, Brooklyn, NY

Background: One strategy for management of patients with ovarian masses is performing frozen sections at time of surgery. Based on frozen section results, the decision can be made to do nothing further or proceed with staging, sometimes completing a bilateral salpingo-oophorectomy and hysterectomy. Frozen sections of ovarian masses can be very difficult since ovaries may harbor metastasis that can look similar to the primary ovarian tumors. Performing cytologic smears at the time of surgery may be beneficial in facilitating the frozen diagnosis.

Design: At our institution, we perform on average 1031 frozen sections per year, of which 18% are done on ovarian tumors. From June 2016 to June 2017 we prospectively prepared additional cytologic smears with Diff-Quik stain on all ovarian frozen sections comprised of two H&E sections. For quality assurance purposes we compared results of frozen section discrepancies and deferrals with those of the previous year from June 2015 to June 2016.

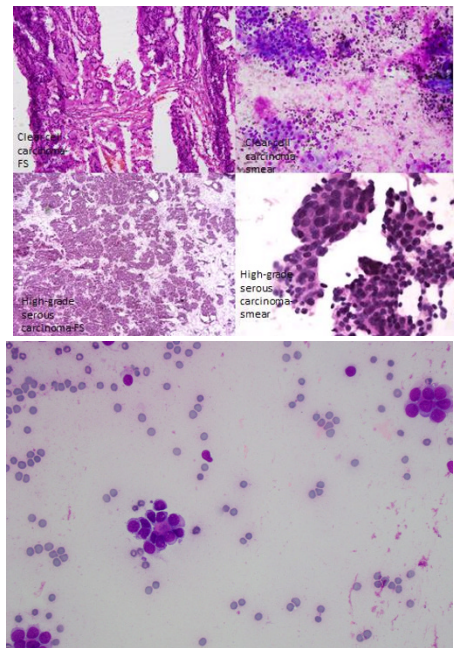
Results: In comparison of June 2015 to June 2016 with June 2016 to June 2017, the overall frozen sections numbers increased but with a steady flow of ovarian frozen sections (Table 1).

With introduction of cytologic smears to ovarian frozen sections, the number of discrepancies and deferrals decreased from 7.9% to 3.5 % for ovarian tumors. The most benefit of smears was seen in high-grade primary ovarian carcinomas (Figure 1), metastatic tumors and spindle cell lesions. Granulosa cell tumors frequently exhibit grooves and Call-Exner bodies on cytologic preparations (Figure 2).

Five high-grade serous tumors were deferred for permanent sections without cytologic examination from June 2015 to June 2016 and only one was deferred with cytologic smears from with June 2016 to June 2017. One frozen diagnosis of benign ovarian cyst was changed to clear cell carcinoma on permanent sections without cytologic examination from June 2015 to June 2016. A similar case from June 2016 to June 2017 with cytologic examination was correctly diagnosed (Figure 1). The least benefit was seen in benign versus borderline mucinous and serous lesions.

Table 1

Year	2015/2016	2016/2017
Total number of frozen sections	780	1282
Ovarian frozen sections	164	167
Primary carcinoma deferred/discrepant	6	1
Granulosa cell tumors deferred	1	0
Other deferred/discrepant (including borderline tumors, metastatic tumors and spindled lesions)	6	5
% of deferrals/discrepancies	7.9	3.5



Conclusions: This study, performed at a general surgical pathology practice without a subspecialty service and where all pathologists do cytology, shows that smears are extremely helpful at time of ovarian frozen sections. Along with careful gross examination of specimens and microscopic evaluation of H&E slides, cytologic smears can lower the number of ovarian frozen section discrepancies and deferrals.

2150 Creation and Implementation of a Novel Report Format for Integrated Molecular Pathologic Diagnosis

Jennifer Cotter[1], *Joanna C Green*[1], *Alexander Judkins*[1]. [1]Children's Hospital Los Angeles, Los Angeles, CA

Background: As molecular testing becomes a core component of diagnostic pathology, it is clear that the common practice of separately reporting histopathology and molecular findings is inadequate. Frequently molecular testing results are added to pathology reports in the form of an addendum, which is situated below the line diagnosis, and in some cases may never be created. We developed a new vehicle (Integrated Report) for results of all tissue-based histologic and molecular studies for CNS tumors, in keeping with the recommendations of the 2016 revision of the WHO Classification of Tumors of the CNS, 4th ed.

Design: Creation of an Integrated Report for CNS tumors required development of new clinical processes and workflows, as well as a clinical informatics strategy, devised within the confines of our reporting software (Cerner CoPath). Our model enables faculty members to edit and release component reports (cytogenetics, chromosomal microarray, Sanger sequencing, next-generation sequencing) into the body of a pre-existing surgical pathology report. The Integrated Report is then created as a collaborative document shared among all parties, and final interpretation is issued by the surgical pathologist after consultation with appropriate faculty. The Integrated Diagnosis appears at the top of the final report.

Results: Feedback from clinicians has been uniformly positive. Although the report was designed to have interactive and collaborative elements, our experience demonstrated the need for a molecular pathology/histopathology working conference, at which individual patient cases are discussed in a round-table format, with oncologists in attendance. Once this conference was established, histopathologists and molecular pathologists reported feeling a greater level of confidence in the final Integrated Report.

Conclusions: Implementing an Integrated Report for surgical pathology requires cooperation among a broad group of stakeholders. Safeguards must be put in place to prevent incomplete reports from being issued, and responsibility for individual test results must remain clearly defined. A conference model fosters discussion and interpretation of individual cases. Diagnostic accuracy can be enhanced by integration of molecular genetic features into tumor diagnosis, and likewise, patient care can be improved by the integration of light microscopic and molecular techniques into a single final pathology report. We intend to employ this report format for non-CNS tumors in the near future.

2151 Diagnostic Utility of Fluorescence In Situ Hybridization (FISH) Testing on Cytology Cell Blocks for the Definitive Classification of Salivary Gland Neoplasms

Natasha Darras[1], *Kelly Mooney*[1], *Steven Long*[1]. [1]Stanford University School of Medicine, Stanford, CA

Background: A number of benign and malignant salivary gland neoplasms are characterized by specific chromosomal aberrations. Fluorescence in situ hybridization (FISH) is an ancillary study routinely used in conjunction with fine-needle aspiration biopsy (FNAB) to evaluate salivary gland neoplasms. The aim of this study is to determine whether FISH testing performed on cytology cell blocks improves the ability to diagnose salivary gland neoplasms by FNAB.

Design: A retrospective analysis of 42 cases of salivary gland neoplasms diagnosed by FNAB and sent for FISH testing from our institution between 2012 to 2017 was performed. The indication for FISH testing was subclassification. Clinical information, cytologic diagnoses, FISH results, and available histopathologic follow-up were reviewed.

Results: Of the 42 cases submitted for FISH testing, 6 cases were excluded due to inadequate/equivocal FISH results (insufficient cell block cellularity, poor signal quality or a variant abnormal signal pattern). 27 cases had histopathologic follow-up. One case was nondiagnostic by cytology, but FISH testing was successfully performed. Of the 36 cases included in the analysis, 13 cases (36%) were subclassified following FISH testing, 9 (25%) of which were confirmed by histopathologic diagnosis. All cases with available histopathologic follow-up had concordant FISH results. In cases with histopathologic classification, all 3 PLAG1 rearrangements were detected in pleomorphic adenomas, all 2 MYB rearrangements were detected in adenoid cystic carcinomas, all 3 MAML2 rearrangements were detected in mucoepidermoid carcinomas, and the 1 ETV6 rearrangement was detected in mammary analogue secretory carcinoma (see Table 1).

Table 1. Distribution of FISH results for histopathologic diagnoses

Final histopathologic diagnosis	FISH results
Basal cell adenoma	MYB negative (3)
Pleomorphic adenoma	PLAG1 positive (3) MYB negative (2) MAML2 negative (2) ETV6 negative (1)
Warthin tumor	MAML2 negative (1)
Lymphoepithelial cyst	MAML2 negative (1)
Adenoid cystic carcinoma	MYB positive (2)
Carcinoma ex pleomorphic adenoma	MAML2 negative (1)
Acinic cell carcinoma	MAML2 negative (1) ETV6 negative (3)
Epithelial myoepithelial carcinoma	MYB negative (1)
Mucoepidermoid carcinoma	MAML2 positive (3) MAML2 negative (2) MYB negative (1)
Mammary analogue secretory carcinoma	ETV6 positive (1)
Poorly differentiated/ undifferentiated malignancy	MAML2 negative (2) HER2 amplification negative (1) MYB negative (1)

Conclusions: FISH testing performed on cytology cell blocks is a useful adjunct in establishing the diagnosis of salivary gland neoplasms by FNAB, and will likely play a complementary role in subclassifying salivary gland neoplasms according to the novel Milan System for Reporting Salivary Gland Cytopathology.

2152 Comparing Pathology Report Quality Indicators in Two Distinct Whipple Resection Specimen Examination Protocols

Ryan DeCoste[1], *Drea Uzans*[1], *Weei-Yuarn Huang*[1]. [1]Queen Elizabeth II Health Sciences Centre and Dalhousie University, Halifax, NS

Background: Whipple (pancreaticoduodenectomy) resections generate complex pathology specimens. In pancreatic ductal adenocarcinoma (PDAC), key pathologic prognostic factors include size, grade, lymph node and margin status. However, reporting is complicated by variation in margin terminology and gross examination techniques, shown to influence tumor and margin assessment. In 2012, our institution switched from a traditional grossing protocol, sectioning in the plane of the distal common bile duct, to an axial sectioning approach. We hypothesize that this led to more complete reporting of quality indicators in Whipple Resection specimens for PDAC.

Design: Pathology reports from two cohorts of Whipple resections for PDAC (2001-2009 and 2012-2017; total N=132) were analyzed for reporting elements including tumor size, stage, grade, lymph nodes, margins, lymphovascular (LVI) and perineural invasion (PNI), and number of slides examined. The 2001-2009 cohort was grossed using a traditional approach while the 2012-2017 cohort employed an axial technique. Continuous data were compared using two-tailed *t* test and categorical data were compared using Fisher's exact test.

Results: Eighty-one and 51 cases were identified from 2001-2009 and 2012-2017, respectively. In the second cohort, an increase was seen in the reporting of stage (100% vs. 21%, $p<0.01$) and LVI (92% vs. 58%, $p<0.01$), average number of reported margins/surfaces (7.2 vs. 3.8, $p<0.01$), cases reporting all 5 CAP protocol mandatory margins (86% vs. 32%, $p<0.01$), number of lymph nodes (16.9 vs. 8.8, $p<0.01$), and number of slides (28.1 vs. 18.2, $p<0.01$). No differences were seen in the reporting of size (100% vs. 98%, $p=0.51$), grade (96% vs. 98%, $p=0.56$) or PNI (84% vs. 72%, $p=0.14$). In the second cohort, we identified involvement of 5 posterior (10%) and 12 SMV/portal vein (23.5%) surfaces, recommended to be reported in the AJCC 8th edition. SMV/portal vein surface involvement was associated with positive SMA/uncinate margins in 10/12 cases ($p=1E-06$).

Conclusions: There is a trend towards better quality pathology reports in 2012-2017. This cohort showed significant increase in reporting of prognostic factors including margin/surface assessment, as well as increased lymph node yield. A possible drawback of this approach is the increased number of slides generated. Other potential contributing factors include greater availability of CAP protocols, increasing subspecialty practice and updates to the AJCC staging criteria during this interval.

2153 Quality Control of Fresh Biospecimens; What You See Is Not Always What You Get

Aaron E Diederich[1], *Vincent D Quintiliani*[2], *Zachery vonMenchhofen*[3], *Xavier Arthur*[2], *Dee McGarvey*[2], *Zubair Baloch*[4], *Virginia LiVolsi*[5]. [1]University of Pennsylvania, Philadelphia, PA, [2]University of Pennsylvania, [3]Philadelphia, PA, [4]Hospital of Univ. of PA, Philadelphia, PA, [5]Univ. of Pennsylvania, Philadelphia, PA

Background: Human disease research requires access to well characterized biospecimens. The Cooperative Human Tissue Network (CHTN) is a prospective human tissue procurement resource supported by the National Cancer Institute. The Eastern Division (ED), located in the Department of Pathology at the University of Pennsylvania Health System, procures and distributes fresh biospecimens directly from the gross pathology station to research laboratories across the USA and Canada. This function differs from classic bio-banked specimens which are distributed after storage as frozen or fixed samples.

Design: In our system, during tissue collection, the specimen is annotated as to the specific anatomic site, diagnostic classification (normal, benign, malignant) and known diagnosis (if available). Our standard procedures require Quality Control (QC) and Quality Assurance (QA) on each collected solid tissue sample. Freshly procured samples are distributed prior to QC procedures which require fixation into a FFPE block and a corresponding hematoxylin and eosin (H&E) stained slide.

The QC & QA assessment involves Histopathological Review (HPR) by a board certified anatomic pathologist, who evaluates the tissue aliquot and classifies it as Confirmed (comparable to the diagnosis of the fresh sample), Denied (in comparison to the fresh sample) or Unusable/Inconclusive.

The purpose of this study is to assess the correlation between the fresh (gross) diagnosis and the final diagnosis. The CHTN ED designed, validated and implemented a web-based laboratory information management system (LIMS). Data for this study were collected from the HPR assessments made during 2014-2016 and compared to data entered for the biosample at the time of tissue procurement.

Results: The original diagnoses were Confirmed in 494 (78.9%) and Denied in 95 (15.2%) of 626 fresh samples distributed. However, in most Denied cases, the sample was still usable either for the project for which it was collected or for an alternative project. An additional 36 (5.9%) were deemed Unusable/Inconclusive, often because of extensive necrosis.

Conclusions: The QC/QA comprising of HPR is essential for biobanking to ensure successful research on human tissues. In our study, by employing a web-based LIMS, 78.9% of procured fresh specimen diagnoses correlated with the onsite data and were found adequate and usable for research studies.

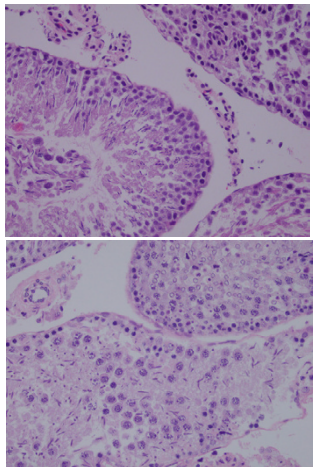
2154 Comparison of Two Fixatives in Quality of Testicular Biopsies

Joseph C Drwiega[1], *James L Ellenburg*[1], *Anna M Posey*[1], *Matthew Goldberg*[1], *Peter Kolettis*[1], *Jennifer Gordetsky*[1]. [1]University of Alabama at Birmingham, Birmingham, AL

Background: Testicular biopsy (TB) is critically important to management of male-factor infertility. The results of TB are predictive of sperm retrieval during testicular microdissection. For urologists, Bouin solution (BS) has traditionally been the recommended fixative for TB specimens. While buffered formalin (BF) is the most common fixative used in Pathology, its use as a TB fixative has been questioned because it may cause histologic artifact, potentially hampering assessment of spermatogenesis. We evaluated biopsies fixed in BF and BS to determine if there was a difference in the quality of H&E histology.

Design: Patient records were queried for service codes corresponding to TB specimens. A retrospective chart review was performed to identify the fixative used for each TB. Biopsies were identified from 12 patients, 6 fixed with BF and 6 fixed with BS. Representative slides were evaluated by a GU pathologist blinded to the fixative used for each case. Nuclear, cytoplasmic, and basement membrane (NM, CM, and BM) detail, and nuclear and cytoplasmic granularity (NG and CG), were graded as crisp (high quality) or blurred (low quality). In addition, two rats' testicles were harvested. Each was bivalved, with half fixed in BF and half fixed in BS, to yield 8 slides total. These were evaluated by a GU pathologist in a similar manner as described above.

Results: 22 slides from 6 BS-fixed specimens and 12 slides from 6 BF-fixed specimens were graded based on above quality metrics. NM detail was crisp in 12/12 (100%) BF slides and in 10/22 (45.5%) BS slides. NG was crisp in 12/12 (100%) BF slides and in 22/22 (100%) BS slides. CG was crisp in 10/12 (45.5%) BF slides and in 16/22 (72.7%) BS slides. CM detail was crisp in 12/12 (100%) BF slides and in 20/22 (90.9%) BS slides. BM detail was crisp in 12/12 (100%) BF slides and in 12/22 (54.5%) BS slides. For the rat testes, all parameters were graded as crisp in 4/4 (100%) BF slides. The BS-fixed tissue had crisp CM detail (4/4;100%), CG (4/4;100%), and BM detail (4/4;100%). NM detail was blurred in 2/4 (50%) slides, and NG was blurred in 3/4 (75%) slides.



Conclusions: Slides from BF-fixed specimens were of high quality in the evaluated metrics. CG was the only metric that was found to be low quality from one specimen fixed in BF. BS slides demonstrated more variability in quality across all metrics, with each specimen having at least one metric that was found to be low quality. Overall, using BF for TB is superior to BS in terms of histologic quality.

2155 Frozen Section Experience for Breast Conserving Therapy: Analysis of Frozen Section Discrepancies

Ellen East[1], *Cody Carter*[1], *Arielle Kanters*[1], *Celina G Kleer*[1]. [1]Michigan Medicine, Ann Arbor, MI

Background: Intraoperative frozen section of breast tissue for margin analysis (FSM) decreases reoperation in women undergoing breast conserving therapy. False negative margins due to sampling error (SE) or interpretive error (IE) may occur in lesions with subtle gross or histologic findings, such as carcinoma in situ or invasive lobular carcinoma. We aim to characterize cases where frozen section analysis fails to correctly characterize margins with the goal of reducing reoperation.

Design: Key word search identified cases over a 1 year period, 2016-2017. Clinicopathologic features including age, diagnosis, number of parts and blocks submitted for FSM, margin status, discrepancy between margin status at frozen and final report, surgery location, turn around time, and re-excision were recorded.

Results: 296 specimens from 276 patients were identified, including 37 re-excision specimens. Mean age was 58.6 (range 17-85) and 275 (99.6%) were female. Specimens included lumpectomies (246, 83.1%), excisions (43, 14.5%) and mastectomies (7, 2.4%). A median of 1 part (range 1-8) and 4 blocks (range 1-24) were submitted for FSM. Most surgeries (228, 77.0%) were performed at an ambulatory surgical center (ASC) that only performs breast FSM, while a subset (68, 23.0%) were done at a large hospital that performs frozen section for all surgical specialties.

Of malignant cases (n=245), 184 (75.1%) had negative margins and 62 had close and/or positive margins for in situ and/or invasive disease. 47 (15.9%) cases had FSM discrepancy, which was attributed to SE (41, 87.2%), IE (4, 8.5%) or both SE and IE (2, 4.3%). SEs were found on additional blocks for permanents (20, 42.6%), deeper sections of frozens (14, 29.8%), or both deeper and additional sections (3, 6.4%).

High grade DCIS was the most common diagnosis in FSM discrepant cases, followed by IDC grade 2-3 and ILC (any grade) (Table 1). FSM discrepancy was not related to number of parts (p=0.532) or blocks submitted (p=0.420). TAT at the ASC was lower (35 min, range 11-120) than at the main hospital (42 min, range 13-138, p=0.011). There was no difference in parts (p=0.53) or blocks (p=0.42) submitted between sites.

Table 1. FSM discrepancies, n=47

	Close	Positive
Carcinoma in situ		
High grade ductal carcinoma in situ (DCIS)	14	4
Intermediate grade DCIS	7	1
Low grade DCIS	2	0
DCIS grade not specified	1	0
Pleomorphic lobular carcinoma in situ	1	0
Invasive ductal carcinoma (IDC)	9	2
Grade 1	1	1
Grade 2	4	0
Grade 3	3	1
Grade not specified	1	0
Invasive ductal carcinoma with lobular features (IDC-L)	1	0
Grade 1	1	0
Invasive lobular carcinoma (ILC)	4	2
Grade 1	1	0
Grade 2	2	0
Grade not specified	1 (residual)	2 (residual)

Conclusions: While in most cases frozen section accurately assesses margin status, SE is the main cause of discrepancy for in situ and invasive disease. Cases of high grade DCIS, grade 2-3 IDC, and ILC are overrepresented in FSM discrepancies. These results will help optimize frozen section sampling to accurately assess margins in such cases.

2156 What Is The Ideal Screening Strategy For Double Hit Lymphoma?

Ghazaleh Eskandari[1], *Chen Chen*[1], *Christine G Roth*[1]. [1]Baylor College of Medicine, Houston, TX

Background: Double hit lymphoma (DHL) with MYC,BCL2 and/or BCL6 gene rearrangements corresponds to a clinically aggressive disease with poor outcomes to chemotherapeutic regimens for diffuse large B cell lymphoma(DLBCL).The significant morphologic & phenotypic overlap with DLBCL represents a challenge to laboratories in the timely identification of DHL. The goal of this study is to identify the most efficient screening strategy to identify DHL, as well as barriers affecting the appropriate work-up.

Design: All cases of high grade or large B cell lymphoma from October 2016 to August 2017 were identified, excluding cases of Burkitt lymphoma, T/histiocyte cell rich B-cell lymphoma, plasmablastic lymphoma & primary mediastinal B-cell lymphoma. Cases were re-reviewed and the following variables recorded: germinal center(GC) vs non-GC phenotype, double expressor phenotype with overexpression of the MYC and BCL2 proteins(DE),Ki-67 proliferative index, and typical large cell morphology. Standard work-up at our institution includes fluorescence in-situ hybridization for MYC,BCL2 and BCL6 gene rearrangements. In May 2017, the protocol was modified to include standardized IHC ordering panels.

Results: 38 cases were identified, including 28 needle core biopsies,1 bone marrow biopsy and 9 excisional biopsies.4/38 cases (all core biopsies) were excluded due to lack of material for FISH studies. All 34 cases had appropriate IHC work-up except for MYC immunohistochemistry(IHC), which was not performed on 4 cases due to insufficient tissue(1) or lapse on the part of the pathologist(3). There was a 63% reduction in missing IHC stains post implementation of the standardized IHC panels, with 1/16 cases post May 2017 missing IHC stains, as compared to 3/18 cases pre May 2017.

Overall,10/34(29%) cases were GCB & 24/34(71%) were non-GCB phenotype.21/33(63%) were DE & 12/34(35%) showed a Ki-67 proliferative index of >90%.2/34(6%) cases were DHL. 1/2 DHL showed typical DLBCL morphology as compared to 27/32 non-DHL(p=0.216). 2/2 DHL showed a GC phenotype as compared to 8/32 non-DHL(p=0.024).2/2 DHL showed a DE phenotype as compared to 19/31 non-DHL(p=0.27).1/2 DHL showed a Ki-67 proliferative index of >90% as compared to 11/32 non-DHL(p=0.654).2/2 DHL cases showed both GC+ and DE+ phenotypes as compared to 6/25 non-DHL(p=0.01).

Conclusions: Standardized panels promote adherence to appropriate IHC protocols for DHL. Stratifying FISH testing to GCB subtype or GCB+DE+ phenotype would reduce unnecessary FISH testing by 70% and 76% respectively.

2157 Utility of Core Needle Biopsy in Retroperitoneal Liposarcoma: A Fifteen Year Review

Ashley Flaman[1], *Carolyn Nessim*[2], *Denis Gravel*[3], *Iris Teo*[3], *Bibianna Purgina*[4]. [1]Ottawa, ON, [2]The Ottawa Hospital, [3]Ottawa Hospital, Ottawa, ON, [4]University of Ottawa/Ottawa Hospital, Ottawa, ON

Background: In the retroperitoneum, adipocytic neoplasms are considered to be liposarcoma (LPS) until proven otherwise. Management varies depending on the histology, ranging from observation to a wide multivisceral en bloc resection, with or without pre-operative radiation. Accurate diagnosis is thus essential to management planning and in many institutions core needle biopsy (CNB) is routinely performed. Limitations of CNB of retroperitoneal (RP) adipocytic neoplasm include inadvertent sampling of normal fat, fibrous tissue, or necrosis, sampling of dedifferentiated component only and sampling bias where classic histologic features are absent.

We aim to determine 1) how frequently CNB of RPLPS provides a useful diagnostic result and 2) if the CNB diagnosis is representative of the subsequent resection. Few studies have examined the utility of CNB in RPLPS and, knowing its limitations, one must consider the possibility that CNB represents a redundant step in the management of these patients.

Design: A retrospective review of the laboratory information system (LIS) at our hospital was performed to identify all CNB and resections of RPLPS from 2002 to present. In addition, for each of the resections, the patient's history was reviewed to identify if a pre-operative CNB had been performed. Data was collected on CNB adequacy, histologic features, and diagnosis, and on the subtype and grade of the resections.

Results: LIS review identified 89 cases of RPLPS; 64 new primary lesions and 25 recurrent. 27 patients had both a CNB and resection, 46 had resection alone, 10 had CNB alone, 2 had fine-needle aspiration biopsy and resection, and 4 were consult cases for which biopsy status was unknown. Cases with CNB that had resections that confirmed LPS were categorized based on utility of biopsy (Table 1).

Sensitivity of CNB for LPS was 81%. FISH for MDM2 was used in 4 CNB with equivocal features; 3 resembled normal fat and 1 was dedifferentiated. Of the 15 cases diagnosed as LPS on CNB, subtype was given in 12 (80%). 3 cases (2 well-differentiated LPS and 1 pleomorphic LPS) were reclassified as dedifferentiated LPS on resection.

Table 1: Diagnosis on CNB

Diagnosis	#	%
LPS or "favor LPS"	15	56
Descriptive only; LPS included on differential diagnosis (DDX)	3	11
Other diagnosis favored; LPS included on DDX	4	15
LPS not given on DDX	4	15
No lesional tissue	1	4

Conclusions: Over the past 15 years in our institution, RPLPS was definitively diagnosed on 56% of CNB and listed in the differential diagnosis for an additional 26%. Utility was improved in recent cases with equivocal features when FISH for MDM2 was used. Even with the known limitations, CNB remains a viable tool for diagnosis and management in RPLPS.

2158 Practical Approach to the Use of Helicobacter Immunohistochemistry Based on a Single-Institution Retrospective Quality Assurance Review

Erna Forgo[1], *Teri Longacre*[2], *Brock Martin*[3]. [1]Stanford University Medical Center, Stanford, CA, [2]Stanford University, Stanford, CA, [3]Stanford Univ Med Ctr, Stanford, CA

Background: *Helicobacter* infections cause chronic gastritis (CG) and are a risk factor for gastric neoplasia. While its presence is usually detectable on H&E stains, immunohistochemistry (IHC) is frequently applied to avoid missed diagnoses. Recent studies suggest limited use of IHC may safely reduce unnecessary health care costs.

Design: The pathology database at a single-institution academic medical center was queried for gastric specimens with *Helicobacter* IHC performed between 7/2016 and 6/2017. Reports were reviewed for histologic diagnosis, IHC result, and pertinent history. Detection rates were determined for various histologic diagnoses and clinical settings and compared to published rates. Retrospective slide review was performed for a subset of outlier cases. Based on the overall results, an approach to the use of *Helicobacter* IHC was developed and potential cost savings calculated.

Results: Of 667 cases with *Helicobacter* IHC performed, 63 (9.5%) were positive. Among positive cases, chronic active gastritis (CAG) was the most common original diagnosis (n=55, 87.3%). For the remaining 8 positive cases, 7 received an original diagnosis of chronic [inactive] gastritis, and 1 contained invasive adenocarcinoma. Upon retrospective review, 6 of these 8 cases showed focally active gastritis. *Helicobacter* was detected in only 1 biopsy with mild CG, occurring in a patient with a known history of treated *Helicobacter* infection. In the absence of active inflammation or history of treated *Helicobacter*, all IHC performed at the request of the treating clinician was negative (n=259), including 158 cases of CG, 35 cases of reactive (chemical-type) gastropathy, and 66 histologically unremarkable specimens.

Conclusions: In the absence of chronic active gastritis or a history

of treated *Helicobacter* infection, performing IHC offers minimal benefit over screening by routine H&E stains. As such, application of IHC can be limited to cases without apparent organisms on H&E stains in the setting of (1) CAG, (2) moderate to severe CG, or (3) history of treated *Helicobacter* infection. This limited application of IHC would have spared 287 cases from unnecessary testing over a single year at our institution, equating to an estimated cost savings of at least $88,542.37 based on available Medicare reimbursements rates. These findings support published recommendations from the Rodger C. Haggitt Gastrointestinal Pathology Society for identifying *Helicobacter* in gastric biopsies.

2159 BRAF Mutation Cross-Contamination Is Not Identified In A Large Series Of Slides Sectioned Using A Fully Robotic Microtome (Tissue-Tek Smartsection®)

Regan Fulton[1], *Kelly Turner*[2], *Scott Crawford*[3], *Allen M. Gown*[4], *Hanli Liu*[5], *Sandra Bohling*[4], *Cathy Natividad*[2], *Erico von Bueren*[6], *Alyicia Rios*[7], *Harry Hwang*[8]. [1]PhenoPath and Array Science, LLC, Seattle, WA, [2]PhenoPath, [3]Array Science, LLC, [4]PhenoPath Laboratories, PLLC, Seattle, WA, [5]PhenoPath, Seattle, WA, [6]Sakura Finetek USA, Inc., Torrance, CA, [7]Sakura Finetek (USA), [8]PhenoPath Laboratories

Disclosures: Regan Fulton: *Employee,* Horizon Discovery
Scott Crawford: *Employee,* Array Science LLC.
Erico von Bueren: *Employee,* Sakura Finetek USA
Alyicia Rios: *Employee,* Sakura Finetek USA

Background: An increasing number of molecular diagnostic tests are performed on patient tissue scraped from glass slides sectioned on a manual microtome. In the case of RNA-based assays, extensive cleaning of instruments and apparatus are undertaken to prevent cross-contamination of specimens or the introduction of RNAses. With respect to DNA or RNA-based assys, little is known about the frequency of carry-over contamination between positive and negative samples during microtomy. Now that fully-robotic microtomy stations are becoming available, we asked whether the Tissue-Tek SmartSection was capable of producing a large number of sections without cross-contamination in a real-time PCR assay. During the production of slide sections from FFPE blocks, a robotic microtome interacts with the surface of each block and section: cooling and robotic handling of blocks, determining block height, humidifying and trimming the block surface, cutting sections and transferring them through the circulating water bath to the roller and finally placement on the slide by a second robot.

Design: A 2-core cell culture microarray (Horizon Discovery, UK) containing a single BRAF (V600E)+ cell line and a second microarray with an EGFR+ cell line were alternately sectioned, one-by-one, for total of 99 slides. Slides were cut at 4um and blades were replaced after each section. BRAF studies were performed on pooled extractions from 5 slides. Positive controls consisted of BRAF+ samples from the start and end of sectioning. Testing of BRAF-/EGFR+ samples was performed on 5 pooled samples taken at intervals spanning the series of 93 slides. The presence or absence of the BRAF mutation was detected using a real time PCR lab developed test method.

Results: BRAF positive samples displayed the expected positive result at the beginning (slides 6-10) and end (slides 95-99) of sectioning, while the BRAF-/EGFR+ samples spanning slides 11-93, at intervals, remained negative.

Conclusions: No specimen cross-contamination was found using a DNA-based BRAF(V600E) PCR test on sections cut from cell culture microarray blocks using a Tissue-Tek SmartSection Fully Robotic Microtome. Future studies testing limiting dilution and RNA-based assays, as well as a comparison with manual microtomy are warranted.

2160 Impact of Cessation of Reflex Immunohistochemical Staining for Helicobacter pylori on Gastric Biopsy Turnaround Time

Maira Gaffar[1], *Danielle Harrell*[2], *Jennifer R Reppucci*[1], *Zhongbo Jin*[1], *Gregory Olsen*[1], *Ashwini Esnakula*[1], *David Hernandez Gonzalo*[3], *Jesse Kresak*[1], *Xiuli Liu*[1], *Michael Feely*[1]. [1]University of Florida, Gainesville, FL, [2]University of Florida, [3]University of Florida-Shands, Gainesville, FL

Background: While once common practice at many institutions, the routine use of upfront or reflex staining for *Helicobacter pylori* (HP) on gastric biopsies has been increasingly scrutinized. In addition to detection rates of HP, more rapid turnaround times (TAT) are often cited as an argument for this practice. Although limited studies have examined the effect selective versus reflex staining has on the detection rate of HP, the impacts on TAT of gastric biopsies have not been extensively reported. In this study, we sought to examine the influence cessation of upfront HP immunohistochemical (IHC) staining had on our institution's gastric biopsy TAT.

Design: We reviewed gastric biopsy reports collected over a 12 month period including the 6 months preceding (reflex period) and 6 months following (selective period) the cessation of reflex HP IHC. Cases that were limited to targeted biopsies of polyps or masses were excluded. Data regarding the use of HP IHC and TAT were recorded, with the latter defined as the number of business days (d) that elapsed between date of collection and date of report finalization. If HP IHC was reported as an addendum, the date of addendum finalization was considered the end point.

Results: A total of 2451 gastric biopsy reports were retrieved; of these, 1258 were from the reflex period and 1193 from the selective period. The mean TAT for the reflex period was 1.9 d (± 1.2; range: 1-14). Conversely, the mean TAT for the selective period was 2.5 d (± 1.4; range: 1-12), a difference which was statistically significant (P<0.0001). When examining by the day, 973 (77.4%) reflex cases were finalized within 2 d, while 760 (63.8%) selective cases had TATs within the same time period (P<0.0001). Cases finalized within 4 d were also found to be significantly different, with 1209 (96.2%) reflex and 1078 (90.4%) selective cases being signed out within that timeframe (P<0.0001). Restricting examination to only HP gastritis cases, there was no statistical difference between reflex and selective cases reported within 2 d [87.5% (98/112) vs. 78.7% (74/94), P=0.1309] or within 4 d [99.1% (111/112) vs. 94.7% (89/94), P=0.0949], respectively.

Conclusions: Practices converting to selective HP IHC from reflex testing may experience a minor increase in gastric biopsy TAT. However, there is no significant difference in the TAT of those cases diagnosed as HP gastritis, which may be more clinically relevant.

2161 Communicating Certainty in Pathology Reports: Interpretation Differences Among Staff Pathologists, Clinicians and Residents in a Multi-Institution Study

Blake Gibson[1], *Elizabeth McKinnon*[2], *Rex Bentley*[3], *Jeffrey Mohlman*[4], *Benjamin Witt*[6], *Eric Yang*[6], *Marie DeFrances*[7]. [1]UPMC, Pittsburgh, PA, [2]Durham, NC, [3]Duke University Med Ctr, Durham, NC, [4]University of Utah, Salt Lake City, UT, [5]Huntsman Cancer Hospital, Salt Lake City, UT, [6]Stanford University School of Medicine, Stanford, CA, [7]University of Pittsburgh Medical Center

Background: Pathology reports are the main modality for communicating results to other physicians. No data has been generated related to interpretations of pathology reports or comfort wording or reading them across multiple U.S. academic institutions.

Design: Anonymous surveys were completed at three major U.S. academic institutions by 18 practicing staff pathologists, 12 pathology residents, 53 staff clinicians and 50 resident/allied health professional clinicians at five standard tumor boards. All participants rated % certainty associated with 7 terms: "diagnostic of", "consistent with", "we favor", "suggestive of", "suspicious for", "compatible with" and "we cannot rule out". Pathologists answered 2 questions related to the ability to clarify a diagnosis using a comment and comfort wording pathology reports. Clinicians answered questions on how often they read a pathology report comment, if they find the comment helpful, and how comfortable they are in reading pathology reports

Results: A wide range in % certainty was found for each of the 7 diagnostic phrases. For both clinicians and pathologists, "Diagnostic of" demonstrated the best agreement, while % certainty for "compatible with" ranged from 0% to 100%. Both staff and resident clinicians showed wide variability in interpreting the phrases, with residents reporting an even broader range of responses. Staff and resident pathologists are more similar in interpretation. The majority of staff clinicians are "very comfortable" reading a pathology report, while only 8% of resident clinicians are "very comfortable" reading a pathology report. 65% of staff clinicians report "always" reading the comment, yet only 20% "always" find the comment helpful. Less than half of resident clinicians "always" read the comment, and only 16% of resident clinicians "always" find the comment helpful. For staff pathologists 50% feel "very comfortable" in wording a pathology report. In contrast, only 18% of resident pathologists feel "very comfortable." Compared to staff pathologists, a greater portion of resident pathologists believe a comment can only "sometimes" clarify a diagnosis.

Conclusions: The understood level of certainty for diagnostic phrases varies widely amongst pathologists and clinicians. The phrases "diagnostic of" and "consistent with" have the strongest agreement in meaning. The weakest agreement is "suspicious for" and "compatible with." Efforts to standardize diagnostic terms may improve communication.

2162 Assessing Tumor Cellularity for KRAS and BRAF Molecular Testing

Faaria Gowani[1], *Yaolin Zhou*[2]. [1]University of Oklahoma Health Science Center, Oklahoma City, OK, [2]University of Oklahoma HSC

Background: Molecular testing of solid tumors relies upon the proper selection of malignant cells in a background of inflammatory,

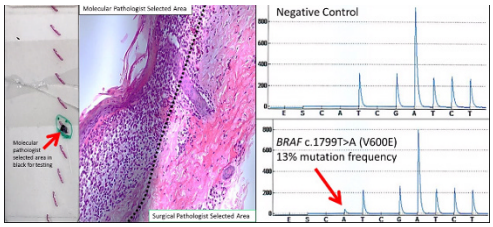
necrotic or normal epithelial/stromal cells. Tumor cellularity must be above the assay's lower limit of detection as testing suboptimal areas can lead to false negative results.

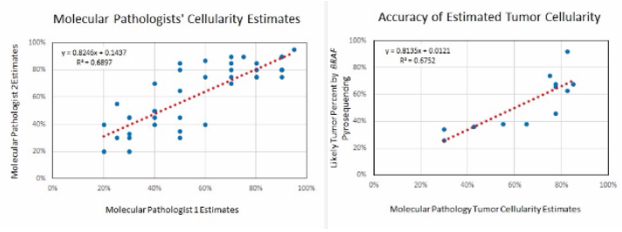
Design: We evaluated 47 cases submitted for *KRAS* (n=18) and/or *BRAF* (n=33) testing from May 2017 through August 2017. Two molecular pathologists independently reviewed 44 of 47 H&E slides and estimated tumor cellularity in the areas selected by the submitting surgical pathologists as well as areas selected by the primary molecular pathologist. We determined interpathologist variability of cellularity estimates and reviewed corresponding pyrosequencing results for 12 *BRAF*+ and 6 *KRAS*+ cases.

Results: There was high precision between molecular pathologists in estimating tumor cell burden (Figure). Their estimates averaged within 11% of each other (standard deviation 9%). Likely tumor cellularity percent were predicted from pyrosequencing results. Mutant allele frequencies below 50% were assumed to be heterozygous, but mutant frequencies above 50% (2 *BRAF*+ melanomas) indicate mutant allele-specific imbalance with loss of heterozygosity or gene amplification.

Our results suggest more accurate estimates for *BRAF*+ cases, which tend to be more homogeneous histologically (Figure). Our *BRAF*+ cases included 7 melanomas, 2 papillary thyroid carcinomas, 1 colon adenocarcinoma, 1 glioma, and 1 langerhan cell histiocytosis (Figure). In contrast, our molecular pathologists may have underestimated cellularity for *KRAS*+ colon adenocarcinoma cases that tend to have greater inflammation.

Our molecular pathologists identified 12 cases (27% of cases with dual-review) where the surgical pathologist selected areas with predicted ≤20% cellularity. Unchanged, these selections could lead to false negatives. Our molecular pathologists made significant changes to the original selections and detected mutations in 9 of these cases.





Conclusions: Our findings suggest that our molecular pathologists were very conservative when evaluating H&E slides for molecular testing, which is preferred to overestimating cellularity. Greater awareness of the pre-analytic factors that impact molecular testing may improve accuracy of pathologists' tumor cellularity estimates and reduce false negative results. Additional correlation studies on tumor cellularity estimates and mutant frequencies would also be helpful.

2163 PREVIOUSLY PUBLISHED

2164 PREVIOUSLY PUBLISHED

2165 Validation of Whole Slide Imaging for the Evaluation of Lymph Node Metastases in Breast Carcinoma

Niloufar Hosseini[1], *Hala Faragalla*[1], *Fang-I Lu*[2], *Livia Florianova*[1], *Anna Marie Mulligan*[3], *Kiran Jakate*[4]. [1]University of Toronto, Toronto, ON, [2]Sunnybrook Health Sciences Centre - University of Toronto, Toronto, ON, [3]Toronto General Hospital, Toronto, ON, [4]St. Michael's Hospital, Toronto, ON

Background: Whole slide imaging (WSI) is becoming increasingly used for primary pathology diagnosis. There is a need to validate WSI for small focal findings for which discrepancies can arise between the standard glass slide (GS) and digital slide (DS) evaluation. In breast carcinoma, nodal metastases are classified by size to macrometastases (>2 mm), micrometastases (0.2-2mm and/or > 200 tumor cells) or isolated tumour cells (ITCs) [< 0.2 mm and/or < 200 tumor cells]; this categorization impacts staging and management. We aim to validate WSI in the context where metastases may be small and precise measurement is required for classification.

Design: 60 axillary lymph node H&E GS were scanned at 20x (Aperio Scanscope AT Turbo Leica). They included 31 nodes with metastatic breast carcinoma (19 micrometastases, 7 ITCs, 5 macrometastases) and 29 nodes negative for carcinoma. The original diagnoses were assigned based on careful review and measurement with ocular micrometer by two authors (NH and KJ). All metastatic foci were visible on H&E (i.e. did not require immunohistochemistry). Three pathologists (A, B and C) reviewed the set of 60 GS and DS with a 3-week washout period in between. Each slide set was de-identified by assigning random study numbers. A brief tutorial of the DS software was provided. For each slide, lymph node status, size of metastatic foci and time expenditure (for the last 10 slides) were recorded. A questionnaire asking about confidence with rendering diagnoses on WSI followed. Rate of agreement between GS and DS diagnoses for each pathologist was reported as an intraobserver agreement, and the rate of concordance between pathologist's diagnosis and original diagnosis was defined as diagnostic accuracy.

Results: Table1 shows results of GS and DS for Pathologists A-C. Average time expenditure was 2:20 minutes per GS and 2:39 minutes per DS across pathologists (p=0.35, Paired t-test). Average measurement for largest metastatic focus was 2.1 mm for GS and 2.0 mm for DS (p=0.04, Paired t-test). Pathologist A felt the most confident and Pathologist C the least confident to make the diagnosis on DS.

Table 1

	Intraobserver agreement n/total (%)	Diagnostic accuracy- GS n/total (%)	Diagnostic accuracy-DS n/total (%)	Major discrepancy[1]-GS n/total	Major discrepancy-DS n/total	Uninterpretable[2]- GS n/total	Uninterpretable-DS n/total
A	54/60 (90)	50/60 (83)	56/60 (93)	7/60	4/60	1/60	None
B	52/60 (86)	51/60 (85)	51/60 (85)	4/60	5/60	4/60	4/60
C	47/60 (78)	56/60 (93)	45/60 (75)	2/60	2/60	2/60	12/60

[1] Major discrepancy: missing micrometastasis or macrometastasis or measurement difference leading to lymph node category discrepancy

[2] Cases for which the pathologist was unable to make the diagnosis with H&E alone

Conclusions: Diagnostic accuracy of DS was comparable with GS for Pathologists A and B. For Pathologist C, a low level of confidence with DS may have impacted accuracy and the interpretability rate with this modality. Labs implementing WSI for primary diagnosis should first assess the comfort level for individual pathologists interpreting DS, and provide training and support accordingly.

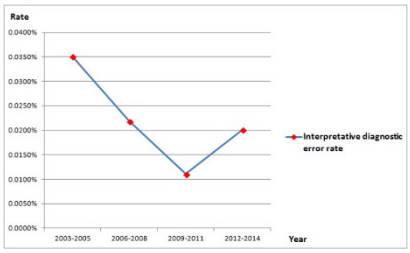
2166 Daily Consensus Conference Significantly Reducing Harmful Interpretive Diagnostic Errors in Surgical Pathology: 12 Years of Experience at a Medical Center in Taiwan

Pin-Pen Hsieh[1], *Szu-Pei Ho*[1], *Jyh-Seng Wang*[1], *Hsing-Hao Su*[1], *Herng-Sheng Lee*[1], *Jia-Bin Liao*[1]. [1]Kaohsiung Veterans General Hospital, Kaohsiung, Taiwan

Background: Routine review of surgical pathology cases is believed to be a good method to reduce interpretive diagnostic errors. Therefore, we evaluated the impact of consensus conference in daily practice of surgical pathology in Taiwan.

Design: We retrospectively studied our archives of amended surgical pathological reports in Kaohsiung Veterans General Hospital in Taiwan between 2003 and 2014. Daily consensus conference for selective cases (first diagnosed malignant cases and difficult cases) with 5-8 pathologists was started since 2006 before sign-out.

Results: A total of 358,835 surgical pathological reports and 467 (0.130%) amended reports were found between 2003 and 2014, including 77 (0.021%) harmful (defined as delay diagnosis or therapy, or patient with consequences) interpretive diagnostic errors during this period. The harmful interpretive diagnostic error rates in 4 equally divided time periods (2003-2005, 2006-2008, 2009-2011 and 2012-2014) were 0.035%, 0.022%, 0.011%, 0.020%, respectively, and the data showed significant error reduction (p= 0.022) since daily consensus conference begun in 2006.



Conclusions: We proposed this quality assurance model as an effective tool for reducing harmful interpretive diagnostic error, particularly in the areas where subspecialties are not so common.

2167 Low-grade Appendiceal Mucinous Neoplasms: Improvements and Challenges in Reporting

Shaomin Hu[1], *Nicole Panarelli*[1]. [1]Montefiore Medical Center, Bronx, NY

Background: Pathologic evaluation of low-grade appendiceal mucinous neoplasms (LAMNs) is often incomplete or inaccurate, leading to confusion about optimal post-operative management. Criteria for categorizing LAMNs were recently refined in the American Joint Committee on Cancer (AJCC) Cancer Staging Manual, 8th edition. Categories T1 and T2 are no longer applicable to LAMNs. Acellular or cellular mucin in the subserosa and serosa are classified as T3 and T4a, respectively. In this study, we evaluated the effect of these criteria on the accuracy and completeness of LAMN diagnoses in our practice.

Design: We retrospectively identified all LAMNs received in our institution over a 17-year period. The reports were reviewed for mention of mural, subserosal, and serosal extension of mucin and epithelium, and T category. We reviewed the slides to evaluate these features and determine the T category according to the AJCC 8th edition manual.

Results: Study cases included 74 LAMNs. Pathology reports lacked mention of one or more of the features enumerated in 18 of 31 cases (58%) prior to and in 15 of 43 (35%) cases after implementation of the AJCC 7th edition in 2010 (Table 1). A T designation was originally reported in 14 (19%) cases, which were originally classified as Tis (n=7), T1 (n=1), T2 (n=1) or T4a (n=5). These were re-classified as Tis (n=5), T3 (n=2), or T4a (n=7) using the AJCC 8th edition criteria. Two cases originally diagnosed as Tis were re-designated as T4a. Overall, 10 out of 15 (67%) T4a cases were either not assigned a T designation or were originally assigned a lower T category, resulting in absence of critical clinical information. Cases with obliterated subserosa and tumor <1mm from the serosa can make application of the 8th edition T3 category challenging (n=7, 9%). Assigning T4a was problematic when organizing mucin was associated with attenuated, denuded, and/or poorly oriented sections (n=4, 5%).

Table 1. Pathologic Features and AJCC 8th Edition Designation of Study Cases

Features	Prior to AJCC 7th edition (n=31)	After AJCC 7th edition (n=43)	AJCC 8th edition (n=74)
LAMN confined to the lumen (n=12)			Tis, n=12
Present	8	4	
Reported	5 (63%)	3 (75%)	
Intramural or subserosal acellular mucin (n=33)			Tis, n=19 T3, n=14
Present	15	18	
Reported	12 (80%)	9 (50%)	
Intramural or subserosal cellular mucin (n=14)			Tis, n=4 T3, n=10
Present	5	9	
Reported	2 (40%)	6 (67%)	
Acellular mucin involving serosa (n=9)			T4a, n=9
Present	3	6	
Reported	1 (33%)	2 (33%)	
Cellular mucin involving serosa (n=6)			T4a, n=6
Present	1	5	
Reported	1 (100%)	5 (100%)	

Conclusions: Applying standardized criteria to the pathologic evaluation of LAMNs substantially improves the completeness and accuracy of reporting. Diagnostic challenges persist in some cases, particularly those with extensive mural fibrosis and mucosal denudation.

2168 Assessment of Proliferation Index (Ki-67) in Invasive Breast Carcinoma: A Comparative Study of Visual Estimation and Digital Image Analysis

Seema Jabbar[1], *Paul C Yell*[1], *Yisheng Fang*[2], *Venetia Sarode*[3], *Katja Gwin*[1], *Yan Peng*[1], *Hong Zhu*[4], *Helena Hwang*[5], *Sunati Sahoo*[1]. [1]UT Southwestern Medical Center, Dallas, TX, [2]UT Southwestern Medical Center, [3]University of Texas Southwestern, Dallas, TX, [4]University of Texas Southwestern, [5]UT Southwestern, Dallas TX

Background: The utility of the proliferation index (Ki-67) in invasive breast carcinomas (IBC) is not well established. ER, PR, and Her2 are routinely evaluated in invasive breast carcinomas as standard of care, while Ki-67 is not currently included in this panel. Nevertheless, several laboratories routinely evaluate Ki-67 in IBC, including at our institution. The difficulty in evaluating Ki-67 consistently is a large drawback to implementing routine Ki-67 evaluation. The aim of this study was to evaluate interobserver agreement and compare visual estimation with an image analysis system of Ki-67 staining.

Design: Seventy-five consecutive invasive breast carcinoma core biopsies were evaluated in this study. Ki-67 staining was performed on formalin-fixed paraffin-embedded (FFPE) tissue sections using Ventana monoclonal antibody (clone 30-9) with heat induced epitope retrieval. Three dedicated breast pathologists blinded to the original Ki-67 value estimated the overall average score across the sections including the hot spots using a schematic diagram available from CAP for scoring of ER and PR stains. These slides were digitally scanned using Aperio Scanscope AT Turbo. Representative invasive tumor regions were manually selected using Imagescope software and quantitative analysis was performed using Aperio Nuclear algorithm. Inter-rater reliability among the pathologists was measured using intra-class correlation coefficient (ICC) and the ratings between image analysis and each pathologist was evaluated by Bland-Altman method.

Results: The inter-rater reliability was 0.859 (95%CI: 0.802-0.903), which demonstrates excellent agreement among the three pathologists. When comparing image analysis versus visual estimation by the three pathologists, the bias (mean difference) was -6.537 (95%CI: -8.116, -4.957), -12.537 (95%CI: -15.450, -9.264) and -15.137 (95%CI: -17.998, -12.276); all comparisons were statistically significant ($p<0.05$).

Conclusions: Visual estimation of Ki-67 by pathologists using a standard guide can minimize subjectivity. Image analysis and visual estimation showed statistically significant variation in this study. Further investigation is needed to determine the reasons for the variation, including possibly modifying parameters in image analysis that may lead to better concordance.

2169 Prospective Consensus Reporting by Gynecologic Pathology and Dermatopathology Improves Diagnosis of Vulvar Biopsies

Susanne Jeffus[1], *Charles Quick*[1], *Chien Chen*[1], *Jennifer Kaley*[1], *Jerad Gardner*[1], *Sara Shalin*[1]. [1]University of Arkansas for Medical Sciences, Little Rock, AR

Background: Vulvar biopsy interpretation and reporting, particularly of vulvar dermatoses, can be challenging. We questioned whether a prospective consensus reporting of vulvar biopsies by surgical pathologists (SP) and dermatopathologists (DP) would improve overall diagnostic specificity and patient care.

Design: Consecutive vulvar biopsies between 1/1-6/30/2017 were reviewed prospectively by one of three gynecologic SP and one of three DP. Preliminary, independently generated, diagnoses were recorded and then shared in consensus review (SP+DP). A third pathologist adjudicated cases without consensus. The following data elements were collected for each case: division (SP/DP), age, site, clinical history, diagnostic category (neoplastic, inflammatory, both, other), preliminary diagnosis (SP/DP), final (consensus) diagnosis, adjudication needed (yes/no), ancillary tests, diagnostic discrepancy (major vs minor). A major discrepancy was defined as a diagnosis affecting patient care (increased surveillance, different treatment). A minor discrepancy was defined as differences in terminology that did not impact patient care.

Results: Eighty-four biopsies (48 SP, 36 DP) from 70 patients (mean age 53, range 17-85) were reviewed. Forty-two (50%) cases were neoplastic (N), 38 (45%) reactive/inflammatory (I) with the remaining (5%) showing both or other features. Clinical history was provided in 71 (84%) cases (SP 75%, DP: 97%); detailed clinical information (description of lesion, clinical differential diagnosis) was provided in 27 (56%) SP and 33 (92%) DP cases. Independent diagnoses were in agreement by SP and DP in 62 (74%) cases. Consensus review resulted in agreement in all cases; adjudication was needed in 6 of the 22 (27%) cases with initial diagnostic disagreement. Major and minor initial diagnostic discrepancies constituted 11% (Table 1) and 15%, respectively. Independent diagnostic agreement increased over time with a reduction in major (6 to 3) and minor (9 to 4) discrepancies between the first and second half of the study period. Ancillary stains were ordered in 32 (38%) cases.

Table 1. Major Initial Diagnostic Disagreement (total: 9, neoplastic: 5, inflammatory: 4)

Clinical History	Preliminary SP Diagnosis	Preliminary DP Diagnosis	Stains	Consensus Diagnosis
Not given	LSIL/VIN 1 vs reactive	Squamous atypia with ulcer and HPV effect, favor HSIL/VIN2	PAS -	LSIL/VIN 1
Leukoplakia	Reactive squamous mucosa with hyperkeratosis and parakeratosis	Lichen sclerosus, hypertrophic variant		Lichen sclerosus, hypertrophic variant
Lichen sclerosus	Mild atypia suggestive of LSIL/VIN1	Mild spongiotic dermatitis	PAS -	Mild spongiotic dermatitis
Not given	Mild spongiotic dermatitis	Suggestive of superficial hemangioma	PAS -	Superficially sampled hemangioma
Condyloma	Condyloma/LSIL/VIN 1	Angiokeratoma		Angiokeratoma
Lesion	Superficial fungal infection	Lichen simplex chronicus with rare budding yeast forms c/w normal flora	PAS +	Lichen simplex chronicus with rare budding yeast forms c/w normal flora
Lesion and non-healing ulcerated mass	HSIL/VIN 3 and acanthosis	HSIL/VIN 3 and HSV	HSV + VZV equivocal Spirochete -	HSIL/VIN 3 and HSV
Condylomas	LSIL/VIN 1	Lymphatic changes consistent with previous excision, no HPV effect		LSIL/VIN 1
h/o VIN 3	LSIL/VIN 1	Focal HSIL/VIN 3, background of LSIL/VIN 1		LSIL/VIN 1

Conclusions: Prospective review of vulvar biopsies by both surgical and dermatopathologists improves overall reporting accuracy and specificity, better guiding patient management. Consensus review allows pathologists to gain more diagnostic confidence in interpretation of inflammatory (for SP) and neoplastic (for DP) vulvar biopsies over time; therefore, intradepartmental consultation is of value in select cases.

2170 Carrier-Based Multi-Tissue Block (CBMTB) of Normal Tissues as On-Slide Quality Control for Automated Immunohistochemical Staining Procedures

Achim Jungbluth[1], *Miriam Fayad*[2], *Guray Akturk*[1], *Michael H Roehrl*[3], *Denise Frosina*[2]. [1]MSKCC, New York, NY, [2]Memorial Sloan Kettering Cancer Center, [3]Memorial Sloan Kettering Cancer Center, New York, NY

Background: The rise of precision medicine implies a steadily increasing demand for results in a steep increase in the number of diagnostic tests. This is especially true for immunohistochemistry (IHC) which serves as one of the main diagnostic pillars. Proper quality control for all diagnostic tests is mandatory and in IHC the field has moved to on-slide controls applied to all slides carrying test tissues. We previously developed a multi-tissue block method consisting of a carrier tissue, in which cores of other tissues are inserted. We now employed the CBMTB approach consisting exclusively of normal tissues to generate a universal on-slide control for automated IHC assays.

Design: Various tissues, shapes, and sizes for the carrier block as well as for the inserted tissues were tested. Cores were manually extracted/inserted using standard derm punch devices (1.52mm). All IHC assay were performed on Leica-Bond-3 and Ventana Benchmark Ultra platforms. Tissues were prospectively collected for the generation of CBMTBs as tissue controls for IHC.

Results: Different CBMTB formats depending on the automated stainer platform were developed. Rectangular (14x6mm) as well as round (12mm) proved to be optimal formats for Leica-Bond and Ventana Ultra platforms respectively. The following tissue cores were manually inserted: 2mm: spleen (carrier), colon, skin; 1.5mm: lung, kidney, liver, testis, tonsil, and placenta. Manual generation of 1 CBMTB took <5 minutes. The present normal tissue CBMTB was employed to all our clinical IHC protocols and proved to be a suitable control for >85% of our more than 200 clinical routine IHC protocols.

Conclusions: CBMTBs consisting exclusively of normal tissues are ideal on-slide controls for a wide array of IHC protocols and antibodies. CBMTBs make ideal use of the entire block area with the carrier serving as scaffolding for the inserted tissues as well as a control tissue itself. CBMTB formats can be adjusted to the automated stainer platforms. Most importantly, instead of conventional single positive or negative control tissues, the present tissue combination generated distinct staining patterns for each antibody thus increasing significantly the quality control of IHC processes.

2171 Interobserver Agreement in Assessment of Dysplasia in Barrett's Esophagus Using Digital Pathology: Applications for Intradepartmental Consensus Diagnoses

Liang-I Kang[1], *Jon Ritter*[2], *Danielle Carpenter*[3], *Bella Goyal*[2], *Dengfeng Cao*[2], *ILKe Nalbantoglu*[4]. [1]Washington University School of Medicine, St. Louis, MO, [2]Washington University School of Medicine, Saint Louis, MO, [3]Saint Louis University, [4]Washington University in St. Louis, Saint Louis, MO

Background: Assessment of dysplasia in Barrett's esophagus is known to have variable interobserver agreement. Therefore, such cases are discussed in intradepartmental consultation or consensus conference for quality assurance (QA). The objective of this study is to evaluate whether digital pathology is an equivalent modality as glass slides for QA for dysplasia in Barrett's esophagus.

Design: A pathology database search was performed for all Barrett's esophagus cases with intradepartmental consultation or consensus conference from 2015 to 2017. All available biopsies (bxs) were reviewed by one pathologist (IN) and one resident (LK), and bxs with classic histologic features were selected. Bxs with adenocarcinoma, and bxs in which none of the reviewing pathologist or study pathologists had ever seen before were excluded. One representative slide from 19 remaining bxs (Negative for dysplasia [ND]=4, indefinite for dysplasia [IND]=7, Low grade dysplasia [LGD]=4, and high grade dysplasia [HGD]=4) were de-identified and scanned using the Philips Ultra Fast Scanner 1.6® at 400X magnification. Four study pathologists, including two GI pathology fellowship trained, with a range of 1-25 years of experience, scored the bxs as one of four options: ND, IND, LGD, or HGD. Intraclass correlations (ICC) were compared between the four reviewers. Correlation is interpreted as excellent (>0.75), good (0.5-0.75), fair (0.25-0.5), and poor (<0.25). Percentages of clinically significant discrepancies from the original diagnosis (defined as ND to IND/LGD [or vice versa] or IND/LGD to HGD [or vice versa]) for individual pathologists and group consensus (calculated as mode) were assessed.

Results: The overall ICC among the four reviewing pathologists was 0.613 (good). Clinically significant discrepancies between the group consensus for each case and the original diagnoses were 32%, while individual pathologists ranged from 21% to 42%. In general, increasing experience was associated with lower discrepancy rates and a greater tendency to downgrade diagnoses. After a period of washout (>1 month), the study pathologists will review the glass slides to control for intraobserver variability between digital and glass slides.

Conclusions: ICC on digital slides is comparable to published previously published rates of agreement for Barrett's esophagus on glass slides, which suggests that digital pathology is adequate and practical for intradepartmental and interinstitutional consultation needs.

2172 Observer Variability Among Pathologists with Varying Levels of Expertise in the Assessment of Donor Liver Frozen Sections

Matthew Keeney[1], *Sarag Boukhar*[2], *Andrew Bellizzi*, *Daniel Pelletier*[3]. [1]Iowa City, IA, [2]University of Iowa Hospitals and Clinics, Iowa City, IA, [3]University of Iowa Hospitals and Clinics

Background: Donor liver frozen section (DLFS) assessment is a widely used and accepted tool in graft selection. DLFS specimens are often viewed after hours, which shoulders fellows and pathologists with variable expertise with the responsibility of frozen section evaluation and reporting. We sought to determine the interobserver reproducibility of DLFS assessment among pathologists with varying levels of specialty training.

Design: 25 consecutive DLFS cases were reviewed blindly by 11 observers, including 4 gastrointestinal (GI) fellowship-trained pathologists, 3 practicing surgical pathologists without a prior GI fellowship, and 4 surgical pathology (SP) fellows. Percentage of steatosis, degree of portal inflammation, degree of inflammatory activity, stage of fibrosis, and overall impression were assessed. Concordance was estimated using the interclass correlation coefficient (ICC).

Results:	ICC (confidence intervals) all observers	ICC of GI faculty vs non-GI faculty	ICC of GI faculty vs SP fellows
Macrovesicular fat %	0.71 (.58-.83)	0.76 (0.52-0.89)	0.70 (0.50-0.84)
Impression of viability (y or n/u)	0.58 (0.43-0.74)	0.52 (0.34-0.71)	0.33 (0.09-0.59)
Portal inflammation (0-3)	0.47 (0.32-0.66)	0.60 (0.42-0.77)	0.44 (0.20-0.67)
Fibrosis stage (0-4)	0.44 (0.30-0.62)	0.44 (0.25-0.64)	0.34 (0.19-0.61)
Microvesicular fat %	0.04 (0.006-0.11)	-0.01 (-0.08-0.11)	0.14 (-0.03-0.39)

Conclusions: 1. Observers demonstrated substantial agreement for degree of steatosis. This is reassuring, as macrovesicular fat content is one of the most important criteria in predicting allograft viability.

2. Assessment of fibrosis, which is especially important in allograft livers after cardiac death, was less reproducible with only fair to moderate agreement.

3. Observer experience does not appear to impact ICC significantly.

4. Training sets and correlation conferences have been shown to improve interobserver correlation in some situations, and may be helpful in improving analysis of DLFS.

2173 Equitable Cytopathology Workload Distribution can be Achieved Using Royal College of Pathologists Guidelines

Elham Khanafshar[1], *Sarah Calkins*[2]. [1]Univ. of California, San Francisco, San Francisco, CA, [2]UCSF FNA Clinic, San Francisco, CA

Background: Workload equity in the Cytopathology Division was previously established by quarterly workload reviews and consensus negotiations by faculty within the Division (Table 1). In search of a more objective method, RVU or modified RVU-based methods had been considered previously but as many studies have pointed out are suboptimal for workload evaluation, especially in cytopathology. Our goal was to evaluate the Royal College of Pathologists (RCP) guidelines on staffing and workload for histopathology and cytopathology departments (4th Ed) in an attempt to find an objective metric by which to analyze workload equity within our Cytopathology Division.

Design: In our Division, we have 7 cytopathology service rotations that need to be covered daily by cytopathologists. These rotations vary from direct patient care in pathologist-performed Fine Needle Aspiration (FNA) clinic and Rapid On-Site Evaluation (ROSE) during radiology FNA procedures to exfoliative cytopathology sign out. Additionally, not all cytopathology faculty cover all 7 services. Using RCP guidelines, we reviewed all cytopathology cases during academic years 2015-2016 and 2016-2017 and assigned RCP points for each case. Our institution has an active pathologist-performed FNA clinic and uses ROSE routinely. Point assignment for these activities was determined using an internal time study and developing a point system based on those results, as suggested in the RCP. These point assignments were then used to compare RCP workload distribution with our previous consensus workload. FNA clinic service (rotation A) in 2015-2016 was set as a gold standard of a day's work, which corresponds to 62.71 RCP points.

Results: RCP point assignments showed a similar curve of distribution for each cytopathology rotation as previously scheduled (Figure 1). However, areas of imbalance were identified. In the 1st phase of addressing the imbalances, the credit for rotations D and G were traded. By using telepathology ROSE, we redistributed some cases from rotation E to rotations B and F. This brought B and F workloads closer to the gold standard and resulted in a decision to decrease service credit for rotation E to 0.7 (Figure 2). As ongoing process improvement, we are using RCP points to further make appropriate changes.

Rotations	Credit (day/rotation)
A	1
B	1
C	0.5
D	0.5
E	1
F	1
G	0.6

Figure 1: Workload Distribution, Initial Review

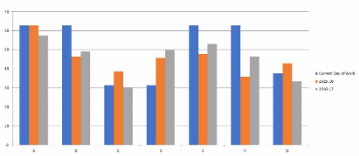
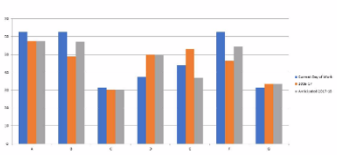


Figure2: Workload Distribution, Phase 1 Change



Conclusions: RCP is an objective metric by which to assign workload equity across various services, especially in cytopathology where there is abundant rotation-specific diversity.

2174 Minimal Endoscopist Compliance with the 2016 American College of Gastroenterology's Barrett's Esophagus Management Practice Guidelines

Armen Kharajian[1], *Kathleen Byrnes*[2], *Rifat Mannan*[3], *Lysandra Voltaggio*[2], *Elizabeth Montgomery*[4]. [1]Baltimore, MD, [2]Johns Hopkins Hospital, Baltimore, MD, [3]The Johns Hopkins Hospital, [4]Johns Hopkins Medical Institutions, Baltimore, MD

Background: The American College of Gastroenterology (ACG) published updated practice guidelines for the management of Barrett's Esophagus (BE) in January 2016 (e-pub in November 2015) that introduced a length requirement (≥ 1 cm) and advised against performing biopsies of normal-appearing gastroesophageal junctional (GEJ) mucosa. As these guidelines become incorporated into clinical practice, the number of GEJ biopsies should decrease. Our gastrointestinal (GI) pathology division worked with several gastroenterologists to create a note that is added to all reports from biopsies labeled as GEJ that references the ACG 2016 guidelines. To assess compliance, we evaluated the number of GEJ biopsies over a one-year span pre and post guideline publication, including an eight-month grace period after publication to allow for adaptation. The note was implemented following this eight-month grace period.

Design: The pathology database was searched for all GEJ biopsies one year prior to the e-pub date of the new practice guidelines (11/3/2015) as well as an additional year following the eight-month grace period allowing for acclimation. Follow-up biopsies for cases that had our note were examined to determine if the note helped remind clinicians to biopsy the distal esophagus rather than the GEJ.

Results: Whereas 837 GEJ biopsies were received for the year prior to the updated guidelines (4,551 total esophagogastroduodenscopies [EGDs]), 869 were received for the year following the eight-month grace period (4,545 total EGDs). 145 patients were reported with our note with seven having follow up GEJ/esophageal biopsies. Of those seven, five had GEJ biopsies (one of which included many other sites along the esophagus for mapping) while two had distal esophageal biopsies only. There were no cases of dysplasia or carcinoma among the GEJ samples.

Conclusions: The ACG has recommended that biopsies for BE should only be performed when salmon colored mucosa extends ≥ 1cm from the GEJ. Furthermore, the ACG has strongly recommended that normal Z-lines or Z-lines with less than 1cm of variability should not be biopsied. Our study shows that the recommendations have yet to be well-implemented in daily practice as endoscopists continue to biopsy the GEJ. Quality metrics have begun and will continue to play a large role in both the evaluation of physicians as well as reimbursement. Coordination and feedback between pathologists and clinicians will increase the cost effectiveness of care that we provide to our patients.

2175 Structured Implementation of Changes for Success -- How We Reduced Specimen Oversampling with Desired Outcome

Zongshan Lai[1], *Osama Alassi*[1], *Christopher Hysell*[1], *Kimberly Pieters*[1], *Christopher Dalton*[1], *Jennifer Lehmann*[1], *Zhenhong Qu*[1]. [1]Beaumont Health, Royal Oak, MI

Background: Healthcare reform imposes a pressing need for efficiency and cost-effectiveness. However, changes are difficult. In addition to psycho-social inertia, concerns about the risk to patients and professional liability also contribute to strong resistance. We report how we effectively overcame resistance and implemented desired changes in reducing specimen oversampling.

Design: Historically, oversampling of breast cancer case in our institution resulted from surgeons dividing a tumor resection case into multiple parts, and pathologists taking an excessive number of samples from each part. Strong resistance to changes in such practices was anticipated from three main stake holders – pathologists, surgeons and pathologist assistants. We took a structured approach to overcome resistance and implement the changes:

1) Collate data from 3 different sources for evidence-based argument: our tissue sampling data to illustrate the need to change, information from peer institutions to create the sense of "social approval", and relevant/credible scientific literature.

2) Spell out key components of the project: **P**urpose, **P**lan, **P**rocess and **P**rocedure (4P's). Flowchart and diagrams were created for effective communication and implementation guidance.

3) Set specific criteria for implementation: **A**ctionable, **A**chievable, **A**ccountable, **A**ssessable and **A**mendable (5A's).

Results: Effective communication to stakeholders the reasons for the change, and developing a specific plan and processes, are critical to overcoming resistance. Tangible data/evidence against presumptive concerns is very effective to fend off resistance. The 5A's strategy makes each step of the plan specific and tangible to act upon and breaks main task into small ones that seem achievable. Our overall sampling has been reduced from prior 37.9 ±19.4 to 29.5±12.7 blocks/case afterwards (P=0.004), and for lumpectomy alone, the reduction was from prior 29.5±19.9 to 25.5±9.5 (p=0.005). Goals were met with an estimated savings of >$60K/year. No increase in tumor detection error was detected.

Conclusions: Most resistance to change is psycho-social and cultural. A structured approach with a clear goal based on tangible data, a detailed plan and process are effective means to overcome resistance to change. Using the short set of implementation criteria (i.e. 5As) is a pragmatic strategy to achieve the project goal. The approach is applicable to other similar operational scenarios.

2176 Value of Second Opinion in Prostate Needle Core Biopsies

Luisa A Lerma[1], *Funda Vakar-Lopez*[2], *Lawrence D. True*[3], *Maria Tretiakova*[2]. [1]University of Washington, Seattle, WA, [2]University of Washington, Seattle, WA, [3]Seattle, WA

Background: Internal reviews of the pathology material for incoming patients with previous diagnoses are intended to reduce clinically significant errors, and are standard of care at tertiary medical centers. This safety net, however, is not without cost; time and monetary investment are incurred by both receiving and sending institutions. This study investigates the discrepancy types and rates for prostate needle core biopsies between our institution (U) and referring institutions (RU).

Design: Retrospective analysis of 428 consecutive prostate needle core biopsies received for review or consultation by our institution, over 95% of which had all parts and stains reviewed. Each case was analyzed for discrepancies in Gleason grade and Grade group (GG) assignment, histotype, tumor extent, extraprostatic extension (EPE), seminal vesicle invasion (SVI), perineural invasion (PNI), and lymphovascular invasion.

Results: Overall, 49.8% of cases had at least one discrepancy, and 6% had more than one [Table 1]. Grading disagreements were identified in 17.3% of total cases, 81% of these cases resulted in an increased Gleason grade. Ten cases (2.3%) changed by two grade groups. Radical prostatectomies (PR) were available for 14 cases with GG change: 11 cases had a GG which was most consistent with the revised biopsy GG assigned by U, 2 cases had GG more similar RU and 1 patient had clinical progression with intervening biopsy. Histotype underreporting was identified in 12 patients: 10 cases with ductal adenocarcinoma, 1 case with small-cell neuroendocrine differentiation and 1 atrophic adenocarcinoma. Number of cores involved by cancer was divergent in 70 cases (16.4%), and not documented in 52 cases (12.1%). Stage was increased by our institution in 15 cases (3.4%), including one consult case (a deferred diagnosis), which our institution classified as cancer. EPE or SVI were detected on review in 14 cases (3.3%). PNI was documented as absent by RU and reclassified as present in 25 cases (5.8%); the opposite occurred in 7 cases (1.6%).

Table 1. Detailed list of discrepancies in 428 prostate biopsies.

Grade discrepancies:	Increased by U		Decreased by U	
	N	%	N	%
GG 1 vs 2	21	4.8	3	0.7
GG 2 vs 3	12	2.8	3	0.7
GG 3 vs 4	3	0.7	2	0.5
GG 4 vs 5	6	1.4	1	0.2
GG change by 2	9	2.1	1	0.2
Presence of pattern 5	11	2.5	0	0
Gleason score change without GG change	10	2.3	2	0.5
Gleason score by RU irrelevant (prior Rx)	0	0	2	0.5
Stage and histotype discrepancies:	**Identified by U**		**Identified by RU**	
EPE missed entirely or partially	12	2.8	0	0
LVI	0	0	1	0.2
SVI	2	0.5	0	0
Ductal phenotype	10	2.3	0	0
Neuroendocrine variant	2	0.5	0	0
Missed cancer	1	0.2	0	0
PNI discrepancy	45	10.4	7	1.6
*PNI not mentioned by RU, negative by U	51	11.8	0	0

*Not considered as true discrepancy.

Conclusions: The investment into reviewing or consulting is important due to the high rate of differing diagnoses that are found between referring institutions and tertiary centers. Patient treatments rely on standardized reporting, which will continue to evolve and become more nuanced in the future.

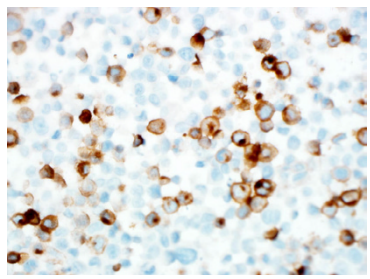
2177 Impact of Decalcification Time on Immunohistochemical Detection of PD-L1 Expression in Cultured Carcinoma Cell Lines

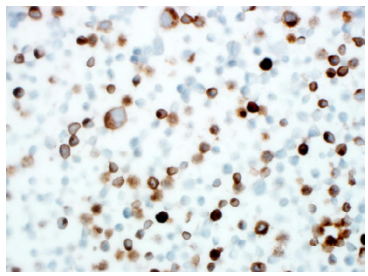
Fan Lin[1], *Jianhui Shi*[2], *Angela Bitting, Benjamin Lin*[3], *Haiyan Liu*[2]. [1]Geisinger Medical Center, Danville, PA, [2]Geisinger Medical Center, Danville, PA, [3]Geisinger Medical Center

Background: PD-1 blockage therapies have demonstrated some efficacy in the treatment of malignant tumors, such as lung non-small cell carcinoma, urothelial carcinoma, and melanoma. One of the important technical questions, frequently raised and without a clear answer yet, is, How reliable is the detection of PD-L1 expression in decalcified tissue? In this study, we investigated the impact of decalcification time on PD-L1 expression in cultured cancer cell lines using the Ventana SP263 clone.

Design: Six known carcinoma cell lines (breast, lung, colon, pancreas, kidney, and uterine cervix) were obtained from American Type Culture Collection. Cell blocks were constructed from each cell line. Cell pellets containing a mixture of equal proportions of the 6 cell lines were first fixed in 10% neutral buffered formalin for 8 hours and then decalcified in Decalcifier B (Fisher Healthcare, item #23245683) for the following durations: 0 minutes (no decalcification), 30 minutes, 60 minutes, 3 hours, 6 hours, 1 day, 3 days and 1 week. Following decalcification for these various durations, PD-L1 (Ventana SP263 clone, prediluted) staining was performed on these sections using the Ventana Ultra staining platform. Complete or partial membranous staining was considered positive. The percentage of tumor cells stained was recorded, with a 5% incremental increase, and compared to the sample with no decalcification.

Results: Approximately 30% of the tumor cells in the sample with no decalcification showed strong membranous staining. Regardless of the decalcification time, all decalcified samples demonstrated similar staining results (strong membranous staining in 30% of the tumor cells). Microscopic photos of the samples are shown in Figures 1A (no decalcification) and 1B (1-week decalcification).





Conclusions: Our preliminary results using cultured cancer cell lines demonstrate that a prolonged decalcification of 1 week has little negative impact on the detection of PD-L1 expression when using the Ventana SP263 clone.

2178 Hit or a Miss: Histopathologic-Endoscopic Correlation in Gastric Mucosal Biopsies

Yongjun Liu[1], *Annie J Tsay*[2], *Dipti Karamchandani*[3]. [1]Penn State Health Milton S. Hershey Medical Center, Hershey, PA, [2]Penn State Health Milton S. Hershey Medical Center, Hershey, PA, [3]Penn State Hershey Medical Center, Hershey, PA

Background: Upper gastrointestinal tract endoscopy is a common outpatient procedure performed due to diverse indications. Frequently, gastric mucosal biopsies are taken for subsequent histopathologic evaluation. Current literature shows a variable degree of concordance between endoscopic and histopathologic findings. We aim to study the spectrum of histologic findings seen in gastric mucosal biopsies and their concordance with various endoscopic findings.

Design: In this IRB approved study, we retrospectively reviewed pathology database to identify gastric mucosal biopsies performed in adult patients (age range: 18-99 years) from 01/01/2016 to 08/31/2016. The corresponding clinical and endoscopic findings were retrieved from electronic medical record.

Results: The study included 566 gastric mucosal biopsies taken from 520 consecutive patients, comprising of 311 females (52.3±13.8 years) and 209 males (55.3±14.1 years). Endoscopic findings were broadly classified into: normal (27%), inflammatory changes which included erythema, granularity, and edema (48%), polyps (9.7%), ulcer/erosions (5.6%), nodules/papules (3.5%), atrophy (1.9%), mass (1.2%), enlarged gastric folds (1%) and miscellaneous (2.1%). The histopathologic findings corresponding to the major bulk of the

endoscopic findings are tabulated in Table 1. Additionally, of the 7 biopsies diagnosed endoscopically as masses, 4 (57%) showed a neoplastic process (3 adenocarcinoma and 1 lymphoma) and 3 showed inflammatory/hyperplastic changes with or without granulation tissue, suggesting proximity to a mass lesion.

Table 1. The Histologic Findings Corresponding to the Major Bulk of the Endoscopic Findings

Histologic Findings	Endoscopic Findings			
	Normal	Inflammatory Changes	Ulcer	Nodules/Papules
No pathologic alteration	65 (43.0%)	79 (28.8%)	3 (9.4%)	1 (5%)
H. pylori positive chronic gastritis	5 (3.3%)	22 (8.0%)	2 (6.3%)	3 (15.0%)
H. pylori negative chronic gastritis	64 (42.4%)	96 (35.0%)	0 (0%)	3 (15.0%)
Ulcer with or without chronic gastritis	0 (0%)	0 (0%)	15 (46.8%)	0 (0%)
Intestinal metaplasia (with or without chronic gastritis)	7 (4.6%)	16 (5.8%)	3 (9.4%)	2 (10.0%)
Reactive gastropathy	10 (6.7%)	52 (19.0%)	8 (25%)	5 (25.0%)
PPI effects	0 (0%)	5 (1.9%)	0 (0%)	0 (0%)
Neoplasm	0 (0%)	1 (0.4%)	1 (3.1%)	2 (10.0%)
Other benign findings	0 (0%)	3 (1.1%)	0 (0%)	4 (20.0%)
Total	151	274	32	20

H. pylori - Helicobacter pylori; PPI - proton pump inhibitor

Conclusions: Less than half (43%) biopsies with normal endoscopy showed no pathologic alteration (NPA) on histologic examination and were concordant, while the remaining 57% showed positive findings including 3.3% biopsies with *Helicobacter pylori (H. pylori)* associated chronic gastritis. All these 3 patients had clinical symptoms of epigastric pain, and one of them also had a history of recurrent *H. pylori* with resistance to treatment. Remarkably, 29% of the biopsies with inflammatory-type endoscopic appearance also showed NPA. In our study, *H. pylori* positive gastritis most commonly presents as inflammatory changes on endoscopy, however can also present as ulcer, nodules/papules, prominent folds and even as normal endoscopy. Lastly, while some endoscopic findings (e.g., masses) are highly concordant with a positive histopathologic diagnosis, other endoscopic findings are associated with a varied spectrum of histopathologic findings.

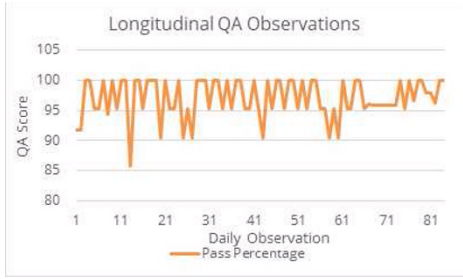
2179 A Novel Two-Fold Process for Quality Assurance in the Nation's Largest Volume Digital Scanning Facility

Mark Lloyd[1], *David Kellough*[2], *Trina Shanks*[2], *Amitabh Deshpande*[2], *Sunil Singhal*[3], *Anil Parwani*[4]. [1]Inspirata, Inc., Tampa, FL, [2]Inspirata, Inc., [3]Inspirata, Inc., Tampa, FL, [4]The Ohio State University, Columbus, OH

Background: With the advent of the first FDA-cleared digital pathology system it will be paramount to create and optimize Quality Assurance (QA) processes. Our institution is retrospectively scanning slides from every cancer case created at our Comprehensive Cancer Center histology laboratory. We scan all slides in each cancer case except 1st cut frozen sections, unstained slides, smears, re-cut H&E made with IHC stained slides, control only slides and slides for which there is no label. The facility is running seven (7) high-throughput slide scanning instruments 24/5 at an average rate of 3,400 whole slide images (WSIs) each day. Two different QA procedures have been in place for over 180,000 retrospectively scanned.

Design: Process 1: Scanner data is reviewed for each slide at the end of every run and observed issues are logged and reported. Resultant graphs are updated daily and trends are monitored weekly. Process 2: One percent (1%) of all WSIs are manually inspected at a minimum of three magnifications including 5x, 20x and 40x. Elements reviewed include Case ID-Label matching, ROI capture of all tissue, blurriness/focus and a quantitative scoring system is applied. At 20x and 40x, five (5) random areas determined to be of interest (tumor, gland, areas stained with IHC or special stains, etc) and a point is awarded for each defect-free area with a total possible score of 10.

Results: Over a total of 180,000 WSI the Pass Rate for our QA process is 97.15% with an average QA Score of 9.40 at a 1% review rate over a 4-month scanning period from May 15th through September 12th. Process 1: 73.1% of the slides which failed the QA process scored 0 of 10. Process 2: 26.9% scored more than 0 but less than the predetermined threshold QA Score of 8. The average score was 6.50. The variance of failure between the 7 scanners ranged from 1.2% to 7.2% with an average of 2.98% of the reviewed slides.



Conclusions: Determining and monitoring the maintenance of our desired level of quality for WSIs is an essential component for the success of digital pathology. Now with large volumes of QA data from a production scanning facility we can share our process and findings which may become a model for all future large and small volume digital pathology facilities.

2180 Digital Pathology Rescan Rates and Common Errors Evaluated over 150,000 Whole Slide Images

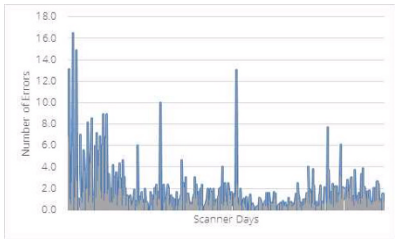
Mark Lloyd[1], *David Kellough*[2], *Trina Shanks*[2], *Elizabeth White*[2], *Amitabh Deshpande*[2], *Sunil Singhal*[3], *Anil Parwani*[4]. [1]Inspirata, Inc., Tampa, FL, [2]Inspirata, Inc., [3]Inspirata, Inc., Tampa, FL, [4]The Ohio State University, Columbus, OH

Background: In 2017, the FDA has allowed the marketing of the first whole slide imaging (WSI) device for primary diagnosis. As adoption of slide scanning is expected to increase, our team has been ramping up our scan volumes to thousands of retrospective slides per day-averaging over 13,000 per week, and studying rescan rates and common errors. Our experiences running multiple slide scanning instruments in a high-volume facility allow us to collect these data and share our unique experiences.

Design: Seven (7) slide scanners are monitored daily for 85 consecutive days (17 five-day work weeks) for WSI defects including failed ROI detections, slides skipped, slides dropped by the slide handler, tissue not detected, failed bar code reads and other observed faults. Each fault is classified into one of five categories for tissue not detected, barcode errors, ROI errors, slides lost or other. The total scanning errors and bar code error rates are recorded and monitored weekly for over 130,000 WSI acquisitions across each of seven slide scanning instruments.

Results: 129,716 WSIs were acquired and a total of 1,522 errors were recorded representing 1.07% of all scans. The range of observed errors was 0-16.5% (45 of 273). The error rate reduced from 3.4% (n=5231) in the first three days of scanning to 1.2% in the most recent 3 days (n=6725) across all seven scanners. 38.9% of errors were no tissue scanned and 44.1% were barcode errors. The remaining three categories of errors represented 0.19% of all slides scanned and 17.0% of all errors. Of all slides submitted for rescanning 96.6% were successfully rescanned. Of all slides submitted for rescanning following a barcode error 71.0% were successfully read on the slide scanning instrument.

Slides	Tissue not Detected	Bar Code Error	ROI Error	Slide Lost	Other	Total Scanning Errors
129,716	592	671	129	118	12	1,522



Conclusions: Tracking errors rates for WSI acquisitions over time has helped our facility streamline and optimize operations. Recording our findings has also demonstrated, that with our processes, errors can be monitored and corrective action can be swift and effective. These findings ensure the slide scanning device manufacturers, in tandem with dedicated and experienced slide scanning facility staff, can safely and effectively acquire WSIs sufficient to meet the near term needs of prospective scanning for primary digital diagnosis.

2181 Validation of Immunohistochemical Tests Performed on Cytology Cell Block Material

Renuka Malenie[1], *Swati Satturwar*[1], *F. Zahra Aly*[2], *Ann Sutton*[3], *Adriana Knoffelmacher*[4]. [1]Vidant Medical Center, Greenville, NC, [2]East Carolina University, Greenville, NC, [3]ECU Brody SOM, Greenville, NC, [4]MD Anderson Cancer Center, Houston, TX

Background: The Clinical Laboratory Improvement Amendments of 1988 requires laboratories in the USA to verify performance of patient tests. A questionnaire based survey of US laboratories found that a significant proportion of respondents did not validate immunohistochemical (IHC) tests. This led to the publication of College of American Pathologists guidelines for analytic validation of IHC assays. We describe the practical application of these guidelines in Cytology using a stepwise approach of identifying the antibodies for validation studies, using resection specimens to generate "test" cytology cell blocks (CCB) and exploring the effect of different fixatives (alcohol vs formalin) on the IHC results against the gold standard of formalin fixed paraffin embedded histology material.

Design: We identified the specimens on which IHC studies are most frequently performed and selected a panel of antibodies (CK7, CK20, CK8/18, CDX2, S100, Synaptophysin, CD56, PAX-8, AE1/3, p63, p40, TTF-1, Ki-67) to test using 10 consecutive surgical resection specimens. All antibodies had previously been validated in histology material with >90% concordance using morphology as the reference gold standard. CCBs were created by plasma thrombin method and IHC was performed as previously validated for histology material. The results of the validation study scored percentage of lesional cells staining in the histology and cytology material in quartiles (0-25%; 26-50%; 51-75% and >75%). The CCBs served as both positive and negative control; the negative control being the resident benign population of cells.

Results: IHC studies on CCBs performed equally well with alcohol and formalin fixed cells when compared with reference histology material. There was broad concordance within two quartile intervals of the proportion of cells staining in the CCBs and histology material. CDX2 and synaptophysin did not perform well on CCBs. As CK19 and CD56 were acceptable substitute antibodies, we elected to eliminate CDX2 and synaptophysin from our list of CCB validated antibodies.

Conclusions: Cytology cell block material generated from plasma thrombin method performed equally well whether the cells were fixed in formalin or alcohol. Future innovations on availability of cell cultures prefixed in alcohol or formalin and automation of cell block processing would minimize preanalytic variables allowing laboratories to share validation sets.

2182 False Positive Rates in Rapid HIV Screening Assays in Eastern North Carolina

Renuka Malenie[1], *Swati Satturwar*[1], *Nada A Fadul*[2], *Chris Miller*[3], *Richard J Baltaro*[4]. [1]Vidant Medical Center, Greenville, NC, [2]East Carolina University, Greenville, NC, USA, [3]Vidant Medical Center, Greenville-NC, Greenville, NC, [4]East Carolina University, Greenville NC

Disclosures:
Renuka Malenie: *Research Support*, Gilead
Swati Satturwar: *Research Support*, Gilead
richard Baltaro: *Research Support*, Gilead

Background: This quality project compared two different 4th generation HIV assays used in our center. In February 2015, a STAT rapid 4th generation assay (Alere Determine HIV-1/2 Ag/Ab Combo) was introduced, in addition to the existing assay (Abbott i-1000 AG/AB Combo). In February 2017 we received a grant by FOCUS (Gilead Scientific) for rapid HIV screening of all the patients presenting to the emergency department; as per 2006 CDC guidelines. The 4th generation HIV combination assays detect p24 antigen and anti-HIV antibodies and are CDC recommended.

Design: Both the assays were compared in different settings. Patients in the FOCUS grant from the ED were tested by Abbott, patients from the labor and delivery by Alere and all other hospital patients were tested by Abbott. As per the 2014 CDC guideline a FDA-approved antigen/antibody combination immunoassay is used for initial screening; if nonreactive no further testing was done, if reactive then the specimen was tested with FDA approved antibody immunoassay, if reactive by both it was interpreted as positive. Specimens reactive on screening and nonreactive/indeterminate on the antibody immunoassay were tested by FDA approved HIV-1 Nucleic Acid Test.

Results: Of a total of 24,743 screening tests; 39 were reactive by Alere and 160 by Abbott. Alere had 16 (0.5%) and Abbott had 29 (0.13%) false positives in total. Before the grant, 17/10,191 tested by Abbott (0.1%), and 13/1818 (0.6%), tested by Alere did not confirm positive and were reported as false positive. After the grant Abbott was used for screening 4208 patients from the ED, 5 (0.11%) were reported as false positive. With Alere 3 /410 (0.73%) false positives were reported from the labor and delivery. The Abbott assay used to screen all other patients in the hospital, had a false positive rate of 7/2972(0.23%) patients. Some of the patients on repeat testing, on different dates produced the same results. The positive predictive value was 69% for the Alere test and 80% for the Abbott assay. The specificity remains high, 99.4% for Alere and 99.8% for Abbott.

Conclusions: The Alere assay seems to provide a greater number of false positives as compared to Abbott. The specificity of both the assays remains quite high and is comparable. Even though the assays were used in different hospital settings with different demographics, Alere had more false positives. In this study negative tests by rapid screening were not verified.

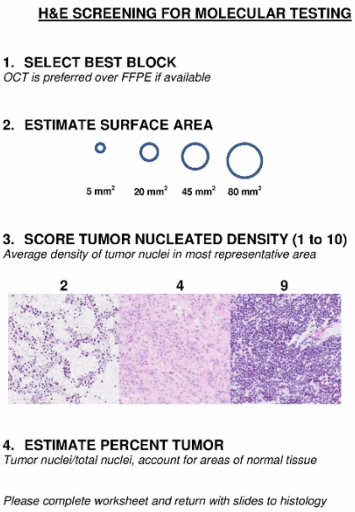
2183 Tumor Nucleated Density Score is a Reliable Predictor of DNA Yield for Molecular Diagnosis

Julia Marcheque[1], *Dejerianne Ostrow*[2], *Monica Mendez*[3], *Jennifer Cotter*[1]. [1]Children's Hospital Los Angeles, Los Angeles, CA, [2]Chlidren's Hospital Los Angeles, Los Angeles, CA, [3]Children's Hospital Los Angeles

Background: As precision medicine becomes a standard model of health care, molecular testing has become part of routine diagnostic pathology. However, the heterogeneity of tumor cells, the presence of inflammatory cells, multinucleation, and the infiltration of tumor cells into healthy tissue may confound tumor cell DNA contribution in genetic/molecular analysis. Providing reliable and sufficient material for an accurate molecular diagnosis is essential. Here we suggest tumor nucleated density, quantified as a "nuclear score," as a visual (and eventually computational) parameter to screen tissue prior to molecular testing.

Design: We retrospectively analyzed 107 surgical cases for which tumor content (percent tumor), surface area, and tumor nucleated density ("nuclear score") were tabulated at the time of light microscopic review, prior to molecular testing. Nuclear score is assigned based on the density of tumor nuclei within a sample on a scale of 1 to 10. The nuclear score scale was validated in a small set of cases by software-assisted manual cell count and calculation of surface area (Aperio ImageScope). We compared each parameter to DNA yield to evaluate the separate metrics of visual assessment. We then created a novel worksheet for pathologist tissue screening including visual guides for surface area and sample images for nuclear scoring, prepared from representative cases.

Results: Our analysis indicates that, as a standalone metric, nuclear score is more closely correlated to DNA yield than percent tumor or surface area. Visual estimation of nuclear score was improved after introduction of the screening worksheet with visual references.



Conclusions: Tumor nucleated density scoring can be utilized as a screening parameter for specimens undergoing genetic/molecular analysis. Furthermore, assessment of nuclear score can be assisted by a visual prompt without introducing bias. Using nuclear score in combination with percent tumor and surface area, pathologists can more readily determine if a given specimen meets requirements for molecular assays. Routine evaluation of nuclear score can also prompt a histology laboratory to prepare a greater volume of material for tumors of low cellularity. With integration of image analysis algorithms, nuclear score may be a promising candidate metric for automated tissue screening using whole slide imaging.

2184 Complete Histopathology Examination of Known/ Reported Tumor Site in Post Neoadjuvant Esophageal/ Gastroesophageal Carcinoma Without Grossly Visible Lesion: Is it Warranted in Routine Clinical Practice

Noor D Marji[1], *Ahmad Alkhasawneh*[2]. [1]University of Florida College of Medicine-Jacksonville, Jacksonville, FL, [2]Jacksonville, FL

Background: Neoadjuvant chemotherapy followed by resection is the mainstay therapy for resectable distal esophageal (DE) and gastroesophageal junction carcinoma(GEJ). Although pre-op imaging or gross examination of resections may not reveal any lesion, microscopic examination may show residual carcinoma. Presently, there is no uniform protocol among institutions for evaluating these specimens, but in our practice we submit the entire area of known tumor site in these cases. In this study, we question the utility of complete examination of known tumor site in cases with no residual gross lesion.

Design: We reviewed all resected DE and GEJ at our institution (2010-2016), and the following parameters were recorded: Age, gender, pathologic findings including gross lesions (mass or ulcer), pathologic T-stage, treatment response (TR), lymph node status (LN) and available pre-op PET scan. Cases were grossed as follows: lesional area was submitted entirely in cases with visible lesion, and the entire known tumor site (reported biopsy site) was submitted in cases with no residual gross lesion.

Results: 81 cases were identified (19 females, 61 males) with mean age 64 (35-83 years). Complete pathologic response was seen in 30% of cases. Pre-op PET scan was performed in 67 patients, and 11 patients with PET+/reduced showed complete histologic response (TR 0). 8 patients has residual mass, all of which showed TR 2-3 with 50% lymph node metastasis. 33 cases showed ulcer, out of which 42% showed complete response.

Gross lesion	Treatment response	Stage T1	Stage T2	Stage T3	LN+	PET +	PET reduce	PET -
No lesion	0 (n=10)	-	-	-	3	1	2	3
	1 (n=17)	11	3	3	3	4	4	5
	2 (n=9)	2	2	5	4	1	5	3
	3 (n=4)	1	1	2	1	1	0	2
Lesion	0 (n=14)	-	-	-	3	4	4	5
	1 (n=5)	3	1	1	0	2	0	2
	2 (n=15)	2	3	10	7	6	5	2
	3 (n=7)	0	1	6	5	3	0	3

Conclusions: 75% of patients with no gross had residual tumor (30% were TR 2-3 and 20% with lymph node involvement). PET scan may provide helpful information about treatment response, but it might be negative (10 patients were TR 2-3). Thorough sampling of cases with no gross lesions is necessary for proper staging of these cases, and submitting the entire known/reported tumor site would be optimum.

2185 Reproducibility of Variant Allele Frequency in Targeted Cancer Next-Generation Sequencing Assays

Anders Meyer[1], *Robyn Sussman*[2], *Ashkan Bigdeli*[2], *Jason Rosenbaum*[3]. [1]University of Pennsylvania, Philadelphia, PA, [2]University of Pennsylvania, [3]U Penn, Center for Personalized Diagnostics, Philadelphia, PA

Background: Adoption of clinical NGS diagnostics in oncology grows in scope and impact. Quantitation of variant allele frequencies (VAFs) becomes more important, as serial analyses are increasingly ordered. Reliable assessment of the performance characteristics is essential in distinguishing whether changes in VAF indicate outgrowth of a new clone or changing disease burden. We define the variance seen in NGS assays and identify potential performance cutoffs to support clinical decision making.

Design: VAF data were collected from a clinical NGS lab with three targeted amplicon-based oncology assays: a solid tumor and a hematologic malignancy panel (complete exonic sequences, 153-genes and 68 genes, respectively) and a reflex solid tumor panel (20 genes, "hotspots only"). 1228 samples were identified that had been sequenced more than once. VAF, read depth, and coefficient of variation (CV) of VAF were calculated for each combination of sample, panel and variant. Concordance among panels was evaluated orthogonally. For each combination, mean filtered allele frequency (VAF) and read depth were calculated as was CV.

CV was plotted against both VAF and read depth and single/multiple regressions performed. Data were analyzed in aggregate and subdivided by type of variant - single nucleotide changes (SNVs) or insertions/deletions (indels).

The K-nearest neighbor (KNN) classifier algorithm was selected as a non-parametric classifier method with inputs of variant and total read depth. Output was post-hoc calculated CV for each variant (binary of above vs. below 10%).

Results: Orthogonal VAF data (between assays) were highly concordant (slopes 0.99-1.0, R-squared 0.98-0.99), suggesting that mean VAFs approach the "true" value in the specimen. R-squared values from multiple regressions of VAF CV against mean VAF and read depth ranged from 0.2 to 0.4. SNV vs. indel categorization did not increase R-squared values. Visual inspection of the linear regression indicated that CV could be narrowed with lower-limit cutoffs on VAF and read depth. Results are shown in Table 1. Using the non-parametric K-nearest neighbors (KNN; 10-fold cross validation, K=5) classifier approach with a cutoff of VAF CV > 10% yielded similar but inferior results.

	VAF CV Mean	% Variants with CV > 10%	VAF CV SD	Mean Depth	Depth SD	Multiple regression R^2
Heme v1	2%	2%	3%	6455	9298	0.38
Heme v2	4%	10%	10%	4070	5459	0.23
Heme v3	4%	10%	10%	2766	2811	0.19
Solid v1	4%	12%	9%	3297	3963	0.26
Solid v2	8%	22%	12%	1868	2459	0.23
PPP	10%	32%	13%	5203	5174	0.22
	VAF cutoff	Depth cutoff				
Heme v1	0.05	50				
Heme v2	0.1	50				
Heme v3	0.05	500				
Solid v1	0.1	100				
Solid v2	0.2	200				
PPP	0.1	1000				
	Parametric			Non-Parametric		
	Remaining Mean VAF CV	% Remaining variants with predicted CV > 10%	% Variants predicted to have reportable VAF	Remaining Mean VAF CV	% Remaining variants with predicted CV > 10%	% Variants predicted to have reportable VAF
Heme v1	2%	2%	99%	2%	2%	99%
Heme v2	3%	5%	91%	2%	4%	87%
Heme v3	3%	5%	85%	2%	4%	87%
Solid v1	3%	6%	89%	3%	6%	85%
Solid v2	5%	7%	73%	3%	4%	49%
PPP	5%	9%	52%	3%	4%	36%

Conclusions: In NGS assays, VAF often correlates with disease burden or clonal evolution. We show mean VAF is highly reproducible between sequencing panels with overlapping targets, and lower-limit cut-offs of read depth and allele frequency can be determined for any assay.

2186 Effects of Improved DNA Quality by Punch from Tissue Block as Compared to Pinpoint Extraction from Unstained Slides on Next Generation Sequencing Quality Metrics

Diana Morlote[1], *Karen Janowski*[2], *Rance C Siniard*[3], *Rongjun Guo*[4], *Tom Winokur*[5], *Gina Coshatt*[2], *Shuko Harada*[5]. [1]University of Alabama at Birmingham, [2]University of Alabama at Birmingham, [3]University of North Carolina, [4]University of Alabama at Birmingham, Birmingham, AL, [5]Univ of Alabama at Birmingham, Birmingham, AL

Background: Next-generation sequencing (NGS) is being increasingly used to obtain clinically actionable sequencing data in the field of oncology. As a result, laboratories need to deliver high quality sequencing data that is both sensitive and specific. Formalin-Fixed Paraffin Embedded (FFPE) Tissue is the main source of testing material for solid tumors. The DNA integrity number (DIN) obtained using the Agilent 2200 TapeStation measures DNA sample degradation and integrity after extraction. We compared the DINs of gDNA extracted from FFPE tissue using the pinpoint method versus punching the tissue block directly and assessed the effect of the DIN on quality control (QC) metrics obtained from NGS assay using the Agilent Haloplex HS custom panel. Haloplex HS utilizes unique molecular barcodes, which eliminates duplication from single DNA by PCR and only analyze "unique" sequence reads.

Design: DNA was extracted from FFPE tissue using the pinpoint method (76 cases) and punching the tissue block directly (124 cases).

DIN obtained by TapeStation and QC metrics of NGS including percentage of unique reads on target and percentage of positions with more than 100 reads were compared. A t-test was used for statistical analysis between the two methods. Correlation analysis was used to assess trends in NGS QC metrics in relation to DIN.

Results: Tissue punches had a significantly higher mean DIN (6.18 ± 0.69) vs. pinpoint extracted tissue (5.08 ± 0.82) ($p<0.0001$). There was a positive correlation between DIN values and percentage of unique reads on target ($r=0.60$, $p<0.0001$) (Fig. 1) and between DIN values and percentage of positions with more than 100 reads ($r=0.62$, $p<0.0001$) (Fig. 2). Overall, sequence QC metrics tends to drop dramatically on the samples with DIN below 4.0.

Conclusions: Our study demonstrated that the samples obtained by punching the tissue block directly yielded a less degraded DNA (higher DIN) and subsequently higher NGS QC metrics than the commonly used method of pinpoint extraction from unstained slides. This is important because a higher DIN appears to lead to more reliable sequencing results.

2187 Increasing the Consistency of Sessile Serrated Adenoma Call a in Cohort of 7,054 Colorectal Polyps using Next Generation Quality with Funnel Plots and an Expert-Led Group Case Review

Asghar H Naqvi[1], *Sahar Al-Haddad*[2], *Jennifer Dmetrichuk*[3], *Michael Bonert*[4]. [1]McMaster University, Hamilton, ON, [2]Mississauga, ON, [3]Hamilton, Ontario, ON, [4]McMaster University

Background: Funnel plots (FPs) yield information similar to kappa-value based inter-rater comparisons, allow one to easily assess pathologist call rates (PCRs) in a large number of cases, and assess for possible diagnostic bias. Next Generation Quality (NGQ) is an iterative, data driven, continuous improvement process characterized by on-going measurement, intervention and re-assessment. Prior work suggests high inter-rater variability in the PCRs of SSA in relation to tubular adenoma (TA).

Design: All colorectal polyp specimens (CRPS) reports were analysed over a two year period (Sep '15-Aug '17) at one teaching institution. PCRs were extracted using a validated hierarchical free text string matching algorithm (HFTSMA) and visualized using funnel plots centered on the group median call rate (GMCR). After one year pathologists were informed of their baseline SSA call rate (CR) in relation to the group, and in Jan '17 there was a group case review/open discussion of ~40 sequential cases signed as SSA with a gastrointestinal pathology expert.

Results: The first and second year had 3656 CRPS/133 SSAs and 3398 CRPS/136 SSAs respectively. 400 reports/CRPS were randomly selected and audited and no categorization error for SSA was identified. The raw SSA PCR (for the 10 pathologists interpreting >250 CRPS) mean/median/stdev/min-max in the first and second year was 3.9%/3.7%/2.8%/0.0-7.9% and 4.1%/3.8%/2.4%/0.8-8.7% respectively. FPs for the first and second year showed 6/4 and 3/1 $P<0.05/P<0.001$ pathologist outliers respectively in relation to the GMCR for SSA. FPs for the first and second year for TA showed 0/0 and 0/0 $P<0.05/P<0.001$ pathologist outliers respectively in relation to the GMCR.

Conclusions: FPs are similar to control charts described in the context of NGQ. Observational data can be used to calculate PCRs and generate hypotheses about reproducibility. Targeted expert-led review may help pathologists calibrate their CR, and follow-up data allows reassessment. Variation in SSA CR still remains high in relation to TA, and on-going re-assessments are planned to determine the change durability/progress. Use of NGQ will be expanded to include a neighboring institution in the future, to assess whether it can be done on a larger scale.

2188 Mismatch Repair Analysis in the Era of Immunotherapy: An Institutional Experience

Nya D Nelson[1], *Emma Furth*[2], *Rashmi Tondon*[3], *Kristen Stashek*[4], *Stuti Shroff*[4]. [1]Hospital of the University of Pennsylvania, Philadelphia, PA, [2]Hospital of Univ. of PA, Philadelphia, PA, [3]Hospital of University of Pennsylvania, Philadelphia, PA, [4]University of Pennsylvania, Philadelphia, PA

Background: The recent accelerated FDA approval of pembrolizumab for site agnostic use in patients with unresectable or metastatic mismatch repair deficient (dMMR/MSI-H) solid tumors has intensified interest in identifying these cancers. Pembrolizumab shows a high response rate as well as durability of response in advanced cancer, and is currently being used as a last line treatment. This has resulted in increased requests for immunohistochemical testing (IHC) at our institution to evaluate for dMMR cancers. We present an analysis of MMR IHC requests and the application of those results for patients at our large cancer center.

Design: Cases were identified from a database search for clinician placed MMR IHC requests from 5/1/17 to 8/23/17. The same period during 2015 and 2016 was also evaluated. Chart review was performed for each patient to determine their primary diagnosis, location and presence of stage IV disease, whether they were being treated with pembrolizumab, and if so whether they had any immunotherapy related adverse events (irAEs). Patients with pulmonary non-small lung cancer, melanoma, primary colorectal cancer and those without stage IV disease were excluded from the study.

Results: Clinician requests for MMR testing on stage IV cancers increased 2-fold from 2016 to 2017, and almost 15-fold from 2015 to 2017. This increase in requests was accounted for by the larger variety of tumors including stage IV colorectal cancer (table 1). Of the tumors tested in 2017, 9% were found to be dMMR (5 of 59). Testing requests were most common in stage IV colorectal (36%), pancreatic (15%), gynecologic (14%), and liver (8%) primaries. dMMR cancer was found in liver (2 of 5), breast, gynecologic, and stomach (1 of 5 each) primaries. Three of those five patients are currently being treated with pembrolizumab, and two have shown no significant response. No significant (grade 3-5) irAEs have been reported.

Table 1. MMR IHC requests on stage IV cancers by primary site from May 1st to August 23rd.

	2017		2016		2015	
primary site	#	%	#	%	#	%
colorectal	21	36%	8	30%	4	100%
pancreas	9	15%	6	22%	0	0%
gynecologic	8	14%	0	0%	0	0%
liver	5	8%	4	15%	0	0%
breast	3	5%	0	0%	0	0%
esophagus	3	5%	2	7%	0	0%
peritoneum	2	3%	0	0%	0	0%
stomach	2	3%	3	11%	0	0%
IVC	1	2%	0	0%	0	0%
kidney	1	2%	0	0%	0	0%
prostate	1	2%	0	0%	0	0%
small bowel	1	2%	1	4%	0	0%
thyroid	1	2%	0	0%	0	0%
unknown	1	2%	2	7%	0	0%
anus	0	0%	1	4%	0	0%
total	59		27		4	

Conclusions: The recent accelerated approval of pembrolizumab for site agnostic stage IV dMMR cancers has resulted in a marked increase of MMR IHC testing at our institution. We anticipate that the number of requests will continue to increase for a wide variety of tumors. The testing results are being used to alter therapy for our patients, reflecting the hope of using this treatment for patients in whom all other treatment options have been exhausted.

2189 Concordance in the Cloud –"Simplicity MDT"- Use of a Novel Multidisciplinary Integrated Quality Assurance Software Tool for Breast Biopsy Risk Categorization, Correlation and Outcome Recording in over 5000 Patient Discussions

Grace Neville[1], *Suzanne Considine*[2], *Paul Walsh*[2], *Michael O'Meara*[3], *Linda Feeley*[4], *Tara Jane Browne*[5], *Fionnuala O'Connell*[5], *Michael Bennett*[6]. [1]Cork University Hospital, Cork, [2]NSILICO, Cork, Ireland, [3]University College Cork, [4]Cork, [5]Cork University Hospital, Cork, Ireland, [6]Cork University Hospital, Cork City

Background: Clinical-Radiologic-Pathologic correlation is the cornerstore of patient management following breast core biopsy. In order to optimize patient safety we developed and previously presented a cloud-based software application – "Simplicity MDT" - that assists in improving performance of the breast core MDTM including safety, administration, data recording and analysis. This screen-projected system includes a proforma enabling real-time documentation of data simultaneously visible to the entire team. The software facilitates recording of surgical, radiological and pathological risk categorisation of each lesion discussed, together with the diagnostic category and outcome. This system then stores, processes and presents the collected data for analysis facilitating governance, audit and research. Over 2 years of follow-up data are presented to demonstrate the utility of this software in data recording and MDT management.

Design: Utilising lean design the software was developed, validated and piloted in a large academic center (approximately 600 new breast cancer diagnoses per year). Specific safety features included screen-projection of data with concordance tracking by a "traffic light" system in real time with flagging of discordant cases, and automatic relisting for rediscussion. The system was integrated into use at weekly breast core biopsy MDTM and projected live. The data generated was automatically processed and presented by the system for review. Additionally all of the data collected was available for further analysis.

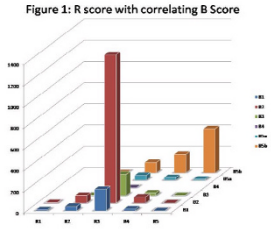
Results: Over 28 months, there were over 5000 discussions representing, 3507 individual patient in 114 MDTMs. As illustrated, high MDT discussion concordance is observed (table 1). 66.9%(n=2300), patients were discussed only once; only 28 patients

(0.81%) were discussed more than 5 times due to case complexity or multiple lesions. Trends around peak and trough activity periods were easily identifiable which can easily be utilized to facilitate decisions around resource management.

R Score and subsequent recorded outcome post MDTM discussion (n=3156 patients):

R Score	Discordant	Benign Concordant	Excise	Malignant Concordant
R1 (n=16)	12.5% (n=2)	87.5% (n=14)	(n=0)	(n=0)
R2 (n=182)	4.4% (n=8)	91.76% (n=167)	3.3% (n=6)	0.55% (n=1)
R3 (n=2197)	3.9% (n=86)	80.66% (n=1772)	8.74% (n=192)	6.69% (n=147)
R4 (n=305)	11.15% (n=34)	13.11% (n=40)	8.85% (n=27)	66.89% (n=204)
R5 (n=457)	0.66% (n=3)	0.66% (n=3)	0.22% (n=1)	98.25% (n=449)

Figure 1: R score with correlating B Score



Conclusions: "Simplicity MDT" facilitates live review of projected data and outcomes resulting in improved patient safety and automates easy retrieval of data for audit, service planning and research. Extension of the software to the complete patient pathway including oncological management may provide additional benefit.

2190 Preparing for the Challenges of AJCC 8th Edition - An Estimate of Effects on an Irish Cohort

Grace Neville[1], *Max Ramia*[2], *John Hogan*[2], *Cynthia Heffron*[3]. [1]Cork University Hospital, Cork, [2]Cork University Hospital, Ireland, [3]Cork University Hospital, Cork, Ireland

Background: Constant review and reconfiguration of tumour staging systems in response to emerging data is crucial to the refinement and improvement of healthcare provision. However, such changes can cause subtle, but noticable, differences in clinical workload. Patients with pT1b melanomas undergo longer clinical follow-up and are considered as candidates for sentinel lymph node biopsy in contrast to those with pT1a melanomas.

International published data at the transition between use of AJCC 6th edition and AJCC 7th edition suggested that the newer staging system may be responsible for an increased incidence of pT1b melanomas.

Now, at the cusp of introduction of the AJCC 8th edition, we examine a sample cohort to estimate the anticipated impact of the AJCC 8th edition on our service.

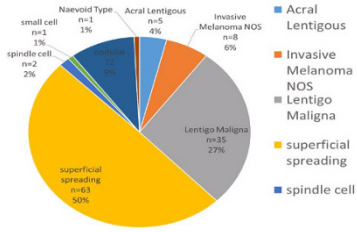
Design: All melanoma diagnoses from a single year (2014) were retrieved. Their datasets were reviewed. Cases were restaged as per the AJCC 6th, 7th and 8th editions.

Results: 127 cutaneous melanoma cases were diagnosed. 51.2% were in females (n=65). Mean age at diagnosis was 63.49 years (range 15.7 – 95.7 years). The most common sites of involvement included head and neck 32.3% (n=41), upper limb 22.8% (n=29) and lower limb 20.5% (n=26).

Of these, 56.7% (n=72) were pT1 tumors, 23.6% (n=30) were pT2, 14.2% (n=13) were pT3 and 14.2% (n=13) were pT4.

n=72	pT1a	pT1b
AJCC 6th Edition	75% (n=54)	25% (n=18)
AJCC 7th Edition	76.4% (n=55)	23.6% (n=17)
AJCC 8th Edition	80.6% (n=58)	19.4% (n=14)

Figure 1: Melanoma Subtype



Conclusions: The previously reported increase in pT1b melanoma diagnosis with introduction of the AJCC 7th edition was not seen in our cohort. The AJCC 8th edition appears to further reduce the likelihood of a pT1 melanoma being categorized as pT1b. The introduction of the AJCC 8th edition is anticipated to improve staging accuracy and may have positive effects on clinical workload with a 4.3% reduction in pT1b diagnoses in our cohort.

2191 Endoscopic Ultrasound Guided Micro-forceps: A Promising Modality for Assessing Pancreatic Cysts

Gregory Olsen[1], *Amy Collinsworth*[2], *Dennis Yang*[2], *Peter V Draganov*[2], *Ashwini Esnakula*[1], *Ashwin Akki*[3]. [1]University of Florida, Gainesville, FL, [2]University of Florida, [3]Bronx, NY

Background: Patients with pancreatic cystic lesions (PCLs) have an increased risk of adenocarcinoma. PCLs pose a diagnostic challenge due to their location and difficulty of access for sampling. The recent availability of novel endoscopic ultrasound guided through-the-needle biopsy micro-forceps (EUS-MF; Moray™ microforceps) is promising as it enables targeted biopsy of PCLs versus the widely used endoscopic ultrasound guided fine needle aspiration technique (EUS-FNA). Data on the diagnostic utility of EUS-MF for PCLs is sparse. We evaluate herein, the utility and diagnostic yield of EUS-MF (vs. EUS-FNA) for assessing PCLs.

Design: We retrospectively reviewed material from PCLs in 21 patients who simultaneously underwent EUS-MF and EUS-FNA over a 21-month period. Pancreatectomy slides were reviewed in patients who subsequently underwent resection. Correlation analysis was performed by Fischer's exact test.

Results: Mean patient age was 62.1 years (range 30-82 years; M - 6, F - 15). Average cyst size was 31 mm (range 15 – 51 mm). Eight cysts communicated with the main pancreatic duct on imaging. Cysts were located in the tail (n=10), body (n=5), and head (n=6) of the pancreas. Overall, the yield of diagnostic tissue was significantly higher in EUS-MF (10/21 cases, 48%) vs. EUS-FNA (3/21, 14%; P=0.043). EUS-MF but not EUS-FNA yielded mucinous epithelium diagnostic of intraductal papillary mucinous neoplasm (IPMN) or mucinous cystic neoplasm (MCN) in 5/21 (24%), serous epithelium in 1/21 (5%) and neuroendocrine tumor in 1/21 (5%) cases. In 3/21 (14%) cases, both EUS-MF and EUS-FNA, yielded diagnostic mucinous epithelium. Neither EUS-MF nor EUS-FNA yielded diagnostic tissue in 11/21 (52%) cases. Cyst fluid CEA levels were elevated (>200 ng/dL) in 4/8 mucinous neoplasms diagnosed by EUS-MF. Material obtained by EUS-MF was predictive of the diagnosis made at resection (IPMN or MCN) in 4/7 (57%) cases. No adverse events occurred during the procedures. Three patients (27%) with inconclusive diagnoses by either technique subsequently underwent resection that revealed an IPMN or MCN. Mean follow-up was 30 weeks (range 2–77 weeks). Overall, 2 (29%) surgical resections showed IPMN with high grade dysplasia but none progressed to adenocarcinoma.

Conclusions: Although adequate sampling remains a problem in the evaluation of PCLs, EUS-MF offers a significant improvement in diagnostic yield over EUS-FNA.

2192 The New Dutch Model for Reimbursement of Pathologists Based on Relative Value Units

Joost Oudejans[1], *Herbert Stel*[2], *James Boers*[3], *Robert Heinhuis*[4], *Roy Jurhill*[5], *Carine Peutz*[6], *Gijs Leeuwen*[7]. [1]Tergooi Hospital, Blaricum, Noord Holland, [2]Hilversum, NLD, [3]Isala Klinieken, Zwolle, [4]PAL Dordrecht, [5]Pathology Friesland, [6]MUMC, [7]Alphen Aan Den Rijn

Background: Value based healthcare requires adequate determination of all costs. Before 2015, this requirement was not met in the Netherlands, because surgical pathologists were reimbursed equally for all specimens, regardless of the complexity of the specimen. Therefore, the Dutch surgical pathologists decided to develop and implement a new reimbursement system that closely reflects the true workload and allows for adequate allocation of budgets.

Design: Based on previously published American and English systems, all histological and cytological samples were separated in 6 different categories reflecting increasing levels of complexity. The category is determined upon acceptance of the material and based on organ and type of procedure and independent from the number of studies ordered by the pathologist. The relative workload for each category was determined by measuring the mean number of all slides that is evaluated for each category, including all additional immuno stains. The ratios between these mean numbers of slides determined the relative levels of complexity between the 6 different categories.

Results: When expressed in minutes, the pathologist's workload was found to vary from 8 minutes for the lowest complexity category specimens (category 1) to 87 minutes for the highest complexity specimens (category 6). This review time includes evaluation of all immuno stains, reporting and extra clinical consultations. The total costs for each evaluated specimen are determined by each department accordingly. Reimbursement fees and costs for each specimen are included in the bundled payment system of the hospital.

The system was authorized by the Dutch health authority and implemented nationally in January 2015 and evaluated in 2017. As expected, pathology workload has shifted from departments with mainly low complexity pathology (like dermatology) to departments with high complexity pathology (like hematology and surgery). This resulted in relocating budgets for surgical pathology between clinical departments.

Conclusions: This new system allows for an adequate determining of all costs involved in surgical pathological evaluation of all specimens, which is crucial in adequate determining of bundled payment costs and is as such an important step towards a value based healthcare approach. Moreover, the system rewards a cost-efficient way of working and can be used to determine the number of FTE surgical pathologists required for each department.

2193 Cytology Specimen Collection Containers That May Cause Mucin-like Contamination

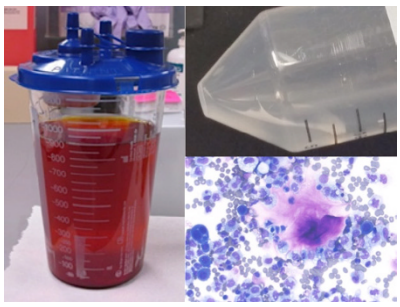
Liron Pantanowitz[1], *Katherine Clark*[2], *Jacqueline Cuda*[3], *Sara Monaco*[2]. [1]Wexford, PA, [2]University of Pittsburgh Medical Center, Pittsburgh, PA, [3]University of Pittsburgh Medical Center

Background: Specific containers used for specimen collection and/or disposal may contain material that resembles mucin. If this material unknowingly contaminates a cytology fluid specimen (e.g. peritoneal fluid) submitted for diagnosis, it could be misdiagnosed (e.g. pseudomyxoma peritonei). Our aim was to evaluate different containers that could be used for cytology fluid collection to determine if they produced this artifact in an effort to determine which containers should be excluded for diagnostic specimens and/or rejected.

Design: After discovering that a particular container used for cytology samples contained mucin-like material (Figure 1), a thorough investigation was conducted of all containers submitted to cytology. This included verifying the intended use of each container with our supply chain department, and using saline to prepare mock specimens from these containers to create ThinPrep and cytospin slides.

Results: Our investigation discovered that the manufacturer of the suction canister identified as causing the observed mucin-like contaminant had recently changed the components of their container lid. All saline samples from canisters with these new lids yielded contaminating mucin-like material grossly visible in the sample and microscopically. After reporting these results to the manufacturer, it was explained that this container was not intended for diagnostic specimens, but rather to be used for disposal of fluids and washings.

Figure 1. Mucin-like contaminating material from suction containers intended for disposal of fluids, not diagnosis.



Conclusions: Our root cause analysis identified the origin of a mucin-like contaminant to be produced by material within a specific suction canister. A list of acceptable containers for specimen collection was subsequently prepared and distributed to hospital personnel by our quality assurance team. We also improved the documentation of samples received in unapproved containers. The intended use of all containers submitted to the cytology lab should be determined before samples are processed in order to avoid artifacts such as contaminating material that may resemble mucin.

2194 Penile Cancer: Discrepancy Data Suggests an Extra Pair of Eyes Make a Difference

Rugvedita Parakh[1], *Funda Vakar-Lopez*[2], *Lawrence D. True*[3], *Maria Tretiakova*[2]. [1]Medina, WA, [2]University of Washington, Seattle, WA, [3]Seattle, WA

Background: Penile cancers are rare in the United States with less than 1% incidence of all cancers diagnosed in men. Majority of neoplastic tumors of the penis are squamous cell carcinomas (SCC) of several subtypes which have distinct anatomic, clinicopathological and molecular features defining their biological behavior. This study compares the second opinions provided at our institution with the original diagnoses for penile mass lesions.

Design: A total 57 cases of penile biopsies and penectomies were reviewed at our tertiary care center from 2010-2015. Out of these 16 were sent solely for p16 IHC staining and/or HPV genotyping. Discrepancies in the categories of diagnosis reclassification, change in grade, tumor extent and staging were analyzed. Changes in important parameters such as lympho-vascular invasion, perineural invasion and ulceration in the original report were also noted. True consult cases referred by the outside pathologist to corroborate their finding or gain more clarity were analyzed to find out the specific diagnostic challenges.

Results: Of the 41 cases, 14/30 (47%) cases reviewed as patient referral had discrepancy. Four (13%) of 30 cases were reclassified with a change in the diagnosis from precursor or pre-invasive lesions to invasive carcinoma in 2 cases and from neoplastic to non-neoplastic diagnosis in 2 cases. pTNM staging was changed in 3 (10%) cases; a change in lympho-vascular invasion in 2 (7%) and perineural invasion in 3 (10%). Change in grading was done in 2 (7%) cases and nomenclature improvements in 3 (10%) cases e.g. Epidermoid carcinoma to Squamous cell carcinoma. 8/11 (73%) true consult cases had similar diagnostic challenges including subtyping of penile tumors e.g. Verruocus carcinoma to SCC, Warty subtype or change in diagnosis from precursor or non-neoplastic lesion to neoplastic entity or vice versa. (Fig. 1).

Category	Slide review For Patient Referral	%	True Consult	%	Number of Cases	%
1- No disagreement	16	53%	3	27%	19	46%
2 - Disagreement	14	47%	8	73%	22	54%
Total	30	100%	11	100%	41	100%
Specific types of discrepancies						
Diagnosis reclassification	4	13%	7	64%	11	27%
Change from neoplastic to non-neoplastic	2	7%	1	9%	3	7%
Change from premalignant to malignant	2	7%	0	0%	2	5%
Change in staging	3	10%	1	9%	4	10%
Missed lymphovascular invasion	2	7%	0	0%	2	5%
Missed perineural invasion	3	10%	0	0%	3	7%
Change in grade	2	7%	1	9%	3	7%
Nomenclature improvement	3	10%	0	0%	3	7%

Conclusions: Our study showed substantial discrepancy rate in diagnoses of SCC and precursor lesions with frequent reclassification of the lesion (e.g. Invasive squamous cell carcinoma to pseudoepitheliomatous hyperplasia), omission of pertinent information, changes in grade and stage, thus potentially impacting patient management and clinical outcomes. Considering the rarity of penile neoplasms, potential psychological impact to the patient and challenge to the treating surgeon combined with a relatively high rate of discrepancies, we recommend that a second opinion should be sought in all the cases.

2195 Second Opinions in Testis: Discrepancy in Germ Cell Tumor Subtypes Raises a Question - How Much is too Much?

Rugvedita Parakh[1], *Funda Vakar-Lopez*[2], *Lawrence D. True*[3], *Maria Tretiakova*[2]. [1]Medina, WA, [2]University of Washington, Seattle, WA, [3]Seattle, WA

Background: Surgical specimens of the testis pose a challenge for accurate diagnosis due to their complexity, the histological resemblances of subtypes of the germ cell tumors (GCT) and the rarity of other entities. This study compares the interpretations made at a large tertiary center with the original diagnosis from the outside institutions.

Design: A retrospective study of 225 orchiectomy and testicular biopsies cases from 2010-2015 was done to identify diagnostic discrepancies in 156 slide reviews for patient referrals and 69

extramural pathologist to pathologist consultations (true consults) which had an established diagnosis in a final report and, therefore, were also analyzed. Discrepancy analysis included the following categories: the histologic type classification, percentage of the components of the mixed GCT, presence of germ cell neoplasia in situ (GCNIS), lymphovascular invasion and report improvement without change in the diagnosis in the neoplastic cases.

Results: The rate of disagreement between primary diagnosis and central review was 50%, and in many cases had multiple discrepancies (Fig. 1). The most common discrepancy was in the fraction of components in mixed GCTs - 25% (39/156), of which 4.5% (7/156) were major and 9% (14/156) were minor discrepancies. [A delta percentage change in subtype of > 20% was defined as major change and < 20% as minor change]. 8% (12/156) of cases missed at least one GCT component in the original report and 2% (3/156) of cases reported an additional component in the original report. GCNIS was not reported in 26% (41/156) of cases. The status of lympho-vascular invasion was changed in 4% (6/156) of cases. Overall, the histotype was changed in 6% (10/156) of cases. A similar trend in distribution of the discrepancies was observed in true consults except for non-neoplastic and non-GCT neoplasms with were reclassified at a higher rate (9% vs 1% in slide reviews).

Category	Subcategory	Slide review	%	True consult	%	Number of Cases	%
A- No Disagreement		78	50%	34	49%	112	50%
B - Disagreement		78	50%	35	51%	113	50%
Histotype reclassification 18/225 (8%)	Germ cell tumor (change from one pure form to another to a mixed GCT, or vice versa)	10	6%	1	1%	11	5%
	Non- neoplastic and non-GCT reclassification	1	1%	6	9%	7	3%
Mixed GCT Change in subtype percentage 58/225 (26%)	Mixed GCT: change in the subtype	39	25%	19	28%	58	26%
	Major change: more than 20% change in at least one component	7	4.5%	2	3%	9	4%
	Minor change: less than 20% change in at least one component	14	9%	2	3%	16	7%
	Additional GCT subtype in original report	3	2%	1	1%	4	2%
	Missed 1 GCT subtype in original report	12	8%	2	3%	14	6%
	Missed 2 GCT subtypes in original report	1	1%	0	0%	1	0%
Other categories with discrepancies	Missed reporting of GCNIS	41	26%	10	14%	51	23%
	Missed reporting lymphovascular invasion	6	4%	4	6%	10	4%
Grand Total		156	100%	69	100%	225	100%

Conclusions: The discordance in histopathologic interpretation of testicular specimens among the pathologists is substantial. GCT reporting and estimation of fraction of components in the mixed GCT had a wide variance, however the percentage thresholds affecting clinical management and patient prognosis are not well established. It is important to standardize thresholds for percentage of each GCT subtype. Immunostains or image recognition tools might help achieve this goal.

2196 Discrepancy in Adrenal Lesions: When in Doubt, Pathologists Didn't Commit

Rugvedita Parakh[1], *Funda Vakar-Lopez*[2], *Lawrence D. True*[3], *Maria Tretiakova*[2]. [1]Medina, WA, [2]University of Washington, Seattle, WA, [3]Seattle, WA

Background: Disorders of adrenal are associated with a complex array of clinical syndromes requiring a thorough scrutiny of morphologic, biochemical & molecular parameters to ascertain a neoplastic entity from various non-neoplastic diseases. Owing to advances in imaging studies, adrenal neoplasms are being detected at an earlier stage & smaller size. Up to 5% of abdominal CT studies result in detection of incidental adrenal lesions of varying sizes, & a significant subset of these lesions are subjected to biopsy frequently posing considerable diagnostic difficulties. This puts an increasing demand for more accurate diagnosis & pathologic indicators of prognosis. This study compares the discrepancy between the pathology reports from our institute to outside diagnosis from the community hospitals to identify areas for perspective improvement in adrenal gland diagnoses.

Design: A retrospective analysis of 69 adrenal biopsies & adrenalectomies from 2010-2015 was performed to understand the discrepancies between the original diagnosis and second opinions. Request from outside pathologist for clarification constituted 18/69 cases. Discrepancy was analyzed according the diagnostic reclassification, changes in the staging, margin status and missed lympho-vascular invasion & report improvement by adding a clinically useful comment.

Results: Overall discrepancy rate was 17%. Most common challenge encountered by extramural pathologists as well as for the cases reviewed for in-house consultation service was diagnosing adrenal cortical neoplasms into its subcategories or differentiating it from close histological mimics (12%). The 2nd discrepancy was noted in prognostic parameters e.g. changes in staging, margin status & missed lympho-vascular invasion (4%) with 1 case in each category. Diagnostic clarification was provided in 1 case. (Fig.1).

Category	True Consult	Discrepancy (Original to final)	Slide review	Discrepancy (Original to final)	Total Cases
Total	18 (100%)		51 (100%)		69 (100%)
1- No discrepancy	12 (67%)		45 (88%)		57 (83%)
2 - Discrepancy	6 (33%)		6 (12%)		12 (17%)
Diagnostic reclassification	6 (33%)	Malignant cortical neoplasm to borderline	2 (4%)	Granulocytic neoplasm to eosinophilic epithelioid neoplasm with comment	8 (12%)
		Neoplastic proliferation to cortical carcinoma		Oncocytic neoplasm of adrenal cortical origin to cortical carcinoma low grade	
		Nonneoplastic to cortical adenoma			
		Pheochromocytoma to cortical adenoma			
		Pheochromocytoma versus cortical carcinoma to cortical carcinoma			
		Adrenal tumor to cortical carcinoma			
Missed pertinent information	0 (0%)		3 (6%)	Change in margin status	3 (4%)
				Change in staging pT2 to pT3	
				Missed lymphovascular invasion	
Diagnostic clarification	0 (0%)		1 (2%)	Metastatic carcinoma consistent with lung primary to Malignant epithelial neoplasm with comment suggesting other possibilities besides lung	1 (1%)

Conclusions: Rate of discrepancy in adrenal diagnoses was relatively low, especially in comparison to similar studies in genitourinary organs where it was 2-3 times higher. Our study indicates that distinction between benign & malignant adrenal cortical &/or medullary neoplasms remains problematic. The earlier imaging studies with newer treatment modalities e.g. embolization require for an update in Weiss criteria & its consistent application. e.g. distinguishing tumor necrosis used in Weiss criteria from pseudo-necrosis because of treatment. Lack of clinical, radiologic findings, endocrine manifestations & incomplete gross descriptions all impact accurate diagnosis.

2197 Substantial Detection of Plasma Cells by MUM-1 Immunohistochemistry in Endometrium, a Significant Quality Improvement in Diagnosis of Chronic Endometritis

Robyn N Parks[1], *Christopher Kim*[2], *Neda A Moatamed*[3]. [1]David Geffen School of Medicine at UCLA, [2]Marin Medical Laboratories, [3]David Geffen School of Medicine at UCLA, Los Angeles, CA

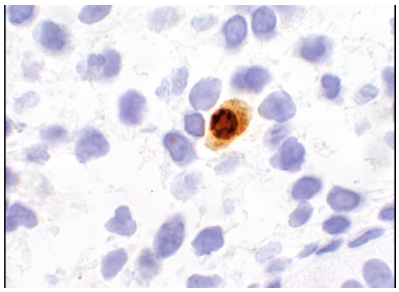
Background: Chronic endometritis is characterized by plasma cell infiltration in the endometrial stroma. It is associated with abnormal bleeding and can lead to infertility. Identification of plasma cells can be challenging by routine hematoxylin and eosin (H&E) stains as they are often obscured by stromal cells and other inflammatory infiltrates. Multiple myeloma oncogene 1 (MUM-1) and CD138 which are widely used as immunohistochemical (IHC) stains in hematopoietic disorders and are markers of plasma cells. Here, we present that MUM-1 is superior to H&E and CD138.

Design: A retrospective study consisting of a total of 318 endometrial biopsies with a clinical request for "rule out chronic endometritis" was performed. All cases had sections stained by H&E and MUM-1 (Table 1). Ninety-nine of them were also stained by CD138 (Table 2). MUM-1 was recorded positive if nuclear and cytoplasmic staining was seen in a plasmacytoid cell. The positive MUM-1 stain also showed the clock-face nuclear pattern of the cells with a clean background (Figure 1). CD138 was recorded positive if the plasmacytoid cells had a membranous staining pattern.

Results: Plasma cells were detected by H&E in 16% (55/318) of the endometrial biopsies. They were detected in 48% (154/318) of cases by MUM-1 (Table 1). When performed, CD138 detected plasma cells in 30% (30/99) of cases. In addition, all slides with CD138 showed a non-specific background staining when compared with MUM-1. The rates of detection for H&E, MUM-1 and CD138 are shown in Table 2 in which MUM-1 detected more plasma cells than H&E and CD138 with statistical significance.

Table 1. Rate of detection of plasma cells in H&E and MUM-1 stained tissues				
Median Age = 36	**H&E**		MUM-1	
Total (n): 318	n	%	n	%
Positive	52	16%	154	48%
Negative	266		164	
Assumed Positivity of PCs		34%		100%
PC, plasma cell				
Two-Tailed, Paired T.Test	H&E vs MUM-1			
p-Value	**<0.001**			

Table 2. Rate of detection of plasma cells in H&E, MUM-1, and CD138 stained tissues						
Median Age = 36	H&E		MUM-1		CD138	
Total (n): 99	n	%	n	%	n	%
Positive	13	13%	36	36%	30	30%
Negative	86		63		69	
Assumed Positivity of PCs		36%		100%		83%
PC, plasma cell						
Two-Tailed, Paired T.Test	H&E vs MUM-1		H&E vs CD138		MUM-1 vs CD138	
***p*-Value**	**<0.001**		<0.001		0.03	



Conclusions: If MUM-1 is accepted as the gold-standard with an assumed detection rate of 100%, comparatively, H&E detects less than 40% and CD138 detects less than 85% of the plasma cells. Adding a MUM-1 immunohistochemical stain to endometrial biopsies is a significant quality improvement in detecting plasma cells in chronic endometritis leading to a superior diagnosis.

2198 Three-Month Trial and Look-Back for New Protocol of Same Day Breast Specimen Prosection: Can We Do Better?

Garrison Pease[1], *Jon Ritter*[2]. [1]WashU/BJC, Saint Louis, MO, [2]Washington University School of Medicine, Saint Louis, MO

Background: CAP's 2015 Q-Probe study revealed that 84% of responding institutions require overnight fixation for all breast specimens, and that 21.1% of hospitals have cut-off time of 2PM or earlier for specimen of any type to be grossed the same day. The Q-probe reports overall turnaround time (TAT) of large and complex specimens as 2.72 calendar days (50th percentile). At our institution, the protocol for grossing large breast specimens, defined as lumpectomies and mastectomies, calls for overnight fixation with prosection and submission to histology the following day. The exception is Friday, when all specimens are grossed the same day. With growing expectations from clinician and patient for expedient results for use in multi-disciplinary patient care conferences and follow-up visits, we analyzed our approach to breast specimens, with regard to day of prosection and overall TAT.

Design: For large breast specimens triaged prior to 2PM Monday through Thursday, prosectors were encouraged to gross and submit to histology the same day. For analysis, specimens were regarded under two main designations, triaged before 2PM and grossed same day (group A) or triaged before 2PM and grossed the next day (group B). These two groups were compared to each other and to the overall total (group A and B and those specimens triaged after 2PM) large breast specimens, with total TAT as primary end-point.

Results: Of 251 large breast specimens, 160 were triaged before 2PM, and 22 were prosected the same day. Groups A (n=22) and B (n=138) were similar in proportion with regard to lumpectomies (41% vs. 38%) and mastectomies (59% vs. 62%), and rate of case delays, such as additional blocks submitted and/or special stains/deeper levels (32% vs. 21%, p = 0.261). The two groups averaged essentially the same number of blocks per specimen (15 vs. 17). When compared to all large breast specimens (38% lumpectomies, 17 blocks, 19% delayed case), the similarities prevailed.

The overall TAT for group A was shorter than group B (3.25 vs. 5.29 days, p << 0.05) and shorter than all large breast specimens combined (4.96 days, p << 0.05).

Conclusions: With a small-scaled three month trial of Monday through Thursday same day specimen processing at our institution, we demonstrated a statistically significant improvement in TAT compared to our baseline protocol. TAT, and therefore patient care, can be expedited consistently with a large-scale introduction of new protocol to submit more large breast specimens the same day.

2199 Single Institution Study of HPV Test Utilization, Results, and Follow-up Management in Cervical Cancer Screening.

Joseph Peevey[1], *Holly Lose*[2], *Timothy Blanke*[2], *Jamie M. Slade*[3], *Haijun (Steve) Zhou*[4], *Kruti Maniar*[3], *Ritu Nayar*[4]. [1]Northwestern Memorial Hospital, Chicago, IL, [2]Northwestern University, [3]Chicago, IL, [4]Northwestern University, Chicago, IL

Background: Screening and management guidelines for the prevention of cervical cancer has evolved significantly within the past decade. The multiple screening and management options have proven to be confusing for both clinicians and patients. Cytology, high risk (hr) HPV testing, cotesting and partial genotyping are screening options for various age groups. Our hospital based laboratory serves academic and private practice physicians in a diverse low risk patient population. We provide clinicians with educational sessions and practice specific data. We utilize ThinPrep for cytology, Roche cobas for hrHPV testing and provide an integrated cytology and HPV report with genotyping data on all cases with cotesting and reflex HPV testing. Our study aim is to evaluate cervical cancer screening ordering patterns and follow-up in our institution with the goal of assessing outcomes and compliance in accordance with current screening and management guidelines.

Design: We collected pertinent information on age, test(s) ordered, Bethesda interpretation, and clinical management including follow-up date and surgical pathology diagnosis (if applicable) on all cervical cytology with HPV+ results in 2016.

Results: Our 2016 cervical cytology volume was 24,491 with 68% being ordered as co-tests; (96.5% in women 30-65 yrs), 28% as Cytology with Reflex for ASC-US (52.5% age 21-29 yrs; 47.4% age 30+ yrs), and 4% as Cytology only. Primary HPV screening with reflex cytology was ordered in <1% of patients. A total of 1,960 Paps had a hrHPV+ test. (Table 1) displays genotyping data for hrHPV+ cases. Among all hrHPV+ women, 729 had follow-up colposcopy. Approximately 65% of women with HPV 16/18 or multiple types and 30% with "other" HPV types underwent colposcopy. 1357 cytology negative women were hrHPV+; 327 of whom underwent colposcopic biopsy, including 229 with non 16/18 HPV types. (Table 2) displays the relationship of HPV genotype with surgical pathology follow-up and diagnosis.

Table 1: HPV Positive cases with HPV Type and Bethesda Category Results

	Unsat	NIL	ASC (ASCH+AS-CUS)	LSIL + LSIL+ASCH	HSIL +	AGC/AIS	TOTAL
HPV 16	1 (0.1%)	112 (5.7%)	41 (2.1%)	24 (1.2%)	24 (1.2%)	6 (0.3%)	220 (11.2%)
HPV 18	0	44 (2.2%)	18 (1%)	17 (0.9%)	0	2 (0.1%)	81 (4.1%)
OTHER HR	16 (0.8%)	1148 (58.6%)	133 (6.8%)	213 (10.9%)	22 (1.2%)	4 (0.2%)	1537 (78.4%)
MULTI-PLE	2 (0.1%)	34 (1.7%)	30 (1.5%)	45 (2.3%)	7 (0.4%)	4 (0.2%)	122 (6.2%)

Table 2: Genotypes with Percentage of HPV+ cases with Surgical Pathology Follow-Up and Surgical Pathology Diagnosis.

	Percent-age with Surgical Pathology Follow-Up	NEG	LSIL	HSIL	CARCINO-MA	TOTAL
HPV 16	141 (65.5%)	48 (6.7%)	51 (7%)	41 (5.6%)	1 (0.2%)	141 (19.3%)
HPV 18	47 (59.2%)	27 (3.70%)	19 (2.6%)	1 (0.2%)	0%	47 (6.4%)
OTHER HR	460 (30.1%)	197 (27%)	211 (45.9%)	51 (7%)	1 (0.2%)	460 (63.1%)
MULTI-PLE	81 (66.4%)	19 (2.6%)	43 (5.8%)	18 (2.5%)	1 (0.2%)	81 (11.1%)

Conclusions: Our results show reasonable compliance with current age specific screening guidelines. The Primary HPV option has not been adopted by our clients. The majority (78.4%) of our hrHPV positive tests were non 16/18 genotypes. Interestingly, we had more cytology HSIL and biopsy follow-up HSIL+ for "other" HPV types than HPV 16/18+. Additionally, a large number of non 16/18+ women were sent to colposcopy, including those with negative cytology, which is inconsistent with the current follow up recommendation of cotesting in 12 months.

2200 Monitoring Error in Histopathology – A Multi-Institutional Audit of Addendum Reports

Sine Phelan[1], *Daniela Catargiu*[2], *Sarah Mahon*[3], *Niall Swan*[4], *Stephen Crowther*[5], *Philip Ryan*[6], *J. Conor O'Keane*[7], *Kieran Sheahan*[8], *Julie McCarthy*[9], *Ann Treacy*[10]. [1]University Hospital Galway, Galway, Ireland, [2]Galway, [3]Dublin 16, [4]St. Vincent's University Hosp, Elm Park, Dublin, Ireland, [5]AMNCH, [6]Royal College of Physicians of Ireland, Dublin [7]Mater Misericordiae Hospital, Dublin, Ireland, [8]St. Vincent Hospital, Dublin, [9]Cork University Hospital, Cork, Ireland, [10]Dublin, Ireland

Background: Identification and review of error is an essential Quality Improvement (QI) activity and is an integral component of the Irish National QI programme in Histopathology. Participating laboratories apply one of 3 codes to all addendum reports, thereby sub-classifying them into:- (i) corrected report(transcription or identification error, without a change to the diagnostic information) (ii) amended report (a change to the pathologic interpretation occurs that may give rise to a change in treatment/prognosis) (ii) supplementary report (new information becomes available). Previous studies have suggested that error rates tend to be underestimated, through inaccurate categorisation. Our aim was to assess the accuracy of addendum report coding in capturing error.

Design: All addendum reports from three participating laboratories for a 6 month period from July-December 2015 were retrieved. All amended and corrected reports and a random sample (20%) of supplementary reports were reviewed by the QI lead pathologist in each laboratory (SP, NS, SC).

Results: A total of 2,724 addendum reports were issued. The use of supplementary reports ranged from 3 -7.7%. The rate of amended reports ranged from 0.04%-0.26%. The rate of corrected reports ranged from 0.1-0.3% (Table 1)

Of a total of 65 amended reports, 7 (10.7%) were revised to corrected and 3(4%) to supplementary reports. Of 144 corrected reports, 11 (8%) were revised to amended and 7(5%) to supplementary reports. 554 supplementary reports were reviewed, 21(3.8%) of which were revised to amended and 12(2%) of which were revised to corrected. The total number of amended reports increased from 65 to 84 on review. The majority of supplementary reports (70%) were issued following immunohistochemistry/special stains. Other reasons included outside review, molecular studies and multi-disciplinary team discussion.

Laboratory	Supplementary	Amended	Corrected
1	385 (3%)	12 (0.09%)	15 (0.1%)
2	939 (5%)	8 (0.04%)	57 (0.3%)
3	1221 (7.7%)	45 (0.26%)	42 (0.26%)
Total	2545	65	114

Conclusions: Supplementary reports were miscoded in 5% of cases, reflecting a potential masking of diagnostic error. The total number of amended reports increased from 65 to 84 on review. Regular audit of addendum reports is necessary to ensure accurate capture of error rates.

2201 Effectiveness of the Adoption of Safety-II Redundant Practices in Surgical Pathology to Reduce Diagnostic Discrepancies and Harm

Stephen Raab[1], *Kim Geisinger*[2]. [1]Jackson, MS, [2]University of Mississippi Medical Center, Jackson, MS

Background: For the past two decades, the frequency of surgical pathology diagnostic error and associated severe harm has remained stable at approximately 20% and 5%, respectively. Safety-I or error control and prevention has been ineffective in decreasing error, largely because of the high level of complexity in diagnostic testing. We used a Safety-II approach, or enhancing what pathologists already do well, to redesign the diagnostic system and studied the effectiveness of Safety-II process change on error and harm frequency.

Design: We performed ethnographic studies of daily practice to assess the processes that pathologists adopted at times of uncertainty. We facilitated pathologists to formally adopt, adapt, and standardize one of these processes, the curbside consultation, and developed a pre-signout, pathology digital imaging (PDI) role-specific rapid (<30 second) redundant quality review with formal consensus activities for high risk discrepancies. We measured post-implementation frequencies of discrepant and potential harm events for biopsy specimens (n=1560) and new workflow timing data. We developed a computational database to analyze system and pairwise levels of agreement by multiple subcategories, diagnostic certainty, and use of other Safety-II processes (e.g., image comparison, ancillary testing).

Results: We found an overall case discrepant frequency of 48.9%. The consensus diagnosis favored the primary, secondary, or neither pathologist in 45%, 42%, and 13%, respectively. Through a process of dyad consensus making, overall and severe harm was prevented in 20.3% and 4.1% of patients, respectively. Based on the frequency of the primary review being different from the final diagnosis, overall and severe harm was prevented in 11.2% and 2.3% of patients, respectively. We found that PDI rapid review required a mean total of 6.6 hours per day (for 1 review and 4 primary pathologists).

Conclusions: We conclude that the explicit adoption of Safety-II pre-signout redundancy markedly decreased the frequency of discrepant events and immediately converted potential harm into no harm events. As weaknesses in pattern recognition processes remain unchecked in solitary pathologist signout models, Safety-II dyad redundancy with consensus creates a culturally safe no-blame system that prevents errors secondary to cognitive failures (e.g., bias, memory gaps) and specimen artifacts. Challenges in implementation reside in cultural practice models and the lack of information technology support systems.

2202 Impact of Laboratory Developed Test for PD-L1 Testing on Healthcare Costs and Turnaround Time: The Johns Hopkins Experience

Ankit Rajgariah[1], *Derek Allison*[2], *Rajni Sharma*[3], *Timothy Amukele*[4], *Peter Illei*[5]. [1]Johns Hopkins, Baltimore, MD, [2]Johns Hopkins University, Baltimore, MD, [3]Johns Hopkins Medical Institutions, Baltimore, MD, [4]Johns Hopkins Medical Institutions, [5]Johns Hopkins University School of Medicine, Baltimore, MD

Background: As new indications for PD-1/PD-L1 based immunotherapy cause an increase in requests for PD-L1 IHC, having a cost-efficient and time-sensitive method of testing is paramount. The current FDA-approved test is expensive and requires specific equipment that most laboratories lack and therefore were forced to send specimens to reference laboratories at higher costs and longer turnaround times (TAT). We have sought to determine the cost savings and impact on TAT for referral versus in-house testing for PD-L1.

Design: We sent our PD-L1 cases to a reference laboratory for approximately 7-month period. We also developed an in-house assay using the FDA approved PD-L1 kit and a laboratory developed test (LDT) using the 22C3 antibody and an automated platform. Costs and TAT were compared. Costs included in the analysis were for cutting slides, shipping, staining and labor when applicable. TAT was defined as the time from ordering the test to the time the result was posted to the electronic health record.

Results: The cases included both surgical and cytopathology specimens, and most cases were diagnosed as either adenocarcinoma or squamous cell carcinoma of the lung. We used formalin fixed paraffin embedded tissue sections for all cytology samples that included cell blocks, tissue clots and core biopsies. Validation costs for the FDA- approved kit were $5000.00 and $1500.00 for the LDT. The validation slides included adequate control tissues and cases that were tested by the reference laboratory. There was an over 95% concordance between the three assays. The mean cost per case was $383.16 for the referral cases, $115.50 for the in-house FDA-approved kit and $40.50 for the in-house LDT.The mean TAT per referral test was 16.4 days versus 6.0 days for in-house cases ($p<0.01$).

Conclusions: Costs of PD-L1 IHC are significantly higher when performed by a reference laboratory. In-house assays are cheaper but require extensive validation and training in interpretation. Another advantage of in-house PD-L1 testing is the significantly reduced TAT, and, as a result, improve our delivery of high value care. At this time, further investigation regarding testing cytopathology cases is warranted.

2203 Rapid Prescreening as a Quality Assurance Tool Performs Better at Detecting the Higher Grade Abnormalities on Pap Tests - BD FocalPoint Profiler (FP) Provides Additional Benefit

Marc Ranson[1], *Karen Cormier*[2], *Brandy Callahan*[3], *Gabor Fischer*[4]. [1]University of Manitoba, [2]Diagnostic Services Manitoba, [3]Diagnostic Services Manitoba, Winnipeg, MB, [4]Diagnostic Services Manitoba / University of Manitoba, Winnipeg, MB

Background: Random 10% rescreening can be replaced by alternative methods (rapid prescreening – RPS or rapid rescreening – RRS) as a quality assurance (QA) method for gynecologic cytology. We have introduced RPS as a QA tool in our laboratories and investigated how this approach performs at flagging different subtypes of squamous

and glandular abnormalities. We have also analyzed whether BD FocalPoint profiler (FP) has any benefit as an additional QA process in flagging any particular subtype of atypias.

Design: BD SurePath Pap tests went through RPS after being analyzed by FP prior to screening. Potentially atypical slides detected by RPS and all slides flagged by FP were submitted for QC review to be rescreened by cytotechnologists. The rest of the cases went through routine screening. Both the flagged and non-flagged cases by each method were compared to the final diagnostic interpretation to see whether the atypia was confirmed or not.

Results: 244 out of the 2143 Pap tests (11.4%) showed atypia (ASC-US+ or AGC+) on the final interpretation. While RPS flagged 57.5% of the cases with ASC-US (50/87), it picked up 80.9% (38/47) of the cases with HSILs and 76.2% of LSILs (77/101). Both ASC-H cases were flagged by RPS (2/2, 100%). The total number of glandular lesions were low (0.3%), but it showed a similar detection pattern: 100% of adenocarcinomas were flagged by RPS (3/3) as opposed to 25% of AGCs (1/4). The overall detection rate of all atypias was lower by FP than RPS (39.8% vs. 70.1%), however adding the FP as an additional step improved the overall detection rate of all atypias to 76.2%, ASC-US to 67.8%, LSIL to 79.2%, and HSIL to 83%.

Conclusions: The efficiency of RPS as a QA method seems to increase with the degree of atypia; the higher the grade of the abnormality on the Pap test, the better the chance of being detected by RPS. FP shows a similar detection pattern and overall it seems to provide some additional benefit to the QA process when performed in conjunction with RPS regardless of the degree of atypia.

2204 Can Eliminating Atrophic Paps Safely Reduce the Number of Unsatisfactory Pap Results?

Heidi L Reinhard[1], *Nicole C Williams*[1], *Catherine Abendroth*[1]. Penn State Milton S. Hershey Medical Center, Hershey, PA

Background: Recent evidence suggests that high risk human papilloma virus (HR-HPV) testing may supplant the Pap test as the primary cervical cancer screening test. It has been suggested[1] that the negative predictive value of HR-HPV testing may be compromised when DNA copy number is low due to scant cellularity; therefore Paps that are unsatisfactory due to insufficient cellularity can cause management dilemmas. The Bethesda System allows atrophic Paps to be called adequate. Furthermore, post-menopausal women may have fewer risk factors than the general population. As a quality improvement project, we sought to determine if eliminating atrophic Paps from the unsatisfactory group could safely reduce the total number of these problematic cases.

[1] Jastania R, Geddie W, Chapman W, Boerner S: *Characteristics of Apparently False-Negative Digene Hybrid Capture*

Design: Paps with corresponding HR-HPV test between 1/1/16-12/31/16 were identified from our pathology information system. Slides from those that were unsatisfactory due to insufficient cellularity were reviewed for features of atrophy. Adequacy, presence/absence of epithelial cell abnormality (ASC-US+) and atrophic versus non-atrophic was correlated with HR-HPV result.

Results: There were a total of 6087 Paps with corresponding HR-HPV test. The overall HR-HPV positivity rate for satisfactory Paps was 12.1%: 40.8% for abnormal Paps, 9.9% for negative Paps, and 6.9% for unsatisfactory Paps. Of unsatisfactory Paps, 19% were atrophic and 81% were non-atrophic, with HR-HPV+ rates of 2.4% and 7.9% respectively. The overall HR-HPV+ rate in atrophic Paps with satisfactory cellularity was 5.0%.

Cytology- 2016		# of Cases
Total		6087
	HPV positive	725 (11.9%)
	HPV negative	5362 (88.1%)
Satisfactory- (Negative and Positive)		5869
	HPV positive	710 (12.1%)
	HPV negative	5159 (87.9%)
Abnormal Paps (ASCUS+)		414
	HPV positive	169 (40.8%)
	HPV negative	245 (59.2%)
Negative Paps		5455
	HPV positive	541 (9.9%)
	HPV negative	4914 (90.1%)
Unsatisfactory		218
	HPV positive	15 (6.9%)
	HPV negative	203 (93.1%)
Unsat Non-Atrophic		177
	HPV positive	14 (7.9%)
	HPV negative	163 (92.1%)
Unsat Atrophic		41
	HPV positive	1 (2.4%)
	HPV negative	40 (97.6%)
Satisfactory Atrophic		540
	HPV positive	27 (5.0%)
	HPV negative	513 (95.0%)
Atrophy - Negative		529
	HPV positive	22 (4.2%)
	HPV negative	507 (93.8%)
Atrophy - Abnormal (ASCUS+)		11
	HPV positive	5 (45.5%)
	HPV negative	6 (54.5%)

Conclusions: In this QI study, the HR-HPV+ rate of unsatisfactory Paps was about half that of the total population, lending credence to the concern of false negative HR-HPV due to low DNA copy numbers in these specimens. The HR-HPV+ rate of unsatisfactory but atrophic Paps was markedly less than that of non-atrophic unsatisfactory Paps, perhaps reflective of fewer risk factors in this largely postmenopausal population. This is supported by a similarly lower HR-HPV+ rate in atrophic versus non-atrophic satisfactory Paps. Nearly one-fifth of our cases read as unsatisfactory could have been interpreted as atrophic but adequate; significantly reducing the number of problematic unsatisfactory results.

2205 Retrospective Review of Lung Fine Needle Aspiration Telepathology Results for Quality Assurance Metric in Our Institution

Shira Ronen[1], *Tamar Giorgadze*[2], *Juan C Felix*[3], *Lauren Parsons*[4], *Bryan Hunt*[1]. [1]Medical College of Wisconsin, Milwaukee, WI, [2]Medical College of Wisconsin, Milwaukee, WI, [3]Medical College of Wisconsin, [4]Children's Hospital of Wisconsin/MCW, Milwaukee, WI

Background: Rapid on-site evaluation (ROSE) results of endobronchial ultrasound-guided fine-needle aspiration (EBUS-FNA) help achieve higher adequacy rates and fewer unnecessary passes. However, the time required by cytopathologists to be present for on-site assessments is significant and affects other clinical responsibilities. Therefore, telepathology (TeleP) was implemented in our institution to serve as a time saving tool. In this study, we compared our ROSE results of EBUS-FNA via TeleP to the final cytology diagnosis and corresponding surgical pathology as a cytology quality assurance metric.

Design: Two hundred and one EBUS-FNA specimens that were initially diagnosed by TeleP over the past 2 years were reviewed. These results were compared with the final cytology results and the concurrent surgical pathology results. Discordant cases were defined as a difference between these results and these cases were reviewed by two cytopathologists.

Results: There were 68 lung specimens and 133 lymph node specimens. A 97% (195/201) correlation between the TeleP ROSE and final cytology diagnosis was observed. A total of 6 out of 201 cases (3%) with discrepant results were identified and are listed in Table 1. All 6 discrepant cases were called inadequate by TeleP; 4 cases were finalized with positive or atypical results and 2 cases were finalized as negative. The discrepant cases can be explained by sampling error since during TeleP, only the Diff-Quick stained slides are examined. Correlation with surgical pathology samples was possible in 67 of our cases and only 1 case (1.5%) was discrepant and is explained by sampling error where rare granulomas were seen only in the final surgical specimen and not in the cytology specimen.

EBUS-FNA Site	ROSE via TeleP	Final Cytology Diagnosis	Surgical Pathology Diagnosis	Reason for Discrepancy
Lung	Inadequate	Atypical - Rare atypical cells	Metastatic carcinoma, consistent with prostatic origin	Diagnostic material was present only in the cell block slides
Bronchial brushing	Inadequate	Positive for malignancy -non-small cell carcinoma, favor adenocarcinoma	Not applicable	Diagnostic material was present only in the Papanicolaou-stained slides
Lung	Inadequate	Positive for malignancy- consistent with metastatic renal cell carcinoma	Not applicable	Only one slide had the atypical cells
Endobronchial lesion	Inadequate	Positive for malignancy - Non-small cell carcinoma	Non-small cell carcinoma, favor squamous cell carcinoma	Diagnostic material was present only in the ThinPrep and cell block slides
Lymph node - station 11	Inadequate	Adequate - Negative for malignancy	Not applicable	Lymphocytes were present only in the cell block slides
Lymph node - station 7	Inadequate	Adequate - Negative for malignancy	Not applicable	Lymphocytes were present only in the cell block slides

Conclusions: From our experience, TeleP accurately determined adequacy of EBUS-FNA samples and aids in real-time patient management in 97% of cases while optimizing the time efficiency of the cytopathologist. The few discrepant diagnoses identified were a result of sampling and did not affect patient management.

2206 Quality Control Practices for Chemistry and Immunochemistry in a Cohort of 21 Large Academic Medical Centers

Matthew Rosenbaum[1], *James G Flood*[1], *Kent B Lewandrowski*[1]. [1]Massachusetts General Hospital, Boston, MA

Background: Quality control (QC) of analytical processes is a critical component of laboratory quality management. Understanding the principles of quality control is an essential skill for clinical pathologists. Beyond meeting the required standard of CLIA-88, individual laboratories have considerable latitude to determine their overall QC program, including frequency, number of levels of performed per test, acceptable QC ranges, and corrective action when QC fails.

Design: We surveyed clinical laboratory at 21 leading academic medical centers as determined by the 2016 U.S. News and World Report rankings regarding their approach to QC for chemistry and immunochemistry testing. The survey discussed assay instruments, source of QC material, frequency of QC, number of levels, and what QC rules are in place.

Results: Results were obtained from all medical centers surveyed. Laboratories used a varied range of instruments, with no one manufacturer having total dominance. QC materials were often purchased from a third party (as opposed to the instrument manufacturer). QC frequency varied greatly, from daily to every 2 hours. Although there was variety in the QC cutoffs and repeat rules, a majority of laboratories elected to repeat QC values that were out by 2 standard deviations (SD) and troubleshoot if the repeated value was also out by 2SD. The vast majority of hospitals do not use moving averages as an ancillary QC measurement.

Conclusions: In this study we discovered a large amount of variability of QC practices, which is partially due to local practice patterns, such as the perceived risk of having to repeat a large number of samples in the event of a QC failure. The commonly-seen practice of repeating QCs out by 2 SD warrants attention. Given that this method of QC analysis does not appear to be mathematically derived (in contrast to the Westgard Rules), further study of its efficacy is warranted. All of the laboratories surveyed were large academic medical centers supporting a similar spectrum of clinical services. The variation in practice seen indicates an opportunity to establish an evidence-based approach to QC that can be optimized and generalized across institutions.

2207 Detecting "No Match" Events Using an Advanced Barcode-Tracking System to Improve Patient Safety in the Anatomic Pathology Setting

Christine J Salibay[1], *Javier Sedillo*[1], *Abhishek Singh*[1], *Alaa Alsadi*[1], *Manmeet Singh*[1], *Elizabeth L Wiley*[1], *Tushar Patel*[1]. [1]University of Illinois at Chicago, Chicago, IL

Background: Human error is one of the more common and yet preventable sources of pre-analytic error within the anatomic pathology laboratory. Near-miss events may result in patient harm but are prevented. In an effort to implement protocols to reduce and eliminate near miss events and to optimize laboratory performance, we conducted a comprehensive data analysis using our advanced barcode-tracking system spanning a one year time period of near miss events in our department.

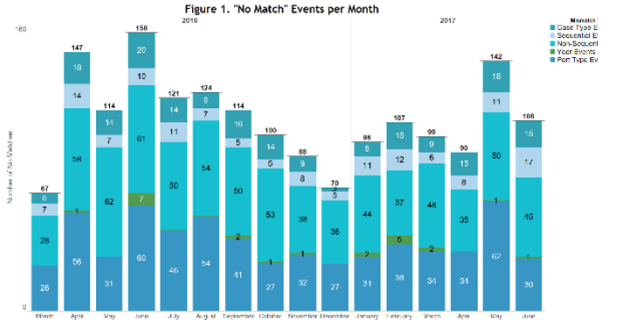
Design: Using an advanced barcode-tracking system by LABLION®, we were able to evaluate the number of mismatch events per user when scanning a block during grossing or a slide during sectioning. When the system detected a near miss event, a distinct warning on the computer screen alerts the user of a "No Match." "No Match" data for every user in the gross room and histology was compiled using Microsoft Excel® and analyzed in Tableau®. Specific mismatch events were defined as following: a case type event was defined as the type of specimen did not match, a year type event was defined as the year did not match, a sequential type event was defined as the specimen number was offset by +/-1 and did not match, a non-sequential type event was defined as the specimen number was offset by greater than +/- 1 and did not match, and a part type event was defined as the specimen part did not match.

Results: From the months of March 2016 to June 2017, "No Match" events averaged 145 per month with 1760 recorded incidents. Non-sequential and part type events were the most frequently encountered and year type events were encountered the least. Figure 1 shows a histogram of each type of "No Match" event per month. User mismatch events in the gross room and histology were quantified and normalized. User mismatch rates ranged from 0.11% to 1.54%, with an overall user mismatch rate of 0.54% in the gross room and 0.46% in histology. Table 1 shows the "No Match" frequency of users including pathology assistants and histology technicians.

Table 1. "No Match" Frequency per User

Grossing			
User ID	No Match Count	Total Blocks Scanned	No Match Frequency(%)
User #2	59	18092	0.33
User #4	10	1928	0.52
User #1	89	16842	0.53
User #3	153	16055	0.95
User #5	6	506	1.2
Sectioning			
User ID	No Match Count	Total Slides Scanned	No Match Frequency (%)
User #7	26	22818	0.11
User #15	24	22090	0.11
User #8	45	16157	0.23
User #16	42	16932	0.25
User #11	30	8421	0.36
User #14	175	33640	0.47
User #9	82	13809	0.59
User #12	69	11107	0.82
User #6	14	1380	1.00
User #13	5	406	1.23
User #10	257	16702	1.54

Figure 1. "No Match" Events per Month



Conclusions: Monitoring of "No Match" events using advanced barcode-tracking has proven to be a tremendously effective tool. Although the overall mismatch rate at our institution was 0.5%, these events still remain a significant risk with high consequence if not identified. Thus, advanced barcode-tracking systems serve as effective safety measures that can prevent a significant, and important source of pre-analytic error in the anatomic pathology laboratory.

2208 Potentially Confusing WHO Tumor Names Pose a Risk to Patient Safety

Jeffrey Schowinsky[1], *Cody A Thomas*[2], *Daniel Reiter*[3]. [1]Univ of Colorado Hospital, Aurora, CO, [2]University of Colorado School of Medicine, [3]University of Colorado

Background: Adverse medical events (errors) present a significant threat to positive patient outcomes. Thus, interest in patient safety measures has increased, including measures to improve or prevent potentially confusing terminology, such as the FDA's requirement that drug brand names neither look like nor sound like a different drug. In reviewing introductions to some WHO monographs for the classifications of different tumor systems there is no discrete mention of whether the patient safety implications of the chosen tumor names were taken into account. We sought to

determine if some potentially confusing names might pose a risk to patient safety.

Design: We chose a few potentially confusing tumors names from the WHO classification systems for soft tissue tumors and hematopoietic and lymphoid tumors. This includes some names where omission of part of the name results in the accurate name of a different tumor (e.g. myxoid liposarcoma (MLS), extraskeletal myxoid chondrosarcoma (EMCS)) or the colloquial name of a different tumor (e.g. nodular lymphocyte-predominant Hodgkin lymphoma (NLPHL)). Other tumors chosen included T- and B- prolymphocytic leukemia (PLL), low-grade fibromyxoid sarcoma (LGFMS), sclerosing epithelioid fibrosarcoma (SEF), and ossifying fibromyxoid tumor (OFMT). We found all patients with these diagnoses in our archives from 2010-2017, and reviewed post-diagnosis physician-authored notes in the medical record to determine how accurately the tumor names were recorded.

Results: In the table, n is the number of patients reviewed per diagnosis. Notes with a potentially confusing, inaccurate/incomplete tumor name are type 1. Notes with the complete name of a different (wrong) tumor are type 2.

DIAGNOSIS (n)	Type 1	Type 2
NLPHL (19)	7	2
T-PLL and B-PLL (11)	4	2
MLS (21)	6	3
EMCS (2)	0	1
LGFMS (6)	1	2
SEF (2)	1	1
OFMT (2)	1	0

Conclusions: Errors in the recording of the names of our chosen tumors in clinic notes occurred at a significant rate. When mistranscribed tumor names can easily result in the name of a different tumor, either as an accurate name (e.g. epithelioid sarcoma, chondrosarcoma), or colloquial name (e.g. Hodgkin lymphoma), this can result in a significant risk to patient safety. We recommend that future panelists involved in devising WHO nomenclature consider the potential risks to patient safety inherent in tumor names, and consider changing tumor names, even historically accepted ones, if it is in the interests of patient safety.

2209 Enhanced Internal Review as a Strategy to Analyze the Impact of Cytotechnology Triage Upon an Increasing Incidence of Altered Cervicovaginal Smears

Luciana Schultz[1], *Aline F Santos*[1], *Beatriz F Cherve*[1], *William R Brito*[1], *Valquiria Araujo*[1], *Maria Ines Schultz*[1]. [1]Instituto de Anatomia Patológica, AC Camargo Cancer Center, Santa Barbara d'Oeste, SP, Brazil

Background: We describe the results of automatic internal review in the subgroup of patients at higher risk for an actionable alteration (25-35y and/or relevant gynecological history), regardless of initial impression.

Design: A search on our database (automatic input upon coded sign-out) revealed a 45% increase in altered cervicovaginal smears (AGC, ASC, SIL, invasive) between 1st and 2nd 2016/semesters (1.68% to 2.44%). The percentage of increase was higher (58%) in patients between 25-35y, compared to <25y (54%) and >35y (28%), and this subgroup was also responsible for 48% of HGSIL diagnosed on biopsies. Although there were no pre-analytical or analytical changes within this period, we decided to focus on this subgroup triage, to verify accuracy of selection. Cytotechnology evaluation of conventional smears (Papanicolaou) followed classic and non-classic criteria for cytopathologic review of all exams suspicious for alteration. Furthermore, all initial negative for intraepithelial lesion or malignancy (NILM) that fell into the designated higher risk group and 10% of the remaining cases were directed for internal review.

Results: We included all satisfactory exams analyzed between Dec/2016-May/2017, of which 1125 (09%) were women <25y, 3178 (26%) between 25-35y and 8037 (65%) >35y. Reviews were performed on 56% of total smears, including 1631 suspicious for alteration, 3226 selective reviews and 2058 random controls. Among all initial NILM, 7/5284 (0.01%) were diagnosed as LGSIL upon review (5/7 directed by selective review). Finally, 11836 (96%) exams were diagnosed as NILM and 504 (04%) as altered (ASC/SIL ratio = 2.3). The distribution of these 504 altered cases, resulted in 10.6% of alteration in women <25y, 6.5% between 25-35y and 1.9% in >35y, corresponding to an increase of 75%, 82% and 28% in each age group, in comparison to the prior 6 months (see Methods: 54%, 58%, 28%). These results show that while the increase in the incidence of cervicovaginal smear alterations seems stable in women >35y, it is still raising considerably in the younger population, fairly proportionate between <25y (no selective review) and 25-35y (with selective review).

Conclusions: Enhanced selective review had little impact on the incidence of altered cases during the study period. Nevertheless, it reassured accuracy in the triage process, allowing to consider that the ongoing increase in altered smears may indeed correspond to regional prevalences, calling for future epidemiological and behavioral studies.

2210 Continuous Specimen Processing and a Dedicated Tissue Acquisition Group in Optimal Pre-Analytical Tissue Processing for Diagnosis and Research

Nancy E Scott[1], *Joseph Maleszewski*[1], *Monica L Kendall*[1], *Susan R Rogers*[1], *Karla J Kopp*[1], *Jodi Carter*[1], *Thomas Flotte*[1]. [1]Mayo Clinic, Rochester, MN

Background: There is a growing awareness in the pathology community that pre-analytic factors are important determinants of success for molecular testing. The importance of cold ischemia time for optimizing results has been validated for proteins, DNA, and RNA. The purpose of this study was to examine the hypothesis that the workflow of continuous specimen processing and a dedicated tissue acquisition group may minimize the cold ischemia times for routinely processed specimens providing significant benefits to the patient and for research.

Design: Specimens from the operating rooms are immediately transported to the frozen section laboratory for gross assessment, microscopic diagnosis, surgical margin status and pathologic staging. After the clinical team has completed their work, trained staff in the frozen section laboratory procure and process the tissues requested by investigators. In this study, the tissue cold ischemia time is defined as the interval between specimen is removed from the patient and the time the research specimens are placed in formalin or frozen. Cold ischemia times were collected for all specimens collected for research in 2013 and 2016.

Results: Tissue for research was obtained from 7,730 specimens including collections of 41 different tissue types. The average cold ischemia times for all of the research specimens in two years, 2013 and 2016, were 45 and 50 minutes, which is within the best practices guidelines of NCI. Specimens for diagnosis have even shorter cold ischemia times since processing of specimens for research is only performed after the clinical evaluation is complete.

Conclusions: The processing of the specimens through the frozen section laboratory would not be the only workflow that could achieve the cold ischemia goals proposed by the NCI. A grossing laboratory that was fully staffed during the working hours of the operating rooms could achieve the same time targets. However, the paradigm of processing all surgical specimens in a frozen section laboratory staffed with a pathologist permits nearly immediate determination that adequate tissue for diagnosis has been obtained. This determination allows for more excess tissue to be available for research and for biobanking of confirmed neoplastic and non-neoplastic tissues. Further, the rapid dissection of the specimens upon receipt minimizes the cold ischemia time which may improve the preservation of structural, protein and molecular features for both diagnosis and research.

2211 Outcome of Quality Improvement for HER2 FISH Test of Invasive Breast Carcinoma by Utilizing Checklist

Jian Shen[1], *Joseph Knezetic*[2], *Nicholas E Dietz*[3]. [1]University of Rochester Medical Center, [2]Omaha, NE, [3]Creighton University

Background: HER2 (human epidermal growth factor receptor 2) expression levels results are important for Trastuzumab target therapy decisions. In our institution, all breast cancer cases are first tested using HER2 immunohistochemistry (IHC). The cases with equivocal HER2 IHC results are automatically reflexed to HER2 Fluorescence in situ hybridization (FISH) testing. In a period of 13 months, 19 of 125 cases required repeat FISH testing with 5 of those 19 failing despite repeat testing and resulting in a non-reportable result. Those five patients with non-reportable results have no reliable information to determine the efficacy of Trastuzumab therapy. The repeat and failure tests add cost to the health care system and negatively impact patient care. We initiated this quality improvement project to address these issues.

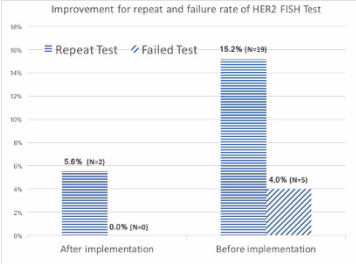
Design: The possible association between different factors with the repeat and failed tests were examined. We concluded that pre-analytical factors and specimen type were the most likely causes and proposed to include the time points related to specimen processing and fixation in our reports. This recommendation also serves as a checklist to start fixation promptly and have the tissue fixed adequately. We then examined how much the repeat and failure rates changed.

Results: We found that in the 19 cases with repeat testing, 12 cases (63%) were surgical resections and 7 (37%) were biopsy specimens, even though resections and biopsies represent 25% and 75% of the total cases respectively. The repeat rate between specimen type is statically significant (38.1% vs. 7.5%, $p<0.001$) (Table 1). In cases with failed testing, there is a similar trend ($P = 0.097$, Table 1). After implementation of recording the time points with the checklist, we collected 35 consecutive test results over 15 weeks. The quality of

HER2 FISH testing was significantly improved with marked reduced repeat and failure rate of HER2 FISH test (Fig1).

Table 1 Repeat and failure rate of HER2 FISH test between biopsy and resection specimen prior to intervention

Type of Specimen	Samples (N)	Repeat HER2 FISH test	Failed HER2 FISH test
Biopsy	94	7(7.5%)	3(2.1%)
Resection	31	12(38.7%)	2(9.7%)



Conclusions: The introduction of recording the time point of each step of tissue processing and adding the checklist reduces the repeat and failure rate of HER2 FISH test, which provides significant benefit of improving patient breast cancer care and reducing overall healthcare costs. The result also showed that controlling pre-analytic variables plays an important role in the adequate molecular testing of surgical specimens.

2212 Is H&E the Optimal Stain for Evaluation of Colorectal Cancer Resection (CRC) Specimens?

Sameer Shivji[1], *James Conner*[1], *Richard Kirsch*[1]. [1]Mount Sinai Hospital, Toronto, ON

Background: Venous invasion (VI) is an important prognostic factor in CRC that is widely under reported. Elastin stains can substantially improve VI detection but concerns remain over the cost and time required to perform and evaluate additional stains. We therefore sought to determine whether an elastin trichrome (ET) stain could be used alone to evaluate prognostic factors in CRC, and how this assessment compared with H&E.

Design: 50 CRC resections (5 H&E and 5 corresponding ET slides/case), including a representative mix of stages and prognostic factors, were used to generate 2 study sets. Each study set included 50 cases with 5 slides each (either H&E or ET). For individual cases, H&E and ET slides were assigned to different study sets. Each set had an equal mix of H&E and ET slides. Observers (2 GI pathologists) were asked to evaluate the first study set for all CAP mandated prognostic factors. After submission of completed scoresheets, participants received the second study set for evaluation. For each prognostic factor, mean detection rates using H&E and ET were compared using the Chi-squared test. The Cohen's kappa statistic was calculated as a measure of interobserver agreement.

Results: Preliminary results, based on 2 observers, showed significantly higher mean VI detection rates with ET versus H&E slides (p<0.0001) (Table 1). Detection rates for small vessel invasion, perineural invasion (PNI), high-grade histology and peritoneal involvement (pT4a) did not differ significantly for ET and H&E slides. Kappa values for assessment of VI, small vessel invasion and tumor grade were higher for ET slides than H&E slides, while kappa values for PNI, pT stage, and histologic type were similar (Table 2).

Table 1. Mean detection rate for prognostic factors (H&E vs. ET)

	H&E	ET	P-value
Venous invasion	20%	54%	<0.0001
Small vessel invasion	21%	16%	0.829
Perineural invasion	39%	40%	0.884
High grade histology	10%	13%	0.506
Serosal involvement (pT4a)	15%	17%	0.700

Table 2. Cohen's kappa statistic for interobserver agreement (H&E vs. ET)

	H&E	ET
Venous invasion	0.39	0.69
Small vessel invasion	0.36	0.50
Perineural invasion	0.24	0.29
Tumour Grade	0.78	0.91
pT stage	0.76	0.80
Histologic type	0.60	0.53

Conclusions: This study demonstrates that an ET stain is at least equivalent, and for some features superior, to H&E for evaluating key prognostic factors in CRC. Should these findings be confirmed by additional observers (in progress), this would make a strong case for the use of ET as the primary stain in the routine assessment of CRC.

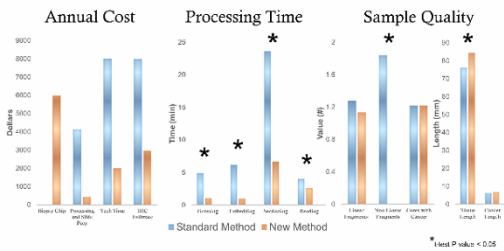
2213 Prostate Biopsy Processing: An Innovative Model for Reducing Cost, Test Time and Improving Diagnostic Material

Dip Shukla[1], *Jennifer Morocho*[2], *Michelle Wahlsten*[3], *Drew Sciacca*[1], *Meghan Pickard*[1], *Deanne C Smith*[4], *Ash Gunderson*[5], *Andy Thompson*[1], *Badrinath Konety*[1], *Christopher Warlick*[1], *Paari Murugan*[6]. [1]University of Minnesota, [2]University of Minnesota Medical Center, Fairview, Minneapolis, MN, [3]Fairview Laboratories, [4]University of Minnesota, Edina, MN, [5]Fairview Laboratories, Minneapolis, MN, [6]University of Minnesota, Minneapolis, MN

Background: Prostate cancer is the 2nd highest-incident cancer in American men, with rising rates over the last 60 years. Needle biopsy is the cornerstone of diagnosis. However, current protocol for processing and reading ≥ 6 separate sets of biopsies per case is uneconomical, time consuming and cumbersome. Tissue fragmentation and loss, reported in ~30% cases compromises cancer quantitation and appropriate management. False negative rate of detection can be as high as 30% as well. We sought to study an innovative alternate method to improve prostate biopsy processing and diagnosis.

Design: Two sets of sextant biopsies from nearly identical locations were obtained using a standard prostate biopsy gun from each of 32 prostatectomy specimens received in the pathology department of a large academic hospital. One set was submitted in standard fashion while the other was submitted using the BxChip™ (Leavitt Medical Inc.), a proprietary biomimetic matrix with 2 mm wide grooves that can accommodate 6 prostate biopsy cores on a single chip (Fig 1). The biopsy core was transferred from needle to the chip groove by capillary action and gentle in-axis rotation. The properties of the multiplex chip allow it to be processed, embedded and sectioned similar to human tissue. Colored dividers between each groove allow identification of the precise biopsy location. Various parameters including time required for grossing, embedding, sectioning and reading, as well as length of tissue, length of cancer and degree of fragmentation were compared to standard method.

Results: A significant overall reduction (>3 fold, p<0.05) in preanalytical and analytical time was observed using the BxChip. Non-linear fragmentation, wherein fragmented tissue pieces are oriented at different angles, causing difficulty in evaluating percent of tissue core with cancer involvement, was absent, in contrast to standard processing. Significantly increased tissue length was available for examination. Storage space was reduced by ≥3 fold. In addition, the efficiency of the new method not only absorbed the cost of the chip but also resulted in overall cost savings. (Fig 2)



Conclusions: The BxChip method reduced prostate biopsy processing time, reading time and cost. Due to its inherent property of holding tissue intact in a single plane between linear grooves and elimination of handling fragile cores during procurement, grossing and embedding, tissue loss and non-linear fragmentation was minimized, with potential increase in diagnostic accuracy.

2214 Red Blood Cell Utilization Outcomes with Prospective Review: A 5-Year Institutional Experience

Kunwar Singh[1], *Shyam Prajapati*[1], *Mark Friedman*[1]. [1]Mount Sinai Health System, New York, NY

Background: Adequate patient blood management aims to optimize patient care and provide methods to reduce health care related costs by ultimately assessing transfusion appropriateness. In our institution, residents and attendings provide this service through prospective audits of blood component transfusions, including red blood cell (RBC) units. The goal of this study is to review the progress of the prospective patient blood management program at a tertiary care hospital.

Design: Documentation of prospective audits began in 2013 and were collected up to September 2017, which were stored in a database. Indications for audit followed AABB transfusions guidelines and institutional best practices. For each of the RBC unit request audits, the pre-and post-transfusion Hgb values, number of units requested and released, and the reviewer's decision during the prospective audit were recorded. The decisions were divided into cases in which the reviewer recommended as requested, modified the request to transfuse the appropriate number of units, did not recommend therefore the patient was not transfused or the patient was transfused against recommendation.

Results: Audits (n=598) that were reviewed showed an average pretransfusion Hgb for requests of 7.6 g/dl. 779 units of PRBC were requested over this five-year period, 54% (n=417) were for 1 unit and 46% (n=362) for 2 units or more. After receiving the allotted units, a posttransfusion Hgb was reported. The mean posttranfusion Hgb was 8.7 g/dl. In 28% (n=168) of cases, unit requests were either modified or not transfused to eventually preserve a total of 23% (n=179) units.

Table 1- Outcome of Decisions from Prospective Audits

Outcome Category	Number of Cases (n=598)
Recommend as requested	346
Modified	86
Not recommended/not transfused	82
Transfused against recommendation	84

Conclusions: Our data suggests that since the implementation of these audits, there is a significant amount of value-added to ensure adequate transfusion appropriateness and preservation of resources. This is in turn reduces health care cost attributed to transfusions and displays the positive impact that appropriate patient blood management can have in a tertiary care hospital.

2215 Impact of Transoral Endoscopic Vestibular Approach Thyroidectomy Procedure on Pathology Examination

Stephen M Smith[1], *Manju Prasad*[1], *Andrea L Barbieri*[1]. Yale University School of Medicine, New Haven, CT

Background: Transoral endoscopic thyroid resection with vestibular approach (TOETVA) is a novel procedure to minimize scarring in select patients undergoing thyroidectomy. Unlike traditional transverse cervical percutaneous thyroidectomy specimens that are typically excised intact, TOETVA-derived specimens are often received fragmented and unoriented. As the pathologic findings in TOETVA specimens have not been previously described, we examined TOETVA specimens to determine how this procedure affects pathological analysis and consequences thereof.

Design: We retrieved all TOETVA specimens from our institution between March 2016 and August 2017. Cases were reviewed and pathologic parameters were assessed, including pre-operative diagnosis, final histologic diagnosis and gross features. Malignant cases were assessed using CAP and AJCC guidelines. Patient follow-up was recorded from the chart.

Results: Forty-three patients underwent TOETVA resection, including 34 lobectomies, 7 total thyroidectomies, 1 isthmusectomy and 1 thyroid cystectomy. Preoperative diagnoses included benign disease in 22 patients, FLUS/HUS in 17 patients, and papillary thyroid carcinoma (PTC) in 4 patients. Twenty-three specimens showed fragmentation with a mean of 4.1 fragments (range: 2-8). Nine patients had PTC at final diagnosis, including one with reportedly benign disease preoperatively and 4 with FLUS/HUS. We confirmed the presence of PTC in all cases with a prior diagnosis (n=4). The mean PTC size was 0.6 cm (range: 0.2-1.1 cm). In one patient, PTC size, extrathyroidal extension and margin status could not be determined due to fragmentation. The mean clinical follow-up time was 3.2 months (range .25 – 15.3 months). Four patients reported vocal cord paralysis and 4 patients reported chin/neck numbness and/or paresthesias. Patients with a malignant diagnosis have shown no evidence of tumor recurrence on follow-up.

Conclusions: We report the first series examining the pathologic findings in patients undergoing TOETVA resections. In 11.1% of malignant cases the final diagnosis was limited due to fragmentation of the specimen with regards to data elements including resection margin, extrathyroidal tumor extension and/or size of tumor. Our findings show that final diagnosis is not compromised in TOETVA resections, but the fragmentation of specimen may limit pathologic examination in some patients. These findings should be taken into consideration when determining if a patient is an appropriate candidate for TOETVA resection.

2216 Communication of Errors in Surgical Pathology: Amend, Addend or Phone a Friend?

Stephen M Smith[1], *Andrea L Barbieri*[1], *Vinita Parkash*[1]. Yale University School of Medicine, New Haven, CT

Background: The amendment rate (AmR) is tracked by many pathology departments as a surrogate measure of error. The accuracy of this measure is dependent upon a consistent taxonomy of post-signout report modification use among pathologists. As addenda allow for an alternate mechanism for post-signout report modification, we sought to better understand the situations in which practicing pathologists used addenda and amendments.

Design: A survey based on a previously published ADASP questionnaire was created using an online survey tool (Qualtrics) and disseminated via social media (Twitter) and email to members of the pathology community over a seven day period. The survey was divided into two segments: demographic information and definitions/perceptions of error, amendments and addenda using case-based scenarios and open-text questions.

Results: Sixty-nine survey responses were received with respondent characteristics including: 79.7% in clinical practice for at least 6 years, 62.7% at a University-Affiliated Teaching Hospital, equal numbers of men and women, and most in the 41-54 year old age range. 95% of respondents reported that their institutions allowed for both amendments and addenda. There was uniform agreement that benign to malignant and malignant to benign changes in diagnoses constituted error and required report corrections in the form of amendments. Primary staging parameters showed greater consistency in classifications as report alterations and attendant increased consensus as to the appropriate report modification. Therefore, stage and margin status were reported as amendments in 79.7%, 88.1% of cases. Minor prognostic parameters showed greater variability in the preferred methodology of post-signout report modification (e.g. vascular invasion 64.4%). 83.1 % of respondents indicated that specimen site and laterality changes required amendments. 98.3% of respondents agreed that clinicians should be directly contacted when harm is caused to a patient as a result of an error, compared to 37.9% when no harm was caused (though 47% were unsure and noted that the circumstances would dictate the need to contact).

Conclusions: Pathologists use amendments and addendums inconsistently, which limits the use of the AmR as a metric for error. There is variability in the use of amendments depending on the perceived harm to the patient. Uniform guidelines for amendment reporting could improve the utility of the AmR as a metric for error and capture additional cases of value for error-rate improvement.

2217 Utility of the Safety Attitudes Questionnaire (SAQ) as a Measure of Safety in a Tertiary Care Teaching Hospital's Department of Pathology

Stephen M Smith[1], *Andrea L Barbieri*[1], *David Dupee*[1], *Vinita Parkash*[1]. Yale University School of Medicine, New Haven, CT

Background: A culture of patient safety is vital to develop and ensure patient safety and high quality. In this study, we sought to assess the attitudes of the safety climate at a large academic institution's pathology department.

Design: The validated Safety Attitudes Questionnaire (SAQ - Short Form 2006), which assesses patient safety climate over six safety domains: Teamwork Climate, Safety Climate, Perceptions of Management, Job Satisfaction, Working Conditions, and Stress, was adapted to measure pathology-specific factors and distributed to members in our department between 10/24/2016 and 12/13/2016. Permission was granted from the University of Texas Center for Healthcare Quality for use of the SAQ and was scored per their algorithm.

Results: There were 126 respondents (%).74% had > 3 years of service, with 37% with > 10 and 21% having > 20 years of service. Attending pathologists formed 25% of respondents, resident/fellow's 19%, pathology assistant's 3%, manager's 10% and clerical/technical's 31%.

The coefficient alpha value for each of the SAQ scales ranged from .90 to .99. Teamwork Climate scores were highest among residents and fellows and lowest among clerical/technical staff (90.2 vs. 63.5).

The overall perception of safety was generally neutral to slightly positive (68.9-80.9). Job satisfaction and working condition metrics showed lower scores among managers, technical staff and attending physicians. Faculty with <5 years experience showed lower scores in their perceptions of the department's safety climate, job satisfaction and working conditions, compared with more senior attendings. Staff/Technologists overall showed disagreeable views of the working conditions and management.

Conclusions: Understanding perceptions of the safety climate in a department can help focus efforts to improve the quality of care, and physician and staff engagement. Our department is using the information from this survey to develop programs to improve engagement of staff and physicians. We demonstrate that the SAQ can be adapted to pathology departments for culture assessment and improvement.

2218 Development and Measurement of Population-Level Quality Indicators Based on Electronic Synoptic Cancer Pathology Reporting: A Pan-Canadian Approach

John Srigley[1], *Claire P Browne*[2], *Shaheena Mukhi*[3], *Mary Argent-Katwala*[4], *Heather Bryant*[3]. [1]Trillium Health Partners - Credit Valley Hospital, Mississauga, ON, [2]Canadian Partnership Against Cancer, Toronto, ON, [3]Canadian Partnership Against Cancer, [4]Canadian Partnership Against Cancer, Toronto, ON

Background: The required elements of the College of American Pathologists (CAP) Cancer Checklists (CCs) are a reporting standard in Canada. Six Canadian provinces implemented discrete data field (level 6) synoptic cancer pathology reporting using the CAP electronic CCs. Pathology and surgical data can be used to derive descriptive and quality indicators, designed to support clinical, program, and health system management. The indicator development process and feasibility of measuring them at the population level are described.

Design: Five multidisciplinary expert panels for breast, lung, colorectal, prostate and endometrial cancer involving a total of 50 clinicians were convened and presented with an initial set of clinicopathologic (24) and data quality (3) indicators derived from respective CAP CCs. The panels used literature reviews and a modified Delphi approach to develop consensus on a final list of indicators. To assess feasibility of inter-jurisdictional comparisons, synoptic pathology data for a six month period (July-December 2016) were obtained from five provinces and correlated centrally by the Canadian Partnership Against Cancer.

Results: The expert panels on consensus recommended 44 clinicopathologic indicators and 3 data quality indicators (compliance rate, completeness rate, and turnaround time). These were classified as descriptive if they measured a parameter not directly modified by a therapeutic intervention or as an outcome measure if an intervention (neoadjuvant therapy, surgery) directly affected the indicator. In total 11 breast, 7 lung, 9 colorectal, 8 prostate, and 9 endometrial indicators were developed across the following domains – subtype distribution (3), grade distribution (3), pT category (9), pN category (14), margin status (9), biomarkers (2) and others (4). Data from five provinces showed feasibility of calculating 47 comparative indicator analyses and generating provider level feedback reports to inform patient care, conversations among clinicians around reducing practice variation, and quality improvement at the local level.

Conclusions: Electronic structured pathology data can be used to generate indicators for comparison across cancer patient populations. The indicators can identify variation in clinical and pathological practice, adherence to guidelines, impact of screening programs on stage distribution, and ultimately improve population-level cancer care and cancer control.

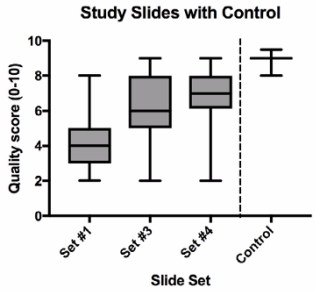
2219 Improving H&E Histology Slide Quality in a Resource Limited Setting: A Quality Improvement Project at Kijabe Hospital, Kenya

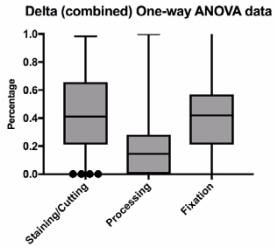
Bobby J Swinney[1], *Jamie Ham*[2], *Philip Ferguson*[3]. [1]St. Bernards Medical Center, Jonesboro, AR, [2]New York Institute of Technology, College of Medicine, [3]Doctors Anatomic Pathology Ser, Jonesboro, AR

Background: As access to treatment becomes more available (lower costs/improved availability) in resource limited locations, accurate diagnoses is critical. This includes the availability of high quality H&E stained slides for diagnosis, which has not been commonly available in resource limited areas. A quality improvement project was carried out at Kijabe Hospital (KH), Kenya to identify the effects of different steps in histology on slide quality with the goal of improving quality in a strategic manner in a resource limited setting.

Design: This study compared H&E slide quality tissue samples from KH under various processing strategies via 4 slide sets: (set #1) entirely prepared at KH; (set #2) tissue processed and sectioned at KH and stained at St. Bernards Hospital (SBH), Joneboro, AR; (set #3) tissue processed at KH and sectioned/stained at SBH; and (set #4) tissue reprocessed, stained, and sectioned at SBH. An addition control set from SBH was utilized to represent a western laboratory quality standard. Slides were scored on a 0-10 scale by 6 pathologists. The control slides were scored along with the study slides, and the difference between sets #1 & #3 (sectioning/staining), sets #3 & #4 (tissue processing) and set #4 and control (fixation) were compared. Scores were analyzed using a one-way ANOVA statistical analysis (Prism 7, GraphPad Software, La Jolla, CA).

Results: Staining/sectioning contributed to approximately 39% of quality degradation, tissue processing 16%, and fixation 44% ($P < 0.0001$). Staining/sectioning were combined in analysis due to limited number of slides available for set #2. Subanalysis revealed staining not to contribute significantly to quality differences (data not shown). The absolute quality scores are shown in Figure 1. and the difference between sets in Figure 2.





Conclusions: Fixation and block sectioning were the most critical steps affecting quality at KH. Tissue processing appears to have the least impact on quality. Slide production is sequential process, and downstream effects on quality due to earlier steps cannot be excluded. These findings will help focus limited resources on tissue fixation and staining/sectioning at KH.

2220 Impact of Rapid On-Site Evaluation (ROSE) on the Diagnostic Rate of Pancreatic Endoscopic Ultrasound Guided Fine Need Aspirations

Hamza Tariq[1], *Cynthia Forker*[1], *Daniel D Mais*[1]. [1]University of Texas Health Science Center at San Antonio, San Antonio, TX

Background: Pathologists have traditionally been the quiet work force in the hospital, keeping information flowing from clinician queries to patient results and providing vital information about patient outcomes. Initiatives such as the CAP Transformation encourage pathologists to assert their value and become further integrated into the clinical care of patients.

We wanted to measure the impact of Rapid On-Site Evaluation (ROSE) by a pathologist on the diagnostic rate of pancreatic endoscopic ultrasound (EUS) guided fine need aspirations (FNA) at our hospital. We thought that our skills were under-utilized at our hospital's pancreatic EUSFNA service. We approached the advanced endoscopy team concerning their historical adequacy rates and asked to be involved in all pancreatic FNA procedures. This study describes the difference in diagnostic rates with and without cytopathologist assistance.

This analysis is a retrospective review of the frequency of pathologist consultation and the rates of non-diagnostic procedures. From 2012 to 10/31/16 we experienced a 45.7% diagnostic rate for EUSFNA and a non-diagnostic/negative (ND-N) rate of 54.2%. Of this ND-N, 73.3% (66 cases) did not have ROSE.

Design: A retrospective review of 219 consecutive cases of pancreatic EUSFNA between 01/2012 to 07/2017 was performed. The cases were divided into groups with and without on-site adequacy evaluation and then further divided by date, which was defined as before clinician intervention (BC), and after clinician intervention (AC). For the group with on-site evaluation, Diff-Quik–stained direct smears were prepared and the remaining material was rinsed into RPMI solution. For the group without on-site evaluation, material was placed into preservcyt.

Results: BC provided 166 cases for review, with 90 cases in the ND-N category and 76 in the positive category. Of the ND-N category, 66 (73.3%) did not have ROSE. Of the positive category 42(55.2%) did have ROSE. AC (11-1-16 to 4/30/17) provided 53 cases for review, with

23 cases in the ND-N category and 30 in the positive category. Of the ND-N category, 16(69.5%) did not have ROSE. In the positive category 27(90%) did have ROSE.

After Intervention		
Nondiagnostic/negative		
No ROSE	16	69.57 %
ROSE	7	30.43 %
	23	43.40 %
Positive		
No ROSE	3	10.00 %
ROSE	27	90.00 %
	30	56.60 %
	53	24.20 %
Before Intervention		
Nondiagnostic/negative		
No ROSE	66	73.33 %
ROSE	24	26.67 %
	90	54.22 %
Positive		
No ROSE	34	44.74 %
ROSE	42	55.26 %
	76	45.78 %
	166	75.80 %
	219	

Conclusions: We came to the conclusion that we were able to positively impact the diagnostic rate on pancreatic EUSFNA cases with ROSE. Doing so, drastically decreased the ND-N rate and increased the positive diagnostic rate of these procedures at our hospital. Improving pathologist/clinician communication helps improve patient care.

2221 Utility and Cost-Effectiveness of Deeper Sections: A Retrospective Analysis

Talent Theparee[1], *Crystal Bockoven*[1], *Charnell Johnson*[1], *William Watkin*[1]. [1]NorthShore University Health System, Evanston, IL

Background: Obtaining deeper levels from the paraffin block is often required when initial histological sections do not adequately resolve the diagnostic issue. However, additional deeper sections add significantly to technologist workload, cost, and turnaround time. In this study we catalogue the reasons that pathologists order additional levels and how often they resolve the diagnostic problem. We also attempt to identify technical and tissue factors which may contribute to the need for additional levels and analyze cost effectiveness.

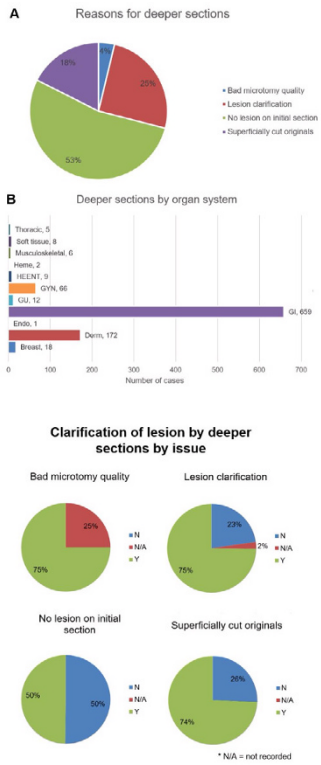
Design: Cases requiring deeper sections from December 2016 to July 2017 were extracted from the LIS. Participating pathologists listed reasons for ordering deeper sections in the following categories: bad microtomy quality, lesion clarification, no lesion on initial section, and superficially cut originals, and documented whether the deeper sections resolved the issue. Tissue type, tissue size, and number of pieces of tissue in the cassette were documented.

Results: 958 cases consisting of 1382 paraffin blocks with deeper sections from December 2016 to July 2017 were extracted from the LIS (Figure 1). The majority of cases requiring deeper sections were biopsies (91%).

Deeper sections resolved the issue in 588 cases (61%) while in 355 cases (37%) no additional lesions were found. Up to 56% of cases with superficial sections or no lesions demonstrated a finding on deeper sectioning. Additionally, deeper sections helped clarify 75% of all lesions discovered in earlier sections (Figure 2). Tissue size was larger in clarified cases versus non-clarified cases.

Comparison of turnaround times (TAT) between the deeper sections group and a matched control group during the same time period demonstrated an 18.6 hour increase in TAT for the deeper sections group.

Past work in 2014 by Stuart et al. calculated costs for retrospective deeper sections to be 2.15 times the control and 1.56 times for prospective (automatic) deeper sections. However, the case volume of the deeper section group in our study was only 5% of the matched control group. Thus, moving to a prospective deeper section model would cost approximately 1.4 times our current overall cost.



Conclusions: Deeper sections are an invaluable tool for the evaluation of tissue, especially small biopsies. However, the decision to prospectively or retrospectively evaluate deeper sections should be based on the caseload, workflow, and turnaround time demands of each institution.

2222 Comparison of FDA-Approved and Laboratory-Developed HER2 Immunohistochemical Assays Using College of American Pathologists Proficiency Testing Data

Megan Troxell[1], *Jason L Hornick*[2], *Andrew Bellizzi*[3]. [1]Stanford University Medical Center, Stanford, CA, [2]Brigham and Women's Hospital, Boston, MA, [3]University of Iowa Hospitals and Clinics, Iowa City, IA

Background: In 2014 the Food and Drug Administration (FDA) issued draft guidance for regulatory oversight of laboratory-developed tests (LDTs). Although in January 2017 the FDA deferred issuing final guidance, the intimation is that FDA-approved assays are inherently superior to LDTs. Beginning with the first mailing of the 2017 College of American Pathologists (CAP) HER2 proficiency testing (PT) survey, laboratories were asked whether they run an FDA-approved or LDT HER2 assay.

Design: CAP HER2 PT surveys consist of 20 breast cancer tissue microarray (TMA) cores. For the HER2-A survey, the number of laboratories running each assay was recorded. Data from the 2017 HER2-A and B surveys was combined to compare the FDA-approved Pathway, 4B5 LDT, FDA-approved HercepTest, and A0485 LDT assays. For these, the number of TMA cores agreeing with the expected result and with 2+ and unacceptable results was recorded. Chi-square test for independence and Chi-square test with Yates correction were used with $p<0.05$ considered significant.

Results: The 1122 laboratories participating in the HER2-A survey used the following assays: Pathway 59%, HercepTest 12%, 4B5 LDT 12%, SP3 6%, CB11 4%, A0485 LDT 3%, EP3 2%, other 2%. Overall performance data for the 4B5 and A0485-based assays is presented in Table 1.

Table 1: Performance of FDA-Approved and Laboratory-Developed HER2 Assays

Assay	Agree	2+	Unacceptable	Total N (Cores)
Pathway (4B5)	95.73%	3.94%	0.33%	28144
4B5 LDT	95.32%	4.24%	0.44%	4741
HercepTest (A0485)	94.39%	4.56%	1.05%	5223
A0485 LDT	92.27%	7.43%	0.30%	1332

The 4-way comparisons for the % agree, 2+, and unacceptable categories were each significant ($p<0.00001$). Pairwise comparisons are presented in Table 2.

Table 2: P Values for Pairwise Comparisons

Comparison	Agree	2+	Unacceptable
Pathway vs 4B5 LDT	0.21	0.36	0.26
HercepTest vs A0485 LDT	0.0045	<0.0001	0.015
Pathway vs HercepTest	<0.0001	0.043	<0.0001

The Pathway vs 4B5 LDT comparisons were not significant. HercepTest had a higher % agree and a lower % 2+ than the A0485 LDT but a higher % unacceptable. Pathway had a higher % agree and a lower % 2+ and % unacceptable than HercepTest.

Conclusions: The performance of FDA-approved and LDT HER2 immunohistochemical assays, as evidenced by the Pathway vs 4B5 LDT comparisons, appears comparable.

2223 Lean Optimization of Breast Core Biopsy Process in a Core Surgical Pathology Laboratory

Ruan C Varney[1], *Natalie Karmo*[1], *Jacqueline Copeland*[1], *Richard Zarbo*[1]. [1]Henry Ford Hospital, Detroit, MI

Background: The Henry Ford Core Surgical Pathology Laboratory receives same-day undissected breast core biopsies transported within a 40-mile radius via multiple couriers from 6 affiliate hospitals and medical center locations with goal of final pathology report in 48 hours of specimen receipt. Due to multiple root causes our breast biopsy turn-around-time (TAT) was in excess of goal resulting in missed tumor board presentations, anxiety for physicians and stress for patients from delays in care management. We challenged our processes to assure a same-day goal to include receipt, tissue examination and histology processing of all breast core biopsies from all sites within the System to provide pathologists with glass slides for interpretation by 8am the next morning.

Design: Process redesign was accomplished from March-September 2017 by work teams along the path of workflow empowered to implement changes based on Lean principles and Daily Management board monitoring of metrics of success to include internal process turn-around-times (TAT), specimens not processed within the day, delivery to pathologists and TAT to signout.

Results: Redesign improvements focused on visual management to identify the incoming stream of breast core specimens as a priority at receipt and throughout the process. Teams adopted standardized bright pink colored stickers as visual aids at the sending laboratory sites. This continued through surgical accessioning with generation of bright pink cassettes and continued with visual control of specimens delivered to pathologists' assistants who fast-tracked dissected specimens as priority in histology through embedding to microtome to staining to slide delivery to pathologist's desk before 8am the next morning. Histology tissue processor TAT was reduced by 4 hours specimens and specimens that had been received but delayed beyond the next available tissue processor were improved by 86%. TAT from specimen receipt to the glass slide receipt by pathologists improved by 60% (avg. 62 to 24 hrs.). Overall TAT from specimen receipt to pathologist sign out improved by 20% (avg. 41 to 33 hrs.)

Conclusions: Visual controls and Daily Management metric boards in accession, gross dissection and histology processing work cells were instrumental in tracking process inefficiencies and focusing teams in testing rapid corrective action to meet daily targets. Improvements were sustained with daily and weekly team huddles for communication of planned changes to accomplish and sustain the goal.

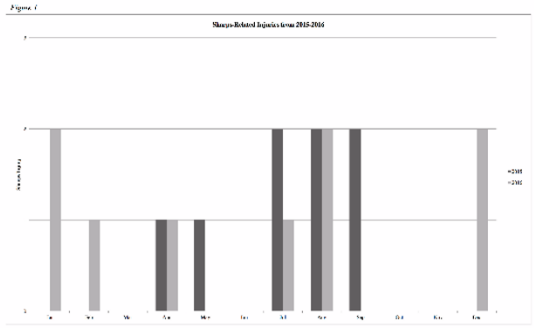
2224 Injury Rate Versus Sharps Use at an Academic Pathology Program from 2015-2016

Ashley Volaric[1], *Jennifer Williams*[1], *Minor Monge*[1], *M. Beatriz Lopes*[1]. University of Virginia Health System, Charlottesville, VA

Background: Sharps-related injury from handling blades during anatomic pathology workflow is a common problem in academic pathology programs where trainees are at greatest risk for injury. However, there is a relative scarcity of literature concerning this commonly encountered problem, and as such, little is known about what are considered "acceptable" injury rates at comparably-sized institutions. Our pathology program is a large academic program that consists of approximately 30 trainees and processes about 30,000 surgical pathology and 275 autopsy cases annually. As expected, our trainees and technologists experience sharps-related injuries every year. To better track these injuries and determine need for intervention, a study regarding sharps-related injury versus sharps use was conducted over the course of two years (2015-2016).

Design: Number of sharps handled and sharps-related injuries from anatomic pathology staff, including trainees and technologists, were tracked at our institution from 2015-2016, across the surgical pathology and autopsy services. Sharps were defined as any blade handled during the course of performing anatomic pathology-related work (cryostat/microtome blades, autopsy blades, surgical pathology blades, etc.).

Results: The number of sharps-related injuries was comparably low in 2015 (8) and 2016 (9). The number of injuries appeared increased during the summer months of July-September, especially in 2015. The overall number of blades handled by the anatomic pathology department annually is approximately 177,000. The ratio of sharps-related injuries to sharps usage is approximately 0.005% across both 2015 and 2016. See Figure 1 for number of sharps-injuries monthly from 2015-2016.



Conclusions: The number of sharps-related injuries remained consistent from 2015-2016 at approximately 8-9 injuries per year, for a large academic pathology program. The majority of the injuries, especially in 2015, occurred during the summer months July-September, which is the transition period for new trainees. The ratio of sharps usage to resultant injury is exceedingly low at 0.005%, across 2015-2016, supporting the notion that sharps-related injuries, although a consistent part of the anatomic workflow, are rare compared to the number of blades utilized daily by staff. In determining effective intervention strategies to further mitigate this risk, it is critical that more data regarding injury rate and sharps usage is gathered and published by similarly-sized academic pathology programs.

2225 Re-evaluating Utility of the Immunohistochemistry for Detecting H. Pylori Infection

Kai Wang[1], *Upender Manne*[1], *Isam-Eldin Eltoum*[1], *Rongjun Guo*[1]. University of Alabama at Birmingham, Birmingham, AL

Background: Helicobacter pylori (H. pylori) infection is a major cause of peptic ulcer, chronic gastritis, gastric carcinoma, and gastric lymphoma. Presence of active chronic gastritis is the clue for H. pylori infection and in many of these cases, H. pylori organisms can be identified on H&E stain, but sometimes immunohistochemical stains may be needed to demonstrate the organism, specifically in the presence of active gastritis. Not uncommonly, testing is also extended to conditions other than active gastritis, including inactive gastritis, reactive gastropathy, and normal histology. This may constitute an over-utilization of immunohistochemical stains. The objective of this study is to assess over utilization of immunohistochemical stains for the presence of H. pylori organisms in a large academic center and estimate cost associated with non-value testing. Our goal is to help in defining guidelines for utilization of immunohistochemistry to demonstrate H. Pylori.

Design: Our electronic database was searched for all pathology reports with H. pylori immunohistochemistry performed from 01/01/2016 to 06/30/2017. The pathological diagnosis and immunohistochemistry stain results were collected. Independent re-reading the original H.&E. slides by two diagnostic pathologists will be performed if needed.

Results: Immunohistochemistry stains for H. Pylori organisms were performed on 556 cases during this period. The frequency of positive staining varies between the different histological findings on H&E. As expected, chronic active gastritis showed the highest rate of presence of organism (Table). Stains were negative or low in case of normal histology, chemical and reactive gastritis, and erosion.

Histologic findings on H&E stained slides	Frequency of H. pylori detection by immunostains
Normal histology	0/25 (0%)
Chemical/reactive gastritis	0/35 (0%)
Gastric erosion	1/21 (4.8%)
Chronic gastritis (not otherwise specified)	41/271 (15.1%)
Active chronic gastritis	91/177 (51.4%)
Total	133/556 (23.9%)

Conclusions: Our preliminary results indicated that there is no need for H. pylori ancillary testing if the histological diagnosis is reactive gastropathy or normal. These cases account for 10.8% (60/556) of the H. pylori testing. Further study is underway, including independent re-reading the original H&E. slides from the other categories (active chronic gastritis, chronic gastritis not further specified, erosions, etc.) by two diagnostic pathologists through double- blind approach. We believe we will be able to identify the histological features that further reduce the utility and thus related cost.

2226 Quality Assurance in Dermatopathology: A Single Institutions 5-Year Experience

Yiqin Xiong[1], *Patrick O'Donnell*[1], *Laura Brustolon*[1], *April C Deng*[1], *Kristine M Cornejo*[1]. [1]University of Massachusetts Medical School, Worcester, MA,

Background: Review of revised pathology reports and comparing concordance with outside evaluations are valuable tools for improve pathology service.

Design: All amended dermatopathology reports and cases reviewed at another institution from a tertiary Medical Center over a five-year period were retrospectively reviewed.

Results: 38,231 dermatopathology cases were reviewed from 2013-2017 and 160 of these cases (0.42%) were amended. Of all theamended reports, 96 (60%) were due to systematic, 12 (7.5%) were due to interpretative and 57 cases (35.6%) were due to typographical errors. Some cases contained an error in more than one category. Most errors (n=86; 55%) did not affect clinical management such as changing procedure types, missing frozen section diagnoses and premature signout. 72 cases (45%) were considered clinically significant and included laterality/site errors (n=45; 63%), change in diagnosis (n=9; 12.5%), staging inaccuracy (n=3; 4.2%), typographical errors in the diagnosis (n=6; 8.3%), entered wrong diagnosis (n=2; 2.8%), and problems with tissue or requisition submission (n=4; 5.6%).

364 dermatopathology cases were reviewed by an outside pathologist from 2013-2017 and 301 (83%) were returned with reports on file. 290 cases (96%) were considered concordant, 6 cases (2%) were partially concordant and only 5 cases (2%) were discordant. The discordant cases were due to differences in interpretation such as presence or absence of a vasculitis or mild squamous dysplasia, a folliculocentric granulomatous infiltrate vs an interface dermatitis with follicular involvement, a trichoepithelial proliferation vs follicular mucinosis and a radiation dermatitis vs an atypical vascular lesion. The partially concordant cases were mainly due to differences in interobserver subjectivity such as the degree of squamous or melanocytic dysplasia.

Conclusions: Our dermatopathology reports are infrequently amended, and most revisions do not impact management. The majority of the cases considered to be clinically significant are due to site/laterality errors (63%) and only a minor component due to misinterpretation (12.5%). The majority of the cases sent for outside review were concordant or partially concordant (98%), while only a minor subset were considered discordant (2%). Overall, the low amendment and discordant rates highlights the overall success of our quality assurance efforts. Improvements in systematic shortcomings, particularly in misidentification will greatly help to resolve these defects.

2227 Identifying ALK+ Lung Adenocarcinoma: Practical Insights Learnt from Concurrent Fluorescence in situ Hybridization (FISH) and Immunohistochemistry (IHC) Test of 126 Clinical Specimens

Hong Yin[1], *Christopher Q Zhang*[2], *Shaobo Zhu*[1], *Michele Zelonis*[3], *Dana Snyder*[3], *Kaitlyn Schiccatano*[3], *William Quinones*[3], *Zongming Eric Chen*[1]. [1]Geisinger Medical Center, Danville, PA, [2]Lafayette College, [3]Geisinger Medical Center

Background: The great therapeutic success of ALK inhibitor drugs has made it mandatory to test ALK gene rearrangement in lung adenocarcinoma. FISH was the only test until recently, FDA approved, an IHC assay as a valid alternative. Comparing to FISH, IHC test is faster and cheaper, thus quickly gaining popularity among labs as an ideal screening tool for ALK+ tumors. Our lab just accomplished an extensive verification process. Herein, we share some useful insights that may facilitate adoption of the new testing approach.

Design: To verify the ALK IHC test performance, concurrent FISH and IHC testing was performed using 126 clinical samples, including cytology, biopsy and surgical specimens. For IHC, Ventana ALK (D5F3) CDx assay was performed using Benchmark Ultra platform. The result interpretation was per recommended guideline. In anticipation of unequivocal staining pattern, an "indeterminate" category was deliberately added to modify Ventana's dichotic scoring system. For FISH analysis, Vysis ALK break apart FISH probe kit was used and results interpreted according to vendor's instruction. For each specimen, IHC result was reported first before the initiation of FISH analysis

Results: ALK IHC unequivocally identified 4 positive and 103 negative samples, in complete accordance with FISH results. Intriguingly, 19 (15%) samples were IHC "indeterminate". They included 1 positive and 18 negative determined by FISH analysis. A retrospective review highlighted some important features of these samples: all except one were cytology specimens; all contained limited tumor cells with abundant non-tumor cells including macrophages in background; necrotic tumor debris was frequently found. Many tumor cells in these specimens showed moderate to strong granular cytoplasmic staining indistinguishable from true positivity. They would have been incorrectly scored as positive if a dichotic system had to be used. Comparing to FISH, another shortcoming of the IHC test was its staining variability between runs to an extend repeating test is required to achieve optimal results.

Conclusions: For identifying ALK+ lung adenocarcinoma, results from ALK IHC and FISH tests show great concordance. The IHC test can function as an effective screen tool. However, in practice, equivocal staining exists. Modification of the dichotic scoring system to include "intederminant" category is recommended. It is important and necessary to perform FISH on all IHC indeterminate samples.

2228 Reduction of BCR-ABL Ordering Errors through Multipronged Quality Improvement Interventions

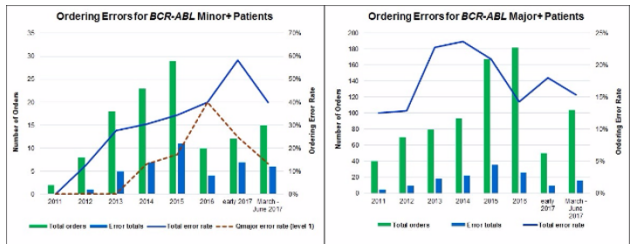
Feng Yin[1], *Wei Zheng*[2], *Misty D Lucas*[3], *Richard A Allen*[4], *Yaolin Zhou*[4]. [1]University of Oklahoma HSC, Oklahoma City, OK, [2]Emory Univ/Medicine, Atlanta, GA, [3]University of Oklahoma HSC Molecular Pathology, Oklahoma City, OK, [4]University of Oklahoma HSC

Background: *BCR-ABL* testing is essential for diagnosis, treatment, and monitoring in patients with chronic myelogenous leukemia (CML) and acute leukemia. The availability of various *BCR-ABL* assays may lead to inappropriate orders and patient harm. Our aim was to promote appropriate ordering of *BCR-ABL* tests through a multipronged approach.

Design: We retrospectively reviewed 1,026 *BCR-ABL* orders from 2003 to June 2017 and classified ordering errors as level 1 (incorrect, e.g., *BCR-ABL* major quantitative assay on patients with *BCR-ABL* minor+), level 2 (duplicate or redundant, e.g., simultaneous orders on bone marrow and peripheral blood), level 3 (untimely, e.g., quantitative assay ordered before qualitative), and level 4 (specimen quality, e.g., cancellation due to poor sample quality).

Results: *BCR-ABL* minor+ patients (17 B-ALL, 1 AML) had more inappropriate orders than patients with *BCR-ABL* major+ (75 CML). *BCR-ABL* minor+ patients' ordering error rate was 35.04%. Most common errors were inappropriate ordering of *BCR-ABL* major quantitative assay (14.53%; level 1), which could be misleading for disease monitoring. Duplicative/redundant orders (10.26%; level 2), level 3 (5.98%) and level 4 (4.27%) errors were less common. For *BCR-ABL* major+ patients (overall error rate 16.94%), the quantitative assay was often ordered prematurely (6.16%; level 3). Other errors include level 1 (3.08%), level 2 (3.85%), and level 4 (3.85%) errors.

The number of *BCR-ABL* orders increased from 2011 to 2015, as did associated error rate. In 2016, we began a series of quality improvement interventions which correlated with declines in rates of ordering errors (Figure). We worked with IT personnel to clarify ordering options, educated lab managers and registration staff, and reached out to hematology faculty and trainees. In late March 2017, our lab simplified *BCR-ABL* options further by making our qualitative test reflex to *BCR-ABL* major quantitative if appropriate. For *BCR-ABL* major+ patients, there was a small rise in total error rate in early 2017, which decreased in March 2017 when we began to offer *BCR-ABL* quantitative reflexively.



Conclusions: While redundant and duplicate orders waste medical resources, incorrect orders, such as a *BCR-ABL* major quantitation for a *BCR-ABL* minor+ patient, endanger patient safety. Our quality improvement approach, especially with the development of an ordering algorithm, is associated with decreased healthcare costs, and more importantly, improved patient care quality and safety.

Table 1. Total (n=272)

Grossly Normal (n=128)	Grossly Abnormal (n=144)							
	Inflammatory/							
reactive	Primary							
Neoplasm	Metastatic							
Malignancy	Histologically							
Normal	Inflammatory/							
reactive	Primary							
Neoplasm	Metastatic							
Malignancy	Histologically							
Normal								
Simple Appendectomy								
(Group 1, n=197)	46 (23%)	1(0.5%)	1 (0.5%)	29 (15%)	109 (55%)	5 (2%)	1(0.5%)	5 (3%)
Multipart Specimen								
(Group 2, n=75)	14 (19%)	3 (4%)	5 (6%)	29 (39%)	12 (16%)	3 (4%)	6 (8%)	3 (4%)

Table 2. Pathology Diagnosis in each category

Primary Malignancy	Metastatic Malignancy	Benign Inflammatory	Normal				
Low-grade appendiceal mucinous neoplasm	7	High grade serous carcinoma	6	Appendicitis and serositis	167	No Diagnostic Alteration	53
Well-differentiated neuroendocrine tumor (grade 1)	3	Metastatic carcinoma – unknown origin	2	Focal fibrous adhesions	4	Fibrous obliteration of the tip	13
Low grade mucinous adenocarcinoma	1	Metastatic mucinous adenocarcinoma	2	Follicular lymphoid hyperplasia	3		
Sessile serrated adenoma	1	Metastatic pancreatic carcinoma	1	Endometriosis	3		
	Metastatic leiomyosarcoma	1	Granuloma	2			
	Malignant mixed müllerian tumor	1	Mucin with no dysplasia	2			