



MICHIGAN MEDICINE
UNIVERSITY OF MICHIGAN

Department of Pathology

Annual Report

July 1, 2016 – June 30, 2017

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Department of Pathology Faculty, 2016-2017



CHAIR'S REPORT

Charles A. Parkos, M.D., Ph.D.

Carl V. Weller Professor and Chair

The Department of Pathology had another highly successful and busy year. During this time, the University of Michigan Medical School (UMMS) and Michigan Medicine continued to create new leadership roles: Dr. Carol Bradford as the new Chief Academic Officer, Michigan Medicine and Executive Vice Dean for Academic Affairs, UMMS; Dr. Bishr Omary as the new Chief Scientific Officer, Michigan Medicine and Executive Vice Dean for Research, UMMS; and Dr. David Spahlinger as the President of the U-M Health System and Executive Vice Dean for Clinical Affairs in the Medical School.

Last year, Drs. Runge and Spahlinger unveiled an ambitious plan to expand the Michigan Medicine clinical enterprise over the next 10 years to provide primary health care to 400,000 people locally and healthcare access to 3.5 million individuals across the state, reaching west to Grand Rapids and north to MidMichigan. These plans include expanding inpatient capacity at its main hospital location in Ann Arbor with satellite expansion plans in places such as Brighton, West and East Ann Arbor.

Overall, Michigan Medicine had a great year. There was a total cash flow margin of \$433.4M or 9.6% compared to an original forecast of \$215.0M or 5% margin and a FY 2016 performance of 8.3%. Improved performance in FY 2017 is attributable to strong patient care revenues, margin sharing, and philanthropy. The financial performance of the health system in FY17 remained strong compared to FY16. The Hospital and Health Centers (HHC) ended FY17 with an operating margin of \$219.9M and finished well above the budgeted and forecasted amount of \$139.1M. UMMG continues to be a major and increasing source of revenue, with an operating margin of \$208.3M compared to \$170.0M in FY16. While the Medical School budgeted a predicted loss of \$176.6M, a positive research portfolio and strong philanthropy growth associated with Victors for Michigan Campaign resulted in the year-end total margin loss of \$102.0M.

In FY2017, Pathology's faculty continue to receive many outstanding awards/accomplishments/recognition in the Department of Pathology on a national/regional level, some of which include:

Michael Bachman, MD International Business Times coverage on *mBio* study of K. pneumonia.

Ulysses Balis, MD is the recipient of American Joint Committee on Cancer (AJCC) Service Award, presented on September 9, 2016 at AJCC General Session.

Sriram Venneti, MD, PhD is the recipient of the Doris Duke Charitable Foundation 19th Clinical Scientists Award, the Sontag Foundation Distinguished Scientist Award and two UM Pediatric Brain Tumor Initiative Proof of Principal Awards

Allecia Wilson, MD, named President of the Michigan Association of Medical Examiners for 2017

Scott Tomlins, MD is winner of the 2016 Society for Basic Urologic Research (SBUR) Young Investigator Award

Rajesh Rao, MD ASCI Young Physician-Scientist Award

Tom Giordano, MD, elected to the American Thyroid Association's Board of Directors

Nicholas Lukacs, MD, named President-Elect of Society for Leukocyte Biology

We recruited 9 new faculty members since July 1, 2016, including:

Seema Sethi M.D. (Inflammation & Immunology), July 25, 2016
Sarah Choi, MD, Ph.D. (Hematopathology), September 1, 2016
Jean Tien, Ph.D. (MCTP), September 1, 2016
Julia Dahl M.D. (MLabs), September 8, 2016
Omar Moussa, MSc, Ph.D., D(ABHI), (Histocompatibility), January 1, 2017
Aaron Udager, M.D./Ph.D. (GU, H&N), January 1, 2017
Laura Lamps, M.D. (GI), February 1, 2017
Sethu Pitchiaya, PhD (MCTP), February 1, 2017
Jerome Cheng, M.D., (Informatics), April 1, 2017

Other highlights include multiple new leadership appointments and professorships to our Faculty:

Dr. Sean Li, Asst. Director of Transfusion Medicine and Director of the Blood Bank Laboratory, August 1, 2016
Dr. Judy Pang, Cytopathology Director, effective September 1, 2016
Dr. Julia Dahl, Assistant Clinical Professor and Associate Director of MLabs, September 1, 2016
Dr. Eric Fearon was named Director of UM's Comprehensive Cancer Center, September 2016
Dr. Allecia Wilson is the Program Director for the Anatomic and Clinical Pathology Residency Program, September 1, 2016
Madelyn Lew, MD, Director of Medical Student Education, October 14, 2016
Andrew Sciallis, MD, Director of Immunohistochemistry, March 22, 2017
Priya Kunju, MD, Co-Director of Surgical Pathology, April 1, 2017
Dr. Laura Lamps was named the Godfrey Dorr Stobbe Professor of Gastrointestinal Pathology, Director of Gastrointestinal Pathology, and Chief Patient Safety Officer for Michigan Medicine, February 1, 2017

There were 8 faculty promotions in 2016-2017. I thank Dr. Cho, the committee, and staff for all of their hard work on this successful, rigorous and vital departmental function.

FY2017 Pathology Promotions

Professor:

Thomas Wilson MD, PhD

Associate Professor:

Tomasz Cierpicki PhD
Jolanta Grembecka PhD
Bryan Betz PhD
Rohit Mehra MD

Assistant Professor:

Karen Choi MD
David Moons MD
Sean Li MD, PhD

The NCRC space is under the construction-activation phase with plans to move non-stat clinical activities for both Anatomic and Clinical pathology as well as informatics, MLabs and administration in the spring and summer of 2018. Moving into laboratories at NCRC that incorporate Lean design principles will not only align capacity with demand, but will provide an environment that fosters collaboration among staff, trainees and faculty. The move to NCRC reduces Pathology's current geographic dispersion from 10 locations to 5, and positions Pathology to better support strategic Michigan Medicine services, such as transplantation and oncology. Co-location with the UMMS Biorepository will also facilitate activities central to the goal of positioning Michigan Medicine as a leader in precision medicine. For the UH Renovation project, construction documents have been reviewed and feedback submitted. The project will be completed in 19 construction phases. Work

will start in May 2018 as the Surgical Pathology Lab moves to NCRC. The UH Renovation phase has an estimate completion date of June 2021.

The Department of Pathology remains in a very strong financial position. Our contributions to the health system continue to be robust. In particular, Pathology accounted for 10.0% of total hospital gross revenue, but only 4.0% of total expense in FY17. Surgical pathology cases grew (in-house, transfers and consults) at an annual growth rate of 6.1%. Our extramural consultation practice continued to be a key area of practice growth with 14,491 AP cases signed out in FY2017 compared to 13,449 in FY2016, an annual increase of 7.7%. Our autopsy services continued to flourish and increase, mostly driven by increased forensic cases at Wayne County Medical Examiner's Office which performed nearly 3,000 examinations this year. Our Cytopathology service volume decreased slightly, while rapid onsite evaluations continued to play a prominent role in our practice.

Given these caseloads, there was a corresponding 8.1% increase faculty productivity as measured by work-relative value units (RVUs). The clinical laboratories continue to perform increasing numbers of sophisticated tests. In FY17, there were nearly 5.8 million billed tests resulting in an 7.4% increase in gross charges. These respectable increases have come with only 6.9% and 3.0% increases in expenses and staff support. Another important success was our department's ongoing cost saving and conservative measures to preserve blood products. Thanks to efforts of our clinical and administrative teams, the department has seen a 15% reduction in annual blood costs over the past 5 years.

As Vice Chair for Clinical Affairs and Quality, Dr. Jeffrey Myers oversees the Divisions of Anatomic Pathology, Clinical Pathology, Quality Safety, and Veterans Affairs. In addition, he continues to serve as Director of MLabs. Its FY17 total gross charges of \$65M held steady compared to FY16, reflecting a balance of new client acquisition with departure of others. Dr. Myers' has solidified his leadership team with the successful recruitment of Dr. Julia Dahl as MLabs Associate Director, Deirdre Fidler as Operations Manager and Susan Valliere as Business Development Strategist.

Under the directorship of Dr. Scott Owens, the Division of Quality and Health Improvement (DQHI) continues to collaborate on numerous projects such as the Patient Asset Management Initiative, Laboratory Stewardship Program, patient- and family-centered pathology, Quality Improvement Curriculum. The Division is a key stakeholder in the Department's ability to provide reliable, value-added, safe, and patient-centered care to the lives entrusted to Michigan Medicine, the broader University of Michigan Health System, and our outreach clients who become Michigan Medicine patients through the MLabs Division.

The Wayne County Medical Examiner's office has been managed by U-M pathology since October 2014. Contract negotiations were just completed and awaiting County Board approval of a new five-year contract. Wayne County Medical Examiner's Office is led by Chief Medical Examiner, Dr. Carl Schmidt. Other key members of this team are:

Avneesh Gupta, M.D., Assistant Medical Examiner
Leigh Hlavaty M.D., Deputy Chief Medical Examiner
Lok Man Sung M.D., Assistant Medical Examiner
David Moons M.D., Assistant Medical Examiner

The Division of Molecular and Genomic Pathology (DMGP) directed by Dr. Thomas Giordano, DMGP consists of the Molecular Diagnostics Laboratory (MDL), the Cytogenetics Laboratory the Dermatology Molecular Diagnostics laboratory and the MCTP as well as working very closely with the Michigan Medical Genetics Laboratories (MMGL). Tom has made significant progress on a department strategy for future test development, a critical goal as the department prepares to move to new facilities at NCRC amidst a complicated landscape within the hospital system. regulation of LDTs, standardizing laboratory work culture, collaboration with MLabs and commercial laboratories and faculty recruitment.

The Division of Information Technology, led by Dr. Ulysses Balis, accelerated its activity in support of the department's upcoming move to its new home in the North Campus Research Complex (NCRC), with signature initiatives such as PathTrack – a sophisticated tool suite to track every asset being moved between all departmental locations.

As Vice Chair for Academic Affairs, Dr. Kathleen Cho works very closely with the Divisions of Anatomic, Clinical and Experimental Pathology, Education, Faculty Affairs the Molecular Center for Translational Pathology to provide excellent mentorship and support academic advancement through the University of Michigan's complicated promotions process.

Pathology's basic, translational and clinical research programs continue to thrive and funding remains very strong, despite the continuation of a challenging funding climate. The Division of Experimental Pathology (EP), directed by Dr. Asma Nusrat, finished FY17 with an excellent funding record of \$28M, received largely from federal sources with additional funding from non-profit organizations and industry and, impressively, ranked #7 nationally. Research productivity is further evidenced by a high \$125/sq. ft. indirect cost that is allocated to pathology faculty who reside in greater than 64,000 sq. ft. which has consistently surpassed the University of Michigan Medical School benchmark of \$110/sq. ft. These accomplishments are a clear testament of EP faculty outstanding research accomplishments in spite of a very challenging national funding climate.

In particular, new EP grant funding included 39 grant awards with 21 grants from the NIH, 3 from the Department of Defense, 3 career development awards and 12 awards from industry and non-profit organizations. In addition, EP faculty published 278 manuscripts, including papers in high-impact journals such as *Cell*, *Nature*, *Science*, *Nature Communications*, *Journal of Immunology*, *Oncology*, *Biotechnology*, *Mucosal Immunology*, and the *New England Journal of Medicine* among others.

Dr. Steven Kunkel has maintained a leadership role in the University of Michigan Medical School's Office of Research that has developed and continues to implement robust strategic research plans. The Office of Research 2017 initiatives have included management of a central bioprepository, research data warehouse/data direct, biomedical research core facilities, fast forward medical innovation and the launching of seven clinical trial support units.

The Michigan Center for Translational Pathology (MCTP) directed by Arul Chinnaiyan and Molecular Diagnostics Division in Pathology have continued to develop and introduce tests for diagnosis of tumors. Dr. Chinnaiyan and the MCTP recently described the genomic and transcriptomic landscape of metastatic cancer profiled through MiOncoseq. A seminal manuscript describing the first 500 patients was published in the journal *Nature*. In addition to the ongoing clinical trials at U of M, the MiOncoseq test will be licensed to Tempus for use nationally.

The Division of Pathology Education remains strong and was led by the following leadership and administrative team:

Program Director Allecia Wilson M.D.
Associate Program Director Barbara J. McKenna, M.D.
Fellowship Coordinator Marie Goldner
Residency Program Coordinator Pamela Howard
Medical Student Program Coordinator and Conference Coordinator Desire' Baessler

Our Residency Program at the University of Michigan was ranked #1 in the United States among large public hospitals, and #6 overall by Doximity, an online social networking service for U.S. physicians with over 400,000 verified physician members. Our department continues to be able to offer a diverse portfolio of competitive clinical fellowships. There are 9 ACGME-accredited fellowships offering 16 positions, and 10 additional clinical fellowships offering 12 positions. In addition, the Department created The Physician Scientist Training Pathway

(PSTP), which will provide rigorous clinical training and mentorship in biomedical research in a supportive environment with the objective of helping trainees establish successful careers as independent, funded investigators and outstanding pathologists. Upon completion of clinical training, PSTP trainees will enter a postdoctoral research fellowship with 2-year guaranteed financial support, working with a mentor in the Department of Pathology or approved department within the University.

We have over 20 faculty members actively engaged in transitioning to the new Medical School Curriculum to include changes in M1 and M2 teaching along with changes to the M4 elective. Planning is underway for Clerkship X and changes to the Branches. Drs. Nikolovska-Coleska and A. Lieberman, Co-Directors of the NIH T32 training grant, continue to lead a vigorous training program in translational research with six trainees. The Molecular and Cellular Pathology (MCP) Graduate Program, directed by Dr. Nikolovska-Coleska, now has 26 PhD, MD/PhD students in Pathology Department laboratories performing their Ph.D. thesis research and is one of the most competitive grad programs in PIBs.

I continue to meet residency applicants well as regular meetings with our current residents and fellows and am continually impressed with their quality, accomplishments and diversity of backgrounds. Our match results were nothing less than spectacular, filling all six available residency positions with excellent trainees, coming from medical schools in Michigan, Maryland, and Vermont.

Dr. Stephen Chensue is Chief of Pathology and Laboratory Medicine at the Veteran's Administration Ann Arbor Healthcare System (VAAHS) and maintains a close relationship with the University of Michigan's Department of Pathology. Also, the VAAHS is a member of Veterans Integrated Service Network (VISN) and serves the veteran population of Michigan, Ohio, and Indiana. The VAAHS laboratory provides comprehensive anatomical and clinical services with local and regional hospitals and clinics. Its clinical pathology tests increased 5% over the previous period. Due to the increasing population of women veterans, gynecologic pathology is becoming an important component of the VAAHS workload. The Ann Arbor VA laboratory is rated a VA "Center for Excellence" in cytology.

In closing, this past year has been a huge success that was made possible by hard work of our many talented faculty, trainees, and staff. Without a doubt, our department is one of the very best academic pathology units in the U-S and abroad, and a key ingredient to our success is the overarching spirit of collegiality and collaboration. Our leadership team including vice chairs, division and section heads as well as managers are second to none. Our administrative team continues to offer superb service in an increasingly complex business and academic environment. In particular, I'd like to thank Marty Lawlor, David Golden and the members of the finance team; Sarah Dudley-Short and Carrie Scott in faculty affairs; and Vashni Santee, Angie Suliman and Michal Warner for their dedication and reliable support in the Office of the Chair. Thank you all for a job well done!

Division of Anatomic Pathology
David R. Lucas, M.D.
A. James French Professor of Anatomic Pathology
Director, Anatomic Pathology

EXECUTIVE SUMMARY

Anatomic Pathology (AP) had a very productive and successful year across all three missions (patient and family care, research, and education). Demand for clinical services remained strong across the practice, accounting for record growths in surgical cases. Our outside consultation in AP alone increased to over 14,000 this year. Research productivity hit record levels measured across multiple metrics. Our educational programs continue to reflect our collective passion for teaching a diverse group of learners ranging from University of Michigan medical and dental students, residents, fellows, graduate and post-graduate students, and continuing medical education participants.

Dr. Karen Choi joined the faculty in July 2016 as Assistant Professor in the clinical track with primary responsibilities in gastrointestinal pathology.

Dr. Laura Lamps joined the faculty in February 2017 as Professor in the clinical track. She will divide her time between gastrointestinal pathology, where she is service chief, and her newly created role as Chief Patient Safety Officer for Michigan Medicine.

Dr. David Moons joined the faculty in July 2016 as Assistant Professor in the clinical track with primary responsibilities in forensic pathology at the Wayne County Medical Examiners Office.

Dr. Aaron Udager joined the faculty in January 2017 as Assistant Professor in the clinical track. In addition to contributing to the genitourinary pathology and surgical pathology practices, he participates head and neck pathology consultation and research in genitourinary and head and neck neoplasia.

Drs. Doru Andea, Priya Kunju, and Jon McHugh were promoted to Full Professors (effective September 1).

Drs. Sandra Camelo-Piragua, May Chan, Alex Hristov, Judy Pang and Scott Tomlins were promoted to Associate Professors (effective September 1).

Judy Pang became Director of Cytopathology, **Andy Sciallis** became Director of Immunohistochemistry, **Priya Kunju** became Co-Director of Surgical Pathology, and **Laura Lamps** became the service chief for GI pathology.

CLINICAL ACTIVITIES

Our AP services continue to realize strong year-over-year growth, increasing from a total of 107,705 surgical pathology cases (in-house, transfers and consults) in FY2016 to 114,278 in FY2017, an annual growth rate of 6.1%. Our extramural consultation practice continued to be a key area of practice growth with 14,491 AP cases signed out in FY2017 compared to 13,449 in FY2016, an annual increase of 7.7%. Our autopsy services continued to flourish and increase, mostly driven by increased forensic cases at Wayne County Medical Examiner's Office which performed nearly 3,000 examinations this year. Our Cytopathology service volume decreased slightly, while rapid onsite evaluations continued to play a prominent role in our practice.

The total number of work-relative value units (RVUs), the measure by which Medicare and other payers recognize and reimburse professional activity, increased due to growth in accessioned cases. Total RVUs/month increased to 20,516 in June 2017 from 19,097 in June 2016, accounting for a 7.4% year-over-year increase. The number of AP faculty FTEs increased from 34.42 in FY2016 to 38.19 in FY2017; and faculty productivity, measured as RVUs/FTE/month increased by 8.1%, indicating that we are working harder than we did last year.

Surgical Pathology

Surgical pathology services continued to demonstrate strong growth in nearly all services with a 9.3% annual year-over-year growth in case volume (see Table 1). The largest growth in numbers of accessioned cases was realized in our general (Room 1) service which grew by over 1,100 cases.

Surgical pathology continued to support four separate frozen section labs: University Hospital, Cardiovascular Center (CVC), East Ann Arbor, and Mott Hospital. Faculty participating in the Surgical Pathology Officer rotation established in FY2013 continued to play a key role in supporting frozen section practices at CVC and Mott Hospital while also supporting appropriate selection of send out materials.

Table 1: Surgical Pathology Clinical Activity, FY12–FY16

	FY13	FY14	FY15	FY16	FY17	YOY change
Breast	2,330	2,346	2,513	2,478	2,325	(6.1%)
Gastrointestinal	17,570	18,144	19,787	22,799	23,775	4.3%
Genitourinary	2,304	2,381	2,515	2,914	3,354	15.1%
Gynecological	6,166	6,013	6,217	6,765	6,958	2.3%
Surg path– Room 1	9,686	10,658	11,157	12,388	13,544	10.5%
TOTALS	38,056	39,542	42,189	47,294	49,956	9.3%

Pediatric and Perinatal Pathology

The pediatric and perinatal pathology practice continued to flourish in FY2017. As summarized in Table 2, the pediatric surgical service handled 3,498 cases from the CS Mott Hospital ORs, accounting for a 6.4% year-over-year increase from FY2016. There was a total of 1,846 placentas signed out from the Von Voigtlander Women’s Hospital. Pediatric and fetal autopsies increased to 41 and 180 cases, respectively, indicating significant year-over-year increases from FY2016.

Table 2: Pediatric Pathology Clinical Activity, FY12 – FY17

	FY12	FY13	FY14	FY15	FY16	FY17	YOY Change
Peds (IP)	2,177	2,191	2,793	3,426	3,288	3,498	6.4%
Placentas (PL)	1,456	1,650	1,715	1,756	1,822	1,846	1.3%
Pediatric autopsies	29	25	37	32	38	41	7.9%
Fetal examinations	36	115	129	149	151	180	19.2%

In addition to surgical cases and placentas, the pediatric team covered all pediatric autopsy cases from Mott Hospital, most of which were reviewed in grand rounds and morbidity/mortality meetings with various pediatric/perinatal subspecialties. The team participated in over 160 multidisciplinary and teaching conferences at Mott and Women's Hospital at which 1573 patients' cases were discussed.

Dermatopathology

The Dermatopathology service receives diagnostic case material from four primary sources: (1) UMMC (ID) cases; (2) outside contractual (MD) cases; (3) outside cases reviewed for referred patients (TD); and (4) personal consultation cases. We continue our active and integral involvement in the University of Michigan Multidisciplinary Melanoma Clinic and Tumor Board, Multidisciplinary Cutaneous Oncology Clinic and Tumor Board, and the Cutaneous Lymphoma Tumor Board.

Dermatopathology case volumes increased by 13.1% over FY2016, mostly due to increases in MD and outside consult cases and consults (See Table 3).

Table 3: Dermatopathology Clinical Activity, FY15-FY17

	FY15	FY16	FY17	YOY Change
ID	14,183	15,712	15,229	-3.1%
Squares	393	488	545	11.6%
MD	8,836	8,410	12,239	45.5%
Consults	2,421	2,754	3,380	22.3%
Transfers	3,945	4,203	4,310	2.5%
TOTALS	29,778	31,567	35,703	13.1%

Faculty in the Dermatopathology section maintained the rich tradition of excellence in clinical service, education, scholarship and administrative service over the past academic year. **Dr. Doug Fullen** continues in his leadership role as director of the section. **Dr. Lori Lowe** continues to provide excellent clinical service, senior leadership, and dermatology expertise to her colleagues. **Dr. Aleador Andea** continues as Director of the Dermatopathology Molecular Research Laboratory, which successfully underwent a College of American Pathologists (CAP) inspection this past year. In addition to their primary roles in the dermatopathology service, **Drs. Rajiv Patel** and **May Chan** continue to participate in the soft tissue and bone pathology and general surgical pathology (Room I) services, respectively. In addition, **Dr. Patel** lends his expertise in sarcomas in support of the Sarcoma SPORE. In addition to her role in the dermatopathology service, **Dr. Alexandra Hristov** provides invaluable hematopathology expertise to the service and the Cutaneous Lymphoma Tumor Board. **Dr. Paul Harms** continues to balance clinical service, including molecular sign-out in the DMRL, with collaborative basic science research focused primarily on Merkel cell carcinoma.

This was another productive academic year for the dermatopathology faculty with high visibility of our faculty at national and international meetings. **Dr. Andea** remains on the Program Committee for the United States and Canadian Academy of Pathology. Despite the high specimen volume on the clinical service, the dermatopathology faculty remains very productive in scholarly activities. The dermatopathology faculty had 55 peer-reviewed publications or articles in press, 20 abstracts presented at scientific meetings, and moderated one oral abstract session at the United States and Canadian

Academy of Pathology (**Dr. Harms**) during the past academic year. The faculty is actively involved in twelve research grants as principal or co-investigators on these studies. Dermatopathology faculty members were invited speakers at institutional, national or international meetings on 27 occasions. Three dermatopathology faculty members serve on 6 editorial boards. Multiple faculty are members on national and international society committees; notably, **Dr. Hristov** assumed Chairperson of the Membership Committee for the American Society of Dermatopathology.

Neuropathology

Sandra Camelo-Piragua, Andrew Lieberman, Kate McFadden, Paul McKeever, and Sriram Venneti contributed to the neuropathology service. The service signed out 1631 cases this year (not including autopsy), up 9.0% from the 1497 cases signed out in FY2016. There were 846 surgical specimens examined, up from 748 cases in FY2016 and comprising 52% of the case volume. This represents an 13.1% increase in case numbers from FY2016. In addition, consults increased from 248 cases in FY2016 to 312 cases in FY2017, an increase of 25.8%. An additional 138 transfer cases were signed out by the service.

The muscle and nerve biopsy service was staffed by **Drs. Camelo-Piragua, McFadden and McKeever**. In FY2017 they signed out a total of 335 cases, down 9.2% from the 369 cases signed out in FY16.

Brain cutting was staffed by **Drs. Camelo-Piragua, Lieberman, McFadden and Venneti**. In FY2017, 143 cases were examined at brain cutting, a 23% increase from FY2016. This includes UH hospital cases, ME cases, and cases acquired through the UM Alzheimer Center that required a more extensive evaluation. This number also includes cases examined at Mott during pediatric brain cutting, staffed by **Dr. McFadden**.

Neuropathology faculty staffed the following conferences: twice weekly neuropathology case conference; monthly neurosurgery CPC; weekly adult brain cutting; monthly pediatric brain cutting; weekly nerve and muscle conference; weekly brain tumor board; and monthly precision medicine conference.

Neuropathology faculty members taught medical students in the fall and spring semesters during the neuroscience sequence (3 lectures, 3 laboratory sessions). This sequence was held twice during FY2017 due to changes to the medical school curriculum. Faculty members also ran a short course for residents as an introduction to diagnostic neuropathology. Educational activities included sponsorship of an ACGME approved two-year fellowship.

Table 4: Neuropathology Clinical Activity FY15-FY17

	FY15	FY16	FY17	YOY change
Consults	198	248	312	25.8%
Outside Neuromuscular	150	194	179	-7.7%
Inside Neuromuscular	224	175	156	-10.9
Surgical cases	764	748	846	13.1%
Transfers	153	132	138	4.5%
TOTALS	1,489	1,497	1,631	9.0%

Ophthalmic Pathology

Ophthalmic pathology services under the direction of **Dr. Vic Elner** remained stable with 1248 cases signed out in FY2017. Improvements in laboratory management and organization were initiated resulting in improve service delivery.

Nephropathology

Drs. Paul Killen, Jeffrey Hodgins, Evan Farkash, and **Kent Johnson** supported our renal biopsy service in FY2107.

Our renal biopsy practice continued to stabilize in FY2017; accessioning 1,101 cases compared to 1,171 in FY16 reflecting a 6.0% year-over-year decrease (see Table 5). This is the sixth consecutive year in which annual volumes have been above 1,100 cases. Whole slide scanning remains an aspirational goal as a method for archiving and virtual review of biopsies from renal transplant patients.

Table 5: Renal Biopsy Case Volumes, FY13 – FY16

FY13	FY14	FY15	FY16	FY17	YoY change
1,370	1,194	1,121	1,171	1,101	-6.0%

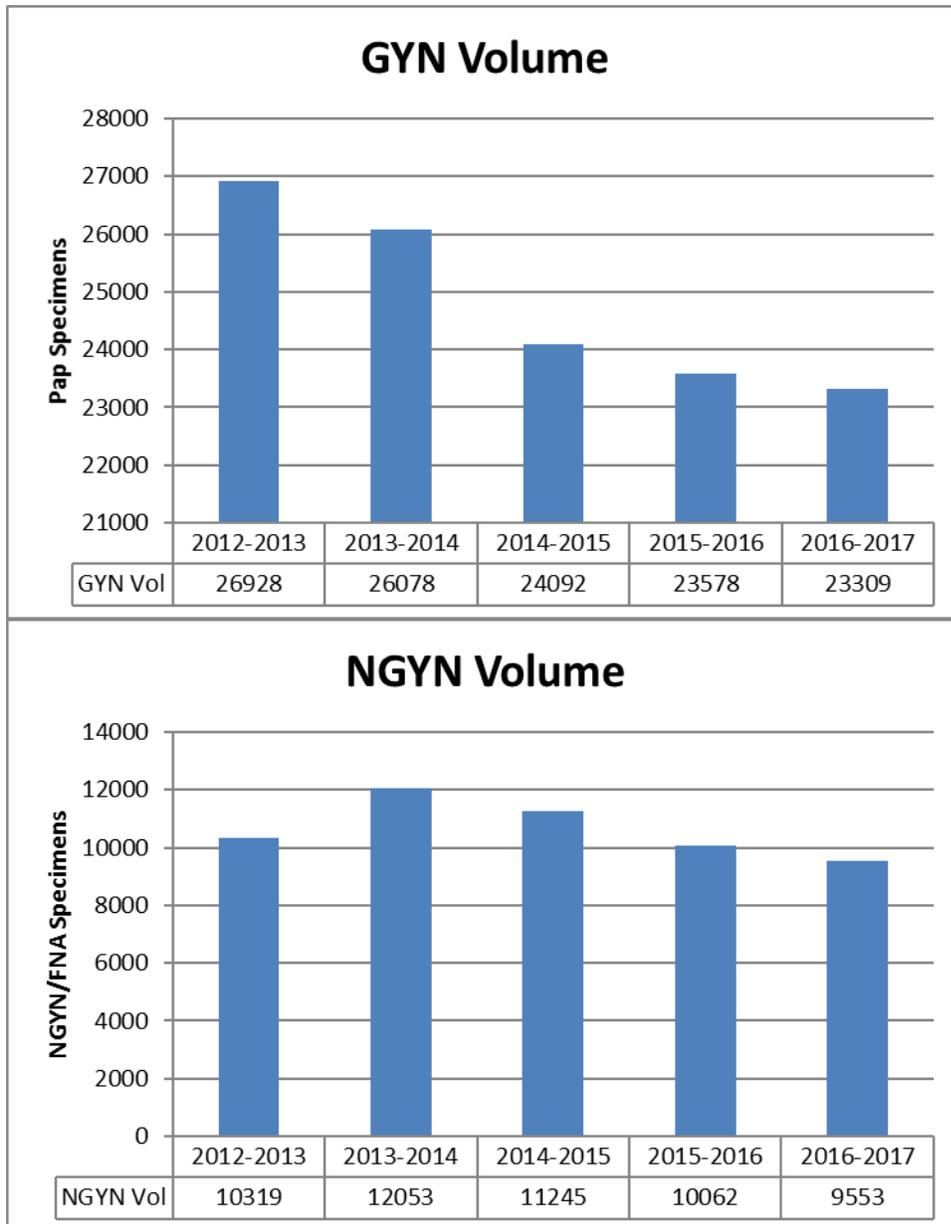
Cytopathology

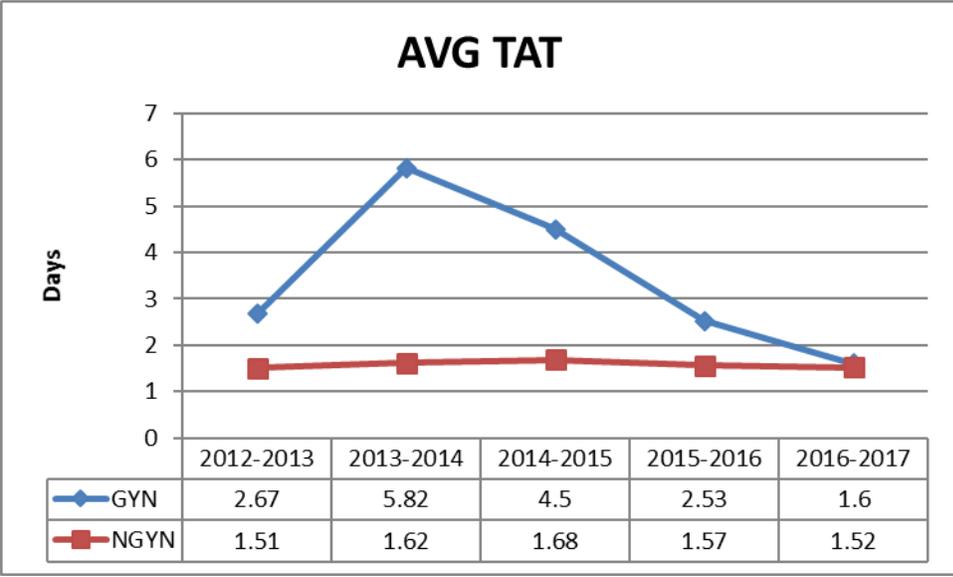
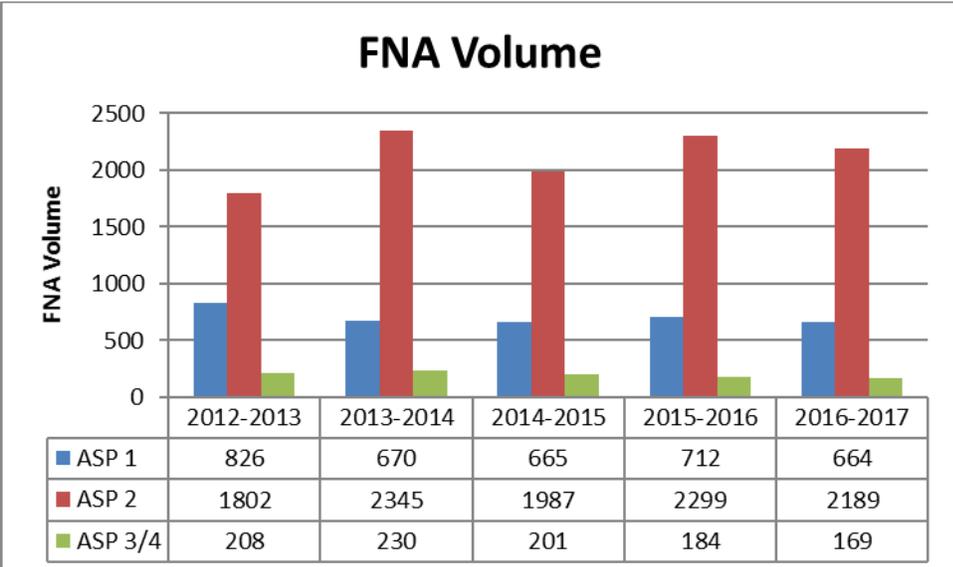
- Our cytopathology fellow, **Dr. Weihong (Michelle) Li**, performed admirably and successfully completed her fellowship in cytopathology.
- The Cytopathology Laboratory performed exceptionally well in this year's CAP inspection with no citations. Kudos to the entire Cytopathology Team for everyone's efforts on a daily basis to keep the laboratory in compliance with CAP checklist guidelines.
- The FNA service continues to be a busy service that strives to provide service excellence in a variety of geographically dispersed settings. ASP2 FNA on-site assistance is provided at the Medical Procedures Unit, Taubman Center Otolaryngology and Endocrine Surgery clinics, Cardiovascular Center, Radiology (ultrasound and CT), Domino's Farms and CS Mott Children's Hospital. Pathologist performed FNAs with and without ultrasound guidance (ASP4 and ASP3, respectively) are performed at Cancer Center Room 32 and at the bedside in the inpatient setting at UMHS.

Table 6: Cytopathology Clinical Activity

	TOTAL VOLUME							
	2009-10	2010-11	2011-12	2012-13	2013-14	2014-15	2015-16	2016-17
GYN TOTAL	36392	34014	32866	26928	26078	24092	23578	23309 -1.15%
TOTAL NGYN/FNA	9398	9812	9664	10319	12053	11245	10062	9553 -5.06%
EXFOL NGYN	6867	7123	7034	7483	8808	8392	6867	6531 -4.9%
ASP TOTAL	2531	2604	2630	2836	3245	2853	3195	3022 -5.42%
ASP1	977	962	862	826	670	665	712	664 -6.75%
ASP2	1276	1423	1526	1802	2345	1987	2299	2189 -4.79%
ASP3/4 (ASP4)	278	219	242	208	230 (93)	201 (160)	184 (106)	169 -8.16% (82)

The mean turnaround time for non-GYN cytology cases, including FNAs, was 1.52 days. Total gynecologic cytology specimens declined slightly as a consequence of changes in follow-up Pap test recommendations for HPV negative women, dropping 1.15% to 23,309. The mean turnaround time for GYN cytology cases was 1.60 days.





Summary of Service Initiatives and LEAN activities in Cytopathology

- Implementation of 88177 CPT code for each additional evaluation episodes until an adequate specimen is obtained for ASP2s (started September 2016) has generated \$93,396. Although overall ASP2 volumes have decreased, when comparing dollars generated, with the addition of the 88177, there is an overall increase in dollars **(FY17 \$953,276 vs FY16 \$913,900 [+4.31%])**
- Mobile telecytology carts have been constructed and successfully employed during this past year to assist with staffing of ASP2 FNA procedures. Telepathology was installed on both carts in MPU. We would like to thank **Brian Smola, Bill Solinski, and Oliver Bichakjian** who have been tremendously helpful in overcoming the barriers in successful and efficient delivery/implementation of this technology. Efforts to continuously improve the quality and implementation of this technology are ongoing.
- Laboratory staff continues to be actively engaged in problem solving and practicing Lean thinking in a standardized manner utilizing the A3 and root cause analysis tools. For instance, Cytopathology developed and presented a poster at the 2016 Quality Month celebration, entitled "Pap Test Turn-Around Time – Challenging Ourselves to Change the Status Quo."

Cytopathology staff also actively participated in Lean projects led by DQHI. Cytopathology, in collaboration with Molecular Microbiology” is participating in the root cause analysis of misrouted Pap test samples from one of our new MLabs clients. In addition, the “Shared ThinPrep Vials” is one of three pilots that were initiated this past year in an effort to develop “PathTrack” a specimen tracking tool that will facilitate safe transfer of specimens and other assets between Pathology laboratories and between UH and NCRC.

Cytopathology, in collaboration with Hematopathology also implemented a new procedure for triage of CSF samples for which both Cytopathology and cell count/differential testing is ordered. The intent is to minimize unnecessary testing and allow Hematopathology to assess samples for which the patient has a history of hematopoietic tumors.

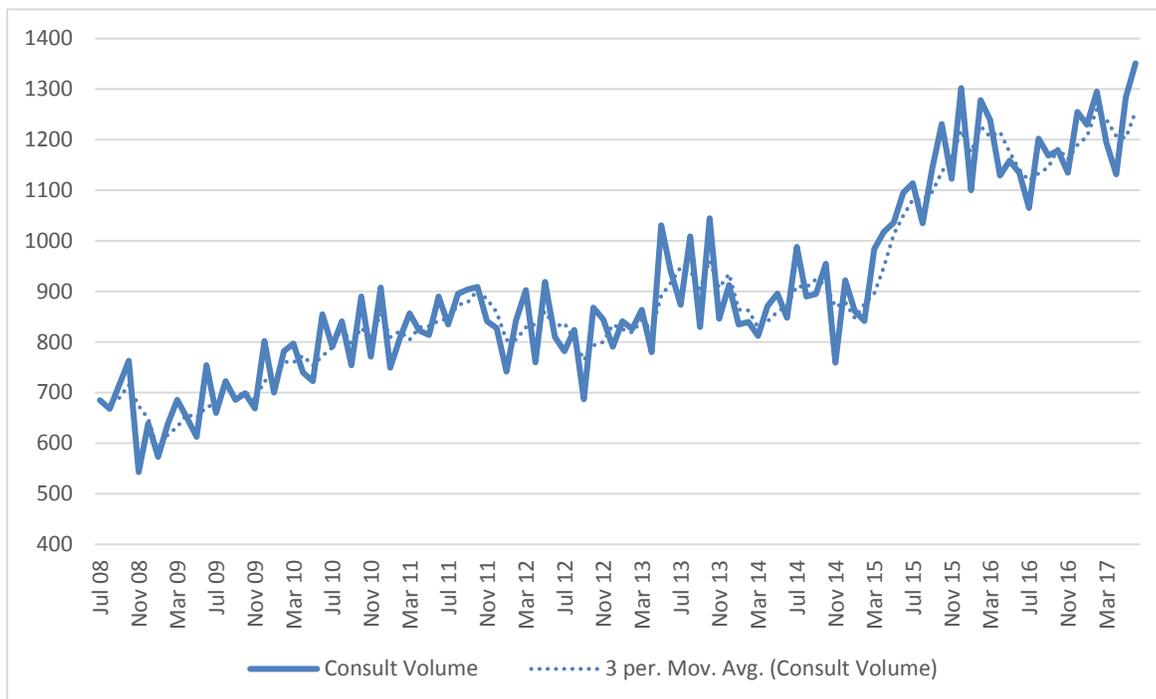
In addition, Cytopathology transitioned to a “paperless” workflow for Pap tests in support of a request from the OB/GYN clinic to discontinue the printing of requisitions for Pap test orders that are placed in MiChart.

- Cytopathology continues to collaborate with the Molecular Diagnostics Laboratory in their development of new assays. Furthermore, cell blocks are prepared using cell lines which are utilized as positive controls for various other FISH assays.
- In collaboration with the breast pathology service, cytotechnologists continue to be involved in utilizing the Ventana iScan Coreo/Virtuoso system for scoring ER/PR and Her2/Neu expression in breast tumors. A total of 5 cytotechnologists are currently trained (**Kalyani Naik, Binita Naylor, Kim Luckett, Brian Smola, and Kent Traylor**) and are performing scoring on approximately 824 breast biopsies (2296 slides) annually. Additional cytotechnologists will be trained.
- The cytopathology staff and faculty are actively involved in the NCRC relocation planning process, as well as planning of the UH space. Modification and optimization of case distribution/sign-out will be ongoing.

Extramural Consultation Practice

Our Surgical and Cytopathology services continue to attract a substantial extramural consultation volume with a record number of cases this year of 14,491, representing a 7.7% year-over-year increase from FY2016. In addition to increasing faculty experience, diagnostic skills and research ideas, our robust consultation practice extends our educational programs, builds client relations, draws revenue for the department, enhances faculty compensation, and helps recruit patients to Michigan Medicine.

Consult Case Volume Jul_08 - Jun_17 (cases signed out/month excluding Heme cases)



AP Consult Volume by Specialty

Specialty	FY14	FY15	FY16	FY17	Percent Change
Breast	465	580	777	600	-23%
Cytology	473	459	572	598	5%
Endocrinology	244	331	380	414	9%
Gastrointestinal	2,876	3,146	3,338	3,450	3%
Gynecological	592	659	899	1,006	12%
Genitourinary	433	493	657	735	12%
Head/Neck	400	370	552	545	-1%
Inside Muscle	223	198	248	312	26%
Dermatopathology	2,328	2,421	2,754	3,380	23%
Eye	52	32	32	41	28%
Pediatric	121	99	124	137	10%
Renal	12	8	10	6	-40%
Bone and Soft Tissue	688	732	886	1,030	16%
Cardiac	2	12	16	6	-63%
Pulmonary	1,750	1,733	2,243	2,350	5%
Grand Total	10,659	11,273	13,488	14,610	

Autopsy and Forensic Services

FY 2016-2017 OVERVIEW

The autopsy and forensic service provided for staff and resident coverage for the performance of autopsies for Michigan Medicine, MLabs, the VA hospital and ancillary research programs (ADRC). The section also provided autopsy and administrative services for the Washtenaw and Wayne County medical examiner functions. The section supports two forensic fellowship positions. Pathology residents complete three one-month rotations on the autopsy service during their training to accomplish the required number of autopsies to fulfill American Board of Pathology requirements.

Educational conference on the autopsy service include a weekly morning gross autopsy review conference, resident grand rounds conferences emphasizing autopsy pathology clinic-pathological correlations and mortality conferences throughout the hospital. Monthly didactic forensic pathology multidisciplinary conferences (CDRT, Suicide, etc.) are also supported by the staff. The autopsy section sponsors two conferences, Advances in Forensic Medicine and Pathology (May) and Medicolegal Death Investigation Course (Nov).

Washtenaw County received re-accreditation by the National Association of Medical Examiners (NAME) for five years.

STATISTICAL REVIEW

During the 2017 academic year the Autopsy and Forensic Service performed a total of 311 autopsy examinations for Michigan Medicine. These included adult, pediatric and brain only examinations.

The service performed 397 full autopsies and 61 external examinations for the Washtenaw County medical examiner and 2169 full and 53 limited autopsies and 759 external examinations for the Wayne County medical examiner for FY2016 with 97% of cases completed under 90 days.

Current Programs

Autopsy Performance: The service has made significant improvements in hospital autopsy completion times with an average time of 36 days for hospital cases, 21 days for Washtenaw cases and 33 days for Wayne cases for 2017.

Forensic Fellowship: The forensic fellowship program continues to attract two fellows per year. The program is proceeding in training high-quality forensic pathologists. We are applying for permission from the ACGME to increase the number of fellows to three with financial support of Gift-of-Life.

Wayne County: Contract negotiations are completed and awaiting County Board approval of new five-year contract.

Livingston County: We submitted a proposal to provide autopsy service for Livingston County with an anticipated increase of 125-150 autopsies.

Accreditation: The Washtenaw County medical examiner office received a five-year re-accreditation in September by the National Association of Medical Examiners.

Staffing

The Autopsy and Forensic Service has a staff of six death investigator/autopsy assistants and one supervisor/coordinator. Staffing is currently depleted to half due to vacancies and medical leave. The staff is responsible for all medicolegal death investigations and medical examiner autopsies, hospital pediatric and adult autopsies, brain only autopsies and removals. At the UM here are 1.25 FTE pathologists assigned to the service following the recent resignation of a 0.5 FTE pathologist. Wayne County currently has 3.0 forensic pathologist vacancies due to staff relocations.

Challenges

Staff: The main challenge at the current time is the recruitment and retention of employees. The current depleted supply of pathologists in combination with excess case load resulting from the current opioid epidemic.

Autopsy/Cooler Space: We intend to augment autopsy space by using Gif-of-Life space for organ and tissue donors which should alleviate storage pressure

RESEARCH ACTIVITIES

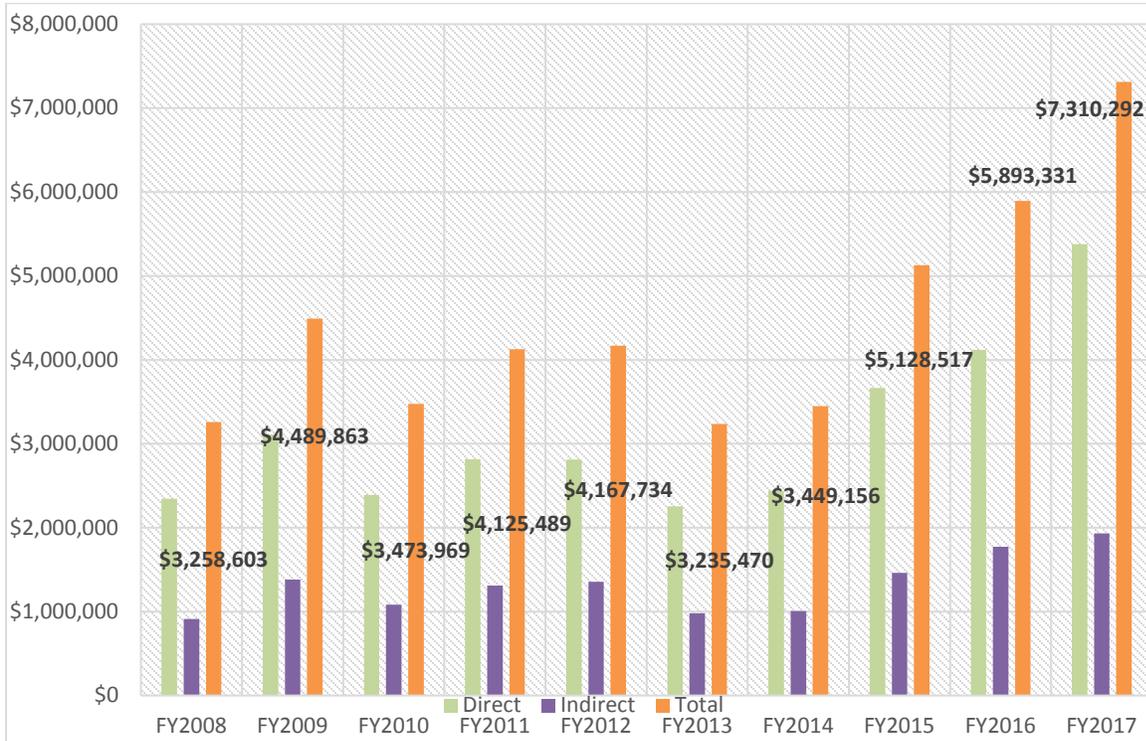
Success and vitality in our research activities remain strong as evidenced by continued visibility in peer-reviewed journals considered high impact by the academic anatomic pathology community. Extramural funding remained remarkably strong despite the unfavorable national funding climate. The number of peer-reviewed publications (in print or in press) increased to 334 (11% year-over-year growth from FY2016) as did invited lectures at 234 (26% year-over-year growth from FY2016). Clearly our faculty remains top-of-mind when looking for cutting edge speakers in AP. Twenty-four different faculty were on editorial board; an attestation to high national recognition by our faculty (see Table 7).

Table 7: Academic Productivity in AP, FY14 – FY16

	FY15	FY16	FY17	% YOY Change
Publications	301	301	339	13%
Invited lectures	187	186	236	27%
Editorial boards	46	58	53	-9%
FTEs funded	7.01	6.42	5.47	-15%
Research expenditures	\$5,128,517	\$5,893,331	\$7,310,292	24%

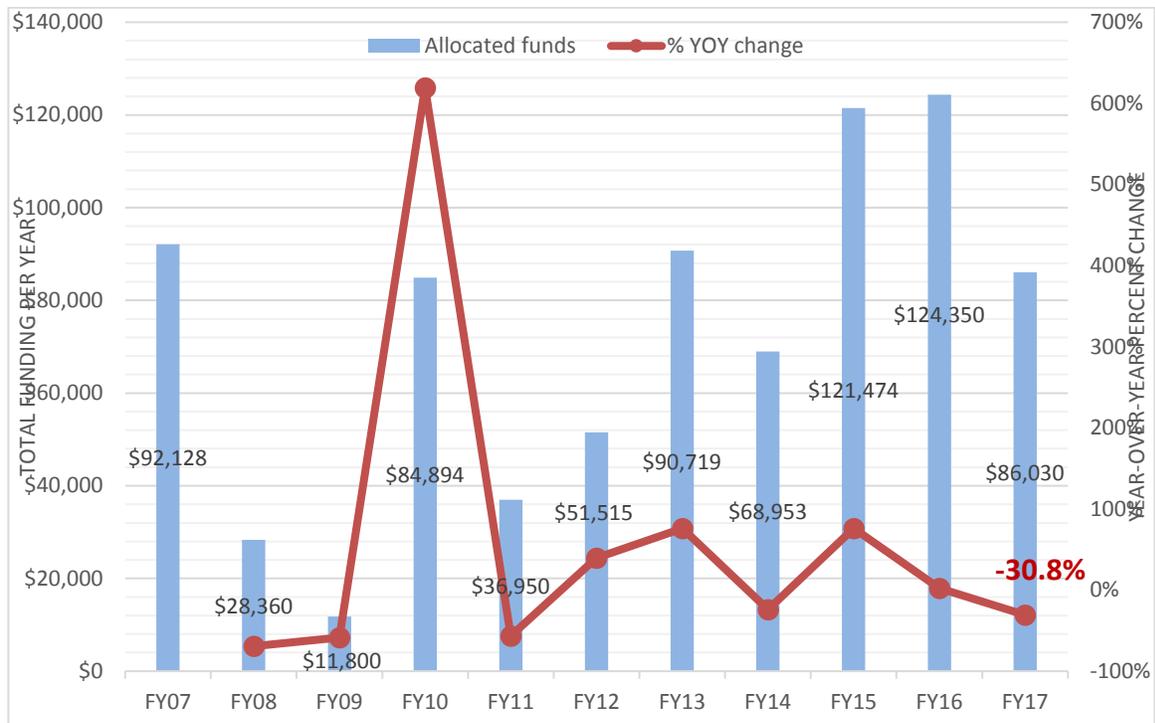
Research expenditures in FY2017 grew by \$1,416,961, reflecting a year-over-year increase of 24% compared to FY2016 and a record level of extramural research support in AP (see Table 8). Major contributions to this year-over-year increase were from **Drs. Asma Nusrat** (\$803,389), **Kathy Cho** (\$394,125), **Scott Tomlins** (\$339,186), **Jeff Hodgins** (\$319,436), **Sriram Venneti** (\$239,136), and **Andy Lieberman** (\$145,728). Research expenditures in FY2017 increase by more than 124% over FY2008 and speak to the vitality of our research mission. The total number of FTEs funded through extramural sources decreased slightly from 6.42 to 5.47. Maintaining current levels of funding in today's environment reflects the remarkable success of our laboratory investigators, all of whom also have substantial commitments to patient care. Addition of young clinician scientists like **Drs. Evan Farkash, Jeff Hodgins, Rohit Mehra, Scott Tomlins, Sriram Venneti, Aaron Udager, and Jiaqi Shi** is an important part of our strategy to maintain the vitality of our laboratory based discovery programs, and hinges on continued attention to the infrastructure required for success

Table 8 – AP Extramural Research Expenditures, FY08-FY17
 Research expenditures grew by \$1.4 million (24%) compared to FY2016.



Intramural funding allocated by our *AP Projects Funding Committee* under the leadership of **Dr. Andrew Lieberman** supported 11 projects by AP faculty, which accounted for \$86,030 allocated in research support. Our trainees served as primary investigators on 4 of these projects. This reflects a 30.8% year-over-year decrease in expenditures in FY2017 (see Table 9).

Table 9 – AP Project Funding, FY07-FY17-Funding for AP Projects decreased in FY2017 to a total of \$86,030.



We hosted our 8th *Annual Research Day* on February 13, 2016 a collaboration with Clinical, Hemato-, Anatomic, and Molecular Pathology, which was renamed “CHAMP Research Day” to acknowledge this collaboration. The day included 27 abstracts presented as posters (21) and platforms (6). Our Keynote Speaker was **Dr. Matt Van der Rijn** (Stanford). The target audience was departmental trainees and faculty with the goal of increasing networking, collaboration and projects.

The *Molecular Pathology Research Laboratory (MPRL)*, under the direction of **Drs. Tom Giordano** and **Dafydd Thomas**, continued to be an important asset for faculty in AP.

EDUCATIONAL ACTIVITIES

Education programs remained strong and included ongoing success. AP faculty continued to be highly ranked among our residents and fellows for their teaching, and played key roles in medical and dental school teaching and post-graduate education. Division faculty served as directors of two successful ongoing seminars that offer continuing medical education to a regional and national audience: *New Frontiers in Pathology* and *Advances in Forensic Medicine and Pathology*.

Education is an essential and vibrant component of our mission. AP continues to provide a robust experience for trainees, including standard rotations in autopsy, surgical and cytopathology as well as required and elective rotations in various subspecialties. Trainees continued to actively participate in various research and quality initiative projects during the course of the year. Residents and fellows served as first authors numerous abstracts at local and national meetings. **Dr. Lisa Wilson** served as Associate Director for the Residency Training Program. **Dr. Andy Sciallis** received the Residents’ Teaching Award.

There were 15 AP fellows this year. Breast, Cytopathology, Dermatopathology (2), Forensics (2), Gastrointestinal, Genitourinary, Gynecological, Neuropathology, Pediatric, Pulmonary, and Surgical Pathology (3), and fellowships were filled by competitive candidates in the 2017-18 academic year.

Pathology faculty accounted for over 600 contact hours with medical students. Many of these hours are accounted for in pathology lectures and labs during the first and second years of the current curriculum. Over 20 faculty members gave lectures and led laboratory sessions throughout the second year curriculum. A significant amount of time from AP faculty was also dedicated to fourth year medical students during pathology elective rotations. Additionally, the Pathology Education Committee was formed last year and serves as an avenue for faculty committed to furthering the department’s educational objectives to find innovative ways for pathology to be integrated throughout all years of the new medical school curriculum. **Dr. Madelyn Lew**, Director of Medical School Pathology Education Curriculum, has play a major role in revamping the medical school curriculum.

Nearly all AP faculty members participate in supporting an impressive array of multidisciplinary conferences including tumor boards for brain, breast, endocrine oncology, gastrointestinal, genitourinary, gynecologic, head and neck pathology, liver, pediatric, sarcoma and lung tumors. Faculty also regularly participate in various other conferences including brain cutting, dementia brain cases, diagnostic dermatology, cutaneous T-cell lymphoma, nephrology, nerve and muscle, multiple pediatric subspecialties (GI, hematology-oncology, lung, surgery), and adult non-neoplastic lung disease. There were many educational conferences targeting primarily pathology trainees in which faculty participate including weekly slide and didactic teaching sessions.

Five Visiting Professors visited our department through the *A. James French Visiting Professorship* each presenting a lecture and slide seminar: **Drs. Edward Stelow** (Virginia), **Elizabeth Montgomery** (John’s Hopkins), **Anais Malpica** (M.D. Anderson), **Megan Dishop** (Minnesota Children’s), and **Marie Robert** (Yale). **Dr. Kristine Konopka** is in charge of organizing this important program.

Multiple faculty members participated in our tenth annual CME workshop, *New Frontiers in Pathology*, presented in collaboration with the A. James French Society. The 2016 course was held at the Graduate Hotel and again yielded very positive attendee evaluations for the quality and content of the program. **Drs. Teri Longacre** (Stanford), **Jesse McKenney** (Cleveland Clinic), and **Jason Hornick** (Brigham and Women's) served as guest faculty. **Dr. Hornick** was the A. James French Lecturer.

Our CME offerings included the seventh year of *Advances in Forensic Medicine and Pathology*, hosted in collaboration with the Washtenaw County Medical Examiner's Office in May 11-12, 2017 at Kensington Court in Ann Arbor setting a new attendance record. Feedback was extremely positive and this will continue to be an annual component of our CME programs.

Division of Clinical Pathology

David F. Keren, M.D., Director

Duane W. Newton, Ph.D., Associate Director

Dr. Keren serves as the Director of the Division of Clinical Pathology and the CLIA Director for the Department of Pathology. Dr. Newton serves as the Associate Director of the Division of Clinical Pathology and as the Director of Microbiology.

Faculty Updates

Dr. Omar Moussa (Associate Professor) joined the faculty on January 1, 2017 as Director of the Histocompatibility Laboratory. Dr. Moussa received a BSc in Chemistry from Mansoura University, Egypt in 1986 and his MSc/ PhD in Biochemistry and Molecular Biology in 1999. He completed his Fellowship in Molecular Microbiology and Immunology at Mansoura University in 2000, followed by a fellowship at the Department of Pathology, Hollings Cancer Center, at the Medical University of South Carolina. He was awarded Best Research Prize Winner from Mansoura University, Egypt in 1999 and in 2002 he was awarded Best Post-Doctoral Presentation Prize Winner from the Medical University of South Carolina. From 2008 to 2011 he served as Director in Training and from 2011 to 2016, he served as Director of the HLA/ Tissue Typing Laboratory at the Medical University of South Carolina. In addition to his work in Histocompatibility, he has received several grants for his work in cancer detection and prevention.

In September 2016, Dr. Sarah Choi joined the University of Michigan, Department of Pathology, Hematopathology Section as an Assistant Professor. Dr. Choi received a B.A. in Cell and Molecular Biology from The University of California Berkeley in 2001 and her M.D./Ph.D. in Cell and Molecular Biology from University of Pennsylvania in 2010. She completed her Residency in Anatomic and Clinical Pathology at the University of Pennsylvania in 2015, followed by a fellowship there in Surgical Pathology and one in Hematopathology at Northwestern Memorial Hospital. She has won several awards including the Outstanding Immunologist Award from the University of California, Berkeley and Research Prizes from the Cell and Molecular Biology Symposium, and the Keystone Symposia.

Faculty Promotions

Congratulations to Dr. Laura Cooling, Associate Director for Blood Bank and Transfusion for her promotion to Clinical Professor effective September 1, 2017. Dr. Cooling received a B.S., a M.Sc. from the University of Iowa and an M.D. from the University of Iowa Medical School. She completed her residence training in Laboratory Medicine followed by a Fellowship in Transfusion Medicine and Pathology at the University of Iowa Hospitals and Clinics. Upon completion of her training, Dr. Cooling served as a Clinical Associate in the Department of Pathology at the University of Iowa Hospitals and Clinics and later as Assistant Professor at State University of New York Health Science Center at Syracuse. She accepted a position as Clinical Assistant Professor at the University of Michigan Medical School in 2000.

Dr. Cooling serves as Associate Director of the Department of Pathology's Blood Bank & Transfusion Service. Dr. Cooling has published over 58 peer-reviewed papers, 21 book chapters, and 4 books. She has presented talks at numerous national and international meetings and educational seminars in her research areas of interest including role and regulation of globo-and lacto-family glycosyltransferases, LKE family and E. coli related diseases, and Platelet glycoimmunology.

Congratulations to Dr. Robertson Davenport, Director of Blood Bank and Transfusion Service as well as Director of Blood Bank Fellowship for his promotion to Clinical Professor effective September 1, 2017. Dr. Davenport received his undergraduate degree from the California Institute of Technology, Pasadena, California in 1977, his M.A. from the University of California, Berkeley, California in 1979, and MD degree from the University of Michigan in 1984. He completed residency training in Anatomic and Clinical Pathology at the University of Michigan in 1988. Subsequently, Dr. Davenport took fellowship training in Cytopathology, and in Blood Banking and Transfusion Medicine, both at the University of Michigan. He is a Diplomate of the

American Board of Pathology (Anatomic and Clinical Pathology) and also holds ABP Subspecialty Certification in Blood Banking and Transfusion Medicine.

Dr. Davenport joined the faculty of the University of Michigan Department of Pathology when he was appointed a Lecturer in 1989, became an Assistant Professor in 1990, and an Associate Professor in 1997. His principal clinical interests are in appropriate blood transfusion practice, therapeutic apheresis, and adverse effects of blood transfusion. His major research interests are in the role of cytokines in transfusion reactions, immunomodulation by blood transfusion, and transfusion transmitted diseases. Dr. Davenport has published over 80 peer-reviewed articles, 3 books and presented talks at numerous national and international meetings in his areas of research including Transfusion reactions and Therapeutic apheresis.

Congratulations to Dr. Duane Newton, Associate Director for the Division of Clinical Pathology and Director for the Clinical Microbiology Laboratory for his promotion to Clinical Professor effective September 1, 2017. Dr. Newton received a B.S. in Biology (1988) and a Ph.D. in Microbiology and Immunology (1993) from the University of Dayton, Dayton, Ohio. He completed Post-Doctoral training at the University of Tennessee and the VA Medical Center in Memphis, Tennessee from 1993-1998, and a Clinical and Public Health Microbiology Fellowship at the University of Rochester Medical Center, Clinical Microbiology Laboratories in Rochester, New York from 1998-2000. In 2000 he was appointed as Manager of the Virology/Immunology Section of the Department of Community Health, Division of Infectious Diseases, Bureau of Laboratories for the State of Michigan and as Adjunct Assistant Professor for the Michigan State University Medical Technology Program. In 2002, he joined the faculty of the Department of Pathology at the University of Michigan Medical School as Clinical Assistant Professor and Associate Director of the Microbiology/Virology Laboratories. Dr. Newton was named Director of Microbiology/Virology Laboratories in 2003, and received his certification as a Diplomate by the American Board of Medical Microbiology in 2004. Dr. Newton has published over 65 peer-reviewed articles and has presented talks at numerous national and international meetings in his areas of research including the development of molecular assays for the diagnosis and management of infectious diseases.

Congratulations to Dr. Chisa Yamada, Assistant Director, Blood Bank and Transfusion Services for her promotion to Clinical Associate Professor effective September 1, 2017. Dr. Yamada received an M.D. from Tokyo Women's Medical University in 1986. She completed residency training in Ophthalmology at Keio University, Tokyo from 1986-1988, serving as Chief Resident from 1987-1988. Following residency training, she completed a fellowship in Ophthalmology at Shizuoka Red Cross Hospital, and Yokohama Municipal Citizens' Hospital, Keio University from 1988-1992. She accepted a position as an attending physician in Ophthalmology at Yokohama Municipal Citizen's Hospital in Yokohama, Japan in 1992 and in 1994, joined the faculty of Nippon Kokan Hospital in Kawasaki, Japan as Chairperson, Department of Ophthalmology. In July 2002, Dr. Yamada initiated residency training in Anatomic and Clinical Pathology at Montefiore Medical Center/Albert Einstein College of Medicine and completed this training in 2006. She then completed a fellowship in Blood Bank and Transfusion Medicine at Johns Hopkins Medical Institutions (2006-2007) and joined the faculty as a Clinical Assistant. In 2008, she accepted a position as Assistant Professor and Associate Medical Director, Blood Bank and Transfusion Medicine at the University of California, Irvine. In July 2009, she joined the faculty of the Department of Pathology as an Assistant Professor. Dr. Yamada has published over 20 peer-reviewed papers and continues to serve as a member on several institutional/regional/international organizations including AABB, ASFA, MABB, CAP, and NeuroSpring.

Faculty Recruits

Dr. Russel Ryan will join the Department as Assistant Professor of Pathology and Adjunct Research Assistant Professor of Life Sciences Institute on July 1, 2017. He received his B.A. in Neuroscience in 2002 and his M.D. from Yale University of Medicine in 2007. He completed both his Anatomic Pathology Residency and Hematopathology Fellowship at Massachusetts General Hospital. In 2015, he became an Instructor in Pathology at Harvard Medical School. He has won several awards including the Dr. Harold H. Lamport Biomedical Research Prize and Perkins Scholarship Prize from Yale and two Research Poster of Distinction awards from Har

Dr. Annamarija Perry will be joining us on July 1, 2017 as Associate Professor of Pathology. Dr. Perry received her M.D. from the University of Zagreb in Croatia in 2004. Until 2006, she pursued her postgraduate studies in “Biomedicine and Health” at the University of Zagreb School of Medicine. From 2006 to 2010, she completed her Anatomic/ Clinical Pathology Residency at the University of Cincinnati in Ohio followed by her Hematopathology Fellowship at the University of Nebraska from 2010-2011. In 2011, Dr. Perry accepted a Clinical Instructor position at the University of Nebraska then appointed as an Assistant Professor at the University of Manitoba/Diagnostic Services of Manitoba from 2012-2017. She is a Diplomate of the American Board of Pathology for both Hematopathology and Anatomic and Clinical Pathology. Dr. Perry is an active member in many national organizations including Society for Hematopathology, American Society of Hematology, and College of American Pathologists. She has published over 33 peer-reviewed articles and 7 books to date.

Kristina A. Davis, MD will be joining the department on July 1 as Clinical Lecturer in Pathology. She obtained her medical degree at the West Virginia University School of Medicine in 2012. Dr. Davis also completed graduate studies in Public Health there in 2009. While in medical school, Dr. Davis was a nominee for the Centers for Disease Control Charles C. Shepard Science Award for her work on “Distribution of airborne influenza virus and respiratory syncytial virus in an urgent care medical clinic”. Dr. Davis started her residency here at the University of Michigan in 2012. She was awarded CP and AP pathology resident of the year in 2016. Dr. Davis went on to complete her fellowship in Blood Bank/Transfusion Medicine at the Mayo Clinic in 2017.

Paul Lephart, PhD, D(ABMM) will be joining the Department as Assistant Professor and Associate Director of the Medical Microbiology Laboratory on August 1, 2017. Dr. Lephart received a B.S. in Medical Microbiology and Immunology from the University of Wisconsin in 1998 and his Ph.D. in Microbiology, Immunology and Molecular Pathobiology in 2006. He completed Post-Doctoral training at Tufts University in Boston, MA from 2005-2007 and University of Rochester School of Medicine & Dentistry in NY from 2007-2009. He was then appointed Technical Director and Associate Technical Director of Microbiology/ Virology at Detroit Medical Center in 2009. Dr. Lephart is a Diplomate of the American Board of Medical Microbiology and has published over 55 peer- reviewed articles.

Stephanie Balow, PhD will be joining the Department on September 1 as Assistant Director of the Cytogenetics Laboratory. She received her B.S. in 2007 from Bowling Green State University and her PhD in 2014 from Case Western Reserve University. She completed her Clinical Cytogenetics Fellowship in 2016 and her Clinical Molecular Genetics Fellowship in 2017, both at Cincinnati Children’s Hospital Medical Center. Dr. Balow received The Marcus Singer Award, Biomedical Graduate Student Symposium from Case Western Reserve University in 2012 and the NIH Genetics Training Grant Recipient from 2009-2011.

Education, Research, and Innovation

The Division of Clinical Pathology produced several highly successful educational efforts this year. The Clinical Pathology Quality Assurance meetings, held quarterly, were attended by over 500 staff during the year, not including those who viewed the Web versions. The Sixth and Seventh Annual Clinical Pathology Symposiums again provided two half days of interactive presentations. In addition, there was a major commitment to ongoing participation of clinical laboratory staff, trainees and faculty in standing departmental education programs as well as in dozens of extra departmental conferences, tumor boards and seminars.

Clinical Pathology Quality Assurance (CPQA) Quarterly Staff Meetings

CPQA Organizing Committee

Suzanne Butch, Brent Temple, Liz Walker, Andrea Arlen, Lisa Brown, Kristina Martin, John Perrin

Four CPQA quarterly staff meetings were held this year as a mechanism to improve employee engagement and to enhance involvement of staff with Lean projects. These meetings are coordinated by the Division of Quality and Health Improvement. The meetings consist of presentation by staff members of their Lean projects

and an informational component where staff is apprised of the current financial situation of the University of Michigan Hospital and Health Systems, the Department of Pathology and the Clinical Laboratories. The CPQA meetings are all videotaped and shown to the staff at Traverwood. Dr. Keren attends those meetings to respond to comments by staff. In addition, the videotapes are available at the Pathology Website.

July 12, 2016: UM Attendance: 150

Speakers:

- Matt Heilbron, Kristy Wendt, MT(ASCP) – “Cellavision Technology”
- George Mitri – “Cord Blood Samples”
- Amy Mapili – “Patient Asset Management Initiative (PAMI)”
- Kristina Martin, MS, MLS(ASCP)CM – Lab Week Highlights
- Angela Wu, MD – “Diversity Equity and Inclusion Committee”
- Suzanne Butch – Drawing
- David Keren, MD – Financial Update

October 11, 2016: UM Attendance: 154

Speakers:

- Turquessa Brown-Krajewski -- “Optimizing Slide Preparation of Neoplasia Samples for Chromosome Analysis Using the Thermotron”
- Amy Drouillard and Merry Muilenberg – Lab Ambassadors
- Suzanne Butch – Quality Month Posters
- Suzanne Butch – Drawing
- David Keren, MD – Financial Update

February 14, 2017: UM Attendance: 167

Speakers:

- Scott McClellan – “Pneumocystic jirovecii: A Paradigm Change in Testing”
- Andrea Arlen, Dayna Goerke, and Kristina Martin – Quality Investigations
- Jodi Kennedy-Stanfield – Phlebotomy’s role in MiPart
- Andrea Arlen – Drawing
- David Keren, MD – Financial Update

April 18, 2017: UM Attendance: 125

Speakers:

- Priti Patel – “Rotem-Rotational Thromboelastometry “
- Sheridan Mattson – “Detecting Synthetic Urine Using Urine Integrity Testing”
- Lab Ambassadors – Lab Week Updates
- Nancy Raynal – “Hematology Process Improvement”
- David Keren, MD – Symposium
- David Keren, MD – Financial Update
- Andrea Arlen – Drawing

Clinical Pathology Symposium

6th and 7th Clinical Pathology Symposium Planning Committee

Andrea Arlen, Lisa Brown, Kristina Martin, Duane Newton, Pam Warwashana, Lina Shao Cathy White, Suzanne Butch, Jill Russell, Jennifer Bergendahl, Carol Young, Josh Bugbee, Lindsay Kocha

6th Annual
Clinical Pathology Symposium
Monday, October 3, 2016

- ◆ **Cardiovascular Center**
Danto Auditorium
- ◆ **For Pathology faculty and staff**
- ◆ **Easy M Learning registration.**
Check with your supervisor first.
- ◆ **Attend one or more sessions**
- ◆ **Earn up to 3 CE credits**
One CE credit per session
- ◆ **Refreshments**
- ◆ **Plan to Participate!**

1:30 PM

Evidence Based Practice Improvements for Phlebotomists and Laboratory medicine: Implications for Enhanced—Front-Practice and Patient Experience




Harry Neusius & Julie Piazza

Objectives

1. Describe ways to integrate research into laboratory medicine departments to support quality improvement.
2. Identify comfort strategies which decrease pain, anxiety, and fear associated with pediatric blood draws.
3. Discuss how to integrate study observations into future training strategies and patient education efforts.

MLearning Code: PATH-62094

2:30 PM

Molecular Testing in the Cancer Center

Jessica Everett



Objectives

1. Understand importance of identifying patients and families carrying germline mutations that increase cancers risk
2. Describe use of molecular testing to identify high risk patients and families
3. Explain differences between molecular testing for treatment decision making and molecular testing for hereditary risk

MLearning Code: PATH-62095

3:30 PM

The Intersection of Germline and Somatic Molecular Testing: Lynch Syndrome Screening

Noah Brown



Objectives

1. Interpret the role that microsatellite instability testing plays in screening colon and endometrial cancer patients for Lynch Syndrome.
2. Understand the utility of BRAF mutation and MLH1 promoter methylation testing in MSI-H neoplasms.
3. Compare the pathophysiology associated with both sporadic and Lynch syndrome-associated microsatellite instability.

MLearning Code: PATH-62096

Questions or comments can be directed to members of the Clinical Pathology Symposium Planning Committee or by calling Kristina Martin. 734-615-8863
Email: martkris@umich.edu

Two half-day Clinical Pathology Symposia were held in the 2017 FY. The 6th Annual Clinical Symposium was held in October 2016 where groupings of laboratory medicine presentations featured discussions on Evidence Based Practice Improvements for Phlebotomists and Laboratory medicine (Mr. Harry Neusius and Ms. Julie Piazza), Molecular Testing in the Cancer Center (Ms. Jessica Everett), and Insertion of Germline and Somatic Molecular Testing (Dr. Noah Brown).

7th Annual
Clinical Pathology Symposium
Monday, April 24, 2017

- ♦ Cardiovascular Center Danto Auditorium
- ♦ For Pathology faculty and staff
- ♦ Easy M Learning registration. **Check with your supervisor first.**
- ♦ Attend one or more sessions
- ♦ Earn up to 3 CE credits One CE credit per session
- ♦ Refreshments provided
- ♦ Plan to Participate!

7:00 am

Are You Safe?



Michele McGee, BS, MT(ASCP)
Medical Technologist Specialist and Safety
Coordinator, Microbiology Laboratory

Objectives

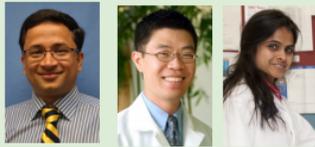
1. Identify Safety Hazards in the Laboratory.
2. List at least three safety requirements.
3. Match safety acronyms to their meaning.

.M Learning Code: PATH-62109



8:05 am

**The Role of Viscoelastic Testing
in the Perioperative Setting**



Subramanian Sathiskumar, MD
Assistant Professor Department of Anesthesiology
Director Transplant Anesthesia

Shih-Hon (Sean) Li, MD, PhD
Clinical Assistant Professor of Pathology
Medical Director, Blood Bank and Immunohematology
Reference Laboratory
Assistant Medical Director, Clinical Coagulation Laboratory

Priti Patel, MT(ASCP)
Senior Clinical Technologist, Hematology Laboratory

Objectives

1. Understand the role of the hematology lab in implementation and oversight of viscoelastic (ROTEM) testing in point of care and central lab settings.
2. The role of ROTEM in patients with end stage liver failure undergoing liver transplant and the potential benefits with case studies
3. The impact observed in the blood bank due to viscoelastic testing performed for OR/ICU patients

.M Learning Code: PATH-62110

9:10 am

Inaugural John Batsakis Lecture

**Improved Quality, Patient Care and
Experience at a Lower Cost:
The Promise of Optimized Laboratory
Stewardship**



Gary Procop, MD, MS
Medical Director for Enterprise Test Utilization and
Pathology Consultative Services.
Director of Molecular Microbiology, Virology, Mycology and
Parasitology, Cleveland Clinic Foundation

Objectives

1. Describe the components necessary for the development of an effective test utilization committee.
2. Recall the advantages and disadvantages of using clinical decision support tools.
3. List three interventions to improve the utilization of high-cost molecular genetic testing.

M Learning Code: PATH-62111

**Forward questions or comments
to members of the
Clinical Pathology Symposium
Planning Committee
or Kristina Martin
734-615-8863
Email: martkris@umich.edu**

The 7th Annual Clinical Symposium was held in April 2017 presentations featured “Are You Safe?” (Ms. Michelle McGee), and “The Role of Viscoelastic Testing in the Perioperative Setting” (Dr. Subramanian Sathiskumar, Dr. Sean Li, and Ms. Priti Patel). The Inaugural John Batsakis Lecture featured guest Dr. Gary Procop, Medical Director for Enterprise Test Utilization and Pathology Consultative Services at the Cleveland Clinic, who presented “Improved Quality, Patient Care and Experience at a Lower Cost: The Promise of Optimized Laboratory Stewardship.”

Current Topics in Blood Banking 2017

Current Topics in Blood Banking Organizing Committee

Suzanne Butch, Terry Downs, Robertson Davenport, Laura Coolingm Holly Wilson, Chisa Yamada, Sean Li, Sandra Hoffman, John Ko

Current Topics in Blood Banking is an annual educational program for medical lab scientists, residents, fellows and faculty, designed to discuss topics related to blood banking, hemostasis, quality and management. For the 2017 Current Topics in Blood Banks Conference on July 15, Courtney McClellan, RN, MSN, CPR, Transfusion Safety Specialist at Children’s Hospital Colorado, was the featured speaker. She presented the annual Harold A. Oberman, M.D. Memorial Award on “Patient Blood Management: Rome Wasn’t Built in a Day”. In addition, there were presentations by Sheri Hagan, MT(ASCP)SBB “What’s Up with DAT’s”, John Ko, MLS(ASCP)CM, Laurence Briski, MD, Stephanie Skala, MD “Case Studies from the Bench”, Laura Cooling, MD “Minding our P’s and Q’s: Platelet Indications, Dosing and Ongoing Questions”, Shih-Hon (Sean) Li, MD, PhD “Point of Care Thromboelastometry and Transfusion Practice in the OR”, Robert Davenport, MD “Statistics for Blood

Bankers”, Theresa Downs, MT(ASCP)SBB “How Do We: Manage Difficult Blood Needs”, and Salike Devine, MT (ASCP) “How to Keep Up: Regulations and Standards”.

Objectives

Education credit is being provided through the Michigan Association of Blood Banks who is approved as a provider of continuing education in the clinical laboratory sciences by the ASCLS P.A.C.E.® Program.

Objectives: At the end of the session the participant will be able to:

1. Describe problem resolution steps for positive DAT's.
2. Apply problem solving strategies to events that occur in the blood bank.
3. Describe the knowns and unknowns for platelet transfusion.
4. Discuss the hurdles involved in implementing a Patient Blood Management Program.
5. Describe how thromboelastography is used in liver transplants.
6. Evaluate statistics presented in papers and product literature.
7. Evaluate options in providing blood components to patients with complex blood needs.
8. Develop a process for remaining compliant with new requirements.

Planning Committee

Suzanne Butch, MA, MLS(ASCP)^{CM}SBB, DLM
 Theresa Downs, MT(ASCP)SBB
 Laura Cooling, MS, MD
 Robertson Davenport, MD
 Sandra Hoffmann, MT(ASCP)SBB
 John Ko, MLS(ASCP)^{CM}
 Shih-Hon Li, MD, PhD
 Holly Wilson, MLS(ASCP)^{CM}
 Chisa Yamada, MD

Blood Bank & Transfusion Service
 University of Michigan Hospitals & Health Centers
 UH2P225/SPC5054
 1500 E. Medical Center Drive
 Ann Arbor, Michigan 48109-5054



Celebrating
77 Years
 of Blood Banking and
 Transfusion Medicine at
 the University of Michigan

Current Topics In Blood Banking 2017

Saturday, July 15, 2017
8:30 am-4:30 pm

Danto Auditorium
Cardiovascular Center
University of Michigan Hospitals
Ann Arbor, Michigan

8 Hours of CE

Affordable

Practical Information

**CE Credits in Blood Banking, Quality and
 General Topics**

Level of Instruction: Intermediate



Academic Productivity

As shown in Table 1, the Clinical Pathology faculty had impressive academic productivity in FY2017. The twenty-eight faculty averaged 3.7 publications (median 3.5) with 95 peer-reviewed publications in press or in print. Many of these appeared in high impact journals including: American Journal of Clinical Pathology, American Journal of Hematology, Annals of Clinical Biochemistry, Clinical Chemistry, Endocrine, Journal of Clinical Apheresis, Journal of Clinical Microbiology, Nature, American Journal of Clinical Pathology and Transfusion. In addition, the faculty reported their work in 67 abstracts with 21 faculty serving as invited lecturers, speakers or visiting professors 75 times, for an average of 2.7 (median 1) per faculty. Finally, our faculty reported service on Editorial Boards or as reviewers for 95 journals including: American Journal of Clinical Pathology, Archives of Pathology and Laboratory Medicine, Blood, Cell, Clinical Chemistry, Cytometry, Human Pathology, Infection and Immunity, International Journal of Laboratory Hematology, International

Journal of Blood Research and Disorders, Journal of Clinical and Experimental Pathology Laboratory Investigation, Journal of Clinical Microbiology, Journal of Infectious Diseases, Journal of Molecular Diagnostics, Journal of Human Pathology, DNA Repair, Modern Pathology, Nature, PLOS ONE, and Transfusion.

Table 1. Academic Productivity in CP FY2017

	FY2016	FY2017
Publications (peer reviewed)	95	103
Abstracts	67	67
Invited lectures	71	75
Editorial Board/Reviewers	71	95

Clinical Pathology Research Fund

Dr. Michael Bachman, M.D., Ph.D. is the Director of the Clinical Pathology Research Fund. The fund is designed to provide faculty and trainees in Clinical Pathology with support for high-quality research projects. Residents and fellows may apply but must identify a faculty sponsor who will oversee the project and project-related expenditures. Projects will be funded to a maximum cost of \$10,000 per project with total program costs of no more than \$60,000.

annually. This year, \$22,780 was awarded. Any faculty, resident or fellow in the Division is offered statistical support at no charge both prior to the application and when preparing an abstract or final report. Projects are assessed and prioritized using the following criteria:

- aligned with institutional, departmental and division priorities
- potential to expand research opportunities
- likelihood to yield peer-reviewed publication(s)
- opportunity to increase collaboration within or across divisions
- opportunity to engage pathology trainees
- likelihood to yield extramural grant support (if appropriate to project)

Awards this year:

1. Noah Brown, MD and Pawel Mroz, MD, PhD
 - Detection and quantification of BCR-ABL1 fusion transcripts in samples from patients with acute lymphoblastic leukemia and chronic myelogenous leukemia by digital PCR
 - i. Awarded 7/22/2016
2. Noah Brown, MD and Carlos Murga, MD
 - Role of the colony-stimulator factor-1 receptor (CSF1R) during lymphoma progression
 - i. Awarded 11/19/2016
3. Jim Varani, PhD and Nate Charles, MD
 - Rapid Progression of Myelodysplastic Syndrome to Acute Myeloid Leukemia is Associated with Acquired Genetic Mutations in KRAS
 - i. Awarded 1/24/2017

Clinical Pathology Fellowships

Blood Bank & Transfusion Medicine Fellowship

Dr. Robertson Davenport served as the Director of the Blood Bank/Transfusion Medicine Fellowship. This year our fellow was Charles Harmon, M.D.

Chemical Pathology Fellowship

Dr. David Keren served as the Director of the Chemical Pathology Fellowship. This year our fellow was Forest Huls, M.D.

Hematopathology Fellowship

Dr. Lauren Smith served as the Director of the Hematopathology Fellowship. This year our 3 first year fellows were Nathan Charles, M.D., Ph.D., Vivian Hathuc, D.O., and Carlos Murga, M.D.

Molecular Pathology Fellowship

Dr. Noah Brown served as the Director of the Molecular Pathology Fellowship. This year our fellow was Pawel Mroz, M.D., Ph.D.

Formulary Committee

Dr. Jeff Warren created the Lab Formulary Committee in 2008. This committee meets monthly to review evidence-based medicine supporting the use of new laboratory testing. Dr. Warren was a featured speaker at the November 2016 Association for Molecular Pathology Annual Meeting where he presented *Development of a Multifaceted Laboratory Utilization Program*. He enjoys researching the development of laboratory-driven system approaches to the ascertainment of patients who may harbor yet-to-be-recognized or defined primary immunodeficiency disorders (PIDDs) and the study of more effective utilization of clinical laboratory testing resources in patient care.

Genetic Testing Resource and Quality Consortium (GTRQC) Pilot Project

David Keren, Lee Schroeder, Sofia Merajver, Lynn McCain, Kara Milliron

The Genetic Testing Resource and Quality Consortium is a Pilot project between Michigan laboratories with genetic testing menus and Blue Cross Blue Shield of Michigan. Drs. David Keren and Lee Schroeder are Co-Directors with Dr. Sofia Merajver joining us as Associate Director and Ms. Lynn McCain is the project manager. Kara Milliron, M.S., C.G.C. is the consultant who expertise is breast and ovarian cancer risk evaluation. The GTRQC is a quality initiative to evaluate and improve the quality of care for patients receiving genetic testing and to address the exponential growth in genetic testing. GTRQC launched in February of 2015 and has made many strides since then. In early 2017, the project was unfunded by BCBS. The team has worked extremely hard submitting new grants. Meanwhile, the Department of Pathology is giving GTRQC bridging support. In August, we prepared and submitted "Identifying Patients at Increased Risk of Hereditary Cancer using InheRET™, a Pilot Study" for January 1, 2018- December 31, 2018. Our purpose is to conduct a pilot study to evaluate the impact InheRET has on removing barriers to identifying patients at risk for hereditary cancers, improving appropriate referrals for further genetic evaluation, while reducing inappropriate referrals and unnecessary testing in both primary and specialty care settings

The Laboratories

The Michigan Medicine Clinical Pathology Laboratories provide excellent full-spectrum services - more than 800 different analytes are available. Expert faculty consultations are offered in all areas including: Blood Bank/Transfusion Medicine Service (which encompasses the Therapeutic Apheresis/Hematopoietic Progenitor Cell (HPC) Procurement Unit, and FDA-approved Good Manufacturing Process-compliant HPC Processing Laboratory, and an Immunohematology Reference Laboratory); Chemical Pathology (which encompasses Special Chemistry, Automated Chemistry, Immunology, Toxicology-Therapeutic Drug Monitoring, Endocrinology and UMHS-wide point-of-care testing oversight); Point of Care Testing; Cytogenetics (which encompasses routine Cytogenetics, Microarray Cytogenetics and Fluorescence In-Situ Hybridization (FISH) testing); Hematology (which encompasses Special Hematology, Automated Hematology, Flow Cytometry and Coagulation); Histocompatibility; Microbiology/Virology (which includes Molecular Microbiology); and Molecular Diagnostics.

Clinical Pathology Operations Manager

Kristina Martin, Clinical Pathology Operations Manager, orchestrates the operations of the Clinical Laboratories in partnership with laboratory managers. Kristina promotes Lean concepts by teaching quarterly basic lean classes and focused sessions for specific needs. She has also assisted in the planning for the Pathology Relocation and Renovation project. Kristina is responsible for the Clinical Pathology Operations meetings, LCC, CP monthly gemba walks and coordination of subsequent projects resultant from these discussions. During 2016-2017 she chaired the CP Symposium and Lab week committees and assists with the CP QA quarterly meeting. Kristina also serves as the department liaison with nursing and providers. She oversees our monthly blood donations which have allowed us to improve our partnership with the American Red Cross. Kristina is very active in the ACLS professional society. She was awarded both the ASCLS 'National Level Omicron Sigma Award' and 'ASCLS Member of the year award' at the 2017 American Society for Clinical Laboratory Science – Michigan Meeting. In February, she presented *Document Control for Control Freaks* during the Biomedical Laboratory Diagnostics (BLD) Seminar Series at Michigan State University. She was also among one of twelve in the July 2016 American Society for Clinical Laboratory Science (ASCLS) Voices Under 40 Spotlight.

Financial Performance

Much of the data we all depend upon are provided by Christine Shaneyfelt who, under the direction of David Golden leads our capital equipment tracking and acquisition as well as financial and utilization data procurement and analysis. There has been an increase of testing activity, however year to year direct comparison (Table 2) are complicated by changes in billing as well as in charges. Notably, one can follow our gross charges that increased by almost \$40,000,000 between FY2016 and FY 2017 and our expenses that increased by a little over \$5,000,000 in the same period. This extraordinary performance is occurring at a time when both the volume and complexity of new testing are increasing. To provide safety and accuracy for our patients, the increase in volume and complexity of testing together with increasing requirements for point-of-care testing has resulted in our 3% increase in our FTE numbers in FY2017. We anticipate further increases to keep pace with our clinical needs for FY2018.

Table 2. Clinical Pathology Laboratories FY2013-2017

	FY2013	FY2014	FY2015	FY 2016	FY 2017	Change
Billed Tests	5,109,497	5,015,219	5,101,062	5,428,130	5,793,260	6.7%
Gross Charges	\$490,563,953	\$546,966,965	\$579,988,161	\$628,121,972	\$674,600,388	7.4%
Expenses	\$72,163,336	\$73,655,845	\$75,673,407	\$76,625,956	\$81,839,778	6.9%
Total FTEs	517.46	534.68	534.8	558.95	575.2	3.0%

Hematopathology Section Report

I. OVERVIEW

The overall activities of the Hematopathology Section are summarized below as well as in individual faculty and laboratory reports.

Faculty Recruitment

Sarah Choi, M.D., Ph.D. started as an Assistant Professor in September, 2017. She joined us after her hematopathology fellowship at Northwestern University. Anamarija Perry (Associate Professor) and Russell Ryan (Assistant Professor) were recruited as new faculty members in the section to start on July 1, 2017.

Operations

Efforts have continued to improve operations and facilitate move to NCRC (PRR). Operations improvements included refining our process to share specimens with cytopathology, moving fluid reports from SoftLab to Pathdx, and implementing on-line (soft) ordering of special stains. We implemented an email notification system for bone marrows to allow faculty to know when important ancillary studies are completed (to allow integrated reporting). Immunohistochemistry optimization and validation has also been a focus with improving CD20 and validating SOX11.

Academic Accomplishments

Faculty members were engaged in academic pursuits including numerous published manuscripts, abstracts, and institutional/regional/national/international presentations (see individual reports for details).

II. Hematopathology Fellowship Program

Three fellows completed the ACGME-accredited training program this year: Nathan Charles, Vivian Hathuc, and Carlos Murga. Self-study was initiated in conjunction with other fellowships in preparation for the 10-year accreditation which will occur next year.

Invited Talks

- 1) **Hathuc V**, Smith L. 2016 Revision of the World Health Organization Classification of Lymphoid Neoplasms. New Frontiers in Diagnostic Pathology conference 2016, Ann Arbor, MI.
- 2) **Charles, N.** U of MI Dept. of Pathology – CHAMP Research Day, Ann Arbor, MI (2/4/17) *“Rapid Progression of Myelodysplastic Syndrome to Acute Myeloid Leukemia is Associated with Acquired Genetic Mutations in K-ras”*

Fellow Abstracts

- 3) Role of the Colony-Stimulator Factor-1 Receptor (CSF1R) T-cell Lymphoma Progression. **Carlos Murga-Zamalloa**, Avery Polka, Noah Brown, Nathaniel Bailey, Ryan Wilcox. United States and Canadian Academy of Pathology (USCAP), San Antonio, USA (2017). **2017 Stowell-Orbison Award, Annual USCAP Meeting.**
- 4) **Hathuc V**, East E, Pang J, Jorns J, Dewar R. A Practical Quality Control Procedure for Decalcified Bone Specimens in Evaluation of ER/PR/HER-2 Immunohistochemistry. United States and Canadian Academy of Pathology meeting 2017, San Antonio, TX (Accepted for poster presentation).

Fellow Publications

- 1) NPM-ALK phosphorylates WASp Y102 and contributes to oncogenesis of anaplastic large cell lymphoma. **Murga-Zamalloa CA**, Mendoza-Reinoso V, Sahasrabudde AA, Rolland D, Hwang SR, McDonnell SR, Sciallis AP, Wilcox RA, Bashur V, Elenitoba-Johnson K, Lim MS. *Oncogene*. 2017 Apr;36(15):2085-2094. PMID: 27694894. **2017 Benjamin Castleman Award, United States and Canadian Academy of Pathology.**

- 2) T-cell Receptor Signaling Activates an ITK/NF- κ B/GATA-3 axis in T-cell Lymphomas Facilitating Resistance to Chemotherapy. Wang T, Lu Y, Polk A, Chowdhury P, **Murga-Zamalloa C**, Fujiwara H, Suemori K, Beyersdorf N, Hristov AC, Lim MS, Bailey NG, Wilcox RA. Clin Cancer Res. 2017 May 15;23(10):2506-2515.
- 3) Multimodal laser-based angioscopy for structural, chemical and biological imaging of atherosclerosis. Savastano LE, Zhou Q, Smith A, Vega K, **Murga-Zamalloa C**, Gordon D, McHugh J, Zhao L, Wang M, Pandey A, Thompson BG, Xu J, Zhang J, Chen YE, Seibel EJ, Wang TD. Nat Biomed Eng. 2017;1. (In press) PMID: 28555172.
- 4) Pyrimidine tract-binding protein 1 mediates pyruvate kinase M2-dependent phosphorylation of signal transducer and activator of transcription 3 and oncogenesis in anaplastic large cell lymphoma. Hwang SR, **Murga-Zamalloa C**, Brown N, Basappa J, McDonnell SR, Mendoza-Reinoso V, Basur V, Wilcox R, Elenitoba-Johnson K, Lim MS. Lab Invest. 2017 Apr 17 (In press). PMID: 28414323.
- 5) Polo-like-kinase 1 (PLK-1) and c-myc inhibition with the dual kinase-bromodomain inhibitor volasertib in aggressive lymphomas. **Carlos Murga-Zamalloa**, Avery Polk, Hanel Walter, Pinki Chowdhury, Noah Brown, Alexandra C. Hristov, Nathanael G. Bailey, Tianjiao Wang, Tycel Phillips, Sumana Devata, Pradeep Poonnen, Juan Gomez-Gelvez, Kedar V. Inamdar and Ryan A. Wilcox. 2017 Blood (under review).
- 6) **Charles NJ**, Boyer DF. Mixed Phenotype Acute Leukemia: Diagnostic Criteria and Pitfalls. *Arch Pathol Lab Med*. In press.
- 7) **Hathuc V**, Smith L. Blood (BloodWork section). Varicella zoster virus encephalitis masquerading as a B-cell lymphoproliferative disorder. (Work in progress).
- 8) **Hathuc V**, Hristov A, Smith L. Primary Cutaneous Acral CD8+ T cell lymphoma. Archives of Pathology and Laboratory Medicine (In press)

Fellow Awards

Benjamin Castleman Award, USCAP, Carlos Murga
 Stowell-Orbison Award, USCAP, Carlos Murga
 CHAMP Research Day (UM) oral award, Nathan Charles
 Making a Difference Award (UM), Vivian Hathuc

Clinical Competency Committee members: Charles Ross (Chair), Dan Boyer, and John Frederiksen

Clinical Hematology Laboratory

Clinical Activity

The Hematology laboratory had a very productive 2016-17. The Hematology Laboratory continues to offer an extended menu of tests in hematology with average increase of 11% test volume increase.

- Validated and implemented Sysmex-XN automation line (went live on July 20, 2016)
- Implemented Cellavision units online and have completed training across all shifts.
- Have been training hem/onc fellows on Cellavision-they absolutely love having remote access to their patient slides. Cellavision for hem/onc fellows and attendings-hem/onc is extremely pleased and appreciative of the ability to use remote viewing of patient cell images. Training performed and documented by our Key Operator
- Validated and implemented WAM 5.0 at main, Canton and Northville labs
- Taken on responsibility/oversight of QC/QA/Staffing of satellite labs (Canton and Northville)

- Validated and implemented iSED analyzers (sedimentation rate analyzers; went live on Nov 17, 2016). This system is much safer for staff, and extremely helpful to phlebotomists and patients. No special and difficult to draw tubes, can be shared with CBCD draws.
- Serial interfaces for Sysmex-implemented/validated-this will greatly help when automation line or TS goes down, and will help keep up with turnaround times
- Worked on and completed purchase of new urine analyzers, performed urine analyzer validation and interface work-first validation was sub-optimal, repeat validations underway
- OR Sysmex analyzer responsibility-our Hem POC Sr. Tech has taken responsibility for these (3) OR analyzers, and is implementing proper competencies and QC by personnel running the instruments
- Participation in UH renovation project
- Staff engagement was substantially improved

Quality:

- Working with CAUTI group and Micro to establish criteria for calling and treating UTI – Antimicrobial stewardship
- Working with Rheumatology clinicians to investigate ESR values on the high end of the spectrum with our newly implemented technology
- Working with Hem/Onc and infusion staff to improve anc TAT. We continuously work on anc TAT, and have done a good job over the last year months (goal is <4% outliers), in spite of dealing with new workflow/software bugs with the automation line. We have seen an overall decrease in TAT in the past year-now rarely over 2.5% outliers and many times around 1%
- Safety project to prevent patient mixup when processing body fluids. Dept. Gemba took place, and staff ideas were developed, new label printer installed at bench, and several improvements identified in processing steps for improvement. Procedures have been modified and enhancements made. A3 performed and presented at the CP QA Quarterly Meeting 4/18/17
- Body fluid and CSF Collected not received specimens-we now call on these if not received in within 2 hrs to track precious specimens-but this has significantly increased the workload in the area to look everything up in MiChart and additionally, make calls for errors in MiChart or transport
- Working with blood bank to launch new (transfusion related) advanced parameter testing available on Sysmex instruments
- Improvements made to shift change procedures in coagulation (after senior tech attended advanced course at Siemens)
- Working on reducing albumin preps, early release of anc even while waiting on albumin preps

Engagement:

- Submitted 6 MQS poster for various sections including POC, flow cytometry, marrows, hematology, coagulation (4 were accepted, and presented at Quality Symposium)
- 2 ASCP abstracts/posters accepted, presented at conference Sep 2016
- Sent one staff member to Siemens advanced training (Linda Johnson)
- Continue to work on staff engagement, received very good results with improvement over last year in every single question –held 4 staff engagement meetings so far, will do 2 more in June
- Staff engagement-clean room-staff are extremely happy with expanded space in our clean room once dirty lab coats were moved to wall hooks inside the lab. Many staff suggestions have been implemented e.g. adding a phone line in the diff area
- 3 staff members received workplace recognition awards (Matt Heilbronn, Todd Teifer, and Chris Smith)

Staffing:

- Completed training 7 new staff members over the last year, including one swing shift position covering specialty areas-flow cytometry and bone marrows along with routine hematology
- Lost 6.5 employees due to transfers, retirements.
- Many of the replacements are yet to start (2 in June, and 3 in July). All will require approximately 12 week training periods on dayshift
- Trained 5 staff members in specialty areas-flow cytometry (Edison Sexton, Dina Eadeh), special coagulation (Christine Falkiewicz), and path review screening (Jaclyn Spalding and Matthew Heilbronn)

- Trained 5 staff members to perform bone marrow differentials (the plan is to integrate all microscopic work into one section-including peripheral bloods, body fluids, CSF and bone marrows)-Mary Jane Liu, Laura Gable, Kate Idalski, Jamie Graham, Alicia Kuzia

Goals for next year:

1. Implement Urinalysis with a new platform working with CAUTI committee
2. Telepathology with NCRC
3. UH renovation & NCRC move
4. iSed optimization
5. Cancer center TAT

Clinical Flow Cytometry Laboratory

General Description

A. Instrumentation, Personnel and Space: The Clinical Flow Cytometry Laboratory is a division of the Consolidated Hematology Laboratory.

1. Current instrumentation includes three Gallios 3-laser, 10-color, 13-parameter Flow Cytometers, one FC-500 1-laser, 5-color, 7-parameter instrument, one Q-Prep Plus robotic pipette/lyse assist device, and support equipment housed in approximately 490 sq. ft. of space.
2. The division averaged 7 FTEs/week drawn from a group of 12 cross-trained technologists. 10 of the techs also work in other areas of the Consolidated Hematology Laboratory. This represents an increase of approximately 1 FTE/week in flow cytometry compared to FY2016.
3. Two technologists left the lab (one to work in a different UM lab with more desirable hours and the other to go to NP school). Two new hematology techs were trained to work in flow cytometry.

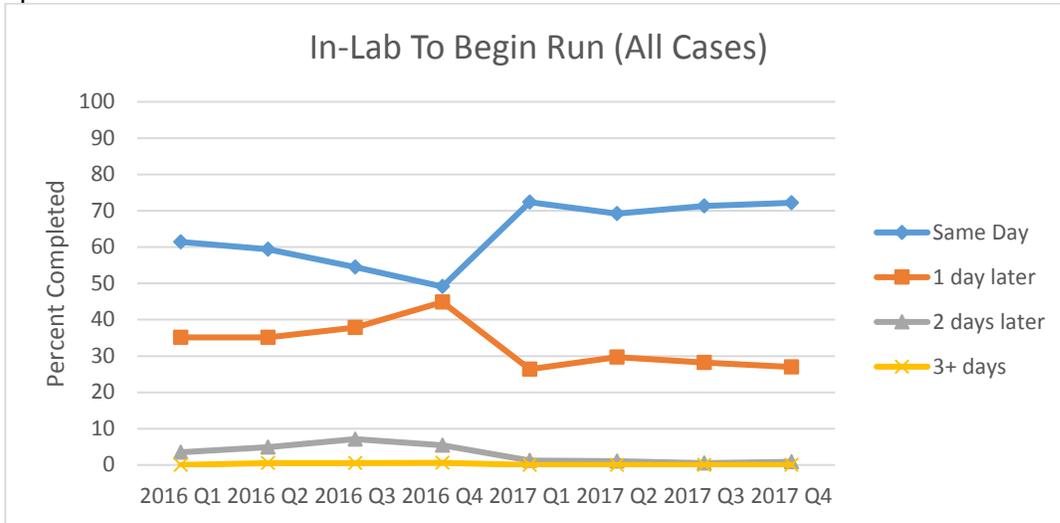
B. Specimens: The laboratory projects a year-over-year decrease of 1.5% in antigen (Ag) “tests” (CDM), a 1.8% increase in revenue, and a 10% increase in expenses. Cost/test increased from \$13.03 to \$14.58.

1. We performed approximately 4700 pathologist-verified tests from June 2015 through May 2016, which was an increase of 2% from the same period one year prior. The proportion of pathologist-verified tests from internal (UM) and external (MLabs) patients was 78% UM and 22% MLabs.
2. Technologist-verified quantitative tests (~4200 cases) include lymphocyte subset analysis, stem cell counts, immunodeficiency testing, CD4 counts, CD4:CD8 ratio determination and PNH-testing. We saw a slight decrease in T-cell quantitative tests and a slight increase in B-cell and stem cell quantitative tests.
3. The number of antigens tested decreased by approximately 1.5% despite a slight increase in the number of specimens analyzed. This difference is most likely due to continued use of the leaner lymphoma immunophenotyping panel introduced in January 2016.
4. Revenue for FY2017 was \$7,392,012 against expenses of \$946,179.
5. Expenses increased by 10%, which was due to increased salary and benefit costs associated with the 1 FTE increase in the lab. Our reagent and equipment costs decreased by 10% from the previous year, but this was not enough to offset the increased labor costs. Our decreased reagent costs are due mainly to our continuing initiatives to use 8 or more antibodies per tube, which reduces the number of tubes run per specimen and reduces the quantity of antibodies used per specimen.

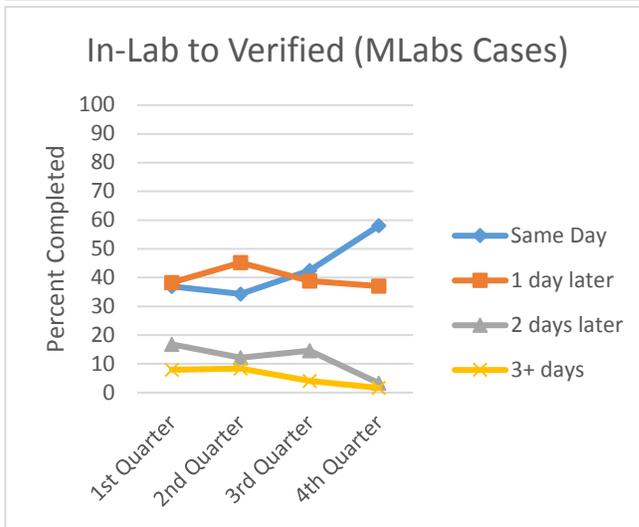
C. Turn-around time: Time from receipt of specimen to run on cytometer decreased. TAT for pathologist-verified cases was similar to last year.

1. The percent of specimens run on the cytometer the same day of receipt increased from approximately 60% in FY2016 to 70% in FY2017. More rapid processing of specimens was enabled by the additional FTE.
2. TAT for MLabs cases was excellent with 80-90% of tests verified within 24 hours of receipt, even with specimens received on Friday or Saturday included in the calculations.

3. TAT for UM cases was stable compared to the prior year, and tends to be longer than for MLabs cases because we analyze the flow results concurrently with the corresponding histopathology specimens.



4.



5.

- D. **Educational Mission:** The laboratory trains Medical Technologists, Pathology Residents and Fellows (Hematopathology and Hematology). Training includes observation of specimen preparation and instrument operation with senior medical technologists, flow diagnostics/reporting with attending Pathologists, raw data analysis and QA/QC/management education with the Medical Director.
 1. We trained 8 MT students and 3 hematopathology fellows during the past year.
 2. Monthly flow meetings are attended by the laboratory director, manager, and technologists to discuss technical issues, test development, and educational topics.

Goals and Progress (highlights)

- A. **Modernize panels:** After purchasing new Galios cytometers that can detect up to 10 different fluorochromes, we have been updating our panels to take advantage of the increased sensitivity of 8-10 color panels and the cost benefits derived from consolidating panels into fewer tubes. Currently, the majority of our leukemia/lymphoma immunophenotyping utilizes at least 8 antibodies per tube.
 1. A 9-color panel for plasma cell evaluation is currently in use, and its development and utility was reported by our group in AJCP (Behdad et al. 2014).

2. A single-tube, 13-antibody panel for B and T cell neoplasms went live in January 2016. Use of this panel has resulted in significant savings in reagent costs and technologist time. In addition, we have been able to perform more detailed analysis of low-cellularity specimens, such as cerebrospinal fluid and tissue cores, by analyzing many antigens in a single-tube assay.
 3. A 4-tube, 31-antibody panel for acute leukemia and chronic myeloid neoplasms went live in June 2017. This panel consolidates the markers needed for characterization of myeloid blasts, lymphoid blasts and myeloid maturation into 4 tubes. This panel also allows us to look for abnormal maturation of granulocytes and monocytes, which can be helpful for diagnosis of myelodysplasia. Furthermore, we are able to collect more events per tube than in the old 3-5 color panel, which improves detection of residual leukemia.
 4. A single-tube, 10-antibody panel for circulating cutaneous T-cell lymphoma cells went live in April 2017. This panel enables concurrent evaluation of CD7 and CD26 on T cells, which markedly improves sensitivity for detection of CTCL cells. The combination of all relevant markers into a single tube enables more accurate quantification of circulating CTCL cells.
- B. B-ALL MRD assay:** We are implementing a standardized MRD assay for B-ALL in collaboration with the Children's Oncology Group (COG).
1. A standardized assay for B-ALL MRD was developed for the COG's AALL08B1 trial.
 2. U of M enrolls 15-20 patients on the trial each year and sends flow cytometry specimens to Johns Hopkins.
 3. We began validating the assay in parallel with Johns Hopkins in May 2016.
 4. Per protocol, we submitted dot plots from our first 5 specimens for central QC review, and were approved to continue testing.
 5. 45 of 60 specimens needed for validation have been collected so far.
 6. The validation process should be completed in September or October 2017.
- C. Technical component flow cytometry service:** As part of our reference laboratory work for MLabs, we are exploring options for providing technical flow service to be interpreted by our clients.
1. Planning a trial period this Summer of sending PDFs of specimens from Metro General in Grand Rapids to Dr. Michael Naski (hematopathologist at Metro) for interpretation.
- D. Upgrade specimen preparation assist devices:** One of two PrepPlus robotic pipette/lyse assist machines went out of service last year, and the other has required repairs on a few occasions. Furthermore, the PrepPlus can only cocktail a maximum of 7 antibodies, but our newer panels use 9 – 13 antibodies per tube.
1. After testing Becton-Dickinson's SPA pipette-assist robot at Detroit Medical Center, we decided that it is the best fit for our antibody pipetting needs. Still awaiting approval to purchase the SPA.
 2. Our PrepPlus instrument has required multiple repairs, but is still adequately functional.

Special Coagulation Laboratory

This year, Dr. Sean Li joined as the Assistant Medical Director of the Clinical Coagulation Laboratory. The following are accomplishments with the assistance of our senior medical technologist in the Special Coagulation Laboratory to advance and enhance the services offered by this clinical laboratory and to contribute scholarly activity:

Quality Improvement

Continued participation on the Anticoagulation Subcommittee for the P&T Committee which has been highly productive in establishing a full complement of CPGs for UMHS.

Conducting regular monthly staff meetings to provide education to bench staff and improve employee surveys, has had a very positive response from staff

An RFP was issued for new coagulation analyzers based on mechanical methodology

We successfully completed CAP on-site inspection and are re-certified for 2 years.

The chromogenic Factor 9 assay set up and available as an orderable test

We have set up an Apixaban anti-Xa assay

We have marketed ADAMTS13 to the community through MLabs (standard turn-around time was 10 days for St. Joes, whereas we complete it in a day from receipt)

Scholarly Activity and Clinical Research

Chromogenic Factor 8 assay field study (sponsor:Baxalta)

Our laboratory participated in calibration of the SSC/ISTH Second Coagulation Standard Plasma, Lot #5(Sponsor: National Institute for Biological Standards and Control)

We have been designated a Center of Excellence by Siemens which has resulted in our selection as a clinical site for a multi-year study of their new coagulation analyzers toward FDA approval in the US market. This led to our relocation into the Woodson clinical research space in UH South and hiring of a research technician to support these studies. We have completed Waves A, B and C as well as a number of specific assay studies.

We submitted 2 abstracts related to our work with Siemens to American Association for Clinical Chemistry: Multicenter Study of the Mid-volume Sysmex CS-2100i/2500 System* Compared to the Sysmex CA-1500 System Using Siemens Healthineers Reagents

Multicenter Study of the High-volume Sysmex CS-5100 System* Compared to the Sysmex CA-1500 System Using Siemens Healthineers Reagents

Published collaboration with Blood Bank:

Yamada C, **Pipe SW**, Zhao L, Leichtman AB, Samaniego M, Sung RS and Davenport RD. Coagulation status after therapeutic exchange using citrate in kidney transplant recipients. (2016) TRANSFUSION, 56(12):3073-80.

Education

Dr. Pipe contributes lectures on principles of hemostasis and thrombosis and coagulation laboratory assays to the M2 Hematology sequence for the medical school and within the School of Dentistry. He provides lectures to the Hematopathology Conferences and supervise special coagulation testing interpretations with the pathology residents, Blood Bank fellows and clinical hematology fellows. Dr. Pipe also provides oversight for a Coagulation Rotation for the Hemepath Fellows.

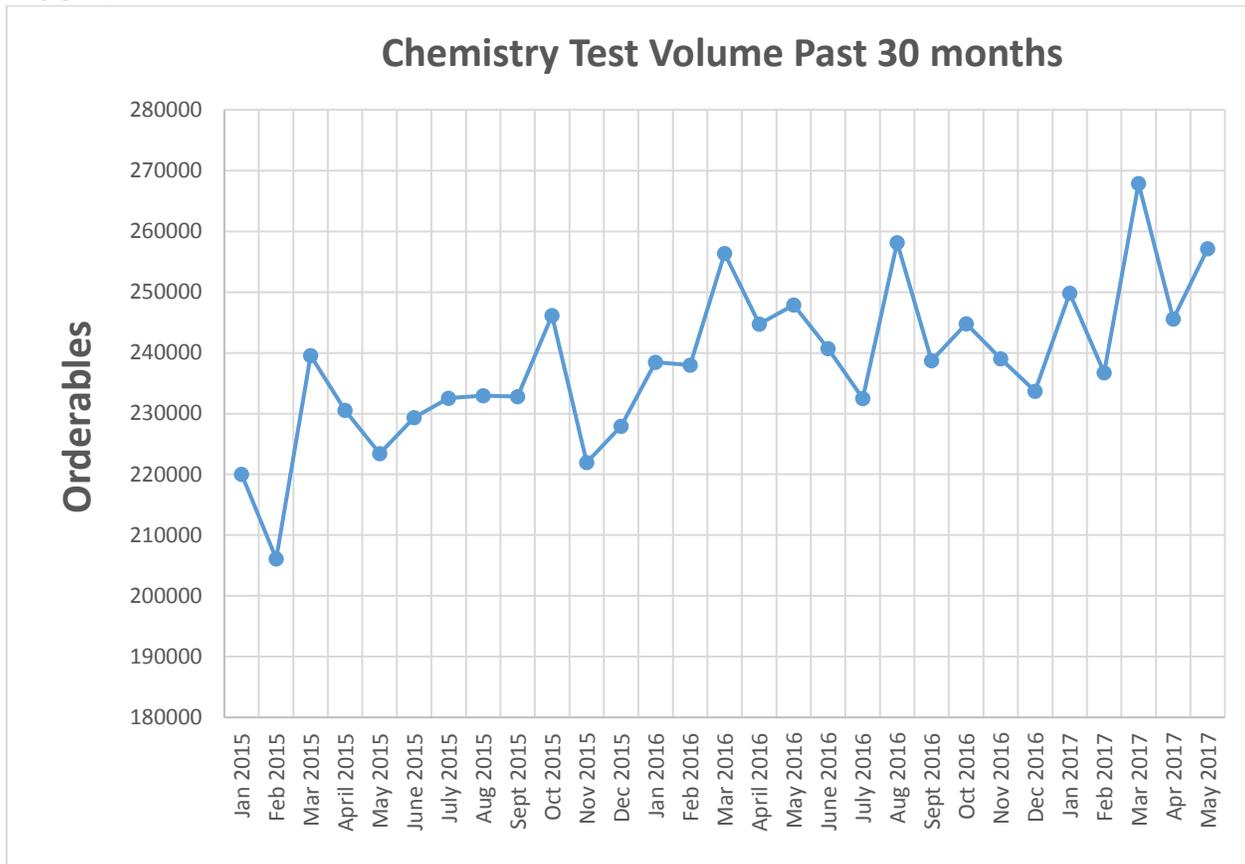
Chemical Pathology Section Laboratories

Don Giacherio, Sue Stern, Lee Schroeder, Hema Ketha, Sean Li

The Chemistry Section, under the leadership of Dr. Donald Giacherio, and the administrative management of Sue Stern MS, MT(ASCP), experienced an approximate 7.0 % increase in overall testing volume this year. The laboratory has performed nearly 10 million tests this past year. Associate Laboratory Directors Dr Lee Schroeder and Dr Hema Ketha both saw significant growth and new test implementation in their specialty areas of Point-of-Care Testing and Toxicology respectfully. Laboratory test volumes continue to grow at a fairly consistent rate, as demonstrated in FIGURE 1. The outstanding efforts of Sue Stern, Merry Mulenberg, and Nick Wesener for the testing and validation of multiple new instrument interfaces in Special Chemistry,

Immunology, and Point-of-Care were extremely helpful in easing the burden of this growth in testing. Dr. Li has served as the Associate Director of the Chemical Pathology Fellowship and works with the Hemoglobinopathy group.

FIGURE 1



The continued increases in both sample volumes and the percentage of STAT samples (FIGURE 2) have put pressure on the laboratory to maintain the high standards set for rapid turn-around times. Currently, the laboratory is experiencing days where approximately 35 % of orders are STAT. While the laboratory strives to consistently meet its goal of less than 2% of STAT samples exceeding 45 minutes TAT (FIGURE 3), this has grown increasingly more difficult with the increase in total and STAT samples. Over 99 % of STATS are consistently verified within 1 hour of receipt, and 99.5% of routine samples are verified within 120 minutes of receipt.

FIGURE 2

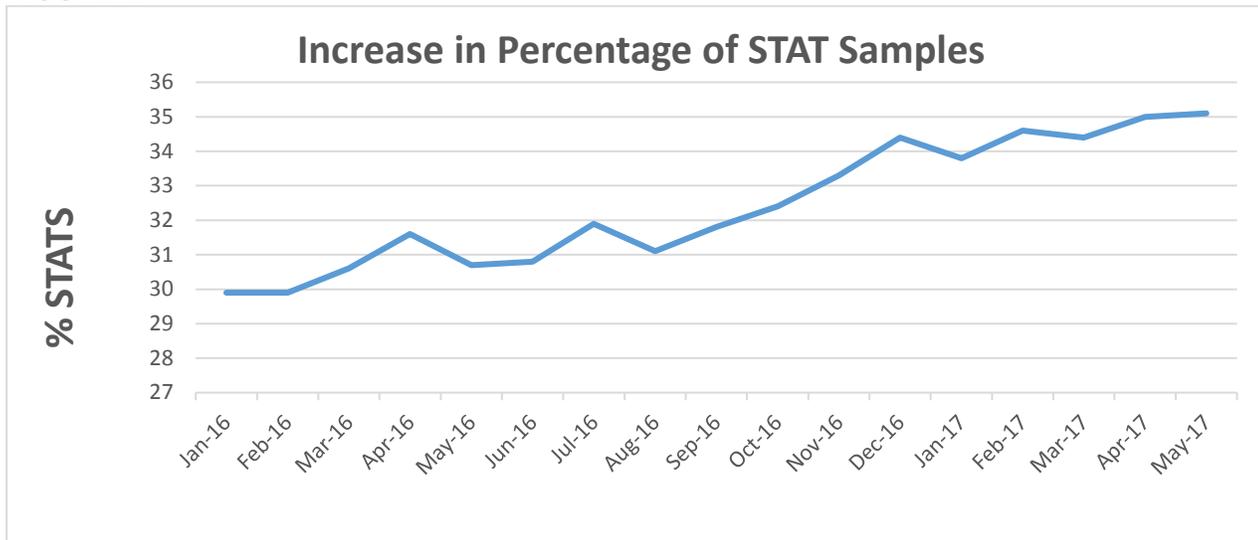
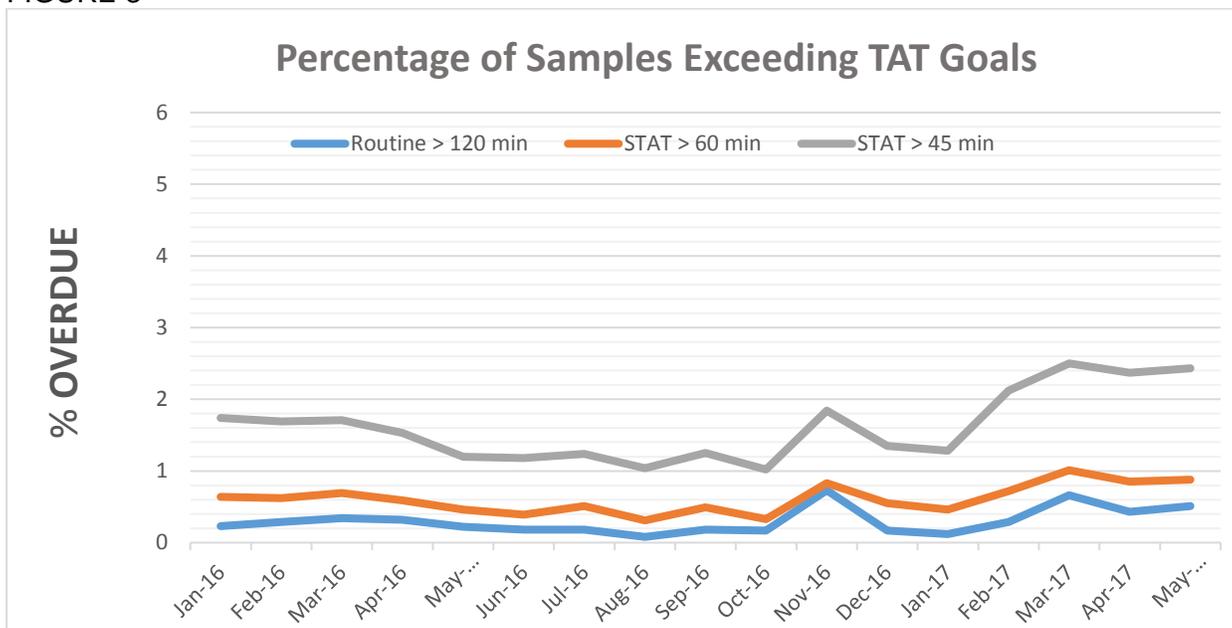


FIGURE 3



Major focus areas of the automation section included the planning for a new core laboratory function in the hospital and the active search for replacement instrumentation. Several members of the laboratory staff met with the Pathology Relocation and Renovation (PRR) staff and architects to thoroughly elucidate current state of the laboratory and prioritize key future state objectives. The result of these multiple meetings was a consensus design that should allow for installation of a new chemistry automation line during the renovation project and streamline sample flows. Continued refinement of core laboratory structure and elucidating the details of construction phasing for the project will be a major focus of the upcoming year. In preparation for the PRR project, the laboratory installed and validated three new Siemens Centaur immunoassay analyzers and 4 new Siemens ADVIA 1800 chemistry analyzers on the existing laboratory cell automation track. These new analyzers are on a shorter term negotiated contract and will bridge the gap between the start of the PRR project and the eventual installation of a new chemistry automation system. Dr Giacherio, Sue Stern and Eric VasBinder reviewed multiple proposals for new chemistry instrumentation and decided on two Roche C502 analyzers as a replacement for the ageing Roche Integra 800 analyzers that perform drug screening and therapeutic drug monitoring. These analyzers should be installed in the fall of 2017.

The Special Chemistry section of the laboratory was also heavily invested in planning for the PRR project. David Harro, Tony Sinay, and Janet Bolterman attended many planning meetings and mock-up sessions. With the move of DHEA testing to LC-MS and the discontinuation of the plasma renin activity RIA, the special chemistry group was able to celebrate the elimination of all radioactivity from the laboratory. This has significantly reduced the amount of monitoring for OSHA and Radiation Safety Services that was being done weekly. Thanks to the efforts of Tony Sinay and Pathology residents Cody Carter, Ellen East, and David Manthei, the laboratory has put a huge amount of effort into validating an automated plasma renin mass assay that will be operational this August. Work has continued on complicated validation of two other high volume send out tests, antimullerian hormone (AMH), a marker of ovarian reserve for the reproductive endocrinology clinics, and fecal calprotectin, a new diagnostic and prognostic marker for inflammatory bowel disease. Dr Giacherio and Tony Sinay have taken the lead on AMH validation and have been the leads on the complex task of validating the fecal calprotectin assay. Because these are considered laboratory developed tests (LDT's) and lack any consistent standardization across reagent manufacturer's, validation and correlation requirements are significantly more rigorous. Both are expected to be implemented by this fall. Both are in the top ten highest volume send out tests. Volume of more common tests has continued to grow significantly. The section has seen a 40 % increase in the Quantiferon Gold TB screening test, and a 10 % increase in Hemoglobin A1C testing.

The Drug Analysis and Toxicology section of the laboratory has also been heavily involved in the PRR project. Dr Ketha and multiple laboratory staff have been active in the planning of new toxicology space in the core laboratory after the renovation project begins. Staff have emphasized lean design principles to streamline workflows and minimize travel distances from sample prep to analyzer in the new plans. The group also focused on LC-MS assay development this past year. Dr Ketha, laboratory supervisor Sheridan Mattson, Sr Technologist Larry Clayton, and all the medical technologists in the Toxicology section have been actively involved in new assay development. Brian Wright completed validation of an LC-MSMS assay for fentanyl, which is becoming increasingly more prevalent as an abused drug in the area. Larry Clayton has been instrumental at developing an LC-MSMS assay for plasma metanephrines. This test has become the recommended screening test for pheochromocytoma, and completes the laboratories comprehensive list of tests now available for the workup of potential pheochromocytoma patients. It also brings in-house one more of the top ten send out volume tests. Assays for the anti-epileptic drugs levetiracetam, topiramate, and zonisamide have been developed on an LC-MSMS platform. Dr Ketha and Brian Wright have worked extremely hard at developing and validating a new methodology for urine drug screening on the Waters Zion QTOF LCMS system. This testing should improve detection of multiple opiates and benzodiazepines in urine samples and is targeted for implementation this fall. Validation work was begun on LC-MSMS assays for Vitamins A and E, which were both in the top ten volume send outs for the year.

The Immunology section of the laboratory acquired an Optilite analyzer from The Binding Site. This immunoassay platform will take over the testing for free light chains, quantitative immunoglobulins, and IgG subclasses. It will also allow for the future evaluation of new Hevylite assays in the workup of monoclonal gammopathy patients. This will allow the laboratory to phase out two older nephelometers and simplify workflow. The Immunology Laboratory is close to implementing the Image Navigator system, an automated ANA fluorescent microscope slide reader which was installed and validation studies for this LDT have been ongoing. Donna Bush and Chris Offord have led the validation and training efforts for this new system. Immunology should begin using this system for ANA by IFA, Crithidia anti-dsDNA by IFA, and ANCA testing in the next two months. Immunology is also about to implement the reverse testing algorithm for syphilis testing, which will automate current manual testing in that area. Work continues with the scanning of older patient files on monoclonal gammopathy workups to simplify the process of reviewing previous results. Drs Keren and Schroeder are also working with Path Informatics for a streamlined method of pulling all patient data together during an SPEP evaluation.

The Chemistry section laboratorieess continue their significant role in education. Dr Forest Huls is completed his year-long Chemical Pathology fellowship, Pathology residents on a monthly rotation through the laboratory met daily with Drs. Giacherio, Schroeder, Ketha, and Keren and spend additional time with the supervisory staff and senior clinical technologists. Six medical technology students spent 4 weeks each rotating through

the laboratory sections. In addition, the lab hosted Pediatric Endocrinology fellows for one week of laboratory testing exposure, and five Adult Endocrinology Fellows for a two-day exposure to LC-MSMS and endocrine immunoassay tests. Dr Giacherio, Dr Ketha, Eric VasBinder, Sheridan Mattson, and Brian Wright also spent 8 contact hours each with pharmacy graduate students, demonstrating technologies for therapeutic drug monitoring. Individual scientific publications will be covered in the faculty annual reports for Drs Giacherio, Schroeder, and Ketha.

During the coming year, the laboratory will be actively involved in planning for the hospital renovation and core laboratory design. We expect delivery of replacement analyzers for drugs of abuse screening and therapeutic drug monitoring. The laboratory is also working with cardiology and the ED on the potential implementation and use of high sensitivity troponin assays for quicker rule out of chest pain patients. Finally, validation of the new LC-MS/QTOF system will open up numerous possibilities for quality improvements of urine drug screening and detection of opiate use and abuse.

Specimen Processing

Harry Neusius, Bonnie Grayson, Don Giacherio, David Keren

Specimen Processing continues to be the hub of pathology specimen receiving and processing activities. Volumes continue to increase and specimen handling duties have become more demanding. Technology advances and the ensuing need for sophisticated testing involves a constant changing of tests ordered and changing of specimen requirements. Specimen Processing receives and triages between 9,000 and 12,000 orderables daily. In addition, the staff processes nearly 21,000 Fed Ex packages of specimens received annually from outside referrals and testing requests. The unit services the clinical pathology laboratories, anatomic pathology, as well as the UMHS MLabs outreach operations. Specimen Processing staff also cover client services for UMHS users, as well as MLab clients after the MLabs customer service offices are closed. SP also handles all send out testing and external result entry processes.

Specimen Processing is managed by Harry Neusius and supervised by Bonnie Grayson. Additional management staff include 5 FTE associate shift supervisors, 2 FTE training specialists and a 1 FTE senior medical technologist.

Specimen Processing has had significant LEAN training related to work processes. They are regularly involved in assessing operations and adjusting to customer and departmental needs. Examples of this are the following activities completed this year and include significant actions to try to minimize the misplacement and loss of testing specimens:

- **CAP Proficiency Testing Samples**

Specimen Processing assumed responsibility for the receipt and distribution of laboratory proficiency testing samples. Since the laboratory is open 24/7, staff are available to receive samples and get them distributed to the testing laboratories in a timely fashion. Crucial documentation of receipt information and timely distribution to the testing laboratories is critical to adhering to regulatory requirements related to the handling of proficiency testing samples

- **Management of Inpatient Cancellation labels**

A needed process for the handling and processing of cancellation of nurse collect testing ordered on inpatient floors was needed to assure proper handling of these orders.

A form was created and process outlined to get the necessary information to the testing laboratories by specimen processors, for handling.

- **Staffing Schedule Adjustments**

Staff breaks and lunch schedules were adjusted on all 3 shifts to better meet departmental needs to accommodate busy volume periods in the department.

- **FedEx Trash Hold**

Because of increased lost specimens and the need to handle incoming referral testing and consult specimens to prevent loss and delays, a new process was developed to hold trash bags and containers for 24 hours to allow for investigations of lost specimens.

- **Real Time QA**

Real time quality review of all work ordered in Specimen Processing was initiated, including U of M work and MLabs work, to uncover any order errors quicker and before final results are generated. This will improve first-time quality for the ordering process.

- **Front Counter Reorganization**

A reorganization of the front counter, allowing for better sorting of incoming work, along with clear visuals of work to be done. This has allowed for better handling of stat and time critical specimen handling, along with better ability to prioritize the incoming work.

Trash bins were relocated away from the area where specimens arrive on the counter to help eliminate the loss of specimens. Carts were placed under front counter to hold separate bins for specimen types, in addition to providing a place for saving of transport bags for later checking to assure all specimens have been removed.

- **Add On Reports**

Working with MiChart to standardize the Add-On procedure to be consistent between inpatient and outpatient add-on requests. This will allow for easy assessment of any missed add-on orders and follow through to meet clinical needs.

- **Printing of Hematology Fluid**

Assisted hematology laboratory in getting printed requisitions for all fluids to facilitate testing within the laboratory and review of order process to assure order accuracy and appropriateness.

- **FED EX Receipt and Reconciliation**

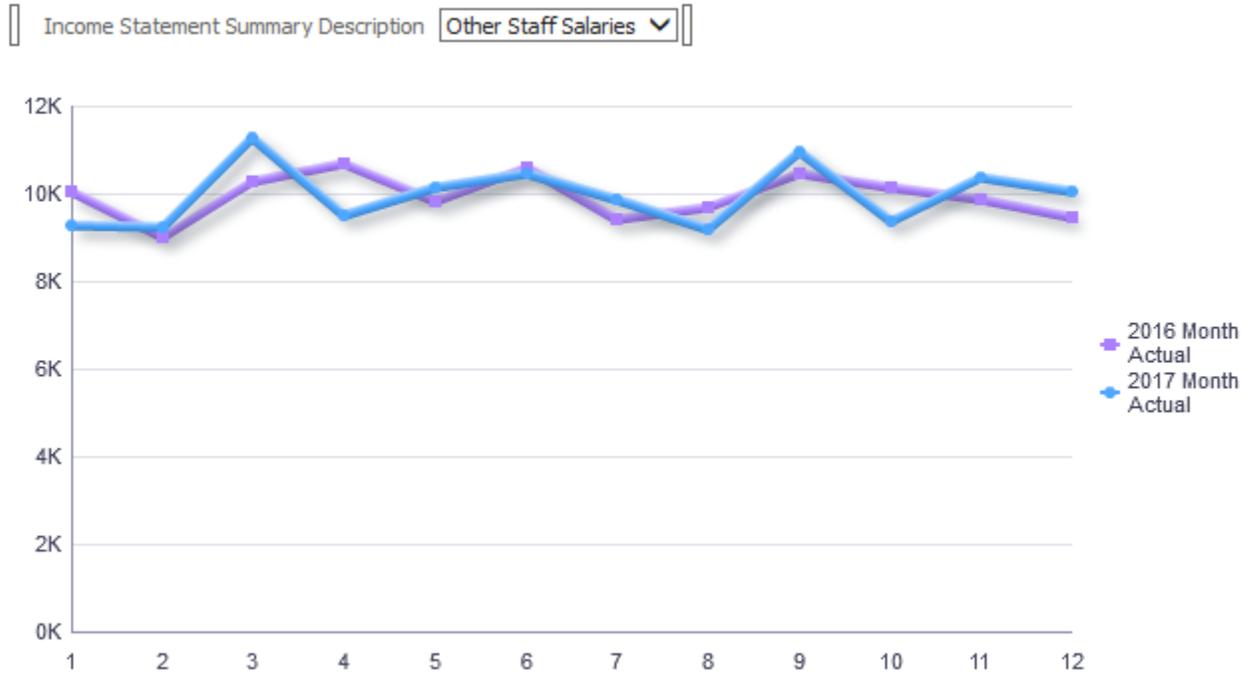
Tracking process implemented to allow for logging and tracking of the receipt and distribution of consult and AP specimens arriving into Specimen Processing.

This allows for better tracking of specimen arrival if issues should arise.

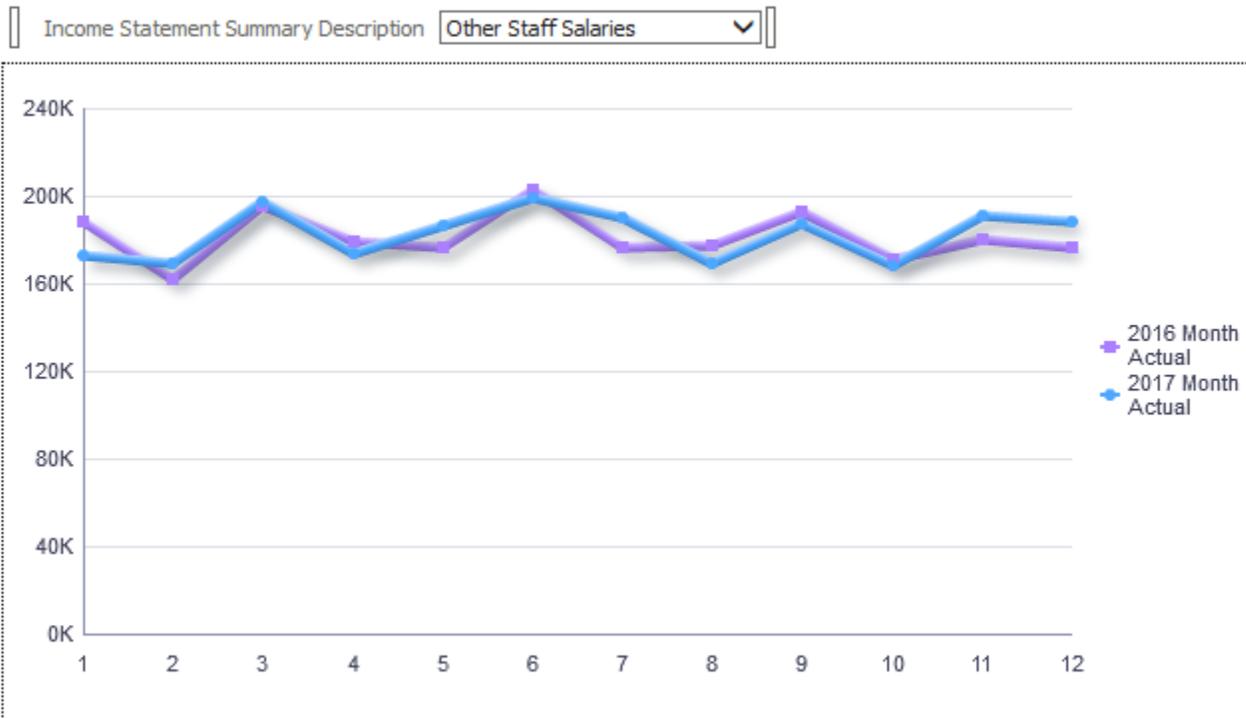
In addition to the activities associated with improving operational effectiveness for the core responsibilities of Specimen Processing, the unit has been significantly challenged by staffing issues. The relatively low salary scale for Specimen Processors has resulted in higher than expected turnover rates. When combined with medical leave absences, this has resulted in an average of over 3 open positions per month in SP. This creates an unusual challenge to maintaining productivity standards. All the SP staff should be commended for their willingness to step up and work the extra hours necessary to meet the needs of the laboratories served by SP.

Even with these challenges this fiscal year, trend analysis of components of the primary expense associated with specimen processing operations remained relatively consistent with those of FY 2016. Variables such as paid FTE's, paid hours, and paid dollars staying flat as illustrated in the following charts in the face of expanding responsibilities within specimen processing, increasing work volumes, and the numerous open positions needing to be covered is a tribute to all staff.

Trend Analysis - Hours



Trend Analysis - Dollars



Specimen Processing staff have also been involved in the Pathology Relocation and Renovation project this fiscal year. They have been intricately involved in the planning process for the North Campus Research Complex N-LNC specimen processing area and also in the development of plans for the new core laboratory U-LNC specimen processing area. Staff were significant participants in developing and supporting the process changes needed for the move of laboratories to the NCRC laboratory space and in the collaboration with the core laboratories in the new University Hospital space.

Staff have also been collaborating on the development of the new Asset Management process being developed to better track specimen transport within the department.

Specimen Procurement

Inpatient Phlebotomy:

Jodi Kennedy-Stanfield assumed supervisory responsibilities for the inpatient phlebotomy team and has done an excellent job of improving work environment culture and performance. She continues to be plagued with constant turnover of staff and the constant hiring and training tasks for new staff. Additional staffing support has been implemented to help maintain continuity for open positions. An additional training specialist position was also created to help with the training and competency assessment of phlebotomists. Additional efforts by the department to help stem this exodus of staff by incentivizing retention and rewards for the inpatient phlebotomy team should be investigated.

Inpatient phlebotomy continues to provide support of the MLabs outreach business activities, including nursing home phlebotomy services. This is a significant role for the Department of Pathology to play in supporting the continuum of care for patients needing short term and long term medical care by UMHS care providers.

1. MLabs Client Nursing Homes

Inpatient phlebotomy continues to service MLab client nursing care facilities.

Phlebotomists are dispatched Monday through Friday to:

- Glacier Hills Care and Rehabilitation Center
- The Bluffs at Regency Park
- Evangelical Home of Michigan-Saline

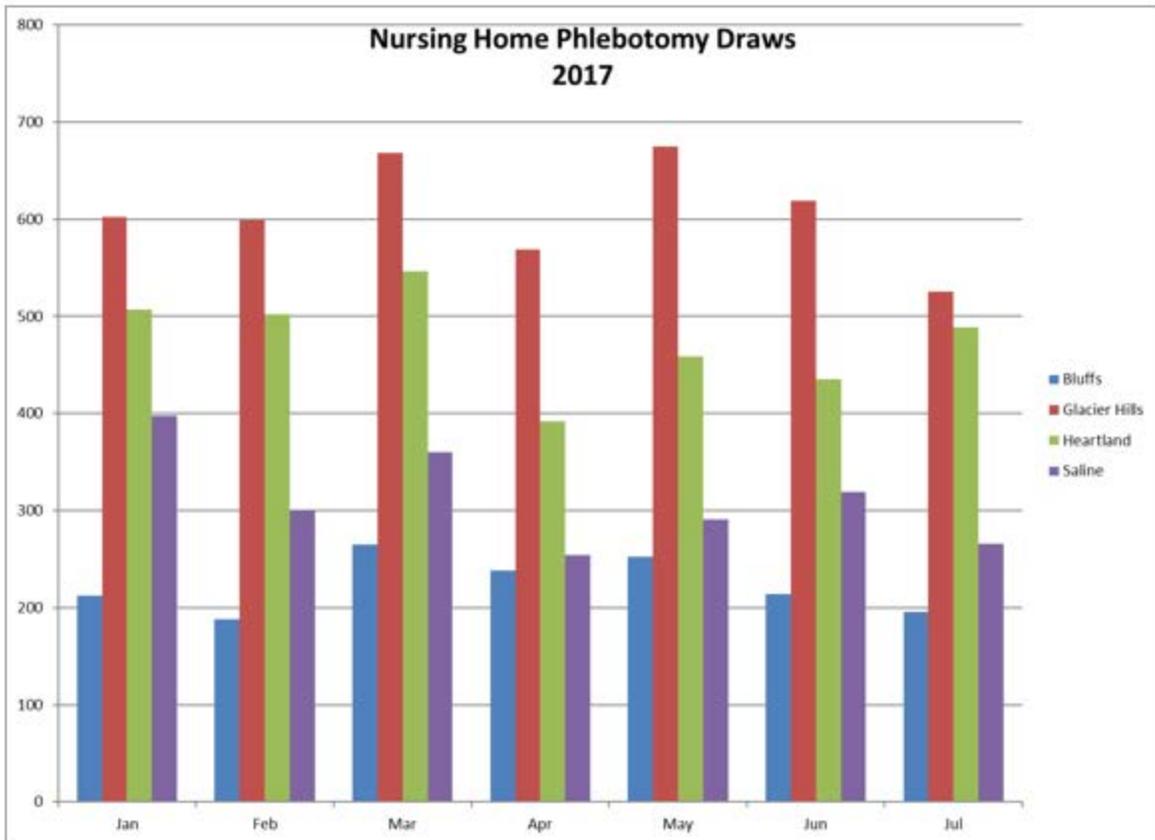
Phlebotomists are dispatched Monday, Wednesday, and Friday to:

- Heartland Healthcare Center

Volumes:

Specimen volumes have remained consistent over the last fiscal year.

Staffing includes 3.5 FTE's, scheduled amongst the 4 nursing home locations.

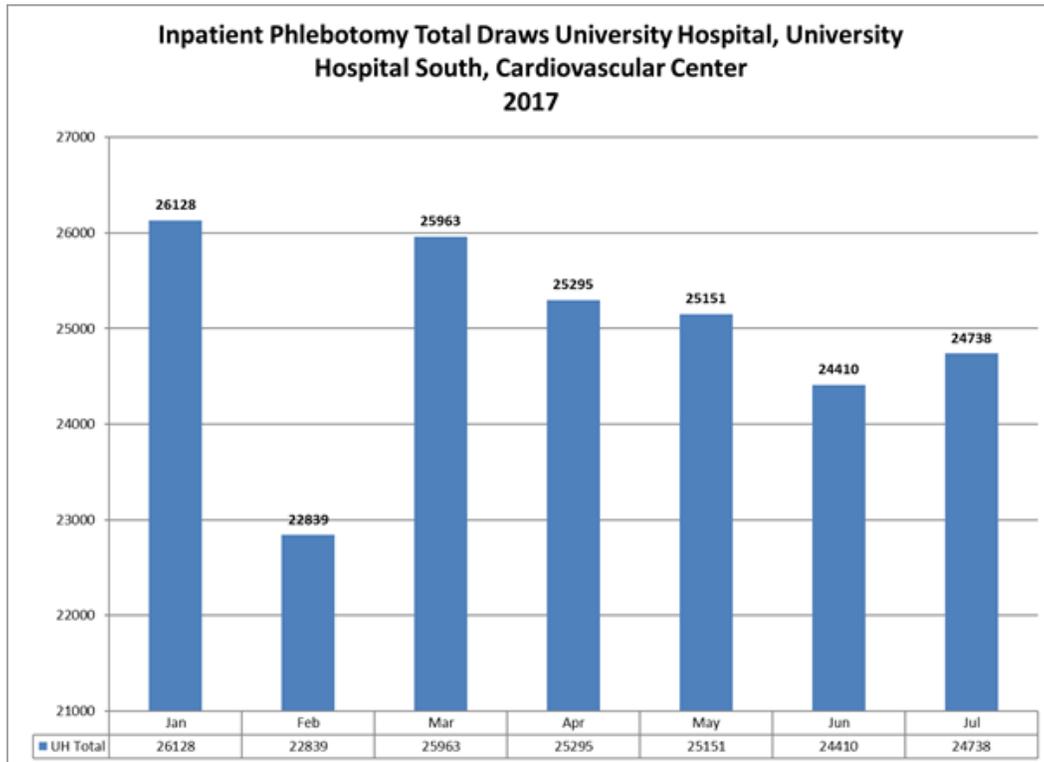


2. University Hospital, University Hospital South, Cardiovascular Center:

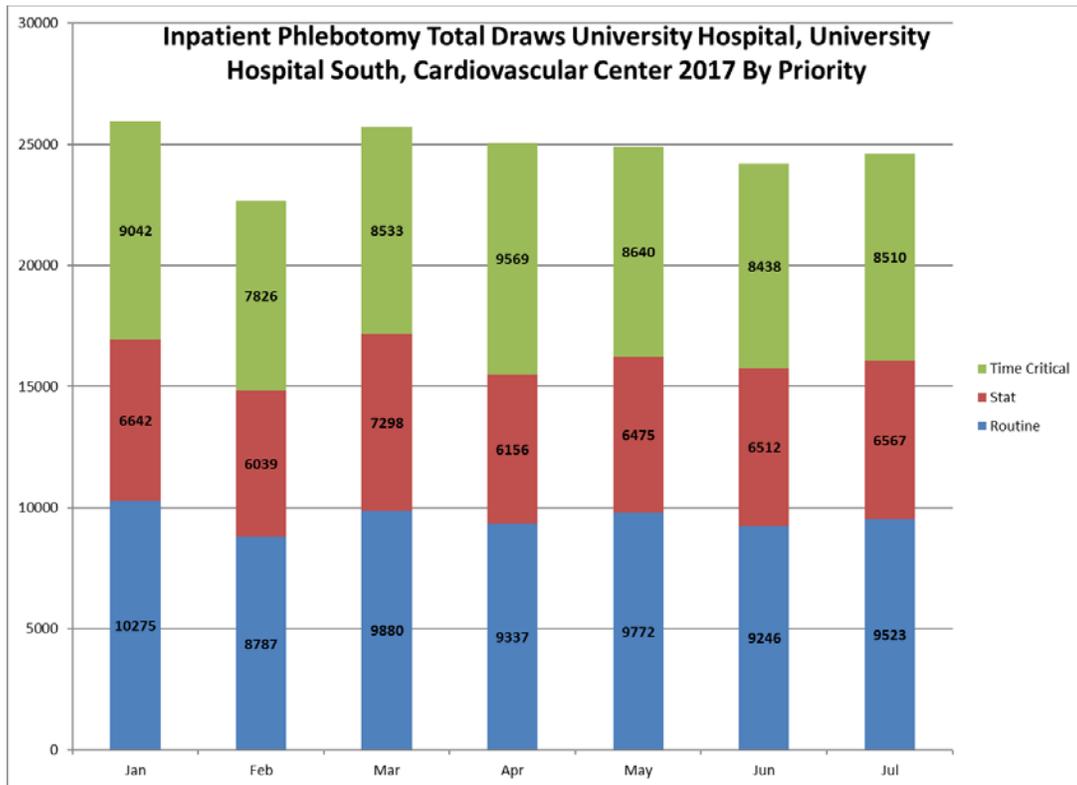
The inpatient phlebotomy team continues to service the University Hospital, Cardiovascular Center and the new short term University Hospital South unit. In addition to supporting this volume of work, the team also supports the Prioritized Discharge program, MiPart, that focuses on prioritizing select patients, marked for early discharge. This impacts the efficiency of the team as a result of the piece-meal work process. We continue to provide appropriate collection of these patient samples in a timely and effective manner with no negative impact on the discharge program.

Volumes:

Volumes for the inpatient team remain relatively stable.



Significant impact on the team occurs from the high numbers of stat and time critical orders. More stat and time critical orders are realized than routine draws. This significantly impacts the ability of the team to meet clinician expectations for timely collection and resulting. Several groups have assessed the phlebotomy process, including in 2008, 2011, 2015 and 2016. High turnover of staff is another contributor to this issue and should be addressed. Phlebotomist pay and incentivizing in order to maintain necessary experienced staff should be implemented.

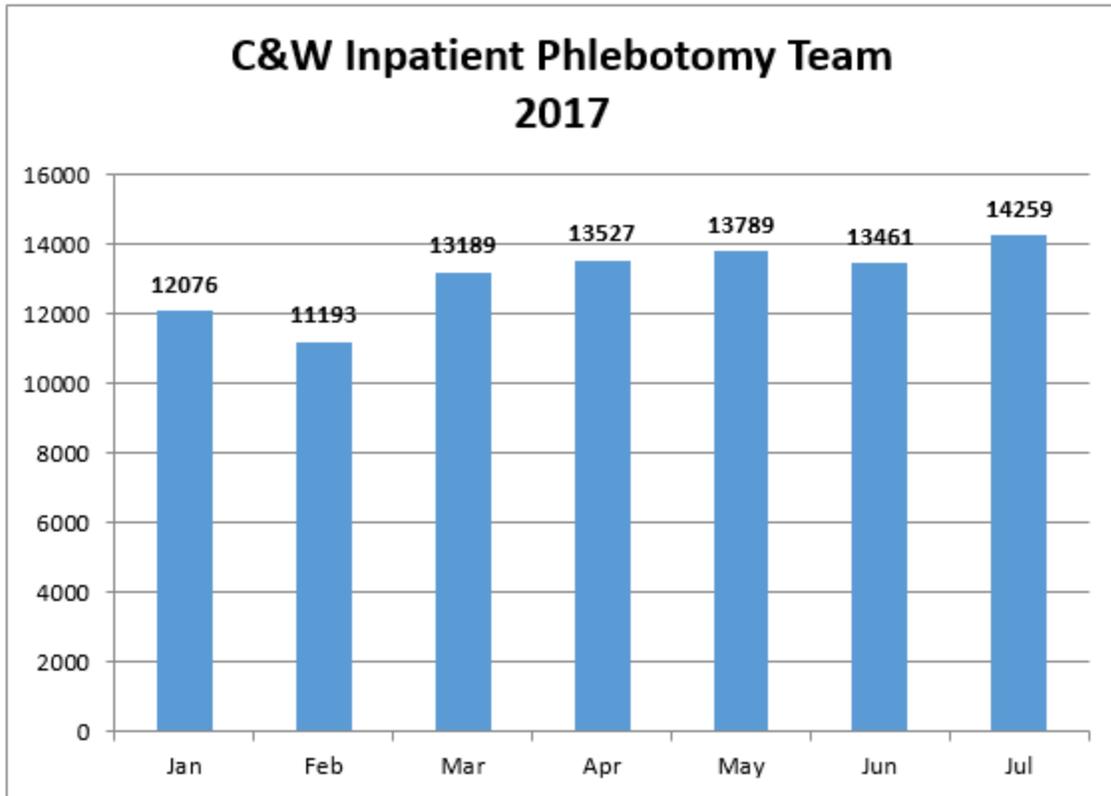


Inpatient Phlebotomy Committee:

An institutional committee to review phlebotomy practices and procedures in order to facilitate an improvement in customer service components of phlebotomy was created. The committee is continuing to operate and to evaluate and recommend methods to better align phlebotomy performance with clinical needs.

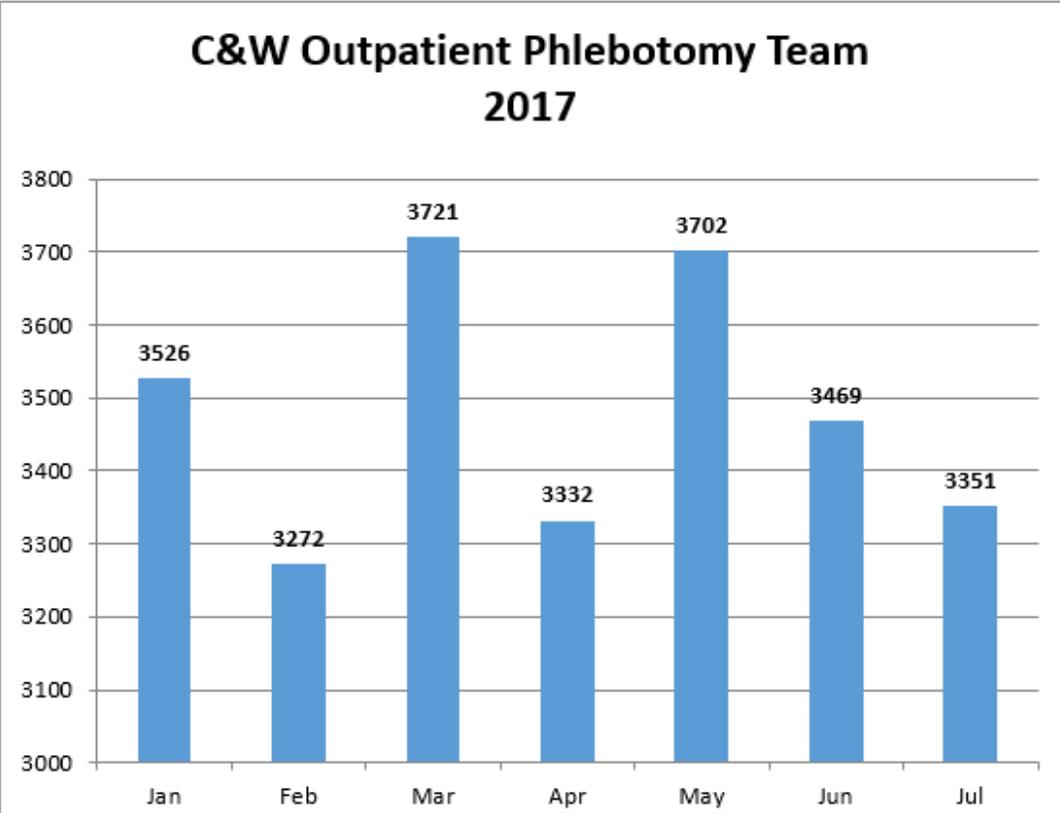
3. C&W Mott Children’s Hospital Inpatient Phlebotomy Team:

The inpatient phlebotomy team in C&W Mott Children’s Hospital is comprised of a skilled team of phlebotomists with significant pediatric phlebotomy experience. Staff are advocates of minimizing pain and anxiety for pediatric patients and have worked closely with the Child Life department to hone those practices. This last year they participated in a research project to evaluate skill levels and the impact of those skills on the observed levels of patient pain and anxiety by both the child’s parent and a trained, unbiased observer. Results are being compiled for later publication. The phlebotomy manager presented preliminary data at the national meetings of the Clinical Lab Managers Association and the American Society for Clinical Pathology this year.



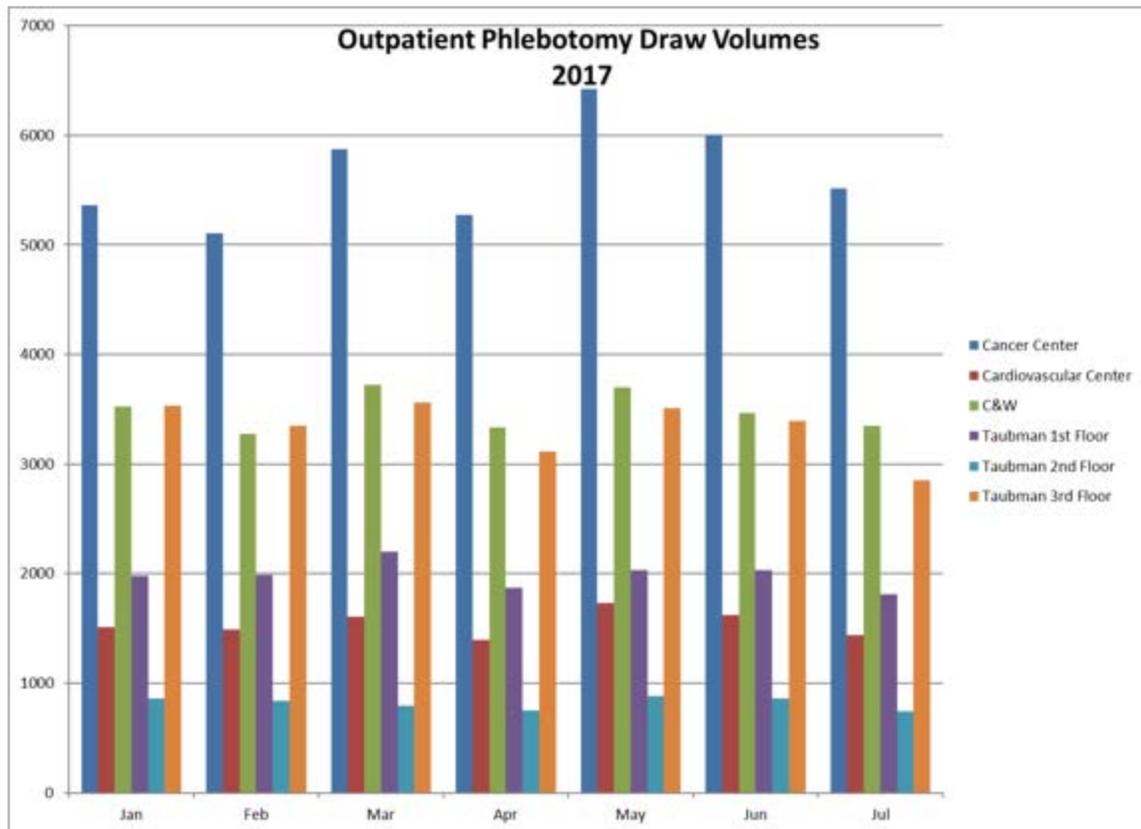
4. C&W Mott Children’s Hospital Outpatient Phlebotomy Team:

The C&W outpatient phlebotomy team services a rather stable volume of draws, with slight variances due to seasonal illnesses (March, 2017 flu season) and summer vacation fluctuations (July, 2017). Moderate turnover of positions has stressed the work environment as new staff members are introduced to the team. Supervisory staff are monitoring the work environment in order to provide support and direction to minimize stress and anxiety.



5. Outpatient Phlebotomy Team:

Outpatient Phlebotomy draw volumes show a stable volume of patients over the past 6 months, based on draw locations and patient populations.



The outpatient phlebotomy team continues to be a busy group.

The Cancer Center blood draw station has received funding for renovation activities in FY 2017. The project is currently in the phase of design document development with AEC. Anticipated construction is expected to begin in March, 2018 with completion of the project in May/June, 2018. A committee of clinic and infusion nurses, patient advocates and phlebotomy staff have proposed this final design:

Clinical Microbiology Laboratories

Dr. Duane Newton is the Director of the Clinical Microbiology/Virology Laboratory and Dr. Michael Bachman serves as the Associate Director.

A major focus of activity in the laboratory continues to revolve around the organizational structure and staffing. In the last fiscal year, we replaced multiple positions due to transfers or retirements. All of the retirements were of very senior employees whose technical expertise is impossible to replace. Several approaches have been taken to fill these emerging gaps:

- Several experienced technologists have been hired, including some with specialized expertise
- We continue to identify opportunities to streamline procedures
- Enhanced cross-training to improve flexibility in coverage
- Restructuring senior tech roles to have a balance of technical and operational leadership functions

In addition to efforts related to laboratory staffing, we initiated and successfully completed the recruitment of an additional faculty member. On August 1, Paul Lephart, PhD will join the laboratory as an Associate Director. Paul is currently the Technical Director of the Clinical Microbiology Laboratory at Detroit Medical Center.

Major clinical activities over the last year:

- Selection of Keistra laboratory automation system (BD Diagnostics)

- System will be implemented at NCRC as part of PRR project
- Ongoing efforts to modify workflow in order to ensure alignment with this systems functionality
- Selection of Bactec FX system for automated detection of positive blood cultures
 - System will go live Aug 2017
 - Chosen because of improved analytical performance (increased detection rates, improved time to detection) as well as smaller footprint
- Conversion of platforms for the detection of sexually transmitted infections
 - Consolidated testing of CT/NG/Trichomonas
 - Hologic Panther:
- Implementation of a *Legionella* PCR molecular detection assay
 - Improved inclusivity of pathogenic types compared to existing *Legionella* urine antigen test
- Implementation of re-designed *Pneumocystis jiroveci* assay
 - Decreased hands-on time, decreased analytical time, elimination of use of hazardous gel staining chemicals, improved precision and sensitivity
- Pathology Relocation and Renovation project
 - Staff at all levels have consistently participated in planning at every stage
 - LEAN principles have been utilized to identify optimal workflow
 - Laboratory layout has been finalized
 - Comprehensive equipment and supply lists have been generated and mapped to future locations
 - Organization of nerve center has been finalized
 - Process of evaluating Microbiology functions in UH have begun
 - Multiple meetings with SP and other laboratories to develop vision and goals of integrated core laboratory
- Clinical studies:
 - Ceftazidime-avibactam: Evaluation of Potential Use Against Carbapenem-Resistant *Enterobacteriaceae*
 - In vitro activity of ceftolozane-tazobactam against *Burkholderia* species
 - The Implementation of Bruker Compass and Galaxy Within a High- Volume Clinical Laboratory

The common theme from each of the items describe above is that they are all high impact activities for our patients and the Health System. The laboratory has continued to focus not only on providing results quickly, but has partnered with clinicians to develop mechanisms to enhance optimal utilization of results. These changes have improved the clinician's ability to rapidly make management decisions—therapeutic and infection control—which have the opportunity to improve efficiency within the health system.

In addition, a multidisciplinary working group that includes members from the Microbiology senior staff, the Antibiotic Stewardship team, Adult and Pediatric Infectious Diseases, Pharmacy, and Infection Control, continues to meet to discuss strategies to improve the approach to testing and/or reporting of results from the Microbiology Laboratory. Meeting on a regular basis has provided a forum for both the clinicians and laboratorians to discuss issues or problems with the goal of utilizing our resources in a manner which optimizes the quality of care provided to our patients. Major focal points for meetings this year included: configuration of susceptibility testing panels and development of educational language for results; development of MiChart BPA for appropriate utilization of *C. difficile* testing.

In addition to the clinical duties, the laboratory continues to be active in multiple research projects that involves many bench-level technologists and provides them with opportunities to attend scientific meetings, which additionally enhances the academic visibility of the laboratory and department. Ongoing research projects

include: Next generation sequencing for the identification of pathogens in meningitis and encephalitis; Clinical impact of BioFire GI panel for the diagnosis of stool pathogens in immunocompromised patient; Epidemiology of nontuberculous mycobacterial infections; Hospital epidemiology of carbapenem resistant *Enterobacteriaceae*; MRSA surveillance in radiology patients; Surveillance for multidrug-resistant organisms in nursing home patients; Changing susceptibility to daptomycin in vancomycin-resistant enterococci; Characterization of viral pathogens and subsequent immune response in children with clinical respiratory tract infections; Clinical features and outcomes in immunocompromised and non-immunocompromised adults with RSV; Respiratory virus infections as inducers of CF exacerbations; Effects of multiple cervical inoculations of *Chlamydia trachomatis* and the development of pelvic inflammatory disease in the Baboon; whole genome sequence analysis of hospital-acquired pathogens including *Citrobacter freundii*, *Serratia marsencens*, and *Enterobacter cloacae*. Dr. Bachman, with the help of laboratory staff, is leading an NIH-funded, multi-site study to identify bacterial and patient factors associated with *Klebsiella pneumoniae* infections in colonized patients. This project leverages a multi-disciplinary research team of clinical microbiologists, infectious disease physicians, bioinformaticians, and a biostatistician. He is also currently working on a CDC-funded project to develop a molecular assay to detect colonization and domination of the microbiome with Extended Spectrum Beta-Lactamase (ESBL)- producing bacteria and collaborating in a funded M-cubed project with Dr. Foxman in the School of Public Health and Dr. Wobus in the Microbiology Department to understand the impact of gut bacteria such as *K. pneumoniae* on norovirus disease severity in hospitalized patients.

All laboratory personnel continued to provide instruction to Pathology house officers and Infectious Disease fellows and residents on diagnostic procedures used in the Clinical Microbiology Laboratories. We also provided several laboratory preceptorships for medical students, pharmacy students, and PharmD residents during the year. One Molecular Genetic Pathology fellow, Pawel Mroz, completed a six-week rotation that included an assay development project. Six medical technology students completed their clinical rotations. Infectious Disease Laboratory rounds were held each weekday during which staff members and assigned Pathology house officers interacted with ID team members to answer questions, demonstrate laboratory diagnostic procedures and discuss interesting findings. Numerous in-service education programs were held during the course of the year with individual technologists and Pathology house officers giving presentations to staff members.

Multiple senior staff, including the laboratory's administrative manager, supervisors and senior technologists attended one or more regional or national scientific meetings during the year. Several other staff members attended national and regional scientific meetings of interest. All of the above-mentioned individuals were involved in presenting posters at national meetings, and multiple manuscripts have resulted from these efforts (Clinical Microbiology staff in bold):

Zhao L, Anderson MT, Wu W, T Mobley HL, **Bachman MA**. TnseqDiff: identification of conditionally essential genes in transposon sequencing studies. BMC Bioinformatics. 2017 Jul 6;18(1):326

Martin RM, Cao J, Brisse S, Passet V, Wu W, Zhao L, Malani PN, Rao K, **Bachman MA**. Molecular Epidemiology of Colonizing and Infecting Isolates of *Klebsiella pneumoniae*. mSphere. 2016 Oct 19;1(5). pii: e00261-16.

Holden VI, Breen P, Houle S, Dozois CM, **Bachman MA**. *Klebsiella pneumoniae* Siderophores Induce Inflammation, Bacterial Dissemination, and HIF-1 α Stabilization during Pneumonia. MBio. 2016 Sep 13;7(5). pii: e01397-16.

Mazer DM, **Young C**, Kalikin LM, Spilker T, LiPuma JJ. In Vitro Activity of Ceftolozane-Tazobactam and Other Antimicrobial Agents Against *Burkholderia cepacia* Complex and *Burkholderia gladioli*. Antimicrob Agents Chemother. 2017 Jul 3. ePub ahead of print.

Cha W, Mosci R, Wengert SL, Singh P, **Newton DW**, Salimnia H, Lephart P, Khalife W, Mansfield LS, Rudrik JT, Manning SD. Antimicrobial Susceptibility Profiles of Human *Campylobacter jejuni* Isolates and Association with Phylogenetic Lineages. Front Microbiol. 7:589. PMID: 27199922

Patel TS, Kaakeh R, Nagel JL, **Newton DW**, Stevenson JG. 2017. Cost Analysis of Implementing Matrix-Assisted Laser Desorption Ionization-Time of Flight Mass Spectrometry Plus Real-Time Antimicrobial Stewardship Intervention for Bloodstream Infections. *Journal of Clinical Microbiology* 55:60-67. PubMed PMID: 27795335

Snydman DR, Jacobus NV, McDermott LA, Goldstein EJ, Harrell L, Jenkins SG, **Newton D**, Patel R, Hecht DW. 2017. Trends in antimicrobial resistance among *Bacteroides* species and *Parabacteroides* species in the United States from 2010-2012 with comparison to 2008-2009. *Anaerobe*. 43:21-26. PMID: 27867083

Pendleton KM, Erb-Downward JR, Bao Y, Branton WR, Falkowski NR, **Newton DW**, Huffnagle GB, Dickson RP. 2017. Rapid Pathogen Identification in Bacterial Pneumonia Using Real-time Metagenomics. *American Journal of Respiratory and Critical Care Medicine*. 2017 May 5. [Epub ahead of print] PMID: 28475350

Histocompatibility and Immunogenetics Laboratory

In January 2017, Omar Moussa, M.Sc., Ph.D., D(ABHI) joined the Histocompatibility and Immunogenetics Laboratory as the Laboratory Director, Technical Supervisor and Clinical Consultant. Dr. Moussa was previously the Histocompatibility Laboratory Director at the Medical University of South Carolina. Dr. Moussa has brought a wealth of experience to the lab making this year another extremely productive and successful time period for the lab. Laboratory Manager is Cindy Schall. Laboratory Supervisors are Timm Williams (Serology Section Supervisor) and Katheryn Daavettila (Molecular Section Supervisor). We set additional new goals and implemented many of them, all of which have greatly enhanced laboratory operations and the services we provide.

EDUCATIONAL ACTIVITIES

Monthly laboratory meetings are conducted during which the laboratory operational procedures are reviewed. Changes in the United Network of Organ Sharing (UNOS) regulations in terms of organs allocation are discussed. A presentation is given on a new or current test being performed in the laboratory. This helps to give residents, fellows, and staff updates on the field of Histocompatibility and Immunogenetics.

We continue to provide HLA training to rotating residents/fellows in the areas of molecular HLA typing, flow cytometry crossmatching, and antibody screening. Regular weekly meetings with rotating residents/fellows are also conducted.

Serology Huddles: Serology huddles are conducted on a weekly basis. The days are rotated between Tuesdays and Thursdays. The Huddles are used to convey kudos to staff and any issues or changes that need to be addressed and cannot wait until the staff meeting.

Histocompatibility and Immunogenetics Pathology Fellowship: Dr. Kristina Davis started as a Pathology Fellow of the University of Michigan Department of Pathology Fellowship Program during the 2017-2019 academic year. Dr. Davis' training is pre-approved by ASHI Directors Training and Review Committee (DTRC) under the mentorship of Dr. Omar Moussa.

We presented a series of HLA lectures to the Kidney Tx Group, Lung Tx Group, and Gift of Life Michigan.

Monthly meetings are conducted with the Pediatric Heart Transplant team tailoring policies and protocols for individual patients.

Our Bioinformatics Specialist continues to develop valuable methods to automate data collection in addition to other bioinformatics tools to aid in antibody analysis.

3 abstracts were submitted. All were accepted & will be presented as one oral presentation and two posters at the annual ASHI conference.

Utilization of two Different Luminex Single Antigen Beads Assays (SAB) Platforms in patients with Unusual Reactivity Patterns (poster Presentation)

The Impact of Detecting the Loss of Chromosome 6P in the HLA Laboratory (poster presentation)

In Vitro and In Silico Approach to Identify has-mir-374a Targets Associated with AMR (oral presentation)

OPERATIONAL IMPROVEMENTS

United Parcel Service (UPS): We have now completed over one full year of utilizing the United Parcel Service (UPS) for shipping patient kits and receiving our monthly “mailed-in” patient samples. These monthly samples are critical for the patients who are wait-listed for an organ, for the purpose of monitoring HLA antibodies and also used for the required pre-transplant crossmatch. This change in vendor for mailing the patients samples has been a tremendous success and has been extremely beneficial for our patients.

The Histocompatibility laboratory director and staff are actively attending all of the clinical meetings for the solid organs transplant programs at the University of Michigan. Working closely with the clinical team continued to demonstrate the impact of this meetings on process improvement and patient care.

Assisting with ON-CALL Coverage: Two additional experienced staff were trained to assist with on-call coverage for deceased donor reviews and virtual crossmatch reviews. The expertise of our staff members who help out in this area in cases of emergency calls before the director final review. This is extremely valuable and the efforts in helping our patients get transplanted is fully recognized by our laboratory as well as the entire transplant program.

Appointed an NCRC Move Captain: We appointed an extremely qualified person to be our NCRC Move Captain. This Move Captain attended meetings, communicated tasks to our staff and prepared multiple excel spreadsheets to aid in equipment purchase, validation, and control, in addition to much more.

Instituted Regular Staff Meetings (monthly & weekly): In the monthly staff meetings, updates in HLA testing, UNOS regulation, and organs allocation is discussed. Other critical matters regarding testing procedures changes are also discussed.

Created an Internal Quality Assurance/Quality Improvement Committee: During the committee meeting the DQ/DC, proficiency testing results will be discussed. Turn-around time, ideas for process improvements will be also discussed.

Evaluated the New Immucor Enhanced Single Antigen Bead Assay: The implementation of this additional platform aided in the process of elimination of false positive HLA antibodies patterns that are detected using the current platform in patients with auto-immune components. False positive antibodies patterns can significantly reduce some patients chances of getting organs from immunologically compatible donors.

Incorporated a Second Check System with the Cytogenetics Laboratory on Homozygosity Cases and validated buccal swab DNA testing protocol: Current DNA typing assays are based on using DNA from peripheral blood Patients with 6P partial LOH (loss of heterozygosity) in Chromosome 6 (6P LOH) can be mis-typed as a result of partial loss of 6P in the peripheral blood malignant cells. We potentially saved a patient’s life by pre-emptively identifying the partial 6P chromosome loss which can affect a patient’s HLA type. Patient was initially types as being homozygous in all of the HLA loci using peripheral blood specimen. Buccal swab sample was obtained from the patient and indicated that the patient was actually heterozygote in all of the HLA loci. We have now incorporated a new policy in which we run a check with the Cytogenetics Laboratory whenever we see a homozygous typing for our BM cases.

Implementation of High Resolution HLA typing for hard to match solid organs transplant candidates: We are performing more high resolution typing on donors for patients with allele specific antibodies. This approach has increased the number of patients being transplanted.

Evaluated Next Generation Sequencing (NGS) for HLA molecular typing: Successfully evaluated two major platforms for NGS and generated the standard HLA-DNA panel for the validation process. The two platforms were subjected to a stringent testing process using challenging DNA samples. The introduction of NGS is potential cost saving, process improvement, and future expansion process. Our ultimate goal is to compete for a National Bone Marrow Program (NMDP) reference laboratories contract by 2020.

Completed Molecular Cross-Training for all Technical Staff

Appointed a Captain of our Technical Competency Program

EQUIPMENT IMPROVEMENTS

Purchased a SYSMEX XP300 Hematology Analyzer: We are validating our newly acquired Hematology Analyzer to be used for cell counting for flow cytometry crossmatches. The analyzer will be more efficient and quicker than the manual method, in addition to eliminating human error.

Purchased 2 (-80°) Freezers for Patient's Serum Storage: Currently, we store the patient's serum samples in -20° freezers, however, our goal is to eventually store all of the patient's serum at -80°. For our transplant testing purposes, long term patient serum storage is more stable at -80° versus -20°. We plan to continue to purchase enough -80° freezers to store 100% of our serum.

Evaluated Two Different Platforms for Next Generation Sequencing: Demos were presented on the MiniSeq desktop sequencer; Mia Fora and ILLUMINA TruSight HLA.

Evaluated Two New Flow Cytometer Platforms for Recipient/Donor Crossmatching: Participated in extensive demonstrations and evaluations of the CytoFLEX Flow Cytometer and the FACSVIA. Using new and advanced flow cytometers will give us clearer results for our patients crossmatches.

ACCREDITATION AND PROFICIENCY TESTING:

Successfully Completed Two Major On-Site Inspections – CAP & ASHI – without any Deficiencies

The laboratory participates in several official Proficiency Testing Surveys, as follows:

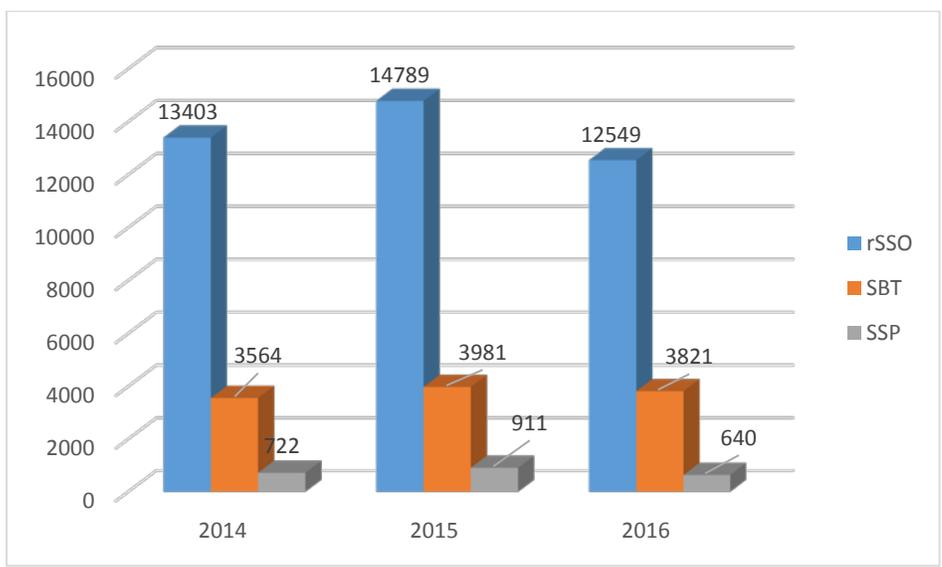
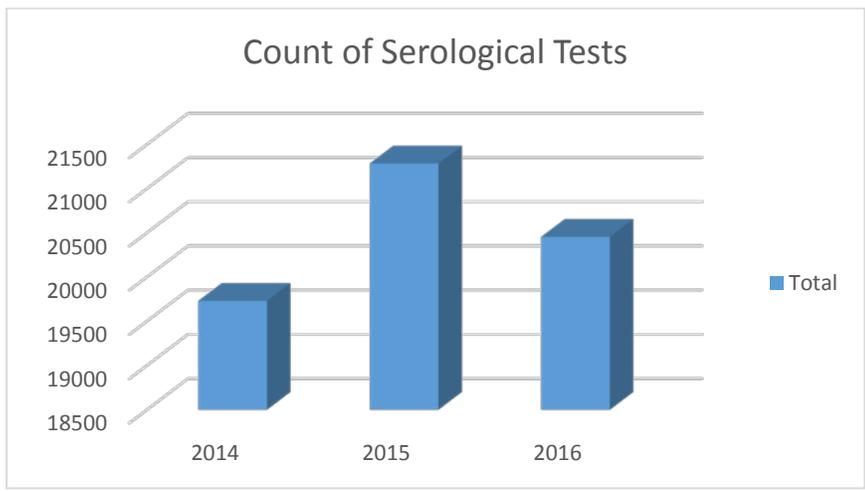
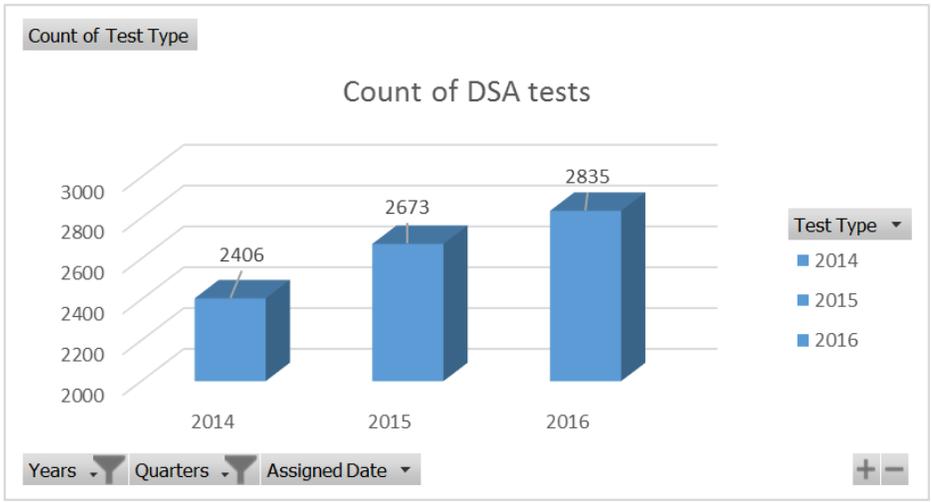
- CAP
- American Society of Histocompatibility and Immunogenetics
- UCLA International MICA Exchange
- OLERUP XM-ONE (Endothelial Precursor Cell Crossmatch)

We have been graded as successful participation for all of our Proficiency Results.

TESTING VOLUME:

Increase in the DSA testing numbers was observed comparing 2015 to 2016 number (see the graph below). The projected numbers for 2017 is expected to be higher.

For other testing such as serology and DNA typing, there is a reduction in the numbers of testing in 2016 as compared to 2015 (see graphs below).



Test: Sequence Specific Oligonucleotide (SSO), Sequence Specific Primers (SSP), and Sequencing Based Typing (SBT).

Clinical Immunopathology

Jeff Warren David Keren Don Giacherio Sue Stern Mary Lou Erber Lee Schroeder

The Clinical Immunopathology Laboratory staff again provided excellent clinical service to our patients, made outstanding progress in planning for the laboratory move to NCRC (scheduled for 2018), and strongly supported the educational and academic missions of the Department of Pathology. Ms. Sue Stern (Chief Technologist, Chemistry Section) and Ms. Mary Lou Erber (Supervisor, Clinical Immunopathology Laboratory) ably oversaw the daily operation of the Laboratory. Drs. Don Giacherio, Lee Schroeder, David Keren and Jeffrey Warren participated in the clinical service, educational and academic activities of the Laboratory.

2016-2017 saw a nearly 10% increase (over 2015-2016) in laboratory test volume. Operation of the Laboratory was enhanced through several test platform upgrades: The Optilite (Binding Site, U.K.) special protein analysis system, the Hydrasys (Sebia) protein electrophoresis system, and a new image analysis system for indirect immunofluorescence ANA and anti-dsDNA testing. (The latter is set to go live in mid-August.)

Clinical training rotations were provided for medical technology students from Wayne State University, Eastern Michigan University, Ferris State University and Michigan State University. In addition to Pathology resident rotations, the Laboratory hosted undergraduate students, University of Michigan medical students and Internal Medicine Rheumatology and Allergy-Immunology fellows. Dr. Forest Huls served the Laboratory as the 2016-2017 Clinical Chemistry fellow. Dr. David Keren organized and ran the monthly protein electrophoresis Clinical Consensus Conference and Dr. Jeffrey Warren, supported by Pathology residents and Drs. Lori Lowe (Pathology, Dermatopathology) and Sandra Camelo-Piragua (Pathology, Neuropathology and Muscle Pathology), supported the monthly Rheumatology-Pathology Case Conference. . Dr. Lee Schroeder, Dr. Sean Li and Dr. David Keren support the bi-weekly Myeloma conference.

Individual faculty academic reports are detailed elsewhere, but the Clinical Immunopathology Laboratory served as a critical resource for Dr. Forest Huls (and colleagues) in his investigations of improved methods to quantify beta-migrating (SPEP) monoclonal proteins and (SPEP) identification of a new generation of therapeutic monoclonal antibodies used in the treatment of patients with multiple myeloma.

Section of Transfusion Medicine

Robertson Davenport, Laura Cooling, Chisa Yamada, Sean Li

Blood Bank

This year, Dr. Sean Li joined as the Associate Medical Director of the Blood Bank Main Laboratory and Immunohematology Reference Laboratory. Total blood components transfused decreased from the previous year. This was large driven by the continued switch from whole blood derived (random) platelets to apheresis platelets. For typical adult dosing a pool of 5 random donor platelets is equivalent to an apheresis platelet unit. There was an increase in red blood cells, in contrast to the previous several years of declines. This increase reflects vigorous clinical activity. The medical staff continues to adhere to evidence based conservative transfusion triggers. The overall laboratory activity, as indicated by total crossmatches, also increased commensurately.

	FY 2016	FY 2017	Percent Change
Red Blood Cells	26515	30905	16.6%
Random/Pooled Platelets	20959	6009	-71.3%
Apheresis Platelets	6394	10120	58.3%
Plasma	6642	6997	5.3%
Cryoprecipitate	6011	6431	7.0%
Total Components Transfused	66521	60462	-9.1%
Total Crossmatches Performed	24026	26815	11.6%

When apheresis platelet utilization is expressed as random donor unit equivalents, the adjusted platelet utilization decreased, while the adjusted total blood components increased. This again reflects the increased level of clinical activity.

	FY 2016	FY 2017	Percent Change
Adjusted Platelet Units	52929	50600	-4.4%
Adjusted Total Components	92097	100942	9.6%

Immunohematology Reference Laboratory

While total activity in the immunohematology reference laboratory was essentially unchanged, there was an increase in complex testing, including antibody identifications, eluates, and adsorptions.

	FY 2016	FY 2017	Percent Change
Antibody identifications	1081	1376	27.3%
ABO resolution	156	111	-28.8%
M-Labs/referrals	8	5	-37.5%
BMT	247	203	-17.8%
Eulates	174	227	30.5%
Adsorptions	317	464	46.4%
Titers	303	324	6.9%
Special antigen typing	6539	6314	-3.4%
Total activity ¹	9781	9861	0.8%

¹ Includes procedures not listed above

Cellular Therapy Laboratory

Total transplant activity was decreased, reflecting the departure of several faculty members in both the adult and pediatric bone marrow transplant programs. However, collection activity was increased from the prior year.

	FY 2016	FY 2017	Percent Change
Collections processed	415	452	8.9%
Bags frozen	542	718	32.5%
Transplants, autologous	116	122	5.2%
Transplants, allogeneic	45	36	-20.0%
Transplants, unrelated	61	44	-27.9%
Transplants, total	222	202	-9.0%

Apheresis Procedure Unit

Activity in the Apheresis Procedure Unit decreased from the previous year. The causes were multifactorial, including alternative therapies for neuromuscular diseases, reduced BMT activity attributable to faculty turnover, alternative therapies for hypercholesterolemia, and reduced activity in the hemoglobinopathy program. In addition, therapeutic phlebotomy was discontinued and this activity was transferred to the outpatient infusion clinics.

	FY 2016	FY 2017	Percent Change
Therapeutic plasmapheresis	1389	1207	-13.1%
HPC collections	416	370	-11.1%
Donor pre evaluations	243	219	-9.9%
LDL apheresis	124	89	-28.2%
RBC exchange	120	103	-14.2%
Total Procedures	2407	2024	-15.9%

Professional Billing

Transfusion Medicine professional billing was decreased from the prior year, reflecting the decrease in apheresis activity.

	FY 2016	FY 2017	Percent Change
Gross charges	\$745,071	\$680,596	-8.7%
Charge units	2,443	2,237	-8.4%

Clinical Trial Activity

Transfusion Medicine participated in a number of important clinical trials. The Cellular Therapy Laboratory and the Apheresis Procedure Unit participated in several clinical trials of investigational cellular therapy products. Two trials involved chimeric antigen receptor T-cells, CTL019, in pediatric patients with relapsed and refractory B-cell acute lymphoblastic leukemia and in adult patients with relapsed or refractory diffuse large cell lymphoma (DLBCL). This novel therapy is likely to significantly impact the outcome of these aggressive neoplasms. The Cellular Therapy Laboratory also completed participation in a complex phase II protocol to treat HPC, Cord Blood ex-vivo with a prostaglandin. This protocol requires 2 technologists 6 to 10 hours to process the products for transplant and is considered a 351 product requiring adherence to stricter FDA guidelines for manufacturing. The Cellular Therapy Laboratory also participated in a phase I study of mesenchymal precursor cells in patients receiving a left ventricular assist device. This protocol requires about 2 hours of technologist time for assisting in preparation of the product for injection and accompanying the Cardiac OR nurse to the operating room to track that product outdate time is adhered to.

Transfusion Medicine supported several clinical trials that are in the early stage of implementation. The Study of Immunotherapy in Newly Diagnosed Glioblastoma (STING) will enroll patients with glioblastoma multiforme. The T-reg Adoptive Therapy in Subclinical Inflammation in Kidney Transplantation (TASK) trial will enroll renal transplant patients with cellular rejection. A Pilot Study of NY-ESO-1c259T Cells in Subjects with Advanced Myxoid/ Round Cell Liposarcoma will enroll patients with advanced sarcomas. All of these clinical trials involve mononuclear cell collection by the Apheresis Procedure Unit and cellular therapy product management by the Cellular Therapy Laboratory.

The Blood Bank had critical involvement in two randomized clinical trials involving transfusion. The ABC-PICU trial compares outcomes of pediatric critical care patients transfused with fresh Red Blood Cells to those transfused with standard storage Red Blood Cells. The High-Titer vs Low-Titer Anti-Influenza Immune Plasma for the Treatment of Severe Influenza A trial compares outcomes of patients with influenza A who are transfused with high titer immune plasma to those transfused with low titer plasma. In both of these trial, the Blood Bank maintains investigational product inventory, performs randomization, and issues the appropriate blood components.

In addition, Transfusion Medicine supported several compassionate use and expanded access programs that offer innovative therapies to Michigan Medicine patients. The Hemopure Expanded Access protocol allows patients for whom blood transfusion is not an option to receive a hemoglobin based oxygen carrier HBOC-201. The LDL Apheresis for Pediatric FSGS protocol allows patients with recurrent focal segmental glomerulosclerosis who do not have an adequate response to standard therapies to receive LDL apheresis. The Humanitarian Use of the CliniMACS CD34 Reagent System allows patients undergoing allogeneic bone marrow transplantation to receive a CD34 selected product with reduced risk of graft-vs-host disease.

Initiatives

The Apheresis Procedure Unit completed replacement of aging equipment with Spectra OPTIA apheresis devices. These new devices offer many advantages including smaller extracorporeal volume, ease of use, and ease of maintenance. The Cellular Therapy Laboratory implemented the Miltenyi CliniMACS cellular selection device. This device will allow Michigan Medicine to participate in novel cellular therapy trials, as well as to perform CD34 selection for clinical care. The Blood Bank secured Department of Energy funding for replacement of the blood irradiator with a non-radioactive device. This will improve security as well as significantly reduce administrative burden and expense.

Point of Care Testing Section of Chemical Pathology and Satellite Support 2017

The Point of Care Testing and Satellite Support sections, under the leadership of Dr. Lee Schroeder and the administrative management of Sue Stern (POC testing) and Theo Jones (Satellite Support services (offsite phlebotomy)), oversee >5,000 test performers of >1 million tests annually over 20 analytes and panels, drawing >300,000 samples from ACUs for M-Labs, and consist of over 100 medical technologist and phlebotomist FTE operating throughout the 30+ UMHS CLIA sites.

Michigan Medicine expansion planning continues, with new West Ann Arbor (75,000 s.f.) opening November, 2017 and Brighton Specialty Center (320,000 s.f.) opening August, 2018. Both sites will have phlebotomy and laboratory services, with an automatic chemistry and immunoassay analyzer at BSC to accommodate a large chemotherapy infusion service and the ambulatory diagnostic and treatment unit. The new onsite tower is also in planning where we intend to offer blood gas and coagulation testing, among other services.

Historically, POC testing was managed by two different groups. Onsite POC testing was managed by Sue Stern in Chemical Pathology and offsite POC testing was managed by Sue Clark in Satellite Support. As of July, 2017 we unified all POC testing management under Sue Stern in Chemical Pathology. This was to streamline policies and procedures and harmonize practices enterprise-wide. It also enabled Satellite Support to focus attention on phlebotomy, which has always represented the majority of their workload.

POC testing section

Test expansion

In the effort to expand POC testing services as requested by ACS leadership and formalized in a survey we conducted in 2015, three initiatives were completed:

- 1) Neonatal bilirubin testing (Piccolo): For years, ACS providers have been requesting an improvement over courier for screening and monitoring neonates for hyperbilirubinemia. While we were able to provide stat courier service, results often became available only after clinics had closed. This prevented providers from initiating neonates on a home phototherapy (bili-blanket) and it is thought led to admissions for intensive phototherapy, particularly if testing occurred on a Friday. We went live with Piccolo bilirubin testing at 4 ACUs May, 2017 and have so far run roughly 100 tests. We are now conducting a chart review to assess the efficacy of the implementation and whether expanding to other sites is warranted.
- 2) Basic and comprehensive metabolic panels (Piccolo): We went live last month with BMP/CMP services using the Piccolo at the 4 ACUs offering neonatal bilirubin. This testing is not meant for routine testing but for patients at increased risk who could benefit from a POC result.
- 3) Influenza testing (Cepheid Gene Xpert): Current practice in ambulatory care is syndromic diagnosis and treatment of influenza, as treatment essentially must be started same day and central laboratory testing effectively provides results after the treatment window. The EDs (both main and C&W) face similar logistical difficulties with influenza treatment. Also, patients admitted from adult ED with pending influenza tests are presumptively isolated and put in private rooms, leading to inefficient use of hospital beds and resources. To this end, we evaluated 3 POC molecular instruments and are now negotiating a contract with Cepheid for the Gene Xpert system. Our plan is to roll these out in the ED laboratories and pilot in 2 ACUs (Canton and Northville) for this year's influenza season.

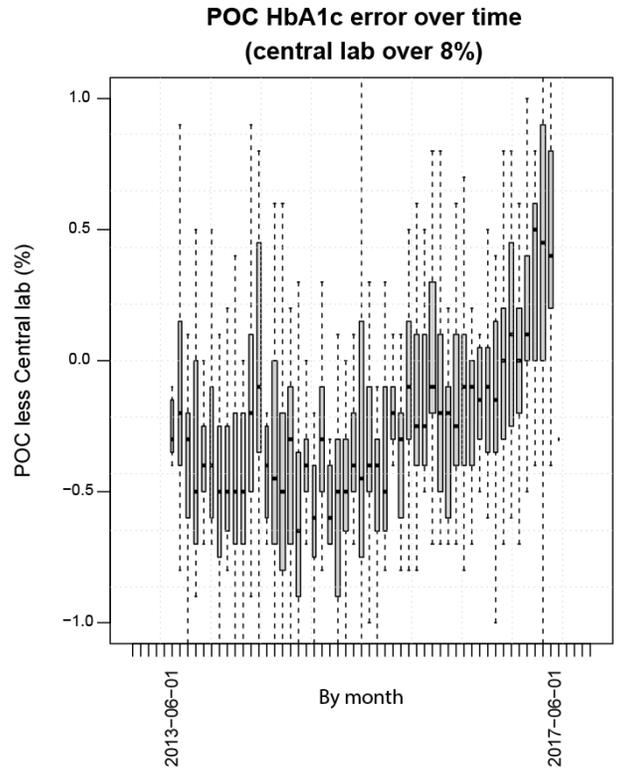
Provider-Performed Microscopy (PPM)

PPM includes several tests including urine sediment analysis, vaginal wet preps, KOH skin preps, semen analysis, and fern testing. In recent years, CMS has been emphasizing the importance of competency assessments of PPM performers. This year we finalized an MLearning module for PPM testing, covering each of these tests and have rolled it out so far to Urology and Dermatology. This, in conjunction with our active proficiency testing of PPM is sufficient for competency assessment as per CAP. We plan to conduct a direct

observation component in the training phase to ensure instrumentation and sample preparation is performed properly.

Quality Monitoring

We continue to use an internally-designed method of mining the LIS to track quality of POC testing through identification of coincident testing events: instances where both a central laboratory and POC version of the same analyte are ordered on the same patient close in time. Using this method, we were able to explore complaints from providers that POC HbA1c results seemed to be increasing compared to central laboratory results. In fact, they were, and compared to 2 years ago, POC A1c results have shifted from being 0.5% below the central laboratory on average (which providers had adapted to), to being 0.5% above compared to central laboratory results (e.g., 8.5% vs 8.0%). We are now in discussions with Siemens to understand the source of the shift. We have also shared this with ACS to coordinate communication to providers. We are working with Path IT to automate this methodology so that we could identify shifts in POC accuracy before it becomes a patient management issue and discovered through provider complaints.



Select POC Test Volumes

Test	2015	2016
Glucose	491,375	545,038
PT/INR	39,414	37,962
HbA1c	28,983	28,847
Blood gas, venous (ED/OR)	27,145	35,475
Urine dipstick	12,411	17,842
Blood gas, arterial (ED/OR) (incr. due to OR interfacing)	3,371	30,404
Urine Tox	3,303	3,044

Other achievements

- Interfaced ED and OR blood gas instruments, reducing transcriptional errors and enabling billing of these services. This was specifically important for the OR since we did not have access to results or testing volumes prior to this as they use Centricity.
- Integrated all proficiency testing failures into a single database to allow mining for patterns across ACUs held by different CLIA directors.
- Consolidated the CLIA director training program with folders maintained at each ACU. CLIA directors now have a checklist to perform onsite annually as well as bimonthly rounds reports from our QA staff who perform onsite visits.
- Worked with Path IT to place label printers in all main, C&W, and CVC ORs to ensure bar-coding of blood gas and hematology POC testing; laboratory-ready label printers are now live in C&W ED.
- In process with an initiative to improve turn-around times for our ED coagulation testing for stroke code patients, with a target of 15 minutes from draw to result.

Future

- We are working with Path IT and the Glycemic Management Subcommittee to develop a glycemia dashboard such that endocrinologists responsible for inpatient glucose control will know in real time when a patient is at risk for hyper- or hypoglycemic events.
- Interfacing POC instruments reduces transcription errors and ensures timely availability of results to all interested parties. This year we plan to work towards interfacing priority instruments including Piccolo, hemoglobin A1c, iStat, hemochron coagulation, and expand use of our interfaced urine dipstick scanners.
- Further harmonize inter-instrument correlation policy across POC testing
- Consolidate policies and procedures between onsite and offsite services
- Initiate training of PPM (a regulatory requirement), and complete enrollment of all PPM providers into MLearning for ongoing competency assessments

Satellite Support

This year brought many changes in Satellite Support, starting with the streamlined focus of the group on phlebotomy (rather than phlebotomy and POC testing management), a change of management to Theo Jones, and reorganizing the supervisor-specific clusters of ACUs.

Manager

Theo Jones accepted the role of Manager in early 2017. He has played an important leadership role in Satellite Support for over 10 years, with 9 years of laboratory management, 9 years of supervisory leadership at the University of Michigan, and 25+ years of Medical Technology experience: "I have a vision for the POC team that will grow it into a highly engaged, inclusive team of healthcare professionals who are inspired and committed to exceeding all expectations." Theo plans to establish a set of committees consisting of phlebotomists and supervisors to engage the entire Satellite Support staff towards quality improvement.

Redistricting of ACU Clusters

Anticipating successive expansions in ambulatory services over the next several years, we have begun the process of strengthening our capacity. To this end, we have created 6 clusters of ACUs along the following lead sites: Canton, Northville, EAA, Briarwood, Brighton, and WAA. With the new 75,000 s.f. WAA opening November, 2017 and 320,000 s.f. Brighton Specialty Center opening in August, 2018., we felt it was prudent to expand our supervisory capacity from 4 to 6 staff so that each of the largest ACUs had a devoted supervisor.

Day in the Life and Phlebotomy Quality Technologist

With the expected expansion in phlebotomy services, quality and harmonization of practice will be essential. We are in the final stages of the interview process for a new Satellite Support Quality Technologist. While we have always hired QA techs for POC testing, this is the first time we have hired one for phlebotomy services. To this end, we initiated a 'Day in the Life' campaign, where we asked supervisors, associate supervisors, and phlebotomists to write about a 'day in the life...' of someone in the blood draw stations: a phlebotomist, a patient, a supervisor, or someone else, and to describe what their day would look like if our blood draw stations were in the ideal state. What we found was a clear desire to improve how health IT is currently serving phlebotomists and patients. To paraphrase one phlebotomist, "if we could only know what test the provider actually wants we could provide an amazing service." Therefore, in the upcoming year we will be working to improve how MiChart can provide the most useful information to our phlebotomists to reduce ambiguity in provider-ordering. This ambiguity currently demands a significant amount of 'detective work', which consumes effort that could be spent with patients to improve their experience and reduce wait times.

Satellite Support Statistics

Redraw rates are an important quality statistic for our section, and is defined as a preventable error requiring the patient to return to the blood draw station for a second draw. This is often due to insufficient sample volumes.

	2016 (Apr-June)	2017 (Apr-June)
Redraw %	0.057%	0.042%
Redraw rate (# patients per single redraw)	1,765	2,368

Michigan Medical Genetics Laboratories (MMGL)

In FY17 MMGL Molecular Genetics partnered with Michigan Center for Translational Pathology (MCTP, Arul Chinnaiyan's laboratory) to develop and validate 12 germline NGS cancer panels: Hereditary Breast and Ovarian Cancer (HBOC) High-Moderate Risk, Hereditary Breast and Ovarian Cancer (HBOC) Comprehensive, Colorectal Cancer, Pancreatic Cancer, Renal Cancer, Paraganglioma, Endometrial / Uterine Cancer, Melanoma, Stomach Cancer, Prostate Cancer, Neurofibromatosis, and a 63 gene Comprehensive Cancer Germline NGS Panel. Additionally, MMGL also developed and validated a bioinformatics pipeline for the analysis of data generated from these germline NGS assays. MMGL has placed 3 of these panels into production and has delayed the release of the other 9 NGS panels in FY17 due to insurance reimbursement issues for NGS panel testing. MMGL and representative of the other molecular laboratories met with the BCBSM leadership team (Thomas Simmer, Marc Keshishian, Jerry Johnson) to present information of why both germline and somatic NGS panel testing should be a covered benefit for their subscriber. We are hoping that BCBS of Michigan will make a favorable decision concerning NGS panel testing later this year.

MMGL has continued to partner with RevCycle on several projects. We have adjudicated genetic testing claims that have been written off by RevCycle that have valid prior authorizations and other issues. Some of the problems we have resolved is where the PA number should be recorded on the HAR (Hospital Accounts Receiving) in MiChart, working on rejected claims for lack of clinical documentation which were present in MiChart but were not sent to the insurance company, assisting in obtaining Advanced Beneficiary Notice (ABN) for non-covered genetic testing for Medicare patients and getting the corrected billing modifier attached to the claim, requesting and obtaining a billing rejection work queues for MMGL. Holding monthly meetings with RevCycle billing leadership to review and resolve any billing issues. MMGL has worked with the RevCycle charge setting unit to review and develop competitive pricing for all of MMGL's genetic testing. We were able to set competitive charges for our germline NGS panels, Spinal Muscular Atrophy testing, ATP7B full gene sequencing, and have started in FY18 to review the charges for the rest of our test menu.

MMGL's Prior Authorization (PA) process is functioning well but we are also continuing to improve it. We are now obtaining PA's for the Pediatric Genetics Clinic, Breast and Ovarian Cancer Center, Pediatric Pulmonary, Adult Pulmonary, Fetal Diagnostic Unit, OB/GYN, Saline Health Care, Northville Health Center, and many others. In addition to obtaining PA, our one PA individual also determines out of pocket cost that a patient might incur and if it is estimated to be \$250 or greater, we consult with the patient if he/she would like to proceed with testing. This OOP service includes MLab client patients also. Two individuals from MMGL sit on the Pathology Prior Authorization committee, which is looking at how to incorporate the PA process in Pathology.

MMGL and MLabs partnered this year and exhibited in March at the American College of Medical Genetics ACMG. This is the first time that MMGL, MLabs or Michigan Medicine had been represented by MLabs

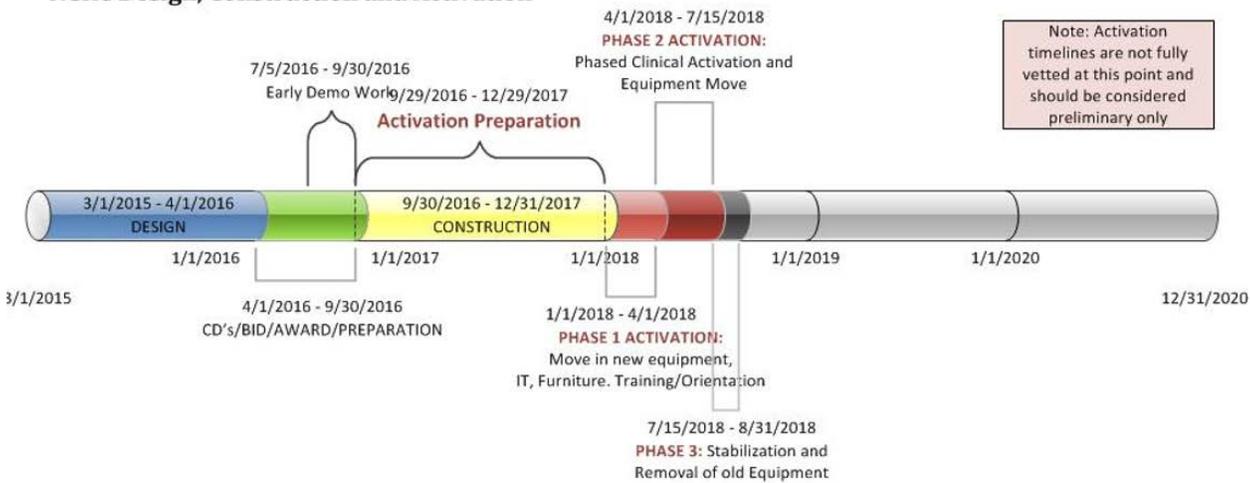
sales/marketing presence at the meeting. While the focus was on the MMGL test menu during this exhibit, all molecular testing in the Department of Pathology represented.

Clinical Pathology in the Pathology Relocation and Renovation

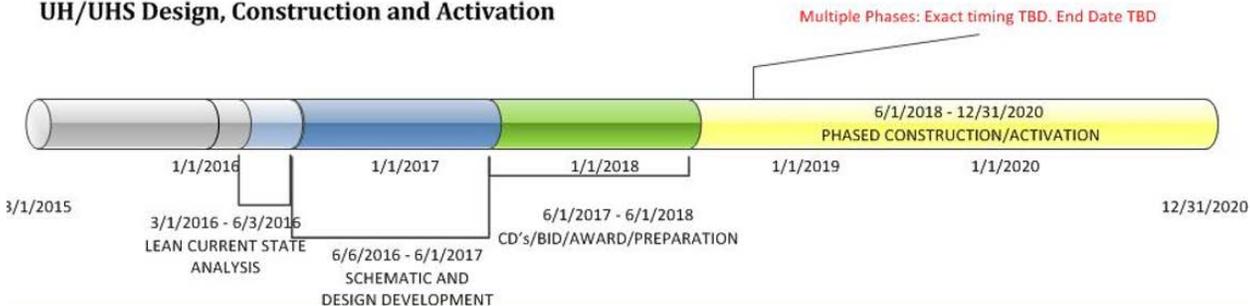
This year marked the last FY that those in research and administration Pathology will be separated because by the end of FY 2018, Pathology should officially be moved in to North Campus Research Complex (NCRC)! The PRR Project Committee has been working extremely hard to get the final details worked out and established. This will happen in multiple phases, as seen below. By July 2018, we should be moved into one central location! They project began in early 2015 and the committee has been working extremely hard ever since to ensure a very smooth transition.

Pathology Relocation and Renovation Project Timeline

NCRC Design, Construction and Activation



UH/UHS Design, Construction and Activation



Division of Pathology Education
Barbara J. McKenna, M.D.
Godfrey D. Stobbe Professor in Pathology Education
Director, Division of Education Programs
Associate Director, Residency Training Program

Overview

As with the University and the Medical School, education is a core mission of the Department of Pathology. For decades, the department has been a key provider of learning for medical students, graduate students, dental students, residents and fellows. Our faculty have been among those most revered and remembered by graduates of the medical school, and have garnered formal recognition in the form of teaching awards over the years. In addition, many pathology faculty members play key roles in education in other clinical departments throughout the Medical Center and in University departments outside of Medicine. Similarly, our trainees are part of the educational process for their more junior counterparts and for others in the health system. The ways in which we fulfill this core mission are constantly evolving and adapting to new circumstances and demands.

Graduate Medical Education--Pathology Residency Program

The Department offers both individual and combined residency programs in Anatomic and Clinical Pathology to its 28 residents, continuing a longstanding tradition of excellence in pathology training. The 2016-17 academic year was marked by significant achievements, as outlined below.

The leadership and administrative team consists of:

- Program Director **Allecia Wilson M.D.**
- Associate Program Director **Barbara J. McKenna, M.D.**
- Fellowship Coordinator **Marie Goldner**
- Residency Program Coordinator **Pamela Howard**
- Medical Student Program Coordinator and Conference Coordinator **Desire' Baessler**

The Residency Program GME Committee included Allecia Wilson, M.D., Barbara J. McKenna, M.D. Michael Bachman, M.D., Ph.D., Jonathan McHugh, M.D., Daniel Boyer, M.D., David Lucas, M.D., Sean Li, M.D. PhD., and the Chief and Assistant Chief Residents Cody Carter, M.D., Sarah Rooney, M.D., and Libby Simon, M.D.

Additional administrative support provided by **Mary Currie**, Administrative Assistant Senior.

Recruitment:

We continue to recruit high caliber residents from a wide geographic region. Choosing from among the over **430 applicants** to the residency program is an exciting challenge, and we were extremely successful. Six residents matched in AP/CP. All incoming first year residents for 2017 were highly ranked by UM in the National Residency Matching Program (NRMP) match. The group includes graduates of medical schools in Michigan, Maryland and Vermont.

- Cisley Hines Wayne State University School of Medicine
- Krista Chain University of Maryland School of Medicine
- Laura Griesinger University of Vermont College of Medicine
- Anna Owczarczyk University of Michigan Medical School
- Ashley Smith Michigan State University College of Osteopathic Medicine
- Alexander Taylor Vanderbilt University School of Medicine

Graduates:

Six residents completed training in 2017. All are proceeding to fellowships, 5 of them remained at Michigan (Dermatopathology, Gynecology Pathology, Surgical Pathology, Forensic Pathology and Transfusion Medicine) and 1 went to Indiana University (Genitourinary Pathology) for fellowship.

- All graduating residents have earned certificates in **Lab Management University**.
- All graduating residents have participated in at least one cycle of the **QI curriculum**.
- All graduating residents have participated in a **CAP inspection** or mock inspection.
- 2 graduating residents completed the **Healthcare Administration Scholars Program**. A 2-year certificate level program covering various topics in Health Care administration, culminating in a senior administrative project.
- **100%** of the graduating class passed the American Board of Pathology certification examination on the first attempt. Our current 5-year certification rate is 96% for first time takers.

Achievements:

Our residents were very active academically, with a total of 25 publications during 2016-17 academic year, 22 abstracts/meeting presentations and over 50 intramural presentations! (*See attachment*)

Select award include:

- International Society of Urological Pathology Stipend Award
- Best Poster, American Society for Clinical Pathology
- Resident Representative Leadership Award, American Society for Clinical Pathology
- Medical Student Academic Excellence and Achievement Gold Award
- Robert C. Hendrix Travel Award, Michigan Association of Medical Examiners

Engagement:

Our residents are active members of the medical and pathology communities, with many engaged in local, regional, and national organizational service.

Departmental and institutional committees include:

- Advisory Council for Patient and Family Centered Pathology Care
- Program Evaluation Committee
- ACGME Self Study Committee
- Histology Committee
- Clinical Pathology Director Search Committee
- Pathology Social Media Team Member
- Pathology Diversity, Equity and Inclusion Committee
- Phlebotomy Working Group
- Pathology Relocation and Renovation Project Resident Representative
- House Officer Quality and Safety Council
- Laboratory Formulary Committee
- Blood Transfusion Committee
- Cytopathology Director Faculty Search Committee

Resident membership and engagement in professional societies include:

- James French Society of Pathologists
- Michigan State Medical Society
- Michigan Association of Medical Examiner's (MAME)
- Michigan Society of Pathologists (MSP)
- Washtenaw County Medical Society
- College of American Pathologists (CAP) with members in the Residents Forum
- United States and Canadian Academy of Pathologists (USCAP) with members on the **Resident Advisory Subcommittee** and **Ambassadors**
- American Society for Clinical Pathology (ASCP) with members as **Resident Representatives, Resident Council and Chair of the Resident Council**
- American Association of Blood Banks
- American Medical Association (AMA) with **Resident & Fellow Section Delegates**
- American Society of Dermatopathology
- International Society of Urological Pathology
- International Society of Gynecological Pathologists
- International Society of Bone and Soft Tissue Pathology
- Hans Popper Hematopathology Society (HPS)
- Rodger C. Haggitt Gastrointestinal Pathology Society (GIPS)
- American Association for Clinical Chemistry
- Association for Molecular Pathology
- American Society for Clinical Oncology(ASCO)

Curriculum

Our residency curriculum consists of daily didactic, gross or slide presentations 13 AP and 7 CP core subspecialty rotations, Quality Improvement course, Path 862 Translational Pathology course (combined with PhD students) and ASCP Lab Management University with certification.

A vibrant and varied morning **Pathology Educational Series** takes place most mornings at 8 am, from September through mid-June. In 2016-17 there were **189** conferences, each offering CME credit! Fifteen were presented by visiting faculty from other institutions, 37 by residents, 11 by fellows, 12 by staff and the remaining 104 were presented by departmental faculty members. In addition, 10 Gross Conferences were conducted by surgical pathology faculty and fellows. The morning conference series may be the one venue that most often draws together residents, fellows, AP faculty and CP faculty.

Our first and second year residents were involved in Quality Improvement and Patient Safety projects. In collaboration with Dr. Scott Owens, Brian Tolle, and Jeffrey Lott from the Department of Pathology Division of Quality and Health Improvement, we ran for the second year our Quality Improvement curriculum. Residents worked through web-based learning modules, attended lectures and discussions, and worked in teams on quality projects that included:

- Documentation in histology and grossing rooms
- Assignment of billing codes during accessioning
- Tracking of cases outside of the slide library

The resident's projects have been presented at AP QA meetings and accepted for presentation at the UMHS Quality Month event in October, 2017.

Ranking:

In 2017, the Pathology Residency Program at the University of Michigan was ranked #1 in the United States among large public hospitals, and #6 overall by Doximity, an online social networking service for U.S. physicians with over 400,000 verified physician members. In addition, a recent survey of graduates of our residency over the past 5 years indicates that 100% of respondents rate the training they received as "excellent."

Doximity list of top Pathology Residencies in Large Public Hospitals, as of 8/14/2017

1. University of Michigan Hospitals and Health Centers
2. University of California (San Francisco)
3. University of Washington
4. University of Iowa Hospitals and Clinics
5. Emory University School of Medicine
6. University of Texas Southwestern Medical School
7. University of Alabama Medical Center
8. UCLA David Geffen School of Medicine/UCLA Medical Center

Doximity List of Top Eight Pathology Residency Programs of all categories, as of 8/14/2017

1. Johns Hopkins University
2. Massachusetts General Hospital
3. Brigham and Women's Hospital
4. Stanford Health Care-Sponsored Stanford University
5. Washington University/B-JH/SLCH Consortium
6. University of Michigan Hospitals and Health Centers
7. University of California (San Francisco)
8. Mayo Clinic College of Medicine and Science (Rochester)

Graduate Medical Education--Fellowship Programs

The fellowship training opportunities at Michigan are substantial and varied. There are now 9 ACGME-approved fellowships, offering 16 approved positions, and 10 additional clinical fellowship programs offering 12 positions. Interest in these fellowships has grown steadily, with increasing numbers of applications each year. Each of the ACGME-accredited fellowships, together with the core residency program, are diligently conducting a 6-month long intense Self-Study activity, as directed by the ACGME, in preparation for a departmental site visit of all accredited programs to follow in 18-24 months. This is part of the ACGME Next Accreditation System, and is an opportunity to examine our past accomplishments and future goals, sharing information between programs.

A Fellow Selection Committee continues to monitor and standardize the fellow candidate application, interview, and offer timeline in a way that insures that the best possible candidates are chosen for our fellowships.

A number of fellows have contributed to the total of publications and abstracts cited above.

Fellows completing training in 2015 moved on to jobs in academic institutions (7), jobs in private practice (9), or additional fellowships (6).

Medical Student Teaching

M1 and M2 Teaching

The Department has a long history of playing an integral role in pre-clinical medical student education. We have had a unique presence in the M1 year, starting with the first sequence, titled Patients and Populations, introducing pathology concepts and terminology. This is reinforced by additional lectures and laboratory sessions in the winter and spring of the M1 year. The M2 systems-based curriculum includes specialty-specific pathology faculty in the planning of each sequence, with Dr. Paul Killen providing oversight throughout the year. Lectures and laboratories are conducted by many pathology faculty members, often in sequences related to there are of interest, although not exclusively. Altogether, there are 20 faculty members involved in conducting lectures and laboratory sessions each year for M1 and M2 students.

Under the direction of Dr. Madelyn Lew, Director of Medical Student Education for the Department of Pathology, faculty have been working with fused sequence directors in the Science Trunk of the new curriculum to fully integrate pathology content into the sequences and develop new ways of delivering educational material during the first year of medical school. The new curriculum also provides opportunities for students to gain more exposure to the daily routine of pathologists in their second year. Faculty are involved in the development of patient-based cases in Clinical Phase I and designing opportunities for Clinical Pathology Faculty to lead small group discussions in this Phase. In this regard, pathology faculty are working in conjunction with faculty from Surgery, Anesthesiology, Anatomy, and Radiology Departments to develop a new month-long Clerkship X rotation, which will be embedded into the Surgery Rotation. Co-directors of the Diagnostics & Therapeutics Branch (Kate Klein of Radiology, Michelle Kim of Rad-Onc, Madelyn Lew of Pathology) are also developing several new electives for third and fourth year medical students in which pathology will be integrated.

M4 Pathology Elective Rotation

The M4 Pathology Elective experience is now under the direction of Dr. Andrew Sciallis. The elective has undergone improvements to tailor to the career goals of rotating students. Through the efforts of faculty and staff, especially Desire' Baessler, medical students now have a structured framework in which they are assigned to specific services that will build on the knowledge base to help them succeed in their chosen career path. This has had very positive feedback and has resulted in a broader understanding of how pathology integrates into the daily clinical practice of all specialties. While students are provided a more structured schedule, there is still flexibility for them to explore additional areas of pathology. Throughout the rotation, students select cases for presentation at weekly sessions with mentors and also for case write-ups to be handed in at the end of the elective. To complete the elective, they write an in-depth paper about a specific topic with relation to Pathology. In the past academic year, 55 senior medical students rotated in Pathology, as well as a several students from other institutions. While a few are choosing pathology as a career, most are taking away with them a broader understanding of laboratory medicine and the role of pathologists in clinical medicine.

Molecular and Cellular Pathology (MCP) Graduate Program

The Molecular and Cellular Pathology (MCP) Graduate Program, under the direction of Dr. Zaneta Nikolovska-Coleska, has 26 students who are presently in Pathology Department laboratories performing their Ph.D. thesis research.

Statistics of our current students

Candidacy exam:

This year, six students (6 PhD) wrote, defended and successfully completed their preliminary exams that allowed them to pass to candidacy during their 2nd year and focus on their research thesis work.

PIBS students graduated in 2016/2017:

Amy Han (Keller)
Edward Grimley (Dressler)
Rebekah Martin (Bachman)
Yuqing Sun (Dou/Hess)

Productivity of MCP students

Individual extramural and intramural fellowship (7)

Sierrah Grigsby (NSF fellowship for 3rd year)
Talha Anwar (F30 for 3rd year)
Shayna Bradford (NIH Research Supplement to Promote Diversity in Health-Related Research)
Abhijit Parolia (DOD Pre-Doctoral Early Investigator Research Award)

Yajia Zhang (DOD Pre-Doctoral Early Investigator Research Award)
Hung-An “Anna” Ting (Rackham Pre-Doctoral Fellowship)
Samantha Saylor (Lauren Marantette Graduate Fellowship in Pancreatic Cancer)

Travel awards (24)

Talha Anwar, Allison Johnson, Justin Serio, Hanjia Guo, Ulas Ozkurede, Shayna Bradford, Mary Morgan, Yajia Zhang, Andi Cani, Kelly VanDenBerg, Abhijit Parolia, Sierrah Grigsby, Carl Engelke, Jacqueline Mann and Paloma Garcia (Rackham (15) and MCP travel awards (9))

Training grants (5):

Jacqueline Mann (PICTP Training Grant for 2nd year)
James Ropa (PICTP Training Grant for 2nd year)
Sabra Djomehri (PICTP Training Grant)
Andi Cani (Training Program in Translational Research)
Hanjia Guo (Training Program in Translational Research)

Other Awards (3):

Emmalee Adelman (Outstanding Abstract Achievement Award, America Society of Hematology)
Rebekah Martin (2017 Omicron Sigma, American Society for Clinical Laboratory Science-Michigan)
Rebekah Martin (2017 Pamela Agren Inspiration Award, American Society for Clinical Laboratory Science-Michigan)

Published papers by our students as first authors: 6

First author (6): Martin, Han, Grimley, Cani, Ting and Lazo de la Vega

Papers published by our students as co-authors: 13

Co-authors (13): Parolia x2, Adelman, Han, Grimley, Cani x5, Garcia and Lazo de la Vega x2

Recruitment activities

New class 2017/2018

In April we finished the recruiting for the fall 2017 class for the Program in Biological Sciences (PIBS) and successfully recruited 6 high quality students. One of the six students deferred his admission to fall 2018.

Students' activities

Academic activities, including mentoring of younger students and undergraduates.

Organizing the annual Department Research Symposium

This year is scheduled for November 10th, 2017 when we will celebrate our 16th anniversary.

Last year the Outstanding Research Award was given to Talha Anwar; Best oral presentation went to Sierrah Grigsby and best poster awards went to Emmalee Adelman and Rebekah Martin.

Social events supported by MCP Program 2016/2017

September 15, 2016 Annual MCP student/faculty picnic – Island Lake Park. This year we hosted a joint picnic with the Immunology program.

December 13, 2016 Happy hour student/faculty mixer – HopCat

May 11, 2017 Happy hour student/faculty mixer – Dominick's

June 24-25, 2017 Student camping trip – Lakeside Resort and Campground, Ionia, MI

August 2017 MCP Ice Cream Social – Med Sci I

Translational Pathology training grant

The Training Program in Translational Research directed by Drs. Lieberman and Nikolovska-Coleska was funded starting July 1, 2016. This T32 grant is supported by the NIH, National Institute of General Medical Sciences. The NIH awarded us 4 pre-doctoral trainee slots for year 1 of the 5-year cycle. The first 4 trainees were:

Trainee	Academic Program	Mentor
Andi Cani	Molecular & Cellular Pathology	Dr. Scott Tomlins
Hanjia Guo	Molecular & Cellular Pathology	Dr. David Lombard
Lucas Huffman	Neuroscience	Dr. Roman Giger
Shawn Whitefield	Microbiology & Immunology	Dr. Evan Snitkin

For year 2 we will again have 4 pre-doctoral trainee slots. The steering committee will meet on June 29, 2017 to select the year 2 trainees.

The TPTR T32 now has a webpage specifically devoted to the project (<https://www.pathology.med.umich.edu/t-32>).

Mentoring

In an effort to address the feedback we received from Rackham during the Program Review last year, we notified all second year students and their mentors of training opportunities to improve the mentor/mentee relationship. They were encouraged to attend a mentoring workshop that was held on the medical school campus on September 28, 2016 before working on a mentoring plan. For the 2016-17 academic year we strongly encouraged this activity. For the 2017-2018 academic year we are requiring a mentoring plan for each new student to our program that is due by the beginning of the fall term (August 31, 2017).

Pathology Research Seminar Series

Dr. David Lombard will be the new director of the Pathology Research Seminar Series starting in the fall of 2017. The feedback from the students is that they want more feedback on their presentations. Dr. Lombard will be in charge of instituting these changes.

Division of Experimental Pathology
Asma Nusrat, M.D.
Aldred S. Warthin Professor of Pathology
Director, Experimental Pathology

The past academic cycle was another highly productive and successful year for Experimental Pathology (EP) faculty. EP faculty continue to be at the forefront of cutting edge research that integrates new discoveries with the practice of medicine. Faculty scientific projects address many aspects of biology, disease pathogenesis and therapeutics. Success of EP research faculty is evidenced by very strong extramural funding as well as by high impact peer reviewed publications. EP division funding of \$28 million dollars was received largely from federal sources with additional funding from non-profit organizations and industry. Experimental pathology funding ranked #7 nationally. Research productivity is further evidenced by a high \$125/sq. ft. indirect cost that is allocated to pathology faculty who reside in greater than 64,000 sq. ft. which is above the University of Michigan Medical School benchmark of \$110/sq. ft. These accomplishments are a clear testament of EP faculty outstanding research accomplishments in spite of a very challenging national funding climate.

New EP faculty grant funding in 2016-2017 included thirteen NIH RO1, U24 and U01 awards, a T32 training grant, several career development awards, private funding, and three Department of Defense grants. New/competing renewal grants received in the past year are listed in the Table below.

NIH		Department of Defense	
Type of Grant	Faculty Name		Faculty Name
R01	Michael Bachman		Arul Chinnaiyan
R01	Tomasz Cierpicki		Asma Nusrat
R01	Yali Dou		Charles Parkos
R01	Jolanta Grembecka		
R01	Jolanta Grembecka		
R01	Jolanta Grembecka/ Arul Chinnaiyan		
R01	Celina Kleer		
R01	Andrew Lieberman		
R01	Andrew Lieberman		
R01	Nicholas Lukacs/ David Lombard		
R01	Asma Nusrat		
R01	Thomas Wilson		
R01	Thomas Wilson		
R21	David Lombard		
R21	James Varani		
Subcontracts to Mayo	Richard Miller		
Subcontracts to State University of New York	Zaneta Nikolovska-Coleska		
T32	Andrew Lieberman/ Zaneta Nikolovska-Coleska		
U01	Arul Chinnaiyan		
U24	Alexey Nesvizhskii		
		Industry & Nonprofits	
		Sponsor	Faculty Name
		CDC	Michael Bachman
		Michigan Public Health Institute	Michael Bachman
		American Association for Cancer Research	Arul Chinnaiyan
		Prostate Cancer Foundation	Arul Chinnaiyan
		Leukemia and Lymphoma Society	Tomasz Cierpicki
		Genentech, Inc.	Greg Dressler
		Harrington Discovery Institute	David Lombard
		St. Baldrick's Foundation	David Lombard
		Ono Pharmaceutical Company	Gabriel Nunez
		American Heart Association of Michigan	Scott Tomlins
		Duke University	Scott Tomlins
		Doris Duke Charitable Foundation	Sriram Venneti
		Sidney Kimmel Foundation	Sriram Venneti
		Career Development	
		Sponsor	Faculty Name
		Crohn's and Colitis Foundation	Veronica Azcutia-Criado
		Crohn's and Colitis Foundation	Naohiro Inohara
		American Lung Association	Catherine Ptaschinski

In the past fiscal year, Experimental Pathology faculty published 278 manuscripts, including papers in high-impact journals such as *Cell*, *Nature*, *Science*, *Nature Communications*, *Journal of Immunology*, *Oncology*, *Biotechnology*, *Mucosal Immunology*, and the *New England Journal of Medicine* among many others as can be seen in the adjoining figure.

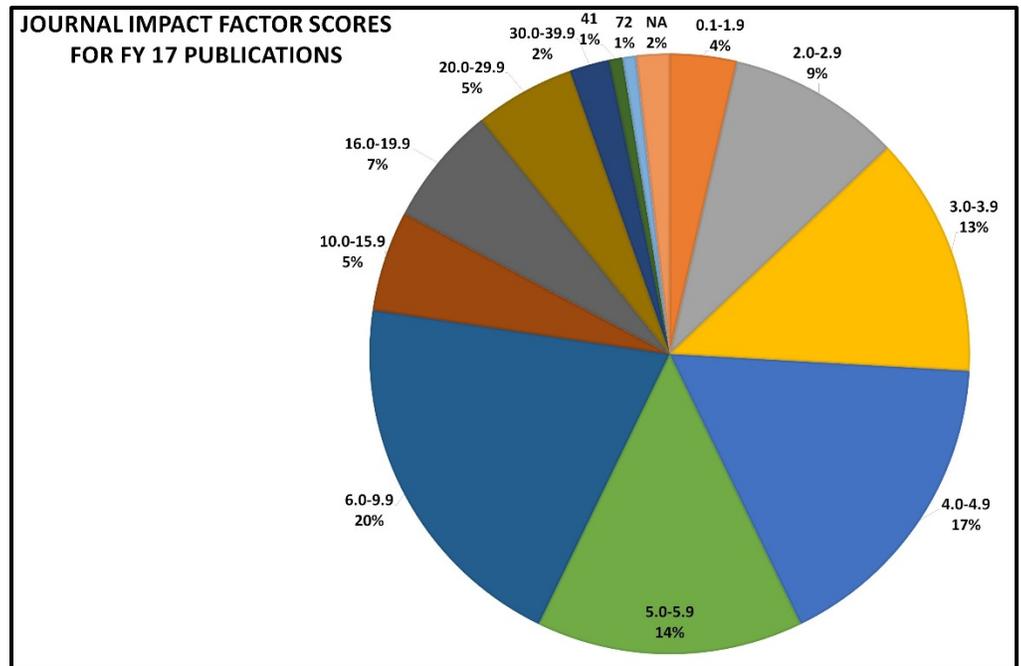
The figure shows the average Journal Impact Factor scores for the past fiscal year using PubMed and EndNote to acquire the data.

EP faculty members have also received a remarkable number of patents and prestigious awards. Eighteen patents have been issued to Pathology Department faculty. Jolanta Grembecka and Tomasz Cierpicki received six patents for small molecules to treat Leukemia. Two patents were issued for the composition of Thienopyrimidine and Thienopyridine compounds.

Nicholas Lukacs received three patents related to his work in nanoemulsion vaccines, and Sem Phan, Nicholas Lukacs, and Steven Kunkel were a part of a stem cell factor inhibitor patent. Zaneta Nikolovska-Coleska received two patents for the use of small molecule MCL-1 inhibitors. Arul Chinnaiyan and Nallasivam Palanisamy were recipients of two patents for RAF gene fusions and RNA chimeras in human Leukemia and Lymphoma. Arul Chinnaiyan and Scott Tomlins were recipients of a patent for recurrent gene fusions in prostate cancer. Tomasz Cierpicki with Jolanta Grembecka have also enhanced their industry participation by licensing menin inhibitors to Kura Oncology with the intent to enter Phase 1 clinical studies for leukemia. Alexey Nesvizhskii received a prestigious award from the National Cancer Institute to establish a Proteogenomic Data Analysis Center which will comprehensively characterize cancer tumor samples with the objective of integrating and analyzing proteogenomic data for development of targeted cancer therapies. Sriram Venneti received the Doris Duke Charitable Foundation's 19th Clinical Scientist Development Award which is designed to provide young faculty protected time to conduct research projects.

Many successful EP Division Faculty are physician scientists that have not only contributed to advancing the research mission of the department but are also actively involved in the Divisions of Anatomic and Clinical Pathology. The Michigan Center for Translational Pathology (MCTP) directed by Arul Chinnaiyan and Molecular Diagnostics Division in Pathology have continued to develop and introduce tests for diagnosis of tumors. Dr. Chinnaiyan and the MCTP recently described the genomic and transcriptomic landscape of metastatic cancer profiled through MiOncoseq. A manuscript describing the first 500 patients was published in *Nature*. In addition to the ongoing clinical trials at U of M, the test will be licensed to Tempus for use nationally. Scott Tomlins has used next generation sequencing to describe the genomic landscape of olfactory neuroblastomas, tubulocystic renal cell carcinoma with poorly differentiated foci, vitreoretinal lymphomas and CIC-DUX4 sarcomas. This group has also described the utility of NGS for assessing clonality in synchronous/metachronous Merkel cell carcinomas and the ability to track prostate cancer progression on serial biopsy.

Nick Lukacs continues to serve as the Scientific Director of the Mary H. Weiser Food Allergy Center (MHWFAC). Gary Huffnagle was recruited as the first Nina and Jerry Luptak Endowed Research Professor in the Food Allergy Center and Dr. Chang Kim will be joining the MHWFAC as an endowed professor in November 2017.



Dr. Kunkel has maintained a leadership role in the University of Michigan Medical School's Office of Research that has developed and continues to implement robust strategic research plans. The Office of Research 2017 initiatives have included management of a central bioprepository, research data warehouse/data direct, biomedical research core facilities, fast forward medical innovation and the launching of seven clinical trial support units.

In closing, this has been yet another highly successful year for the EP faculty.

Division of Pathology Informatics
Ulysses Balis, M.D.
Director, Division of Informatics

Overview

The Division of Pathology Informatics, situated as one of the functional units of the overall Pathology Department, serves the tripartite missions of the department, including: clinical operations support, original research, and education. As an informatics division, it is somewhat unique among contemporary academic pathology departments, in that it maintains both its own technical staffing and associated IT infrastructure, with both elements being wholly-contained within the department and similarly, under the exclusive direction of Pathology leadership. This autonomy affords the division both the ability to carry out internal prioritization of the department's many projects, as well as the ability to independently carry out original IT development efforts. In addition, the division hosts its own active thrusts in fundamental areas of information technology, machine vision and deep learning research, including: computational imaging of WSI subject matter, asset tracking solutions, computational pathology, natural language processing, and medical information interoperability.

Fundamentally, Pathology Informatics operates as a *service unit* of the department, covering a wide range of operational and strategic functions, with these various missions tied together by a centrally-governed team of superbly-trained information technology specialists.

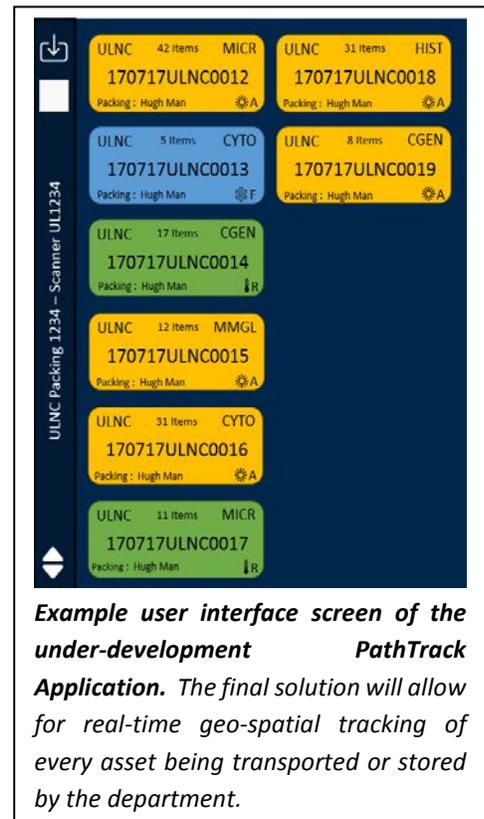
Building upon the substantive developments of the prior 2015-2016 academic year, with this past year, the Division has been able to further expand its scope of optimization activities, both within and external to our central Laboratory Information System, with internal teams now transitioning to major initiatives that emphasize workflow optimization and error-proofing of critical information hand-off data processing stages of the department's overall order-to-results computational pipeline.

This past year also witnessed brisk and accelerated activity in support of the department's upcoming move to its new home in the North Campus Research Complex (NCRC), with signature initiatives such as PathTrack – a sophisticated tool suite to track every asset being moved between all departmental locations. At present, this application is well ahead of schedule in its development and will be unquestionably ready for deployment in April of 2018.

With respect to the core laboratory information system in use by the department, SCC-SoftLab, the Informatics Division made significant inroads in working with our vendor to establish a timeline and process development pathway by which the present six major academic sites that are using slightly differing versions of SoftLab will be able to transition into use of a common version, thereby greatly simplifying software maintenance and enhancement activities for all sites. Coincident with this two-year project will be the division's transitioning from its current use of legacy P7-based servers to the contemporary P8 generation of IBM AIX servers. This transition will also witness an expanded number of testing environments and substantially improved user response time.

Continued Evolution of the Division's Hardware Stewardship Model

While the Division continues to maintain oversight of two geographically distinct data centers, the 2016-17 year witnessed a significant sea change in the overall hardware stewardship approach that will be strategically deployed in the years ahead. Whereas until the present time, the prevailing conventional wisdom in Pathology Informatics always held that at least one instance of an N+1 architecture should be collocated immediately adjacent to the core clinical laboratory, recent innovations in both server virtualization and fault-tolerant systems have made it possible to remotely situate such systems, without the expectation of untoward events



Example user interface screen of the under-development PathTrack Application. The final solution will allow for real-time geo-spatial tracking of every asset being transported or stored by the department.

befalling the lab. Moreover, such an approach affords the lab the direct benefits that come from operating at greater scale (both in terms of the hardware layer itself and in the scale made possible by larger teams of permanently assigned support staff tending to such hardware).

In concrete terms, this equates to the Division working towards the goal of standing down the current 33-year-old University Hospital data center, and transitioning all hardware at that location to the new tier-IV class North Campus Data Center (NCDC), with HITS' Arbor Lakes facility serving as the secondary support center.

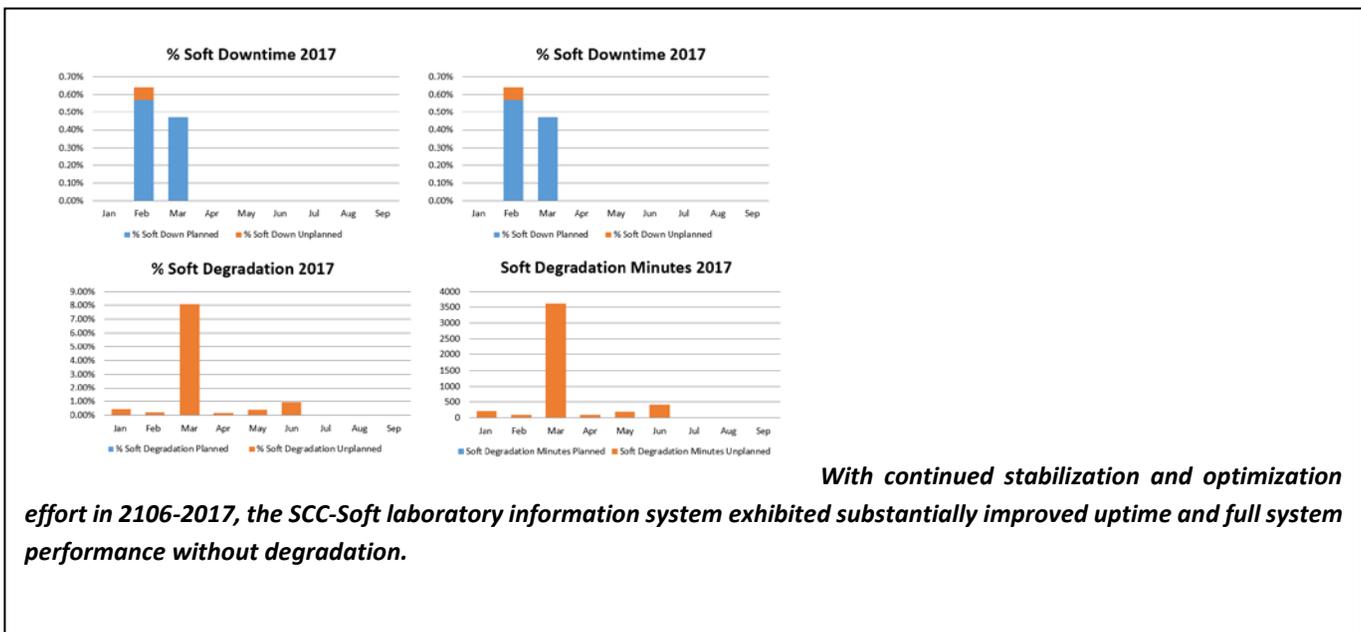
This transition is a significant development in the history of the division, yet its arrival marks the beginning of what should be considered a new era in terms of realizing extremely high service availability metrics matched with full continuity of all on-call personnel. While Pathology will continue to maintain primary oversight authority for the hardware and associated software in both of these new physical facilities, the addition of Health Information Technology and Services (HITS) staff greatly augments the level of service we will be able to provide to our customers. This benefit only increases with the anticipated expansion of scope and scale of the department's IT offerings, so this development couldn't have happened at a better time.

In terms of the governance model associated with the division transitioning to an HITS-managed physical location, a service level agreement and access policy is being drafted presently, with this effort taking place in tandem with the enterprise's chief information officer. It is expected that this transition process will be complete by Q2-2019, approximately one year past the date that the department is expected to assume its new primary location address within the North Campus Research Complex.

Major SCC Enhancements

In a manner similar as seen in prior years, the Informatics Division expended significant efforts on the continued stabilization and optimization of the SCC-Soft laboratory information system (see inset). These enhancements included both the elimination of yet more functional defects/deficits, as well as the addition of long-awaited workflow and/or user interface enhancements. The anatomic pathology module, in particular, witnessed a number of high-importance updates and defect corrections, allowing for greater overall stability. With the anticipated return of the department to what SCC is terming the "new "main-branch" software version in 2019, all remaining operational deficits in AP should be largely resolved.

In terms of specific SCC projects, similarly, the prior academic year witnessed brisk activity for installation of enhancements, with the following list representing the most significant of the many projects that were initiated and completed:



With continued stabilization and optimization effort in 2106-2017, the SCC-Soft laboratory information system exhibited substantially improved uptime and full system performance without degradation.

- Upgraded to Gene Versions 3.6.2.23 & 24
- Significant planning for the anticipated Global SCC Upgrade in 2019
- BPAM (Blood Product Interface) activation
- Call list workflow improvements for MLabs and histology
- SCC Failover testing on P7 hardware
- Secondary SCC P7-based servers moved to the NCASB complex

Major Clinical Laboratory Instrument and Interface Projects

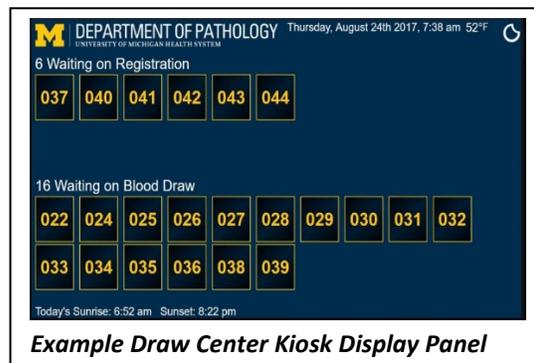
Recognizing the never-ending turnover and expansion of contemporary clinical laboratory instrumentation, the Informatics Division continued in its mission of configuring and attaching instruments to the laboratory network and to the LIS application. The 2016 – 2017 year was as active as the preceding year, in terms of these types of activities, as multiple laboratory sections replaced and/or otherwise expanded their repertoire of instruments requiring bidirectional interfaces (many of which being increasingly sophisticated in their configuration requirements). Similarly, recognizing that the department maintains an active reference lab outreach program, implementation or expansion of system-to-system interfaces similarly surfaced as a significant source of projects for the division. The most important of these activities are enumerated below:

- MiOncoSeq Lab workflow integration
- Radiant / Radiology Breast Imaging report integration with histopathologic stage and grade
- IIB Major Upgrade (IIB is the primary integration engine serving the division)
- WASP instrument interface in Micro
- Continued testing and maintenance of all extant interfaces, per CAP requirements

Major Intra-department IT Projects and Enhancements

The division was very successful this past year in completing a large number of multi-year initiatives that were targeted in support of internal business needs of the department at large. Some of the more important projects are included below, with a brief description:

- QGenda implementation: This third party tool allows for expedited generation and maintenance of on-call and service schedules for professional staff. Prior to its integration, such schedules were manually assembled, with this effort requiring great care and much time. With the new solution, a more thoroughly optimized schedule can be generated in a fraction of the time as required by the previous method. The implementation also included provisioning for automatic population of the department’s internal scheduling calendars from the output of the QGenda scheduling engine.
- Quanta Blood Draw Center Waiting Room Solution: this intermural solution, which is now deployed at a number of the department’s busier blood draw centers, allows patients to anonymously register at automated kiosks, and in so doing, obtaining a call number on a printed label. An associated electronic tote board (see inset figure) displays two sets of numbers: the next number ready for registration and the next number ready for blood draws. Feedback thus far from patients who have made use of the solution has been extremely positive and plans are being developed to further leverage this solution at all departmental blood draw centers.

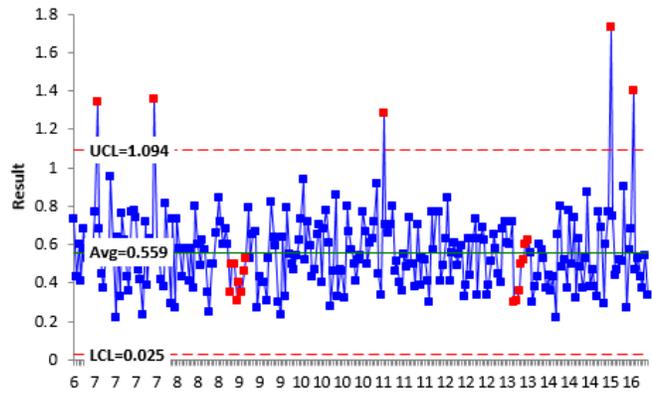


LOCATION	Counts	# >2 minutes	# >5 minutes	# >10 minutes
XCCB	251	0	0	0
CHBD	140	0	0	0
XRHB	131	0	0	0
XBBB	127	0	0	0
XEAB	123	2	0	0
XTB3	119	0	0	0
XMBD	100	0	0	0
XTB1	96	0	0	0
XBB3	83	0	0	0
XBB0	68	0	0	0
XCVB	61	0	0	0
XYBD	56	0	0	0
XCHB	46	0	0	0
XDBH	37	0	0	0
XDBC	34	0	0	0
XTB2	32	0	0	0
XWHB	24	0	0	0
XSHB	23	0	0	0
XLHB	22	0	0	0
XBB2	17	0	0	0
DFP	12	0	0	0
XDBA	8	0	0	0
Total	1610			

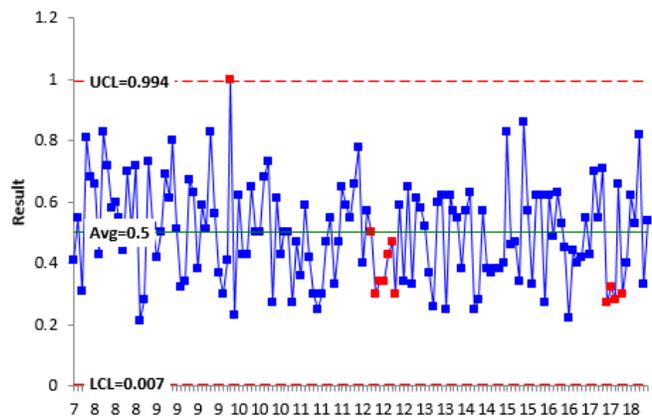
Blood Draw Station	Average	Standard Deviation
Canton	0.50	0.16
Brighton	0.54	0.19
Cancer Center	0.56	0.20
East Ann Arbor	0.57	0.28
Childrens and Womens	0.55	0.17
Taubman 3rd Floor	0.56	0.22

Statistics for 2/17/2016

Cancer Center (XCCB)



Canton (CHBD)



Improvement in waiting time metrics resulting from deployment of the Quanta solution, with the UM Cancer Center and Canton Health clinics being suitable examples where waiting times decreased substantially.

-
- U-M Connected Wireless Network Connectivity at the Wayne County Medical Examiner's Building: The lack of direct UMHS network connectivity was a longstanding source of frustration for faculty and staff at this location, who periodically needed access to UM-Pathology and UMHS resources. Following a lengthy and involved network engineering exercise, the division identified a technical solution by which the UMHS network could be extended to that locale, without compromise of the requisite levels of security.
-
- Slide Library Application: Recognizing a longstanding set of asset racking vulnerabilities, the AP Operations Committee, through the process of generating an A3 assessment and subsequent root cause analysis, consigned the Informatics Division to build and deploy a comprehensive, web-based slide-tracking solution. Upon its development, in less than four months, the solution was activated and the past eight months of experience with the use of this tool suggests that the prior tracking voids have been largely, if not completely alleviated.
-
- WinScribe Update: The department's digital voice dictation software solution was in need of being updated to the latest version, to address a number of operational limitations and defects. This activity was completed in the preceding academic year, with reports back from users being uniformly positive.
-

- Human Resources Tool Suite: A number of longstanding requests for functional enhancements and changes in process workflow were activated this past academic year, allowing the faculty appointment and promotion process to operate with fewer technical challenges.

Major Enterprise-associated IT Projects and Enhancements

The preceding year witnessed a very large number of enterprise-linked projects, with many of these having rigid and brisk timelines. Many of these upgrade activities were commenced in parallel, owing to enterprise development scheduling associated with the primary EHR solution (Epic MiChart), making the demands on our implementation teams even more significant. The major IT projects completed in the preceding academic year include the following:

- Assisted HITS with the implementation of two-factor authentication for all level two-rated data repositories
- Chairside phlebotomy collection roll out
- Emergency Department Bedside Specimen Label printer rollout
- 6D Bedside Specimen Label printer rollout
- MiChart Stage 4 upgrade validation

Staff Maintenance of Competency

With so many hardware and software solutions under the concurrent stewardship of the Informatics Division, there is an ongoing responsibility to ensure that the collective staff of the division maintain and extend their skills for all the applications that we cover. The preceding academic year witnessed significant efforts to augment the division's current matrix model for application stewardship where at any given moment, if at all possible, multiple individuals within the division are capable of fully supporting each and every application layer and solution. This goal continues to be a challenge for the division, given the large number of applications combined with the relatively modest staffing size. Nonetheless, the division's maintenance of competency efforts continued, with the following activities of 2016 – 2017 being representative of these ongoing efforts to expand skill sets:

- Soft Molecular training class on site
- Soft Micro training class on site
- Soft Report training class on site
- Epic Clarity Report training
- SNUG users group and participation in the weekly focus group call– 4.5 PIE (Partners in Excellence for SCC Version 4.5)
- Integrated Workstation (IWS) training, set up, and readiness for go live
- Integrated reports for hem/path – training in development and integration

Staffing Changes

The preceding witnessed a fair degree of turnover, which was addressed with expedited staffing replacements, whenever possible. A complete overview of the preceding year's staffing changes is included below:

- Elizabeth Walker transitioning from Imaging to a new-created communications position
- Creation of a Web Editorial Board, as a separate working group from the extant web operations team
- Addition of a new photography position, primarily in support of the UH autopsy service, filling it.
- Filling the vacant network architect position, with associated training
- Filling the vacant desktop support position, with associated training
- Filling the vacant web architect position, with associated training
- Hiring a web development consultant

Intramural Liaison Activities within the Department

As part of its routine mission, the Informatics Division engages with multiple laboratory sections and department divisions to complete both routine as well as targeted tasks and projects. In carrying out these activities, the Informatics Division interacts daily with essentially every unit of the department, solving both tactical challenges as well as providing strategic input on long-term initiatives. The standing activities and meetings with which the Informatics Division is integrally embedded are enumerated below:

- Participation with CAP interim inspection activities
- PRR project activities
- IT Forum – meeting secretariat
- LCC
- CP Ops
- AP Faculty meeting
- CP Faculty Meeting
- AP Ops
- DQHI daily huddles and reporting
- AP Histology meeting

Liaison Activities with the Greater Health Enterprise

Although the informatics division operates as an autonomous information technology unit, it makes every effort to operate in close coordination with the enterprise-at-large, leveraging enterprise best-practices and IT policies whenever possible. Similarly, the Informatics Division makes full use of enterprise change control policy and protocol and leverages major IT event notification protocols in the exact manner as carried out by HITS. Further underscoring this long-term commitment to partnership with the overall health enterprise IT elements are the extensive liaison and participation activities currently maintained by the division, which collectively insure tight coordination and seamless handoffs of significant IT events and projects. The current enterprise IT initiatives with which the Informatics Division currently interacts and/or participates are enumerated below:

- Epic 2016 version, October readiness
- Network Admission Control Deployment
- MCIT (HITS) committee memberships
 - ITO&M
 - UMHS Service Provider Committee
 - Application Portfolio Management Committee
 - NAC Architecture Committee
 - Data Center Inventory Workgroup
 - Monthly Planned Downtime Review Committee
 - MCIT/Pathology Storage Planning Workgroup
 - MiChart Facility Structure Workgroup
 - Enterprise Imaging Task Force
- Pathology Datacenter Inventory Project
- Continued client interface work with EHRs:
 - Practice Fusion
- Priority “urgent” implementation for priority discharges
- Security Risk Assessment preparations
- Security vulnerability follow up activities
- Security vulnerability management
- Epic Blood Products Administration Module (BPAM) interface readiness
- MiChart Stage 5 readiness

Activities at the National and International Level

The informatics division is visible at a national and international level, with it participating on a number of initiatives that have the potential to fundamentally alter and extend the practice of pathology informatics. For example, the division's interaction with the American joint committee on cancer (AJCC) has been instrumental in allowing the AJCC, in the form of its upcoming eighth edition, to espouse use of web services architectures and an electronic transaction model for dissemination of its staging documentation. Similarly, the division's participation for the past eight years with the test committee for clinical informatics has facilitated the creation of a standalone subspecialty boards in clinical informatics, and in so doing, conferring visibility to the Department of pathology for its seminal role in standing up this long-needed subspecialty credentialing process. Finally, as the lead co-secretariat of the long-running pathology informatics national meeting, the Pathology Informatics division plays an important role in the ongoing annual meeting preparation efforts including meeting site logistics and program content selection. Additional venues where the Pathology Informatics division is visible include the Association for pathology chairs meeting, the American Board of medical specialties, the National Cancer Institute and most recently, the health information Society of Australia combined with the Royal College of pathology of Australasia. Finally, the division presented original scholarly work in the fields of pathology informatics and imaging at no less than nine national and international scientific meetings.

Faculty Development

This past year witnessed the expansion of the division by two faculty members, with Dr. Jerome Cheng joining in April as an Assistant Professor (clinical) and Dr. David McClintock joining at the very end of the academic year as an Associate Professor (clinical). Collectively, their addition places the Informatics Division in the very top echelon of academic pathology informatics divisions, giving it significant capacity to embark on substantial investigative and operational projects. With their arrival, an immediate plan of action was set in place as to how the team should collaborate intramurally, to yield maximal productivity.

Michigan Center for Translational Pathology
Arul M. Chinnaiyan, M.D., Ph.D.
S. P. Hicks Professor of Pathology
Director, Michigan Center for Translational Pathology
Investigator, Howard Hughes Medical Institute

OVERVIEW

The Michigan Center for Translational Pathology (MCTP) was established in 2007 as a focused initiative to bring basic research discoveries in molecular medicine to clinical applications for the identification of biomarkers and therapeutic targets for cancer diagnosis and treatment. This endeavor is supported by the Department of Pathology, Michigan Medicine, the Medical School, and the University President's Office. Our impactful discoveries drive cancer research forward and advance the development of cancer diagnostics and targeted therapies. Further, we are exploring avenues for the development of precision cancer medicine based upon an individual's specific genetic abnormalities underlying his/her disease. The goals of MCTP are not only to improve clinical care for cancer patients, but also to complement the academic goals of Michigan Medicine.

MCTP's overarching mission is to: 1) to establish the University of Michigan as the international leader in discovery and characterization of disease biomarkers and therapeutic targets using an integrated multi-disciplinary, systems biology approach and; 2) establish a new paradigm of bringing personalized medicine to routine clinical care through the use of high throughput sequencing. In parallel with the UM Health System, MCTP also has four core components to the mission: research, education, patient care and service. Our specific goals are to:

- Discover new disease biomarkers and candidate therapeutic targets using genomic, proteomic, and bioinformatics approaches.
- Employ a systems biology perspective in characterizing the molecular alterations in human disease.
- Translate and commercialize molecular discoveries for clinical utility.
- Train the next generation of translational cancer researchers.
- Ensure the long term scientific and funding success of the MCTP.
- Translate next generation sequencing-based approaches (including associated bioinformatics) for clinical use in personalized medicine.
- Transform the practice of pathology and medicine.

Over the past year, the Center experienced continued success in the pursuit of cutting-edge research to advance the discovery of important biomarkers of cancer as well as novel therapeutic targets. Under strong, established partnerships with industries such as Ventana, GenProbe, GenomeDx and WaferGen, we are working to develop novel clinical testing platforms. Joint collaborations on research projects with industry partners include Armune Bioscience to develop autoantibody cancer diagnostics and Oncofusion Therapeutics to design and optimize a new class of highly potent and specific BET bromodomain inhibitors for treatment of castrate-resistance prostate cancer.

Our clinical sequencing study, Michigan Oncology Sequencing Center (MI-ONCOSEQ), continues to experience steady growth since its inception in 2011; nearly 2000 adult and pediatric (under PEDS-ONCOSEQ study) patients have undergone clinical sequence analysis thus far. Additionally, our sequencing facility supports a number of specialized programs and projects. We intake and sequence samples from the Multiple Myeloma Research Foundation (~350 samples thus far) and are under contract to sequence 500 total samples. Through partnership with MLabs, we have a non-exclusive license with Tempus Health, Inc to help develop the OncoSeq assay and we sequenced over 150 patient and validation samples towards this effort. We have a similar agreement with Progenics Pharmaceuticals focused on prostate cancer patients and we have recently begun to receive samples for this project. Internally, we support the Michigan Medical Genetics Laboratories (MMGL), a comprehensive CAP/CLIA certified clinical genetics testing laboratories housed in the

Department of Pediatrics, by providing them with sequencing data for select patients. Listed below is a summary of revenues generated by these programs.

Program	2017 revenue	2018 projected revenue
MMRF	\$898,639	\$675,000
Tempus	\$473,000	Samples not expected at regular intervals
Progenics	N/A	\$500,000
MMGL	\$14,596	\$150,000

Recently, we carried out a comprehensive molecular analysis of metastatic solid tumors of diverse lineage and biopsy site from 500 adult patients (MET500 cohort) enrolled in MI-ONCOSEQ by performing clinical-grade integrative whole exome (tumor/normal) and transcriptome sequencing. Sequencing matched tumor and normal samples from patients identified potentially pathogenic germline alterations and provided high resolution copy number landscapes. RNA sequencing analysis provided insights into the tumor lineage, functional gene fusions, transcriptional pathway activation, viral pathogen, and immune cell landscape. We found that the most prevalent genes somatically altered in metastatic cancer included TP53, CDKN2A, PTEN, PIK3CA, and RB1. Putative pathogenic germline variants were present in 12.2% of cases of which 75% were related to defects in DNA repair genes, most commonly occurring in BRCA1, BRCA2, CHEK2 and MUTYH. Tiering of the molecular alterations identified in metastatic cancers provided a rationale for clinical trial or registry study enrollment in 72% of cases and guideline based recommendations in 16% of cases. Our results demonstrate that integrative sequence analysis provides clinically relevant, multidimensional view of the complex molecular landscape and microenvironment of metastatic cancers. The manuscript presenting the analysis of the MET500 cohort has been published and was featured on the cover of in *Nature* (2017 Aug 2. doi: 10.1038/nature23306). This study also garnered much press interest and coverage including an interview with Dr. Chinnaiyan on Michigan Radio.

We are also continuing the work from the SU2C-PCF International Dream Team through the PCF Continuation grant. As a follow-up to the CRPC mutational landscape study, we are analyzing clinical outcomes data for >400 patients and we hope to complete a manuscript in the near future.

The translational successes outlined above are powered by the basic discoveries from the bench that continue to advance the field of cancer research. Our major research discoveries over the past year follows:

PCAT-14 as Potential Prognostic Biomarker in Prostate Cancer:

We performed Sample Set Enrichment Analysis (SSEA) and identified genes associated with low versus high Gleason score in the RNA-seq database. Comparing Gleason 6 versus 9+ PCa samples, we identified 99 differentially expressed genes with variable association to Gleason grade as well as robust expression in prostate cancer. The top-ranked novel lncRNA PCAT14, exhibited both cancer and lineage specificity. An RNA in-situ hybridization (ISH) assay for PCAT14 distinguished benign vs malignant cases, as well as high vs low Gleason disease. PCAT14 is transcriptionally regulated by AR, and endogenous PCAT14 overexpression suppresses cell invasion. Thus, using RNA-sequencing data we identified PCAT14, a novel prostate cancer and lineage-specific lncRNA. PCAT14 was highly expressed in low grade disease and loss of PCAT14 predicted disease aggressiveness and recurrence (Neoplasia. 2016 Aug;18(8):489-99).

The lncRNA Landscape of Breast Cancer:

Molecular classification of cancers into subtypes has resulted in an increased understanding of tumor biology and treatment response across multiple tumor types. However, most cancer profiling studies largely focus on protein-coding genes that comprise <1% of the genome. Here we leverage a compendium of 58,648 long noncoding RNAs (lncRNAs) to subtype 947 breast cancer samples. We showed that lncRNA-based profiling stratified breast tumors by their known molecular subtypes in breast cancer. We identified a cohort of breast cancer-associated and estrogen-regulated lncRNAs, and investigated the role of the top-ranking estrogen receptor (ER)-regulated lncRNA, DSCAM-AS1. We demonstrated that DSCAM-AS1 mediates tumor progression and tamoxifen resistance and identified hnRNPL as an interacting protein

involved in the mechanism of DSCAM-AS1 action. By elucidating the role of DSCAM-AS1 in breast cancer biology and treatment resistance, this study provides insight into the potential clinical implications of lncRNAs in breast cancer. *Nat Commun.* 2016 Sep 26;7:12791.

RNA-Seq-based Prognostic Signature of Lung Cancer:

Precision therapy for lung cancer will require comprehensive genomic testing to identify actionable targets as well as ascertain disease prognosis. RNA-seq is a robust platform that meets these requirements, but microarray-derived prognostic signatures are not optimal for RNA-seq data. In this study, we utilized RNA-seq data from a lung adenocarcinoma cohort to identify a robust prognostic gene signature that can be directly incorporated into an RNA-seq clinical test for prognostic prediction. Here, we have developed an independently validated four-gene prognostic signature that includes a lncRNA, as well as identification of numerous genes with strongly statistically significant prognostic association for further study. Importantly, this four-gene prognostic signature performed well in stage I patients and EGFR-mutant and wild-type cohorts. Thus, this four-gene prognostic signature could be a clinically useful tool easily incorporated into an RNA-seq clinical sequencing program to individualize lung adenocarcinoma therapy. *J Natl Cancer Inst.* 2016 Oct 5;109(1).

Dysregulation of the Hippo Pathway in RCC:

Mucinous tubular and spindle cell carcinoma (MTSCC) is a relatively rare subtype of renal cell carcinoma (RCC) with distinctive morphologic and cytogenetic features. Here, we carried out whole-exome and transcriptome sequencing of a multi-institutional cohort of MTSCC ($n = 22$). We demonstrated the presence of either biallelic loss of Hippo pathway tumor suppressor genes (TSG) and/or evidence of alteration of Hippo pathway genes in 85% of samples. PTPN14 (31%) and NF2 (22%) were the most commonly implicated Hippo pathway genes, whereas other genes such as SAV1 and HIPK2 were also involved in a mutually exclusive fashion. Mutations in the context of recurrent chromosomal losses amounted to biallelic alterations in these TSGs. As a readout of Hippo pathway inactivation, a majority of cases (90%) exhibited increased nuclear YAP1 protein expression. Taken together, nearly all cases of MTSCC exhibit some evidence of Hippo pathway dysregulation, suggesting a common mechanistic basis for this disease. *Cancer Discov*; 6(11); 1258-66. This article was highlighted in the "In This Issue" feature, p. 1197.

Formation of Gene Fusions in Prostate Cancer:

Approximately 50% of prostate cancers are associated with gene fusions of the androgen-regulated gene TMPRSS2 to the oncogenic erythroblast transformation-specific (ETS) transcription factor ERG. The three-dimensional proximity of TMPRSS2 and ERG genes, in combination with DNA breaks, facilitates the formation of TMPRSS2-ERG gene fusions. However, the origins of DNA breaks that underlie gene fusion formation in prostate cancers are far from clear. We demonstrate a role for inflammation-induced oxidative stress in the formation of DNA breaks leading to recurrent TMPRSS2-ERG gene fusions. The transcriptional status and epigenetic features of the target genes influence this effect. Importantly, inflammation-induced de novo genomic rearrangements are blocked by homologous recombination (HR) and promoted by non-homologous end-joining (NHEJ) pathways. In conjunction with the association of proliferative inflammatory atrophy (PIA) with human prostate cancer, our results support a working model in which recurrent genomic rearrangements induced by inflammatory stimuli lead to the development of prostate cancer. *Cell Rep.* 2016 Dec 6;17(10):2620-2631.

Novel Bioinformatic Tool for Transcriptome Assembly:

Accurate transcript structure and abundance inference from RNA sequencing (RNA-seq) data is foundational for molecular discovery. Here we present TACO, a computational method to reconstruct a consensus transcriptome from multiple RNA-seq data sets. TACO employs novel change-point detection to demarcate transcript start and end sites, leading to improved reconstruction accuracy compared with other tools in its class. The tool is available at <http://tacorna.github.io> and can be readily incorporated into RNA-seq analysis workflows. *Nat Methods.* 2017 Jan;14(1):68-70

Development of Peptidomimetic Inhibitors of ERG Fusions:

Transcription factors play a key role in the development of diverse cancers, and therapeutically targeting them has remained a challenge. In prostate cancer, the gene encoding the transcription factor ERG is recurrently rearranged and plays a critical role in prostate oncogenesis. Here, we identified a series of peptides that interact specifically with the DNA binding domain of ERG. ERG inhibitory peptides (EIPs) and derived peptidomimetics bound ERG with high affinity and specificity, leading to proteolytic degradation of the ERG protein. The EIPs attenuated ERG-mediated transcription, chromatin recruitment, protein-protein interactions, cell invasion and proliferation, and tumor growth. Thus, peptidomimetic targeting of transcription factor fusion products may provide a promising therapeutic strategy for prostate cancer as well as other malignancies. *Cancer Cell*. 2017 Apr 10;31(4):532-548.

Overall, we published 35 papers from July 1, 2016 – June 30, 2017, several in high-impact journals (*Nature; N Engl J Med, Sci. Transl Med, Cancer Cell*). Our publications are highly cited with an overall H-index of 105 for Dr. Chinnaiyan (Web of Science®). Our publications in high impact journals and media exposure were coupled with the recognition of MCTP scientists by their scientific peers. Dr. Arul Chinnaiyan recently received the Heath Memorial Award from MD Anderson Cancer Center and the University of Alabama Paulette Shirey Pritchett Endowed Lecture in Pathology Award.

Many of MCTP's researchers were also recognized for their achievements this past year:

- Yashar Niknafs received 1st place for graduate student oral presentation entitled, "From TACOs to Pandas: My Genomics Journey" at the Cellular and Molecular Biology Annual Fall Retreat. He was also invited to give an oral presentation in a mini-symposium session at the 2017 AACR Annual Meeting in Washington, D.C., and received the PIBS Excellence in Research Award for outstanding research performance. Most recently, he was awarded the Prostate Cancer Foundation Young Investigator Award.
- Steve Kregel was reappointed me for another year on the Cancer Biology T32 Training Grant and was awarded a DOD Postdoctoral Fellowship.
- Scott Tomlins was chosen as a winner of the 2016 Society for Basic Urologic Research (SBUR) Young Investigator Award.
- Sethu Pitchiaya was promoted to research Investigator on 01/17/2017.
- Anirban Sahu was selected by the MSTP Operating Committee as this year's recipient of the Dean's Award for Research Excellence
- Abhijit Parolia was awarded the DOD Early Investigator Research Award
- Sunita Shankar was invited to give an oral presentation in a mini-symposium session at the 2017 AACR Annual Meeting in Washington, D.
- Jenny Choi received a scholarship to attend the Workshop on Techniques in Modeling Human Cancer in Mice being held August 20-27, 2017 at The Jackson Laboratory in Bar Harbor, Maine
- Yajia Zhang was awarded the 2016 Prostate Cancer Research Program (PCRP) Early Investigator Research Award – Predoctoral Fellowship.
- Ajjai Alva and Rohit Mehra, MD, have been funded by Progenics Pharmaceuticals for "A Phase 2/3 Multi-Center, Open-Label Study of 18F-DCFPyL PET/CT Imaging in Patients with Prostate Cancer: Examination of Diagnostic Accuracy (OSPREY).
- Ronald Siebenaler was awarded the NRSA F30 (Dual-Degree) Fellowship
- Prasanna Alluri won the ASCO Young Investigator Award.

In association with MLabs, MCTP's Molecular Testing Lab (MTL) receives orders for and carries out PCA3, Mi-Prostate Score (MiPS) and to a smaller extent, Cell Search Circulating Tumor Cell (CTC) assays. MTL processed a total of 2309 PCA3 and 297 MiPS assays in FY2017. Both MCTP CLIA labs- Molecular Testing Lab at the Traverwood site and the Clinical Sequencing Facility at the Cancer Center- underwent a successful CAP inspection in May 2017. These sites support a number of clinical studies and research projects.

MCTP is sustained by support from multiple sources. This past fiscal year, the Center obtained \$10,091,610 in committed awards. In addition, MCTP discoveries generated \$679,400 of royalties to UM in FY 2017. The total gross charges continue to increase each fiscal year for our CLIA testing. Total gross charges generated in FY 2017 was \$1,098,812.

In the coming year, we will continue to enroll patients to our clinical sequencing program for the purposes of identifying potentially actionable molecular aberrations and inform treatment strategies for patients as well as to understand the molecular mechanisms driving metastatic disease. We predict that our clinical sequence analysis could become a routine test that can be ordered by oncologists to guide decisions about therapies and/or clinical trials. Towards that end, we hope to offer the OncoSeq test formally and more broadly through Pathology's MLabs, similar to our other clinical tests. We are also exploring the application of sequence data to guide the use of immunotherapy. We also plan to propel our clinically promising lncRNA candidates towards prognostic/diagnostic test development, we have several biomarkers in the pipeline for clinical development, with a large focus on prognostic lncRNAs. Finally, basic discoveries elucidating the mechanisms of tumorigenesis have identified various proteins and interactions that are potentially amenable for therapeutic targeting. In collaboration with Dr. Shaomeng Wang, we will continue to develop high-throughput screening to identify small-molecule inhibitors towards these targets that can potentially be used therapeutically for treating cancer.

Division of MLabs
Jeffrey L. Myers, M.D.
A. James French Professor of Diagnostic Pathology
Vice Chair of Clinical Affairs and Quality
Director, MLabs
Director, Pulmonary Pathology Fellowship



OVERVIEW

MLabs offers access to the expertise of the faculty and staff and the sophisticated testing available in the laboratories of the Department of Pathology to those outside of the Michigan Medicine. As we celebrate our 32nd anniversary in the reference laboratory business with another successful year, we thank our clients for the opportunity to provide them with the highest quality reference laboratory services necessary to meet the needs of their patients, their families, and their providers. Our continued successes in nurturing long term relationships with our clients is built on the promise of *expertise delivered personally* with a passionate commitment to service excellence. As a reference laboratory embedded within one of the largest academic medical centers in the country, MLabs is here for the long haul with patients at the center of everything we do.

WORKFORCE

The Department of Pathology has 150 faculty members representing all disciplines and subspecialties, over 30 pathologists and laboratorians in training, and 800 professional laboratorians and administrative staff. We are focused on excellence in the services that we provide today while also supporting the education and research programs that ensure excellence for those who will look to us for care tomorrow. All employees of the Department of Pathology share our vision and support the mission of MLabs.

MLabs Faculty Director

Jeffrey L. Myers, M.D.

MLabs Associate Director

Julia Dahl, M.D.

Staff

The MLabs Division has a manager and seventeen individuals in key administrative, operations, informatics, sales, marketing and client services roles. MLabs informatics staff work closely with counterparts in the Pathology Informatics division who are also dedicated to meeting the demands for IT support in the reference laboratory business. MLabs Client Services is consistently applauded by our clients as one of the most helpful and friendly in the reference laboratory industry. MLabs Client Services answers each call personally, 95% within < 30 seconds. Our trained client service representatives are available to answer questions related to specimen procurement and handling, convey testing status and serve as facilitators for client interactions with technical laboratory staff and faculty. The MLabs Client Services hours are Monday through Friday from 7:00 a.m. to 9:00 p.m. and Saturday 8:00 a.m. to 4:00 p.m. Telephone calls received after-hours, weekends and holidays are handled by our MLabs Specimen Processing Customer Service staff providing 24-hour attention to client needs. In addition to MLabs Client Services, our MLabs homepage and on-line Handbook are user friendly references www.mlabs.umich.edu.

Licensure and Accreditation:

Michigan Medicine, Department of Pathology Laboratories (MLabs) located in Ann Arbor, Michigan maintains Clinical Laboratory Improvement Amendments (CLIA) Accreditation, College of American Pathology (CAP) Accreditation, The Joint Commission Accreditation, American Association of Blood Banks, American Society for Histocompatibility and Immunogenetics (ASHI), State of California Licensure, State of Florida Licensure and State of New York Licensure (for PCA3 testing only).

MLABS DIVERSIFIED CLIENT PORTFOLIO AND SERVICE LINE

MLabs client portfolio includes 752 accounts. We provide reference laboratory services to hospitals throughout the State of Michigan and primary laboratory services to physician offices and nursing homes of strategic

interest to Michigan Medicine (MM). MLabs extends molecular testing, specialized anatomic and hematopathology services and consultations to a national market including other reference laboratories and academic medical centers.

The following is an overview of each market/service line:

Physician Office – MLabs provides laboratory testing to 378 physician offices (all subspecialties) within geographic catchment of MM. Some patient specimens are collected at the physician offices (dermatology specimens, pap smears, urines, cultures) and MLabs provides routine daily courier service to those physician offices for those specimens. However, the physician offices do not provide their own phlebotomy service. Our clients' patients are referred to MM Patient Service Centers where their blood is drawn and specimen(s) couriered to MLabs for testing. We are the exclusive provider of BRCA testing for two large commercial payers (Blue Care Network and Health Alliance Plan) with statewide membership contracted through Joint Venture Hospital Laboratories. We have extended dermatopathology service to select dermatology practices throughout the state. MLabs is interfaced with several common EMRs for electronic result reporting allowing one-half of our physician office clients to receive results electronically; large group practices are interfaced for both orders and results. We are working on multiple interface projects so that we can provide electronic result reporting to all interested parties.

Hospital (HL) and Hospital Pathology Groups (HPG) - MLabs classifies its hospital market into two groups reflecting the primary referral pattern of the hospital. Support of each is unique to the reference laboratory services provided. MLabs hospitals (HL) include those to whom we provide primary reference laboratory and full esoteric testing. Also included in this group are hospitals requesting our specialty services, e.g., renal, muscle, nerve biopsies, flow cytometry, histocompatibility and molecular diagnostic testing. Currently, this group includes 79 hospitals throughout the state and the country.

The hospital pathology group (HPG) reflects 199 clients primarily requesting anatomic pathology and hematopathology consultations with associated specialized testing as appropriate including a large menu of molecular tests performed across a variety of platforms for solid tumors as well as hematolymphoid disorders. This group is significantly larger reflecting the strength of our diagnostic pathologists and the personal manner in which they deliver their expert consultations. Most diagnosis are rendered within 24-48 hours of receipt and results are reported by personal phone call, facsimile, electronically through MLabs Connect (our internet-based secure web portal), or via MiShare (a secure email delivery platform supported by MM).

Reference Lab/Commercial Accounts - MLabs leverages the clinical, educational, and research missions of MM to deliver unique value to our clients and patients as a recognized leader in the field of precision medicine. MLabs' extensive test menu and personal approach to the unique needs of each client has allowed us to serve as the provider of choice for many hospitals, commercial laboratories and academic medical centers throughout the country. MLabs Molecular Diagnostic Laboratory, with a triaged approach to test ordering, offers over 50 qualitative and quantitative single mutation assays as well as actionable NGS panels and other more comprehensive solutions to assist with the diagnosis and management of hematologic and solid tumor malignancies. Our Molecular Dermatology Laboratory offers FISH and comparative genomic hybridization (CGH) array assays to solve some of the most challenging diagnostic problems in dermatologic neoplasms with a focus on melanocytic lesions. Michigan Molecular Genetics Laboratory (MMGL) has an extensive menu of over 70 assays which test for rare genetic disorders. Together, the combined test menu allows us to provide high quality molecular testing across all medical specialties, from inherited genetic conditions to analysis of a broad range of tumor types. Looking toward the future, the Michigan Center for Translational Pathology (MCTP) has developed one of the most comprehensive assays available anywhere, OncoSeq, with proven value in a highly selected subset of patients with advanced malignancies for whom conventional therapies are no longer effective. MLabs looks forward to offering this and other precision oncology assays emerging from our research enterprise to our clients and their patients.

Nursing Home/Acute Care Facilities –Laboratory testing and phlebotomy services are provided to 7 regional nursing home and acute care facilities of strategic interest to MM. MLabs provides qualified phlebotomists specially trained in geriatric draws, accessing lines and port collections to successfully perform this service for

our nursing home/acute care patients. Our nursing home clients are completely interfaced with MLabs for both orders and results via MLabs Connect. All laboratory results on patients from these accounts are also populated into MM's clinical data repository (MiChart) if that patient is known to MM. This allows both hospital and nursing home electronic medical records access to the same laboratory information, improving quality and continuity of care for our MM patients.

FINANCIAL METRICS – TOTAL BUSINESS

MLabs continues to make a notable contribution to the margin that supports all of the missions of MM and the Department of Pathology. MLabs' FY17 Total Gross Charges of \$65 million held steady compared to FY16, reflecting a balance of new client acquisition with departure of others. New client acquisition reflects the success of focused business development efforts in Florida, expansion of our portfolio of commercial clients and growth of our dermatology physician office clients. Client departures were affected by regional hospital acquisitions with alternate healthcare systems capturing reference laboratory referrals from acquired hospitals.

Figure 1: MLabs Total Gross Charges (Professional and Technical) Trend FY11 - FY17 with PB (professional) and HB (facility) detail.

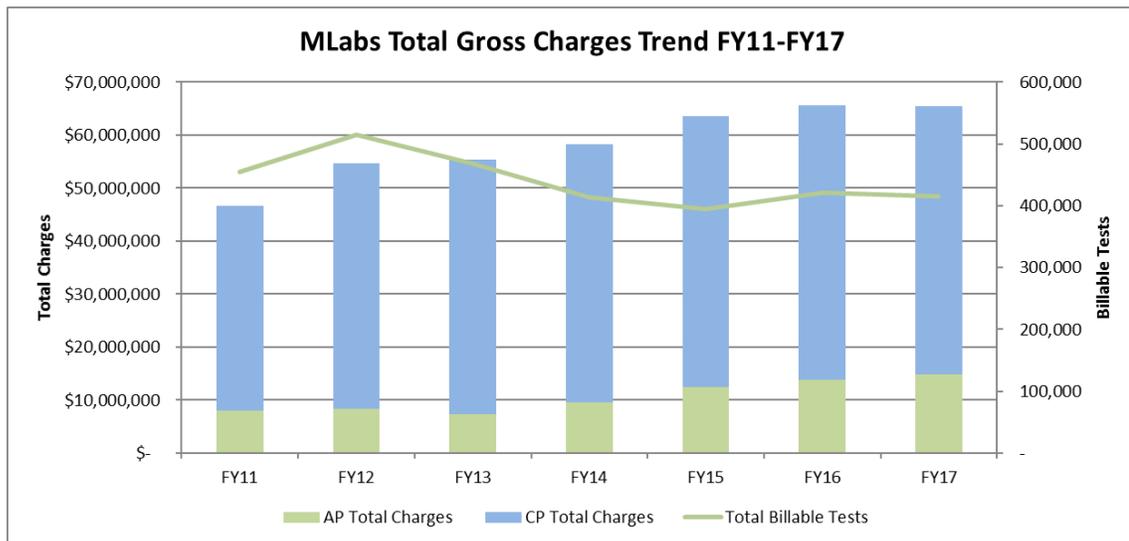


Figure 2: Percentage of Total Gross Charges by Individual Market/Service Line

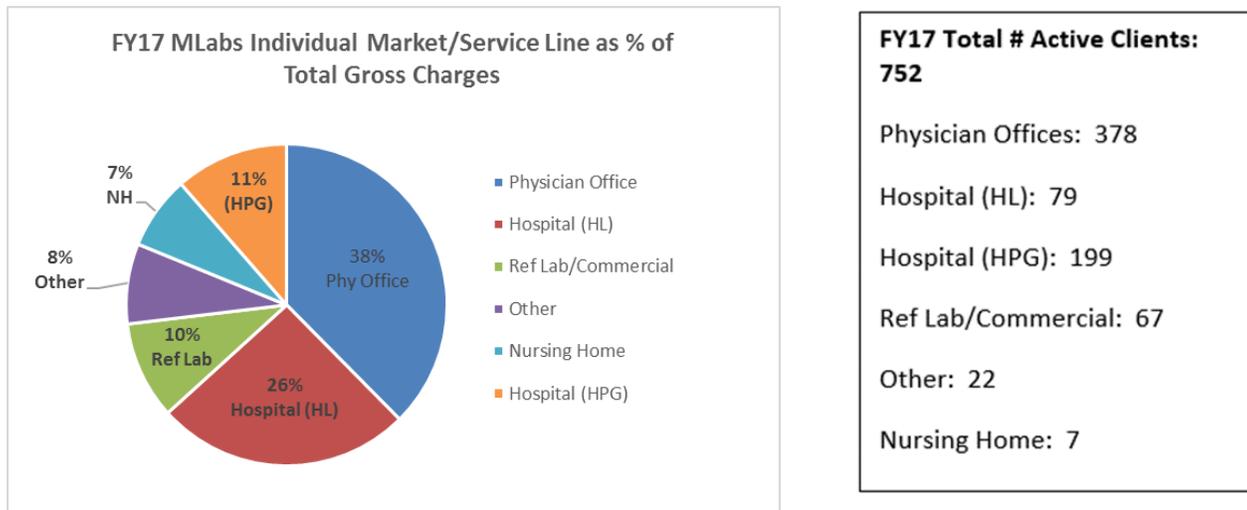
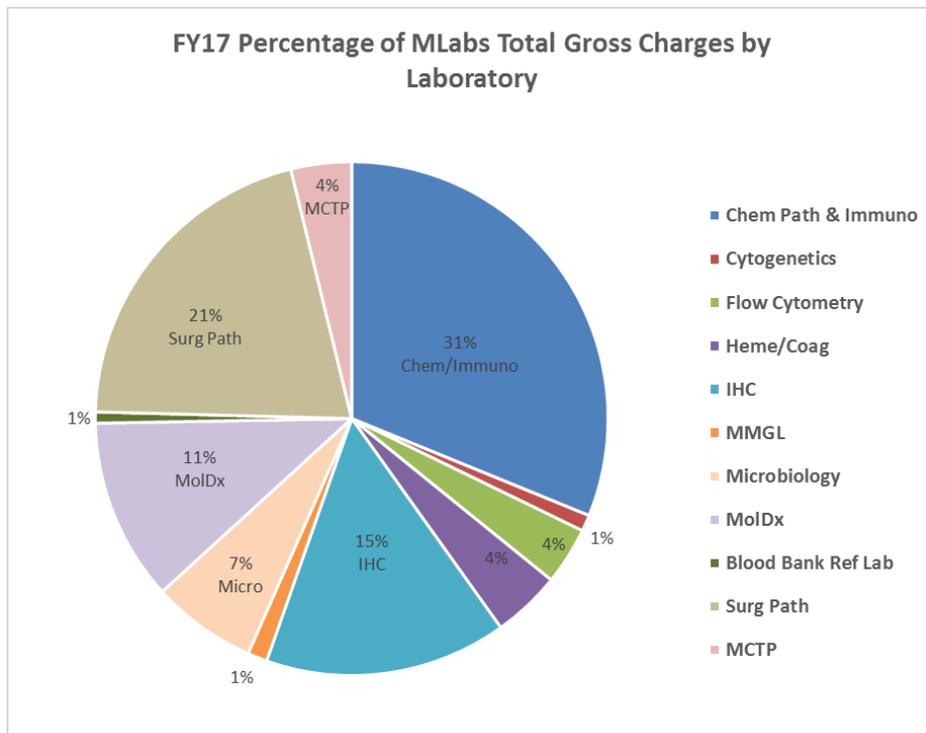


Figure 3: Percentage of Total Gross Charges by Laboratory



SALES AND MARKETING

MLabs primary sales and marketing effort remains focused on making certain that pathologists, hospitals, and reference laboratories everywhere recognize MLabs as the center of excellence for specialized laboratory testing, especially molecular diagnostics, subspecialty services and pathology consultative services. Exhibiting at regional and national meetings affords us an opportunity to be visible and recognized as a national provider of laboratory services. During FY17, MLabs exhibited at four national meetings (USCAP, CAP, ASCP and ACMG) joining our MMGL colleagues for the first time at American College Medical Genetics. Additionally, MLabs exhibited at five regional pathology meetings in Michigan, Florida and Texas, states where MLabs is well recognized for its surgical pathology consultative services.

MLabs Statewide Laboratory Network Participation – JVHL and GLN

Joint Venture Hospital Laboratories (JVHL) is the largest laboratory network in Michigan and is organized as a limited liability company, equally owned by its hospital laboratory members. Michigan Medicine (MLabs) became an equity member of JVHL in 1997 and serves on its Executive, Quality Assurance and Operations Committees.

Great Lakes Laboratory Network (GLN) is a network of hospital laboratories located primarily on the western side of the state. MLabs became a member of GLN in 1996 and plays an advisory role through representation on the Steering Committee.

MLabs helps facilitate departmental issues pertaining to contractual obligations as a member of JVHL and GLN. MLabs serves as a resource for Michigan Medicine’s Managed Care Operations Office with lab related issues.

FY17 KEY ACCOMPLISHMENTS

- Successful recruitment of MLabs Associate Director, Dr. Julia Dahl.
- Sustained success in providing exceptional molecular diagnostics testing, with a focus on medically relevant and well validated assays, to meet a diverse mix of clients reflecting the outstanding combined effort of our molecular and research laboratories, Molecular/Oncology, Michigan Center for Translational Pathology and Michigan Medical Genetics Laboratory.
- Increased market share nationally in anatomic and hematopathology consultations, most significantly in Florida.
- Expansion of MLabs Leadership Team by dividing MLabs Division Manager position into two (2) roles matching leadership presence to the expanded demands in the increasingly competitive and complex market; the Administrative Manager to provide strategy, planning and managerial oversight for operations and the Business Development Strategist to focus exclusively on business development and market segment expansion.
- Increased national awareness of MLabs brand as provider of choice for subspecialty services.
- Successful initial integration of Salesforce as MLabs client relational management tool.
- Extensive preparatory work toward creating an Integrated Call Center for NCRC.

ACKNOWLEDGEMENT

The MLabs Division continues to experience solid growth and remains successful in retaining existing clients in a very competitive market. Its success reflects the efforts of each and every individual within the Department of Pathology, their commitment to service and their ability to push forward with innovative solutions to meet the sophisticated needs of our clients. Few things more clearly demonstrate the rewards realized in working together to achieve excellence in the care provided here and elsewhere, which remains the Michigan Difference.

Division of Molecular and Genomic Pathology
Thomas J. Giordano, M.D., Ph.D.
Henry Clay Bryant Professor of Pathology
Director, Division of Molecular and Genomic Pathology
Professor of Pathology and Internal Medicine

The Division of Molecular and Genomic Pathology (MGP) was created in 2015 and Dr. Thomas Giordano serves as Director. The overarching mission of the MGP Division is to coordinate the activities of the various molecular pathology laboratories within the Department of Pathology and to interface with the Michigan Molecular Genetics Laboratory within the Department of Pediatrics. High levels of coordination between the laboratories will be necessary as the Department of Pathology anticipates the move to the new molecular diagnostic laboratories within the NCRC in the coming year and to fulfill our common goal of precision medicine and oncology. The MGP Division will also have as a goal finding ways to further leverage the substantial genomic data generated by these and other molecular profiling assays for research opportunities.

The Division of Molecular and Genomic Pathology also collaborates with the University of Michigan Comprehensive Cancer Center under the leadership of Dr. Eric Fearon. Together, they are working on developing a strategy to provide complex genomic testing for all advanced cancer patients seen at the University of Michigan. Towards this goal, the Molecular Diagnostics Laboratory has made great progress on developing the OncoPrint Focus next-generation sequencing (NGS) assay, which interrogates a panel of clinically informative genes. Moreover, the MGP division has engaged the leadership of BCBS and BCN to advocate for adequate coverage for NGS-based testing.

In his role, Dr. Giordano serves as the Director of the Molecular Test Committee (MTC) and has created a cohesive vision of the rapidly expanding field of Molecular Diagnostic testing by minimizing duplication and enhancing collaboration. The MTC includes the Molecular Diagnostics Laboratory, Michigan Molecular Genetics Laboratory, Michigan Center for Translational Pathology (MCTP) and other laboratories offering individual molecular testing including Cytogenetics, Dermatopathology, and Histocompatibility. The vision statement indicates that the University of Michigan Hospital and Health Systems will be a principal provider of state-of-the-art, cost-effective molecular diagnostic testing that is supported by reasonable evidence-based medical literature. To achieve this, MTC has established a collaborative forum to engender trust and collegiality and to foster efficient and innovative development of new, clinically relevant molecular testing. The group meets quarterly to:

1. Share current lists and techniques planned for current and future molecular testing.
2. Understand the mechanism to determine how tests are chosen for development (financial, local and national patient need, faculty interest, required space/equipment and the challenge of regional and national competitors).
3. Develop a mechanism to determine which laboratory is most suitable to develop and perform specific new tests.
4. Identify opportunities for collaboration and to minimize duplication of tests and resources.
5. Prepare a unified capital equipment investment plan.

MTC has had quarterly meetings this year that allowed them to share data and anticipate conflicts of testing. A key offshoot of this effort has been the establishment of the Molecular Administrative Group (MAG) that has had extensive involvement in planning the new Molecular Laboratory at the NCRC. The MAG consists of managers or supervisors of each of the individual Molecular laboratories who regularly share relevant issues. Since they will be working together in the NCRC space, this forum serves to enhance cooperation and anticipating potential conflicts.

The Molecular Group of laboratories have made great strides engaging its various staff members so that the laboratories (Table 3), while remaining unique, will function as a cohesive and collaborative group. Working with leadership from our new Division of Quality (Dr. Scott Owens and Brian Tolle), the members of the Molecular Group of Laboratories have donated considerable time and expertise at monthly meetings, inspecting each other's laboratories, and visiting other University facilities in order to make our Molecular facility a reality.

Table 3. Composition of Molecular Group (Director-Dr. Thomas Giordano)

Laboratory	Director	Technical Director/Manager	Manager/Supervisor
Molecular Diagnostics	Dr. Noah Brown	Bryan Betz	Jennifer Bergendahl/ Nanci Lefebvre
Michigan Molecular Genetic Laboratory	Dr. Jeff Innis	Marwan Tayeh	Todd Ackley
Cytogenetics	Dr. Lina Shao	Beth Cox	Turquessa Brown-Kajewski
Michigan Center for Translational Pathology	Dr. Arul Chinnaiyan	Javed Siddiqui	Debbie Snyder
Histocompatibility	Dr. Omar Moussa	Timm Williams	Cynthia Schall
Dermatology Molecular	Dr. Aleodor Andea	Min Wang	

Molecular Diagnostics Laboratory
(Report by Dr. Noah Brown)

Noah Brown, Thomas Wilson, Bryan Betz

Overview

The laboratory is directed by Dr. Noah Brown. The associate medical director is Dr. Thomas Wilson. The laboratory's Technical Director is Dr. Bryan Betz. The technical supervisor/laboratory manager is Jennifer Bergendahl. Laboratory Supervisors are Nanci Lefebvre and Lindsay Kochan. Research and development supervisor is Helmut Weigelin.

Educational and Operational Activities

Monthly lab meetings are conducted during which a member of the staff or faculty will give a presentation on a new or current test being performed in the laboratory. This helps to give residents, fellows, and staff an introduction to new testing, and to give further information as to why certain testing is performed.

The laboratory also conducts regular monthly Administrative Project Meetings, which include the medical director, technical director, attending physicians, supervisors, research and development technologists and fellows/residents associated with the laboratory. These meetings aid in organizing ongoing projects and provide information on new and updated tests and assay problems/issues.

A monthly resident/fellow molecular conference is also conducted. Here the resident/fellow presents a current or proposed molecular test that includes a discussion on the clinical indication and test interpretation as well as considerations involved in designing, developing, and validating that test in the laboratory. The topic is chosen under the guidance of the molecular laboratory faculty.

Operation meetings are conducted as needed with the medical director, associate director, technical director, laboratory manager and supervisor. Discussions focus on operations of the laboratory.

Monthly Manager/Supervisor meetings are now conducted with the laboratory manager, molecular supervisor, FISH supervisor, and research and development supervisor. These meetings discuss the various operational issues, assay workflow concerns, progress in assay validation, employee concerns, and any matters arising from each of our core areas.

Huddles are now conducted on a weekly basis. The days are rotated between Tuesdays and Thursdays. The Huddles are used to convey kudos to staff and any issues or changes that need to be addressed and cannot wait until the staff meeting.

Molecular Genetic Pathology Fellowship

Dr. Pawel Mroz graduated as a Molecular Genetic Pathology Fellow of the University of Michigan Department of Pathology fellowship program's eighth class (2016-2017 academic year).

New Molecular Genetic Pathology Fellows (2017-2018):

- Dr. Nathan Charles
- Dr. Michael Carter

New Tests

07/20/2016: *BRAF* (7q34) Rearrangement by FISH

09/01/2016: *EGFR* Mutation by Next-Generation Sequencing

11/02/2016: *TERT* Promoter Mutation (Tissue)

02/22/2017: *KRAS* Mutation by Next-Generation Sequencing

02/22/2017: *NRAS* Mutation by Next-Generation Sequencing

06/07/2017: *MET* (7q31) Amplification by FISH

Future Tests in Development - (to be completed by June 30, 2018):

- Oncomine Focus Next-Generation sequencing assay – Comprehensive mutation panel to evaluate mutations, copy number aberrations, and gene fusions in solid tumors
- *NTRK1* Rearrangement by FISH – Break-apart FISH assay to guide therapy in lung cancer
- *BCR-ABL1* p210 Quantitative PCR – Monitoring test for CML and ALL
- *BCR-ABL1* p190 Quantitative PCR – Monitoring test for CML and ALL
- *TERT* Promoter Mutation by real-time PCR – High sensitivity test performed on urine to monitor patients for recurrence of urothelial carcinoma
- Myeloid Mutation Panels – Next-Generation Sequencing (Illumina) panels to aid in the diagnosis of MDS and MPN as well as to improve risk stratification and direct therapy in AML and MDS
 - Acute Myeloid Leukemia Panel
 - Myelodysplastic Syndrome Panel
 - Myeloproliferative Neoplasm Panel
 - Comprehensive Myeloid Panel

Specimen Volume

Specimen Volume 1/1/2016 – 12/31/2016: 14232 (this is a 28% decrease from the previous year). The decrease is attributable to reduction of referred testing from two MLabs clients. One client brought testing in-house; the other client was acquired by another laboratory that performs testing in-house.

Test Turn-Around-Time

The average turn-around-time for all assays was 4.13 days. This is an improvement of 0.35 days from the previous year. We actively worked with technologists to reduce test batching to improve test turn-around time.

Educational Improvements

We continue to implement a more rigorous Resident Training program where the residents are actively involved in learning our procedures. Dr. Brown developed, and with the help of our Supervisors and technologists implemented a new in-laboratory procedure-based training program. All first year residents go

through the program and current residents that have not gone through the new training get re-trained. Additional daily didactic sessions are also performed by Drs. Noah Brown and Bryan Betz when residents are on service.

Operational Improvements

Staffing

We promoted Lindsay Kochan to fill our vacant FISH supervisor position and appointed her as move captain for our transition to the NCRC laboratory. We hired a technologist to fill a vacant position in our research and development section who will assist in implementing our ambitious list of new assays. The laboratory employs 22 full-time employees and one part-time employee. Because of the rapidity of test development in the field of Molecular Pathology, two full-time employees are dedicated to research and development.

Additional Instrumentation

Capital equipment acquisitions for 2016 included a 3500xl genetic analyzer to replace a discontinued 3130xl instrument. Two new 7500dx real-time PCR instruments were purchased to support FDA-approved BCR-ABL1 testing. An Evoqua water purification system was purchased to support next-generation sequencing tests.

Clinical Improvements

We met with Blue Cross Blue Shield of Michigan to provide education on the importance of next-generation sequencing test panels and reimbursement. The content was well received and we will be continuing to work with BCBSM to provide feedback and guidance on their reimbursement policy.

Our medical director Noah Brown independently met with several clinical teams to ensure we are meeting their needs, to educate them on upcoming tests and replace send-out testing with in-house molecular tests.

We modified our new employee training program to ensure that our new trainees go through the relevant rotations before their 6-month probationary period is completed. This was modified to ensure that if any issues with the new trainee was noted that this could be monitored and if there were any issues a work development plan could be instituted.

We initiated an introduction to pipetting etiquette training program for new staff. Not all of our new staff have pipetting experience and it is important that all of our staff utilize a standardized method for pipetting.

We received funding to enroll our laboratory into the 'What Motivates Me' program from Culture Works. We have completed two parts of training which allowed staff to take a survey to see what motivates them or helps them to stay engaged at work. We have started to meet individually with each staff member to see how we can sculpt their job to keep staff engaged while at work. We will be meeting with the Leadership Development Manager to provide feedback on the program. We are the first laboratory to participate in this program within Michigan Medicine.

We implemented the use of log books for staff to add daily comments on issues with samples and instrumentation. This has improved communication of important issues between staff who are working on different shifts of the same test rotation.

We are working with representatives from the Pathology Division of Quality and Health Improvement, Clinical and Anatomic Pathology Operations, MiChart and Soft to overhaul the informatics and process for ordering molecular tests to prevent errors, delays or lost specimens.

A modification to the TRG gene rearrangement test procedure was implemented to improve the repeat rate and test turn-around time. The modification was the result of an investigation, which revealed that assay performance can be improved by optimizing the DNA input based on concentration.

Cytogenetics
(Report by Dr. Shao)

Lina Shao, Diane Roulston, Thomas Glover

Overview

The laboratory Director is Lina Shao, M.D., Ph.D., Thomas Glover, Ph.D. (Professor, Department of Human Genetics, Department of Pathology) provided invaluable expertise and sign-out coverage, primarily for constitutional genetics and oncology FISH cases. The Director Emeritus, Diane Roulston, Ph.D., provided 20% effort for the teaching of residents and fellows and clinical service.

Over the past fiscal year, the Cytogenetics Laboratory had 4.6% increase of test volume, mainly in FISH and Cancer Cytogenomic Array. We had a successful CAP inspection. TempTrak was validated extensively and put into use. A new hybridization buffer, IntelliFISH hybridization buffer, replaced the standard buffer in CLL FISH panel and STAT FISH testing procedure. New FISH tests, CRLF2 and JAK2 breakapart FISH tests, were validated and put into clinical use.

Faculty Update

Stephanie Balow, PhD will be joining the Department on September 1 as Assistant Director of the Cytogenetics Laboratory. She received her B.S. in 2007 from Bowling Green State University and her PhD in 2014 from Case Western Reserve University. She completed her Clinical Cytogenetics Fellowship in 2016 and her Clinical Molecular Genetics Fellowship in 2017, both at Cincinnati Children's Hospital Medical Center. Dr. Balow received The Marcus Singer Award, Biomedical Graduate Student Symposium from Case Western Reserve University in 2012 and the NIH Genetics Training Grant Recipient from 2009-2011.

Clinical Services

In FY2017, the Cytogenetics Laboratory had a 4.6% increase in overall sample volume compared to FY2016 (Table 1). A total of 3,944 tests were performed, almost all the oncology tests showed increases in volume while prenatal samples showed continued decline.

The total volume for karyotype was essentially not changed (-8 cases, -0.3%) compared to FY2016. The volumes for tumor/lymph node (+37, +12.9%) and constitutional blood (+39, +11.2%) showed increase; however, the increases were offset by the decline in the prenatal samples. The prenatal samples including amniotic fluid (-27, -38%), chorionic villus (-28, -41.8%), and products of conception (-18, -41.9%) kept declining due to application of non-invasive prenatal screening and a switch from chromosome analysis to a sendout SNP array test.

The volume for FISH tests increased significantly (+117, +13.3%). The main increase came from FISH panels (+80, +46.5%) and FFPE FISH (+36, +66.7%). The number for constitutional FISH tests was essentially not changed compared to FY2016. And the volume of the single probe FISH tests (+3, +0.5%) finally stopped declining since the trend started in FY2013. Under the leadership of senior technologist Hong Xiao, the section validated IntelliFISH hybridization buffer in both STAT FISH and CLL FISH in FY2016, and put into full use afterward. The application of IntelliFISH hybridization buffer in CLL FISH panel alone resulted in improved quality, shortened TAT, and a saving of approximately \$20,000 last year. Our experience in using IntelliFISH in CLL panel was presented as a platform presentation at the Association for Genetic Technologists conference in St Louis, Missouri, and will be presented in the quarterly CP QA conference in July 2017.

The volume for Cancer Cytogenomic Array continued to increase in FY17 (+17.7%, +57 cases). The Cancer Cytogenomic Array test has improved diagnosis, prognosis, and treatment in both hematological malignancies and pediatric solid tumors, and has become standard of care for acute lymphoblastic leukemia and pediatric solid tumor patients at diagnosis.

TempTrak was installed and validated successfully on all the freezers and refrigerators, and put into full use. We acquired a new Thermotron last year. The existing Thermotron was saturated with the preparation of oncology chromosome and FISH slides. The validation of preparation of constitutional blood chromosome slides is ongoing

using the new Thermotron. A new fluorescent microscope with Cytovision station was acquired, so technologists have easy access to the analysis software and we have backup scope for FISH analysis in case one of the FISH scope is down. We validated CRLF2 FISH test for Ph-like B-ALL and JAK2 FISH test as an addition to the existing Eosinophilia panel following the recommendation of WHO 2016 classification, both tests were put into clinical use. We completed validation of multiple myeloma FISH panel which includes a total of 10 probes, and the test is expected to go live early FY2018.

With regard to staffing, the laboratory administrators replaced 2 departing technologists and 2 technicians. The senior technologist for the prenatal section, Lynn Knuderson-Horneber, was promoted to Intermediate Supervisor overseeing the constitutional and prenatal sections. Carrie Laudau was promoted to Senior Technologist for the blood and bone marrow section. Margaret Rayer was promoted to Technologist II specialized in Safety. Locum tenens, Drs. Peebles and Berend, continued to cover the case sign-out activity and have proven extremely helpful before the new assistant director will be onboard.

With regard to employee engagement, under the leadership of Margaret Rayer and Beth Cox, the laboratory continued working on improvement of communication.

Other significant activities included a successful CAP inspection with a minor citation which was corrected onsite, successful recruitment of Dr. Stephanie Balow as Assistant Director for the laboratory, a presentation entitled "Optimizing slide preparation of neoplasia samples for chromosome analysis using the Thermotron" at CP quarterly QA meeting and Quality Month 2016, and continued effort in the PRR project led by move captain Beth Cox.

Education

Residents and fellows from a wide range of specialties performed rotations in the laboratory. These included Pathology residents (5), Clinical Genetics resident (1), and Hematopathology fellows (2). The residents and fellows presented brief talks on relevant topics in cytogenetics for the technologists, making a much-appreciated contribution to continuing education. This year we also had a medical student from M4-clerkship rotating in Cytogenetics.

The laboratory implemented a monthly continuing education program under the leadership of Beth Cox and Leisa Stempek in FY2016. Last year, Dr. Lina Shao, Dr. Tom Glover, Jiong Yang, Sue Miller, Hong Xiao, Margaret Rayer, and Carrie Laudau presented at the monthly continuing education event. An AGT webinar, and resident's/fellows presentation on a wide range of cytogenetic topics were also important additions to the continuing education program. Under this program, technologists have opportunity to accrue 12-hour genetics-specific CME per year, increased exposure to abnormal cases, and better understanding of the operation of other sections within the laboratory.

For conferences, Hong Xiao presented a platform presentation on quality improvement in CLL FISH using IntelliFISH hybridization solution at the Association for Genetic Technologists conference in St Louis, Missouri. Dr. Lina Shao presented two platform presentations on the application of Cancer Cytogenomic Array in ALL and pediatric brain tumors at the Cancer Genomics Consortium conference in Denver, Colorado. In addition, a technologist attended the annual Great Lakes Chromosome Conference in Toronto. Two other technologists attended the 25th Annual Symposium on Molecular Pathology at Beaumont Hospital. Dr. Lina Shao and laboratory staffs authored or coauthored in 3 publications and 8 conference abstracts.

The laboratory continued to benchmark well and maintained Approved Laboratory status for participation in clinical trials for the Children's Oncology Group (COG); 14 case studies were submitted. Dr. Lina Shao is a member of ACMG/CGC workgroup to develop "Standards & Guidelines for interpretation and reporting of copy number changes & copy-neutral LOH in neoplastic disorders", a member of CGC workgroup for pediatric acute lymphoblastic leukemia, and a member of ACMG salary survey workgroup.

Future Plans

We completed the validation of multiple myeloma FISH panel which includes 10 probes and plan to go live early FY 2018. We plan to acquire a Robsep automatic sorter for plasma cell enrichment, which will shorten the hands-

on time for the enrichment process from 2.5 hours to 45 minutes for each case. We plan to acquire a hybridization oven which will use 80% less FISH probes and allow us save reagent cost significantly. We'll work with the PRR team to plan a smooth move to NCRC.

Table 1. Sample Volumes in Clinical Cytogenetics Laboratory (FY2017)

<u>Sample type</u>	<u>N</u>	<u>Change from FY2016</u>
Bone marrows	1,712	-13 (-0.6%)
Tumor/Lymph node	324	+37 (+12.9%)
PB constitutional	386	+39 (+11.2%)
Prenatal		
Amnios	44	-27 (-38.0%)
CVS	39	-28 (-41.8%)
Tissues (POC)	25	-18 (-41.9%)
Total (chroms):	2,530	-8 (-0.3%)
Tissue culture only	22	+9 (+69.2%)
Add tissue culture for AM, CV or TI	15	-3 (-16.7 %)
Total	37	+6 (19.4%)
FISH		
Constitutional genetics	100	-2 (-2%)
Oncology		
Single probe	556	+3 (+0.5%)
Panels*	252	+80 (+46.5%)
FFPE	90	+36 (+66.7%)
Total (FISH):	998	+117 (+13.3%)
Microarray		
Hem- onc	265	+23 (+9.5%)
Solid tumor	114	+34 (+42.5%)
Total (microarray):	379	+57 (+17.7%)
Total tests:	3,944	+172 (+4.6%)

*FISH panel = two or more probe sets utilized per sample.

Division of Quality and Health Improvement
Scott R. Owens, M.D.
Associate Professor
Director, Quality and Health Improvement

Team Members

Andrea Arlen (Clinical Pathology Quality Assurance Coordinator)
Lisa Brown (Administrative Assistant)
Dayna Goerke (Anatomic Pathology Quality Assurance Coordinator)
Kellen Kangas (Compliance Manager)
Jeff Lott (Project Manager)
Amy Mapili (Project Manager)
Marianne Mara (Business Systems Analyst from Pathology Informatics)
Scott Owens (Director)
Brian Tolle (Manager)

Overview

FY2017 saw excellent progress on a number of initiatives and projects carried out and/or contributed to by members of the Division of Quality and Health Improvement (DQHI). Highlights include:

- Concentration of the **Patient Asset Management Initiative** on the goal of tracking specimens as they move between the University Hospital complex to Pathology's new facilities at North Campus Research Center
- Consolidation of partnerships with Internal Medicine centered on test utilization/stewardship, resulting in the **Laboratory Stewardship Program**, with early indicators of a potential for significant impact on cost of care, value creation, and optimization of laboratory testing to achieve better outcomes and access to care
- Further work on **patient- and family-centered pathology** care and the evolution of pathology's role on the patient care team
- Completion of the second full **Quality Assurance Curriculum** for house officers
- The development of an **Annual Quality Plan** reflecting the state of quality-related activities and goals in the Department, in collaboration with key stakeholders including laboratory leadership and the Department's Quality Council
- Completion of a number of **compliance- and accreditation-related activities** including both an inspection of Michigan Medicine laboratories and inspection of a peer institution by a Michigan Medicine team
- Work on the development of a proposal for a Departmental **Safety and Preparedness Officer** position, with the goal of adding value to our operations in addition to fulfilling institutional mandates
- A number of **experimental and scholarly activities**, including a manuscript centered on the use of computer modeling to predict laboratory test results, and discussion with the Master's Program in Integrative Design in the Stamps School of Art & Design

Patient Asset Management Initiative

Fiscal year 2017 saw a consolidation of the Division of Quality and Health Improvement's (DQHI) largest extant program, the Patient Asset Management Initiative (PAMI), with four specific projects developing over the course of the year under the program management of Amy Mapili. With guidance from the PAMI Steering Committee, and collaboration with a number of stakeholders throughout the Department including Pathology

Informatics, the overall scope of this phase of the initiative is focused on specimen tracking, with the goal of having a robust system developed, tested, and validated by the date of the first specimen movement to the new Pathology space at the North Campus Research Center (NCRC), currently slated for 2 April 2018. This system will ensure trackable specimen movement between the Pathology's University Hospital Logistical Nerve Center (U-LNC) to its counterpart at NCRC (N-LNC). Two of the four current projects in the program involve on-site and off-site phlebotomy services, and are focused on ordering and movement of blood-draw specimens throughout the enterprise as they make their way to the Pathology laboratories. A third project involves the ordering, processing, and transportation logistics of cytology *ThinPrep*® specimens that need to be shared between two or more laboratories (for example, when a Pap smear specimen needs to undergo both cytological examination for atypical cells and further testing for human papillomavirus).

The fourth specific project, **PathTrack** can be thought of as uniting the other three, and is a home-grown asset tracking system that is designed to layer upon, and to interact logically and seamlessly with, the laboratory information system (Soft). PathTrack is being designed by members of the Division of Pathology Informatics to provide robust and variably granular asset tracking down to the level of a specific laboratory bench, in order to provide opportunities for continuous asset stewardship, early recognition of assets that do not reach their intended checkpoint(s) along the value stream and, potentially, an opportunity to engage patients in the management of their own assets from both process and patient experience standpoints. In addition to providing more robust asset tracking in current workflows, the team has been careful to engage front-line staff and to explore novel approaches that may not only provide better asset management, but also streamline the overall specimen processing workflow and add value for the enterprise and patients. In addition, we continue to explore other resources both within and outside the institution and the University in order to identify additional expertise in logistics, process and human factors engineering, and the patient experience (including patients themselves) that may be brought to bear on this important work. Finally, the overall vision for this initiative provides a framework for a significant number of potential future DQHI projects, extending from the "distal end" of the patient asset value stream (archiving of physical and digital assets) to the first origins of patient assets in the form of test selection, ordering, and decision support (refer to "Laboratory Stewardship Program" below).

Laboratory Stewardship Program

In the current reimbursement climate, value-based patient care is emerging as a paramount consideration. The approach of maximizing value in patient care provides opportunities for improvement extending from fiscal (decreased cost of care) to outcomes-based, and also has a patient- and family-experiential component. In addition, appropriate test selection and ordering impacts the management of assets in the laboratory value stream, following the maxim that "one sure way not to lose a specimen is by never ordering an inappropriate test." In this way, the other large DQHI initiative entitled "Laboratory Stewardship" has a natural connection with the PAMI described above. For the last several months, Jeff Lott has been leading an initiative that involves collaboration with a number of stakeholders and interested parties from around the enterprise. This collaboration centers on the inpatient enterprise in Internal Medicine (IM), with a Michigan Medicine hospitalist (Chris Petrilli, MD) acting as the point person on the IM side. After several months of work carried out by Brian Tolle, DQHI Manager, in concert with Dr. Petrilli and others, a new committee was formed in early calendar year 2017. This Laboratory Stewardship Committee (LSC; membership in Appendix 1) is organized as a subcommittee of the Laboratory Formulary Committee (LFC) chaired by Dr. Tim Laing, and has as Co-Chairs Drs. Petrilli and Lee Schroeder from Pathology. While the LFC has as its focus new (and often esoteric) tests, with work centering on whether and how to add such tests to the laboratory test catalog versus utilizing "send-out" testing at outside laboratories, the LSC is more focused on frequently-ordered routine testing.

As a first attempt at identifying both the current state and opportunities for improvement, the LSC has chosen to obtain ordering and utilization data on a small number of tests identified based on locally available ordering algorithms, guidelines published by the "Choosing Wisely" initiative, and prior published work done by Procop,

et al. (Cleveland Clinic) and Konger, et al. (Indianapolis VA Hospital). Jeff Lott has worked with Marianne Mara, with help from Matt Johnson (Project Manager in Internal Medicine) and others, to obtain data on thirteen initial target tests (Appendix 2). The goal of this work is presentation of the resulting information regarding a local “report card” on the use of these clinical tests and opportunities for improved utilization at the September 2017 meeting of the Internal Medicine Quality Council, where it is anticipated key stakeholders and physician champions will be identified to begin the work of improving utilization patterns where appropriate. An early indication of the potential of this work for cost savings and optimization of patient care recently came in the form of an estimated annual savings of more than \$100,000 for better inpatient utilization of testing for heparin-induced thrombocytopenia, an Internal Medicine endeavor that Jeff Lott of DQHI played a part in making possible when he turned his attention to this subject and was invited to be a part of this specific project. Another potential “early win” is the recent identification of a nearly global failure of Michigan Medicine clinical practitioners to utilize a “diagnostic algorithm” order for celiac disease testing that has been available for the last year or so, and which was developed collaboratively between our clinicians and pathologists to optimize testing for this disease; this situation should be relatively easily corrected using prompts and other tools available in MiChart to guide ordering patterns. Also, the LSC has identified a significant opportunity to prevent the ordering of thrombophilia testing in the inpatient setting, a practice which results in patients with an extremely low or non-existent risk for pathologic clotting to be automatically referred to outpatient hematology consultations, causing significant access issues for patients who truly need this service.

Finally, in addition to the opportunities to collaborate with Internal Medicine and other clinical partners, this initiative has drawn the interest of the Michigan Medicine and Institute for Healthcare Policy and Innovation (IHPI) Program on Value Enhancement (MPrOVE; <http://ihpi.umich.edu/our-work/strategic-initiatives/mprove>), which we anticipate will add additional collaborative resources as well as providing a further institutional “imprimatur” regarding the importance of this kind of work in the currently evolving healthcare environment.

Patient- and Family-Centered Care

DQHI continues to stand ready to act as part of the “effector arm” for patient- and family-centered initiatives identified as part of the Patient and Family Advisory Council (PFAC) under the leadership of Dr. Jeff Myers. Both Lisa Brown and Scott Owens from DQHI are members of the PFAC, and Lisa has identified patient consultations with pathologists as an area of interest, proposing a pilot project in which patients may have access to a gastrointestinal pathologist in a consultative fashion to help them answer questions and understand their diagnoses of gastrointestinal cancers and/or other diseases affecting the gastrointestinal tract such as inflammatory bowel disease. This pilot is in the early stages of development, but provides an exciting opportunity to begin the process of bringing significant change to the way pathologists contribute to the patient care team.

A collaboration with faculty and staff members in the Neonatal Intensive Care Unit (NICU), focused on the value-added participation of Pathology faculty who perform neonatal autopsies, has continued to grow under the leadership of Brian Tolle and Lisa Brown over the FY2017 time period. This project was outlined in last year’s DQHI Annual Report, and it has now reached the point that the Pediatric Pathology autopsy group can be considered an integral part of the care team with regard to helping providers and families understand autopsy findings and their clinical and family implications for neonates who pass away while in the NICU. This collaboration also involves stakeholders from Social Work and the Office of Patient Experience, and much work has been done to lay the groundwork the novel participation and contribution of Pathology in this process. The transition from initial acceptance by the NICU faculty and staff to operationalization of the process and, at this point, enthusiasm for the participation of Pathology has at times been rocky, but the project is now at the point that the Pediatric Pathologists are accepted members of the patient- and family-facing care team. The next phase of the project involves the Pathology faculty receiving coaching from Social Work and the Office of Patient Experience on additional skills involved in communication with patients and families.

Quality Improvement Curriculum

Under the leadership of Jeff Lott, FY2017 saw the successful completion of the second year of the organized Quality Improvement Curriculum, developed in conjunction with the Division of Pathology Education, for the first- and second-year resident classes. This year's curriculum incorporated a number of changes based on feedback from the prior year's participants, and ran from January through May 2017. In addition, Jeff and Brian Tolle laid additional groundwork for the curriculum this year by generating a list of potential projects based on information gleaned from meetings with key laboratory personnel and leadership in the Anatomic and Clinical Pathology laboratories. This approach had the goal of both boosting the potential for success for each project and better aligning the projects with Departmental and institutional priorities to ensure the best return on investment for the work. The result was three teams of four-to-five residents each pursuing the following projects:

- Improved documentation of problem cases/specimens and near-misses in Histology, with the goal of better identifying opportunities for better communication and process improvement.
- Improved tracking and processing of microscope slides during the period between when they are seen for diagnosis and when they are filed in the slide library, with the goal of more efficient location and delivery of slides when they need to be re-reviewed soon after diagnosis.
- Improved specimen classification and billing code assignment in the laboratory information system at the time of accessioning, with the goal of improving both the efficiency of diagnostic sign-out and ensuring that appropriate fee coding is rendered with the diagnosis of surgical pathology specimens.

The two QA Coordinators (Dayna Goerke and Andrea Arlen) were available to both guide the progress of the projects and to help with continuous improvement and plan-do-check-adjust (PDCA) cycles after the curriculum period and the initial project phases were finished. Some of the projects were submitted and accepted to the Michigan Medicine Quality Month poster session. A representative presentation of one project is attached for reference (Appendix 3).

Because of Jeff's assumption of the leadership role in the previously-discussed Laboratory Stewardship, Andrea Arlen and Dayna Goerke have assumed responsibility for organizing the QI Curriculum in preparation for the 2018 iteration. They are currently in the process of incorporating feedback from this year's sessions and planning the next installment. This year's course will also take into account the timing of our coming move to NCRC, because this will fall in the middle of the time period that the previous two installments took place.

Departmental Quality Plan

In collaboration with stakeholders from throughout the Department, and with input from the members of the Departmental Quality Council under the leadership of Dr. Myers, past and current DQHI personnel including Suzanne Butch, Lisa Brown, Brian Tolle, Andrea Arlen and Dayna Goerke helped to draft an updated Departmental Annual Quality Plan (Appendix 4). This document is a work in progress aimed at reflecting the quality-focused vision, goals, and strategies of the Department of Pathology, emphasizing the multiple participating clinical divisions, the MLabs Division, and the utilization of a Lean culture in our approach to quality assurance, quality improvement, and innovation from a quality standpoint. In addition, it is our goal to have the Plan fully reflect the Departmental commitment to patient- and family-centered care, to incorporate DQHI's work of innovation and transforming the patient experience, and to accurately convey the at times complex interrelation between DQHI and the quality assurance and quality improvement activities of the Clinical Divisions.

The two QA Coordinators also work to interface with and support operational quality in the Clinical and Anatomic Pathology Divisions, with the goal of performing as "expert consultants" to help the laboratory and clinical operations leadership apply the appropriate tools and solutions to their quality-related activities. This entails a number of actions such as assistance with completion of audits on issues like critical value reporting

in the clinical labs and assisting with root cause analyses for a number of events like lost or delayed specimens. One specific item that the Coordinators worked on in collaboration with Jeff Lott was the root cause and current state analysis for an issue of specimen accessioning as relates to the MLabs outreach portion of the Departmental mission, resulting in identification of a number of opportunities for streamlining the system. The interface of the QA Coordinators with clinical operations puts them solidly in roles as the “interface” between operational quality and innovation/value creation opportunities, and this element of their work is constantly emphasized as new projects and activities are presented to them. One future goal is to leverage the expertise of these individuals (and to augment this expertise with additional training) to facilitate a re-emphasis and consolidation of Lean principles in the various clinical laboratories. The vision includes a “Lean certification” for laboratory operations that could serve to ensure and support the use of this toolset in daily problem-solving and future operational planning.

Compliance and Regulatory Activities

Kellen Kangas continued his capable support and planning of Departmental compliance and licensing activities during FY2017. Under Kellen’s direction and with the support of multiple DQHI team members including Lisa Brown, a multi-talented Departmental team served as CAP inspectors for the laboratories at the University of Nebraska Medical Center (Nebraska Medicine). By all accounts, including feedback from the team leader David Keren, MD, this inspection was well-planned and well-executed, providing feedback for the inspected institution as well as learning opportunities for the inspection team.

In addition to our inspection of a peer institution, the Department of Pathology was inspected in early 2017 by representatives from the University of North Carolina. Again, Kellen Kangas provided leadership in preparation and hosting for this event in concert with other DQHI members and laboratory leadership throughout the Department. The inspection went very smoothly, and the response to citations/deficiencies was completed in short order after the inspection. Kellen received very good feedback on his organization and leadership in this endeavor as well.

Kellen continues his support of MasterControl, the Department’s electronic document control system. A new arrangement of support from the Division of Pathology Informatics has provided improved cross-coverage for the technical aspects of the program as well as for periods during which Kellen is away from his desk. This has resulted in fewer technical challenges and better overall performance of the system, which is used for mission-critical documentation and reference, particularly during CAP inspections. Kellen, Brian Tolle, Lisa Brown, and others were instrumental in ensuring compliance for influenza vaccinations for personnel throughout the Department. Finally, Kellen’s continued work on obtaining and maintaining cross-state licensure and certification supports the Department’s outreach mission through the MLabs Division, making it possible to solicit consultation and reference laboratory work from throughout the country.

Departmental Safety and Preparedness

FY2017 saw a collaboration between Duane Newton (Director of the Microbiology Laboratory and Associated Director of Clinical Pathology), Brian Tolle, and Scott Owens to investigate and propose the creation of a Safety and Preparedness Officer position in the Department. At base, this proposal addresses an increase in institutional expectations with regard to planning for natural and man-made disasters in the immediate vicinity as well as in the broader patient-care catchment basin of Michigan Medicine. Following the departure of Suzanne Butch from DQHI, a gap was left in coverage of Departmental safety and preparedness activities, which Suzanne had organized to a large extent even before joining the Division. These activities, including attending Departmental and institutional safety committee meetings fell to Brian Tolle in Suzanne’s absence, a workaround that became untenable with Brian’s other duties and the expanded institutional expectations for disaster drills and other events. Working with Duane Newton, Brian engaged the Operations Managers for Anatomic and Clinical Pathology to brainstorm solutions to this problem, settling ultimately after deliberation on

the creation of a new position of Safety and Preparedness Officer. It is envisioned that, with the appropriate expertise, structure, and organizational framework, this position can ultimately be leveraged to cover not just baseline institutional expectations, but also to incorporate “high-reliability organization” principles into the operational activities of the clinical, research and, potentially, educational, enterprises of the Department. The creation of this position was endorsed by the Departmental Quality Council and preparations are being made to bring the attendant FTE request to institutional leadership in September.

“Experimental” and Scholarly Activity

While much of DQHI’s activity is focused on expert support and consultation for operational quality as well as innovative thinking regarding new ways to increase value and affect the experience of Michigan Medicine patients and families from a Pathology platform, there are a few areas where we strive to incorporate expertise from throughout the University to experiment on new ways of thinking about the work and goals of the Department. One of these projects was outlined in last year’s annual report, and involved a collaboration with colleagues in Computer Science and Engineering to explore the use of machine learning and predictive modeling for test utilization (specifically, the prediction of test outcomes) in the setting of critical care medicine. This collaboration among Jenna Wiens, PhD (CSE Assistant Professor), Eli Sherman (CSE student), UI Balis, MD (Pathology Informatics), Hitinder Gurm, MD (Cardiology), and Scott Owens, MD (DQHI) resulted in a manuscript that was accepted for presentation at the Annual Symposium of the American Medical Informatics Association.

Brian Tolle and Scott Owens have also explored a collaboration with the Stamps School of Art and Design, specifically the Master’s Degree program in Integrative Design (MDes), under the leadership of John Marshall, MFA, PhD. This unique program entails cohorts of students from a variety of backgrounds who are taught through a project-oriented perspective how to apply design principles to a variety of “wicked problems” centered on complex issues that can actually be made worse by a traditional “true-false” approach to problem solving. The MDes program has been tackling healthcare-related issues, and its specific focus for the upcoming 2017-2018 cohort is on appropriate resource utilization in healthcare, a concentration that dovetails well with DQHI’s two main initiatives. The MDes program has numerous collaborators throughout Michigan Medicine and the broader University. We intend to present candidate projects to the cohort students near the end of September, 2017.

Finally, DQHI personnel have been vigorous proponents of the incorporation of Tableau software into the workflow of DQHI and the Departmental measurement of metrics. This software provides a user-friendly way to visualize and manipulate complex data, and has an established institutional presence, including with our close test utilization/stewardship collaborators Internal Medicine. We have worked with David McClintock, MD in Pathology Informatics to begin the process of exploring Tableau’s use in DQHI, and are hopeful that it will provide opportunities to more effectively share data with collaborators as well as to visualize Departmental data in the context of workflow and quality assurance.

Summary

FY 2017 was a busy and productive year for the DQHI team. Our two major initiatives are believed to be of key importance in continuing and improving the Department’s ability to provide reliable, value-added, safe, personalized, and patient-centered care to the lives entrusted to Michigan Medicine, the broader University of Michigan Health System, and our outreach clients who become Michigan Medicine patients through the MLabs Division. We look forward to continuing these initiatives and our work in supporting clinical operations, compliance and accreditation, document control, Departmental safety and preparedness, and innovation in how we care for our patients.

Appendix 1: Membership of Laboratory Stewardship Committee

Co-Chairs:

Christopher Petrilli, MD (Internal Medicine, Hospitalist; MPrOVE member)

Lee Schroeder, MD (Pathology, Associate Director of Clinical Chemistry)

Members:

Robert Chang, MD (Internal Medicine, Hospitalist; Associate Chief Medical Information Officer)

Lauren Heidemann, MD (Internal Medicine, Hospitalist)

David Keren, MD (Pathology; Director of Clinical Pathology)

Migdalia Musler (Associate Chief Financial Officer, University of Michigan Medical Group)

Scott Owens, MD (Pathology; Director, DQHI)

Lindsay Petty, MD (Internal Medicine, Infectious Diseases)

Sarah Taylor (Inpatient Nursing; Adjunct Clinical Instructor, School of Nursing)

Brian Tolle (Pathology; Manager, DQHI)

Standing Guest:

Matt Johnson (Project Manager, Internal Medicine Quality)

Appendix 2: Summary of data obtained for several tests being examined by the Laboratory Stewardship Committee. “Violations” refer to tests ordered inappropriately based on guidelines gleaned from “Choosing Wisely” and/or published studies by Procop, et al (Cleveland Clinic) and Konger, et al (Indianapolis VA Hospital). Additional data available on request.

Summary: Total Violations Per Test

Violations normalized for 1 year period					
Test	Guideline abr.	Source	Total Orders	Violations	% Violations
Comp	1 per 4 days	Indianap	49,667	38,586	78%
Basic	1 per 24 hours	Indianap	124,974	34,080	27%
Thyroid Hormones	Abn TSH before T4/T3, OP only	Indianap	79,592	29,395	37%
Lipid Panel	1 per 6 mos.	Clevelan	75,438	9,768	13%
Celiac Algorithm	Order algorithm	Universit	7,575	7,353	97%
Antinuclear Antibody	Pos screen before sub	Indianap	12,324	7,322	59%
Hemoglobin A1c	1 per 6 wks	Clevelan	48,011	1,468	3%
Thrombophilia Workup	Don't order for Inpatients	Universit	5,138	1,440	28%
Antinuclear Antibody	1 per 6 mos.	Indianap	10,605	216	2%
Rheumatoid Factor	1 per 6 mos. if norm	Indianap	6,005	186	3%
Hemochromatosis	Abn iron sat before HH	Clevelan	262	54	21%
Factor V Leiden	1 per lifetime	Indianap	465	8	2%
Hemochromatosis	1 per lifetime	Indianap	262	7	2%
Prothrombin Mutation	1 per lifetime	Indianap	351	6	2%
HLA-B27	1 per lifetime	Indianap	637	3	0.5%

Total violations observed, various time periods					
Test	Guideline abr.	Source	Total Orders	Violations	% Violations
Thyroid Hormones	Abn TSH before T4/T3, OP only	Indianap	318,366	117,580	37%
Lipid Panel	1 per 6 mos.	Clevelan	301,751	39,070	13%
Comp	1 per 4 days	Indianap	49,667	38,586	78%
Basic	1 per 24 hours	Indianap	124,974	34,080	27%
Celiac Algorithm	Order algorithm	Universit	8,206	7,966	97%
Antinuclear Antibody	Pos screen before sub	Indianap	12,324	7,322	59%
Hemoglobin A1c	1 per 6 wks	Clevelan	192,042	5,870	3%
Thrombophilia Workup	Don't order for Inpatients	Universit	5,138	1,440	28%
Rheumatoid Factor	1 per 6 mos. if norm	Indianap	24,021	742	3%
Antinuclear Antibody	1 per 6 mos.	Indianap	10,605	216	2%
Hemochromatosis	Abn iron sat before HH	Clevelan	1,047	215	21%
Factor V Leiden	1 per lifetime	Indianap	1,858	33	2%
Hemochromatosis	1 per lifetime	Indianap	1,047	26	2%
Prothrombin Mutation	1 per lifetime	Indianap	1,402	22	2%
HLA-B27	1 per lifetime	Indianap	1,912	9	0.5%



Appendix 3 – Representative final presentation by house officers of a QI Curriculum project (see Dr. Scott Owens for document)

Appendix 4 – Draft copy of Pathology Annual Quality Plan (see Dr. Scott Owens for document)

VA ANN ARBOR HEALTHCARE SYSTEM
Stephen W. Chensue, M.D., Ph.D.
Professor of Pathology
Chief, Pathology and Laboratory Medicine
VA Ann Arbor Healthcare System

The VA Ann Arbor Healthcare System (VAAHS) is a University of Michigan affiliated tertiary health care provider for veterans. The VAAHS is a member of Veterans Integrated Service Network (VISN) #10 serving the veteran population of Michigan, Ohio and Indiana. It is one of five Veterans Health Administration (VHA) tertiary care centers in this region. It is accredited by the Joint Commission and is an accredited cancer treatment center by the American College of Surgeons Commission on Cancer.

The VAAHS Pathology and Laboratory Medicine Service (PALMS) maintains a close relationship with the University Department of Pathology. There are currently five full-time, one part-time plus a fee basis consulting dermatopathologist. All pathologists in the VAAHS have medical school appointments and participate in university activities in a manner similar to other departmental sections. Recruitment for VAAHS pathologists is a joint activity and candidates are selected on the basis of academic performance and potential as well as professional competence similar to any departmental candidate. The VAAHS laboratory retains full accreditation by the College of American Pathologists. Likewise, its satellite laboratory at the Toledo Outpatient Clinic is currently fully CAP accredited. The VAAHS PALMS also provides specimen testing for community based outpatient clinics (CBOCs) in Flint and Jackson, Michigan and oversees all ancillary testing at these sites. These sites are fully accredited by the College of American Pathologists (CAP).

In addition to serving its local hospital and clinics, the VAAHS PALMS is currently performing all surgical pathology for the Aleda E. Lutz VA Medical Center, in Saginaw, and VA facilities in Battle Creek and Grand Rapids, Michigan. The Ann Arbor PALMS also performs all gynecologic cytopathology for Saginaw, Battle Creek, Detroit, Toledo, and all affiliated CBOCs. The department provides Telepathology services to the VA Northern Indiana Healthcare System. This program continues with significant success in improving efficiency and diagnostic quality. The VAAHS anatomic pathology section represents one of the most cost efficient within the VHA nationally.

Service	Volume	Target	% meeting
Surgical Pathology	14,450	Diagnostic report < 2 days	96.8
Frozen section	527	Diagnostic Report < 20 min	100
Autopsy	9	Report complete < 30 days	100
Non-gyn cytology	4,989	Diagnostic report non-gyn < 2 days	92.5

There is an extensive quality improvement program within Anatomic Pathology including regular consultations with colleagues at the University of Michigan as well as other outside consultants. There is a comprehensive quality assurance review with analyses of frozen section accuracy, amended diagnoses, surgical appropriateness, turnaround times, report quality, random retrospective review, and follow-up of positive cancer diagnoses. In addition, the VAAHS PALMS has taken the lead with regard to patient safety by implementing preop second review of pathology for patients about to undergo major resections or excisions.

While VHA policy does not require a targeted autopsy rate it encourages performing a maximum number sufficient to examine a variety of diseases and clinical circumstances. Autopsy protocols are submitted to clinical staff for comparison of anatomic diagnoses with to clinical findings. Each autopsy is also evaluated as to correlation of clinical and anatomic pathologic findings by review of the pathologist. Monthly reports are submitted to the VHA central office.

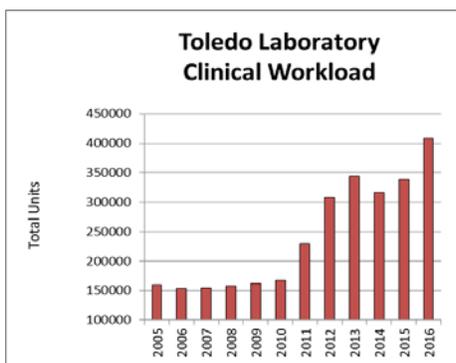
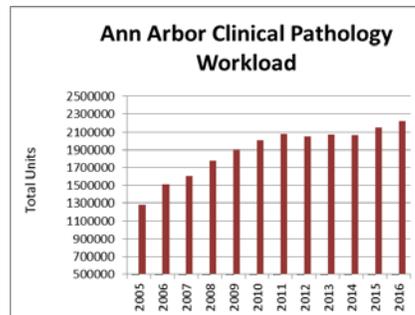
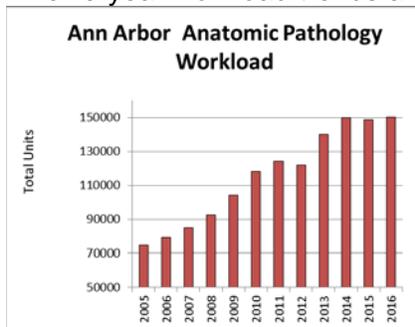
Both non-gynecologic and gynecologic diagnostic cytology is provided. Due to the increasing population of women veterans, gynecologic pathology is becoming an important component of the VAAHS workload. The VAAHS performs all PAP screening cytologies for the northern tier of VISN 10. The Ann Arbor VA laboratory is rated a VA “Center of Excellence” in cytology.

During the period of this report 3,260,869 clinical pathology tests were performed in the Ann Arbor and Toledo laboratories, approximately a 5% increase over the previous period. An extensive quality assurance program is in place monitoring all aspects of clinical laboratory activities, including proficiency testing, precision, turn-around-times, safety, education, and staff competency.

Clinical Pathology Workload	
Chemistry	1,922,209
Hematology/Coagulation/Urinalysis	525,393
Microbiology	119,906
Blood Bank	55,362
Phlebotomy	130,658
Point of Care	98,464
Toledo Outpatient Clinic Laboratory	408,877
Total	3,260,869

The VHA Decentralized Hospital Computer System (*VistA*) is recognized as the most fully integrated medical information system in the nation. Data storage for all components of pathology and the clinical laboratories is available from all VHA and DOD facilities via web-based charting. Digital images of selected patient surgical, cytopathology, and autopsy specimens can also be stored as part of the patient medical record and are accessible to clinicians. The VAAHS laboratories have continued to incorporate as much automation as possible employing state-of-the-art technologies to improve efficiency and informatics management.

Twelve-year workload trends are shown.



Presently, 2.5 resident training positions in the Department's program are supported with funds from the Department of Veterans Affairs. Residents serve monthly or biweekly rotations in Surgical Pathology, Autopsy Pathology, with access to special study programs in Surgical Pathology, Cytopathology and Digital Imaging. In surgical pathology the staff pathologists provide one-to-one mentoring during the surgical case sign out. The resident assigned to surgical pathology, usually a first year resident in training, has the opportunity to examine all of the specimens grossly and microscopically under close one-to-one mentoring by the staff pathologists. The resident interacts with the clinical teams. Weekly Urology Case Review Conferences are held by pathologist staff. The residents obtain a broad educational experience and aid in providing high quality medical care. Residents are invited to join in continuing educational activities in histopathology and cytopathology. Because of the closeness of various sections of the laboratory there is frequent consultation among the pathologists and the residents are involved throughout. Since the VAAHS is physically close to the University, the residents are expected to attend the appropriate teaching conferences at the University. VAAHS pathologist staff contribute to teaching of medical and graduate students at the University of Michigan.

Pathologists participate in various research studies and collaborate with a variety of investigators. The laboratory in general serves the VAAHS research mission by providing anatomic and clinical pathology technical support for approved clinical and basic research projects as needed.

Dr. Chensue has served as Chief of Service since March 2001. He serves on the VA/UoM Affiliation Council as well as local and national VA oversight committees. Staff pathologists at the VA Ann Arbor Healthcare System serve in various capacities involving administrative tasks for the University of Michigan, such as the University Affiliation Council, Resident Selection Committee, the Medical Student Admissions Committee, Graduate student preliminary exam and thesis committees, teaching faculty for post graduate courses in the medical school. At the VAAHS, the pathology staff members serve on all major committees involved with institutional policies and procedures.

In summary, the VAAHS Pathology and Laboratory Medicine Service is the major provider of Anatomic Pathology services for the northern tier of VISN 10. The primary goal of the department is to provide cost effective, high quality diagnostic services and appropriate care to the veteran patients. This is evidenced by its ranking as 19 of 140 VHA laboratories in terms of operational efficiency and its continuing accreditation by external review agencies such as the College of American Pathologists (CAP), the Joint Commission (JC) and the Food and Drug Administration (FDA). All staff members are privileged and evaluated in accordance with their training, experience, continuing education and participation in quality improvement activities. Within the service there is an extensive quality improvement program that integrates with that of the hospital as a whole. The affiliation with the University of Michigan serves to strengthen and improve the quality of patient care to our veterans. The teaching effort involving both residents and medical students is of benefit to the two institutions. The VAAHS PALMS is positioned to continue delivery of high quality service to Veteran patients as demand for medical care continues to mount in the next decades.

Division of Finance and Administration
Martin Lawlor
Director, Division of Finance and Administration

The Division of Finance and Administration, which is under the auspices of the Office of the Chair and directed by Mr. Martin A. Lawlor, Department Administrator, is responsible for the business, operational, and fiscal affairs of the Department of Pathology as mandated by the policies of the Chair, Michigan Medicine, and the University. In addition to directing this Division, Mr. Lawlor served on various departmental, Health System and University committees including the Ambulatory Care Operating Committee, and is co-Chair of the Cancer Center Ambulatory Care Coordinating Group. Mr. Lawlor continues to serve as Chair of the Executive Committee for the Joint Venture Hospital Laboratories. He is also completing a two-year term as Chair of the APC PDAS Committee spanning July 2015 – 2017.

Some key Divisional highlights orchestrated by Mr. Lawlor this academic year include:

- Negotiated a new five-year \$12-million-dollar contract to provide medical examiner services to Wayne County.
- Worked with the Wayne County Faculty and Staff to transition county employees to the Michigan Medicine Department of Pathology.
- Our team successfully completed the departmental audit and WCMEO audit and subsequent follow-ups in 2017.
- Presented financial management talks to the new residents and presented at the Pathology Education series.
- Holds weekly Open Position Review process to review all replacement and new positions, to provide timely response to Department need.
- Oversaw a 15% reduction in annual blood costs over the past 5 years.
- Continued planning space solutions for NCRC Buildings 30, 35, 36 and 60 and incorporating LEAN facility design principles.
- Successfully supported faculty and staff in the implementation of the Department's Point of Care testing menu at off-site clinics.
- Collaborated with Dr. Lee Schroeder to understand space, FTE and equipment needs to expand POC testing at UH and ACUs.
- Worked with Dr. David Keren to establish a multidisciplinary committee to improve phlebotomy services.
- Oversaw the PRR Team as they completed the design of the UH renovation space by June 30, 2017.
- Worked closely with Dr. Parkos and the Vice Chairs for a very successful recruitment year with many new recruits.

We saw our professional revenues increase once again this year. Pathology began professional component billing for Clinical Pathology outpatient services in 4th quarter of 2010, and FY17 net revenue for component billing was \$1,081,959. Michigan Medicine, Department of Pathology was the first group to institute professional component billing in the state of Michigan.

ADMINISTRATIVE SUPPORT CENTER

Administrative Support Center/Pathology Laboratories

The Administrative Support Center for Pathology Laboratories is responsible for the preparation and monitoring of all Hospital laboratories' revenue, expense and capital budgets, and personnel and payroll systems. During this period, total laboratory expenditures were \$126 Million. Pathology is responsible for 10.0% of total Hospital Gross Revenue and 4.0% of total expense. As detailed below, Mr. Thomas Morrow and Kristina Martin are responsible for administration of the Clinical Pathology Laboratories, Ms. Christine Rigney for the

administration of the Anatomic Pathology Laboratories, and Mr. Kellen Kangas for maintaining licensure and accreditation for our laboratories.

Ms. Kristina Martin, Clinical Pathology Operations Manager, oversees our blood donations which have allowed us to improve our partnership with the American Red Cross and set better contract terms. Kristina has assisted with promoting Lean concepts by teaching quarterly basic lean classes and leading monthly gemba walks within the labs. She has assisted in the planning for the Pathology Relocation and Renovation project along with other institutional ambulatory care building projects. Kristina is responsible for the Clinical Pathology Operations & Laboratory Communication Committee meetings. She coordinates subsequent projects resultant from these discussions. Kristina also serves as the department liaison with nursing and the Office of Clinical Affairs.

Mr. Thomas Morrow is the Administrative Manager for the Clinical Pathology Laboratories. The Clinical Pathology Laboratory activity was above last fiscal year's levels, as was Clinical Pathology revenue. Mr. Morrow was instrumental in putting together submissions and ROIs to get our capital needs met, as well as leading LEAN workflow improvements. Several long-term contracts with major vendors like Mayo Medical Laboratories, Ventana and Atlas Medical Systems were re-negotiated under Mr. Morrow's supervision this year.

Ms. Christine Rigney, Anatomic Pathology Operations Administrator for Michigan Medicine, oversees the Anatomic Pathology Laboratories and Autopsy & Forensics Services. All services are provided in the University Hospital, Cardiovascular Center, Children's and Women's Hospital and East Ann Arbor Ambulatory Surgery Center. Ms. Rigney is the AP division lead for facilities, building, renovation and process improvement projects. Included in these projects are the relocation of AP laboratories to NCRC scheduled for 2018, and the Brighton Health Center, 23 hour stay surgical center which will open in 2018.

Ms. Rigney continues to participate and represent Anatomic Pathology with patient safety issues, LEAN projects and to process improvement initiatives with partners such as the Cancer Center, Operating Rooms, medical procedure units, Office of Clinical Safety, Biomedical Engineering and Hospital Finance. She represents Pathology on the Quality Month Committee, Pathology's Diversity, Equity and Inclusion Committee, Departmental Social Media Committee and Pathology's Patient and Family Centered Care Council.

Ms. Christine Baker is the project manager for the Pathology Relocation and Renovation (PRR) Project and is responsible for facilitating and orchestrating the project tasks for the Pathology Department. She leads the planning, design, and activation activities, and works closely with colleagues in Michigan Medicine Facilities and on the design team to ensure the project is on schedule, within scope and on budget. The PRR Project has built an extensive focus on integrating Lean Facility Design tools into the design process, and is the first full-scale Lean Facility Design project at Michigan Medicine. This year, the PRR Project completed design of the nearly 140,000 square feet of laboratory and support spaces at NCRC and transitioned into Activation Planning. The construction activities are underway and anticipated completion is February 2018. In addition, Ms. Baker and the PRR team began the design process for the spaces to be renovated at University Hospital and University Hospital-South, including design of an integrated Core Laboratory and expansion of the Blood Bank and Apheresis units.

Mr. Kellen Kangas, Compliance Manager, is responsible for maintenance of all department and hospital laboratory licensure and accreditation for JC, CAP, CLIA, COLA and MDPH including coordination of external CAP inspection training and survey teams

Office of Academic and Business Affairs—Medical School

Mr. David Golden is responsible for all administrative operations associated with the Department, including management of department finances (budgets, contracts, research grants, forecasts and analysis), as well as clinical billing (professional and technical front end operations), in collaboration with the Chair and Administrative Director. He also implements and directs strategic goals for Medical School operations including development of policy and business plans, management of faculty compensation and departmental

funds, and use of departmental facilities, including modifications, renovations and reassignment of department space.

Mr. Golden managed the Michigan Medicine and All Funds expenditures and forecast processes. Total Medical School All Funds expenditures for FY 2017 (Pathology and MCTP) were \$70.4 Million and Hospital expenditures were \$126 Million. He also developed the 2018 forecast for the Hospital, Pathology and the MCTP. Mr. Golden managed the pre- and post-award research enterprise for both Pathology and the MCTP. There were 154 research proposals submitted to external sponsors this year. 57 of these proposals were submitted to the NIH. Committed awards for FY 2017 were \$29.3 Million. A decrease of 7.1% compared to FY 2016 committed awards. This is the result of declines in committed awards for the MCTP in FY 2016. Actual sponsored research expenditures were \$33.3 Million. A 5.6% increase when compared to FY 2016 actual research expenditures. Overall, the academic side of the Department saw a 10.4% increase (\$5.7 Million) in the following revenue components: net patient care, federal and non-federal research and other revenue (Washtenaw and Wayne County contracts, Royalties, rebill activities, operating transfers) from FY 2016 to FY 2017. Overall gross charges for Pathology's group practice were up 5.4% (\$3.8M). He continues to manage and mentor Karen Giles, Mary Green, John Harris, Laura Labut, Michael McVicker, Nancy Parker, Thad Schork and Christine Shaneyfelt in their analytic and managerial roles.

Ms. Nancy Parker is responsible for all front-end (charge capture) billing operations. Hospital technical gross revenue for FY2017 was \$748M, compared to \$697.4M in FY2016, an increase of 7.2%. Professional fee gross charges were \$73.8M. Ms. Parker is responsible for send-out billing, component billing, MLabs client statements, ensuring the accuracy of the daily billing files, correction of all errors with the appropriate Hospital department and responding to all questions regarding interdepartmental, MLabs or Hospital patient billings.

Mr. John Harris is responsible for oversight of the accounting and financial staff supporting our research programs and the daily management of post award process. Extramural sponsored expenditures for FY 2017 amounted to \$33.3 Million. Mr. Harris manages a staff of four accountants and one procurement specialist. This year, Mr. Harris and his team began managing all faculty and staff effort and funding changes. He also provides many *ad hoc* financial reports related to Medical School and clinical operations.

Mr. J. Thaddeus Schork served as the lead administrative staff member for facilities (building maintenance and renovation), including major renovation projects initiated in the University Hospital and other buildings occupied by Pathology. This is a role that will begin to transition to Mr. Mike McVicker in the FY 2018.

Mr. McVicker is responsible for Medical School financial reporting as well preparing the Medical School budget for the Department. Mr. McVicker also plays a lead role in the administration of our Washtenaw and Wayne County Medical Examiner contracts. He has also taken the lead on the development of an authorization process for molecular diagnostics testing. As mentioned, Mr. McVicker will also be assuming responsibility for space management and major renovation projects initiated in the University Hospital and other buildings occupied by Pathology.

Ms. Christine Shaneyfelt serves as the primary contact for HHC Finance. This includes completing the Hospital budget and developing and managing the departmental capital equipment process. In addition, Ms. Shaneyfelt has prepared a number of financial analyses including profit and loss statements, ad hoc reports, faculty incentive analysis and financial performance reports for both Anatomic and Clinical Pathology divisions.

Human Resources, Faculty Affairs and Education

The team lead for this area is Mr. Kevin Newman, with support from the HR Solutions Center. Our Staff Human Resources Team provides support for Pathology's hospital laboratories (approximately 600 FTEs) and Medical School support staff, including our research programs (approximately 200 FTEs).

Faculty Affairs is the responsibility of Ms. Sarah Dudley-Short, who coordinates appointments, reappointments and promotions for our 162 active faculty. She also is responsible for the 24 supplemental appointments in the Department.

Ms. Marie Goldner is responsible for the Education Office activities including the Residency and Fellowship Training Programs (28 residents and 22 fellows in 9 ACGME and 7 non-ACGME programs) and the Medical Student Education Teaching Programs for the M1 and M2 laboratories and the M4 Clerkship Program.

Ms. Laura Labut is responsible for administration of the Molecular and Cellular Pathology PhD program with 23 students actively pursuing their doctoral degrees. Management responsibilities are focused around curriculum management (including the Research Seminar Series), academic records, budget planning and financial operations, recruitment, and program activities such as the annual departmental research symposium. Ms. Labut is the administrator for the department's three NIH training grants (PIs Steven Kunkel, PhD; Nicholas Lukacs, PhD; Andrew Lieberman, MD, PhD, Zaneta Nikolovska-Coleska, PhD) which support 8 pre- and 8 post-doctoral trainees. Ms. Labut performs the human resource functions for the department's graduate students (30 including 7 non-MCP students with Pathology mentors) and training grant trainees (8).

Office of the Chair

Ms. Angela Suliman is the project manager for the web editorial board as well as the conference coordinator for the Advances in Forensic Medicine & Pathology conference, which was held for its eighth year. In addition, she also provides support to the Administrator, Mr. Martin Lawlor, including scheduling, travel arrangements, data collection, and event planning in addition to supervising and managing activities in the Chair's office. She oversees the reconciliation of the department P-Cards, the renewal of medical licenses and payment of all CME requests for faculty and house officers. She has also continued as the facilitator for Cancer Center Ambulatory Care Coordinating Group.

Ms. Vashni Santee provides support to the Chair of the Department including the management of his calendar, the completion of travel arrangements, the preparation of correspondence including all materials related to the many committees chaired or attended by Dr. Parkos. In addition, Vashni oversees event planning associated with the Chairs' office. She is part of the editorial team that publishes the department's annual magazine, *Inside Pathology* and is a point of contact for other communication matters from the Office of the Chair for the website and annual report.

Ms. Michal Warner is responsible for processing all of the CME requests for the faculty and house officers in addition to reconciling the P-Cards for the Chair and Administrator. Ms. Warner also manages the conference room calendars and provides back-up support for Ms. Santee and Ms. Suliman.

Pathology Professional Fee Billing Office

Ms. Holly Daul continues in her role as Revenue Cycle Director of Professional Billing for the specialties of Pathology, Radiology, Radiation Oncology, Physical Medicine, and Neurology. She supervises 35 FTE staff and is responsible for accounts receivable management and collections of professional fees for services provided by Department of Pathology faculty. Ms. Daul serves on several physician professional fee committees and is one of the Process Owners for MiChart.