DEPARTMENT OF PATHOLOGY
UNIVERSITY OF MICHIGAN HEALTH SYSTEM

Annual Report
2015- 2016

TABLE OF CONTENTS:

Click on the chapter to go to that section.

2015-16 Department of Pathology Faculty

* In all there are 189 Department of Pathology faculty members, including Emeritus and Adjunct Professors. A fraction are pictured here on the steps outside the Medical Science Building II in the fall of 2016.

1. Charles Parkos, MD, PhD
2. Kathleen Cho, MD
3. Jeffrey Myers, MD
4. Scott Owens, MD
5. David Keren, MD
6. Ulysses Balis, MD
7. Arul Chinnaiyan, MD, PhD
8. David Lucas, MD
9. Barbara McKenna, MD
10. Jonathan McHugh, MD
11. Asma Nusrat, MD
12. William Carson, PhD
13. Monique O'Leary, PhD
14. Celina Kleer, MD
15. Rohit Mehra, MD
16. Colin Duckett, PhD
17. Michael Garratt, PhD
18. Charles Ross, MD
19. Joel Greenson, MD
20. Gabriel Nunez, MD
21. Richard Miller, MD, PhD
22. Sean Li, MD, PhD
23. Veronica Azcutia Criado, PhD
24. Jiaqi Shi, MD, PhD
25. Chisa Yamada, MD
26. Karen Choi, MD
27. Zaneta Nikolovska-Coleska, PhD
28. Robertson Davenport, MD
29. Andrew Muntean, PhD
30. Evan Farkash, MD, PhD
31. Sriram Venneti, MD, PhD
32. Rajan Dewar, PhD, MBBS
33. Shuling Fan, MD
34. Allecia Wilson, MD
35. Jeffrey Jentzen, MD, PhD
36. Alexey Nesvizhskii, PhD
37. xx (Lee Schroeder, MD, PhD)???
38. Donald Giacherio, PhD
39. Henry Appelman, MD
40. Rolan Hilgarth, PhD
41. Anuska Andjelkovic-Zochowski, MD, PhD
42. Martin Lawlor

CHAIR'S REPORT

Charles A. Parkos, MD, PhD

Carl V. Weller Professor and Chair

The Department of Pathology had an extraordinarily successful and busy 2016. During this time, the Medical School and Health System underwent many changes in leadership and organizational structure. This new structure involved Dr. Marschall Runge assuming the positions of Dean and EVPMA with Dr. James Woolliscroft stepping down in his capacity as Dean. New positions were created including a Chief Academic Officer, Chief Scientific Officer and Executive Vice Dean for Clinical Affairs. Dr. David Spahlinger was named the Executive Vice Dean for Clinical Affairs in the Medical School and President of the U-M Clinical Enterprise and Dr. Carol Bradford was appointed as the new Executive Vice Dean for Academic Affairs. A search to identify a scientific leader to assume the role of Chief Scientific Officer is underway. Drs. Runge and Spahlinger unveiled an ambitious plan to expand the UMHS 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. Other big institutional changes included merging Medical Center Information Technology (MCIT) and Medical School Information Services (MSIS) to form Health Information Technology and Services (HITS). There are many other ongoing important senior leadership recruitments at the time of this report that I am both optimistic and enthusiastic about and look forward to working with the new leadership moving forward.

During this past year, there were many outstanding awards/accomplishments/recognitions in the Department of Pathology on a national/regional level, some of which include:

Drs. Kathleen Cho and Laurie McCauley were elected into the National Academy of Medicine.
Dr. David Lombard was inducted into the American Society for Clinical Investigation.
Dr. Asma Nusrat was elected as the Vice President and then President of the American Society for Investigative Pathology starting in July of 2016.
Dr. David Keren received the Life Trustee Award for his years of service from the American Board of Pathology.
Dr. Sriram Venneti received the Kimmel Scholar Award for his contribution to brain tumor research.
Dr. Ulysses Balis received the American Joint Committee on Cancer (AJCC) Service Award, presented on September 9, 2016 at AJCC General Session.
Dr. Sriram Venneti received the Doris Duke Charitable Foundation 19th Clinical Scientists Award.
Dr. Jeffrey Hodgin received the Gloria Gallo Research Award, given by Renal Pathology Society.
Dr. Ulysses Balis was appointed to the Database and Information Technology Advisory Committee of the American Board of Medical Specialties.
The Wayne County Medical Examiner's Office earned national accreditation for the first time in 40 years.
Dr. Laura Cooling received the ASFA 2016 Lecturer Award.
As part of an AACR team, Dr. Chinnaiyan was invited to Washington DC to meet with FDA to discuss regulation of NGS tests and provide advice on research strategies aimed at advancing cancer research in line with Vice President Biden's "moon shot vision to cure cancer".
Dr. Carl Schmidt, Wayne County Examiner, was featured in New York Times Magazine, "The Living Dead", for his research on microscopic bacteria that bloom on our bodies after death.

In addition, the University of Michigan rewarded faculty and administrative staff for many accomplishments:

Dr. Scott Owens was the recipient of the Elizabeth Crosby Award (Galens Medical Society) for medical student teaching.
Dr. Alexey Nesvizhskii was one of eight outstanding faculty honored in January by the University of Michigan Endowment for Basic Sciences for excellence in classroom teaching, mentoring, and leadership in the advancement of the teaching mission.
Dr. Richard Lieberman received the Outstanding Consultant Award by Ob/Gyn Residents.
Dr. Henry Appelman was awarded the prestigious Lifetime Achievement Award in Medical Education.
Dr. Eric Fearon was awarded the Distinguished Faculty Lectureship Award in Biomedical Research.
Dr. Lauren Smith was named the UMHS Hospital Ethicist, effective January 1, 2016.

FY16 brought new growth to our faculty, in part to keep up with increased clinical demands and to expand our research mission. During this time, we bade fond farewells to Daniel Ramon, Nathaniel (Nate) Bailey, Maria (Ken) Figueroa and Michael (Mike) Roh. Diane Rolston retired from cytogenetics but will continue service to the department as an active Emeritus faculty. We have recruited 20 new faculty members since July 1, 2015, including:

Kristine Konopka, MD (Pulmonary Pathology), July, 2015
Hemamalina Ketha, PhD (Chemical Pathology (MS testing), July, 2015
Jiaqui Shi, MD, PhD (GI Pathology), July, 2015
Young-Tae Lee, PhD (Epigenetics), July, 2015
Kathryn McFadden, MD (Neuropathology), August, 2015
Catherine Ptaschinksi, PhD (Immunology), September, 2015
Rajan Dewar, MBBS, PhD (Hematology), September, 2015
Muhammad Aslam, MBBS (GI Biology), October, 2015
Veronica Azcutia Criado, PhD (Mucosal Immunology), October, 2015
Monique O'Leary, PhD (Epithelial Pathobiology), October, 2015
Marcin Cieslik, PhD (Translational Pathology), November, 2015
Vasuki Anandan, MBBS (Inflammation & Immunology), May, 2016
Seema Sethi MD (Inflammation & Immunology), July, 2016
Theodore Brown, MD (Forensic Pathology), September, 2016
Sarah Choi, MD, PhD (Hematopathology), September, 2016
Julia Dahl MD (MLabs), September, 2016
Jean Tien, PhD (Cancer Biology), September, 2016

With these new additions, our faculty now is the largest it has ever been and is the third largest at U-M. Nearly two years ago, I appointed Drs. Jeff Myers and Kathy Cho as Vice Chairs to help oversee Clinical and Academic Affairs respectively. With the appointment of David Lucas as Director of Anatomic Pathology, effective December 1, 2015, Jeff stepped down as AP Director to focus on his role as Vice Chair for Clinical Affairs and Quality. While Jeff continues to direct MLabs, the recent recruitment of Dr. Julia Dahl as Associate Director of MLabs has put in place important leadership transition planning moving forward. Likewise, Dr. Cho has done an outstanding job as Vice Chair for Academic Affairs, facilitated by her extensive leadership experience in pathology as well as her strong commitment to faculty and trainee mentoring.

Other highlights that I am very proud to acknowledge are the multiple new leadership appointments and professorships to our Faculty:

Dr. Thomas Giordano was named the Henry Clay Bryant Professor, effective July 2015.
Dr. Thomas Giordano, Director of Molecular and Genomic Pathology, effective July 2015
Dr. Hemamalini Ketha, Director of Toxicology and Drug Analysis and Associate Director of Clinical Chemistry Laboratory, effective July 2015
Dr. Rajan Dewar, Director of Clinical Hematology Laboratory, effective September 2015

Dr. Madelyn Lew, Director of Medical Student Education, October 2015
Dr. David Lucas, Director of Anatomic Pathology, effective December 2015
Dr. Jon McHugh, Director of Surgical Pathology, effective December 2015
Dr. Lauren Smith, Director of Hematopathology, effective January 2016
Dr. David Lucas was named the A. James French Professor, effective February 2016
Dr. Angela Wu, Faculty Lead for Pathology's Diversity, Equity and Inclusion Committee, February 2016
Dr. Duane Newton, Clinical Activation Director for PRR, May 2016
Dr. Sean Li, Asst. Director of Transfusion Medicine and Director of the Blood Bank Laboratory, August 2016
Dr. Judy Pang, interim Cytopathology Director, effective September 2016
Dr. Julia Dahl, Assistant Clinical Professor and Associate Director of MLabs, effective September 2016
Dr. Eric Fearon was named Director of UM's Comprehensive Cancer Center, September 2016
Dr. Allecia Wilson, Program Director for the Anatomic and Clinical Pathology Residency Program, September 2016
Dr. Chisa Yamada, Blood Bank Fellowship Director, July 2017

This past year has been tremendously busy for our departmental promotions committee that continues to do a fantastic job in providing thoughtful reviews and advice to our faculty as they are being considered for promotion. With 16 promotion packets processed this past year, this is one of the largest group of faculty to be considered for promotion ever! I thank Dr. Cho, the committee, and staff for all of their hard work on this successful, rigorous and vital departmental function.

In terms of new programs and leadership moving forward, the new Division of Quality and Safety has done a great job enhancing value in the department and larger health system through efforts that have helped identify and provide solutions to problems related to quality and safety. Under the directorship of Dr. Scott Owens and the mentorship of Jeff Myers, the Division of Quality and Safety has instituted successful new coursework for pathology residents as well as multiple quality improvements and projects. We are confident that pathology quality and safety initiatives will continue to help set new standards in value-added healthcare within in our department and the larger health system moving forward.

Through the hard work of many staff, faculty and project leaders, the space design was completed and demolition of the old NCRC space was just completed at the time of this report. The 18-month construction-activation phase will now commence, and our department is on track for occupancy in the spring of 2018. This $160M renovation project will include space to house non-stat clinical activities for both Anatomic and Clinical pathology as well as Informatics, MLabs and administration. Offices for most of our faculty and suites for our trainees will also be located at NCRC. This past summer, we began planning the renovation of ~45,000sf of space at the University Hospital to house a new Core Laboratory as well as specific hospital-based functions. The UH renovation will be complex as core lab functions will need to be functional during the renovation process. So far the planning team has done a fantastic job! This venture will greatly facilitate the ability of Pathology to provide the highest level of support to UMHS patients and providers. 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 UMHS services, such as transplantation and oncology. Co-location with the UMMS Biorepository will also facilitate activities central to the goal of positioning UMHS as a leader in precision medicine.

The Department of Pathology remains in a very strong financial position; current assets will continue to enable us to recruit new faculty and support the outstanding academics that separate U-M from the rest. Our contributions to the health system continue to be robust. In particular, Pathology accounted for 10.0% of total hospital gross revenue, but only 4.1% of total expense in FY16. Our surgical pathology service continues to grow with an increase of 10.2% in cases that includes an astounding 24.4% increase in consult cases. Given these caseloads, there was a corresponding 8.9% increase in faculty productivity as measured by work-relative value units (RVUs). The clinical laboratories continue to perform increasing numbers of sophisticated tests. In FY16, there were 5.8 million billed tests resulting in an 8.9% increase in gross charges. These respectable

increases have come with only 2.8% and 4.9% 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, an ongoing 4.5M in annual savings on blood products has been achieved since 2012. Other notable successes in the clinical service arena include continued progress on SOFT implementation through continuous team effort on days, weekends and nights led by Dr. Ul Balis, Kathy Davis and the rest of our IT Division.

The Wayne County Medical Examiner's office has been managed by U-M pathology since Oct., 2014 and has been a fantastic addition to our department. This past year autopsy numbers at Wayne CME increased 3.1% to 2784 autopsies. Major successes include Wayne County ME's successful accreditation by the national association of medical examiners (NAME) for the first time in 40 years. This was achieved through hard work from staff and faculty at Wayne County, that was facilitated in part by new faculty recruitment that helped adjust the numbers of autopsies per pathologist as well as to support continued academic development of forensic faculty. Wayne County Medical Examiner's Office is led by Chief Medical Examiner, Dr. Carl Schmidt. Other key members of this team are:

Avneesh Gupta, MD, Assistant Medical Examiner
Leigh Hlavaty MD, Deputy Chief Medical Examiner
Francisco Diaz MD, Assistant Medical Examiner
Kilak Kesha MBBS, Assistant Medical Examiner
Chantel Njiwaji MD, Assistant Medical Examiner
Leonardo Roquero MD, Assistant Medical Examiner
Lok Man Sung MD, Assistant Medical Examiner
David Moons MD, Assistant Medical Examiner (July 1, 2016)
Theodore Brown MD, Assistant Medical Examiner (July 1, 2016)

In addition to being Vice Chair for Clinical Affairs and Quality, Dr. Jeffrey Myers continues to serve as Director of our MLabs outreach program. Now in its 30th year, MLabs has shown continued growth that now includes 738 accounts providing service to 366 physician offices, 6 Nursing Homes, 80 Hospital facilities and 63 reference laboratory/commercial services throughout Michigan. Dr. Myers has done an outstanding job integrating MLabs into our tripartite mission as a leader in the areas of molecular diagnostics and precision medicine and has very recently recruited Dr. Julia Dahl as an Associate Director of MLabs in a pro-active leadership transition plan to grow MLabs in way that complements pathology's academic mission at U-M.

In late winter of 2015, the department also entered into a plan to transition financial support of Paradigm, a nonprofit startup company that offers state of the art next generation sequencing-based genomics analyses of human tumors, to a for-profit entity. In partnership with the Michigan Health Corporation and International Genomics Consortium, Paradigm was transitioned to a for profit entity with UMHS and Pathology remaining significant stock holdings in the new company.

Pathology's basic, translational and clinical research programs continue to thrive and funding remains very strong, despite the continuation of a challenging funding climate. Dr. Asma Nusrat, Director of the Division of Experimental Pathology, has done a fantastic job helping to integrate our research programs and mentoring research faculty in her first year and a half at U-M. Pathology research funding continues to be very impressive with $31.9 million in current committed EP grants. The vast majority of this funding is from federal sources with an additional component of funds from non-profit organizations and industry. While departmental external research support has remained fairly flat, this is impressive given a very challenging funding environment and has increased our national rankings in research funding over the past year. Several Pathology faculty members remain actively involved in the Medical School's Fast Forward Initiative, led by Senior Associate Dean for Research, Dr. Steven Kunkel, which began its third year in July, 2015. These include Drs. Andy Lieberman, Alexey Nesvizhskii (protein folding diseases), Drs. James Varani, Naohiro Inohara, Gabriel Nunez, and Michael Bachman (host microbiome). In order to sustain ongoing research for faculty members with funding gaps in this extremely challenging funding environment, the department established guidelines for obtaining bridging support. Notable research awards and new investigator grants include NIH grants totaling over $23.6M;

nine Department of Defense grants and subcontracts totaling over $2.0M; and foundation, society and private grants totaling over $6.3M. Dr. Nick Lukacs has been named the Scientific Director of the Mary H. Weiser Food Allergy Center which has received $10M as the first installment of a $30M+ endowment. Recruitment efforts are underway to identify established mid- to senior- career mucosal immunologists.

The Michigan Center for Translational Pathology (MCTP), under the direction of Dr. Arul Chinnaiyan, continues to be an international leader in the discovery and characterization of disease biomarkers and therapeutics using an integrated, multi-disciplinary approach as well as helping to establish a new paradigm of bringing personalized medicine to routine clinical care through the use of high throughput sequencing. There were many high impact publications and media exposure that provided high visibility to MCTP and U-M pathology within the molecular oncology space. Arul and his colleagues continue to bring personalized medicine to clinical care through the Michigan Oncology Sequencing Center (MI-ONCOSEQ). The team recently developed a targeted panel called OncoSeq that utilizes in solution hybrid-capture methods focusing "sequencing bandwidth" on the protein coding exons in ~1700 target gene sets to further help identify targetable pathways for treating cancer patients. In January 2016, fifteen distinguished American Association for Cancer Research (AACR) leadership and members, including Dr. Arul Chinnaiyan, from 10 cancer centers and medical institutions all across the U.S. (from nine different states) participated in meetings with top officials from the Food and Drug Administration (FDA) to discuss FDA's current thinking on how the agency might regulate NGS-based tests, as well as interrelated topics, such as laboratory developed tests (LDTs) and companion diagnostics for cancer therapies. The AACR team was invited to a separate meeting with senior staffers for Vice President Joe Biden to discuss ways the Vice President can further his commitment to cancer research.

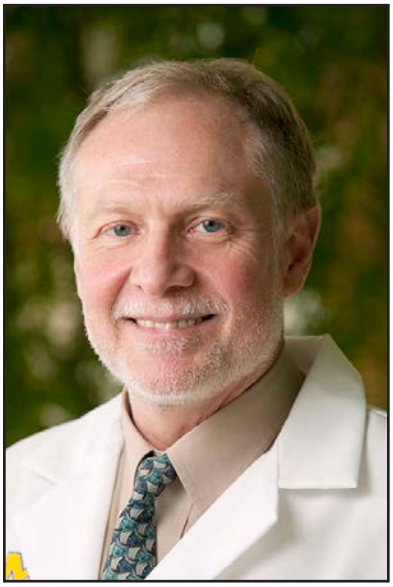
The Division of Molecular and Genomic Pathology (DMGP), directed by Dr. Thomas Giordano, the Henry Clay Bryant Professor of Pathology, had a great year that aims to create a broad vision across the department's various clinical molecular pathology laboratories as well as transitioning the precision oncology assays developed by the Michigan Center for Translational Pathology (MCTP) from research to clinical assays. 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 departmental 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. Notable efforts to build unity and progress in DMGP include team building efforts across U-M laboratories, survey of U-M oncologist molecular testing needs, ongoing monitoring of FDA regulation of LDTs, standardizing laboratory work culture, collaboration with MLabs and commercial laboratories and faculty recruitment.

Our educational programs in Pathology are among the best in the country (#2 among large public universities, and #7 overall) thanks to an outstanding leadership team lead by Dr. Barbara McKenna as director of the Division of Pathology Education. I have had the pleasure of meeting residency applicants as well as regular meetings with our current residents and fellows and am continually impressed with their quality, accomplishments and diverse backgrounds. Our match results were nothing less than spectacular, filling all six available residency positions with excellent trainees. 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. I am pleased to announce the recent appointment of Dr. Allecia (Lisa) Wilson as the new Director of the Pathology Residency Program who will work closely with Dr. McKenna who is now the Associate Program Director. Similarly, Dr. Madelyn Lew was appointed as Director of the Medical School Pathology Curriculum, and she is actively engaged in transitioning to the new Medical School curriculum as well as being part of a group of pathology faculty working to revise the M4 rotation for the new curriculum. The M4 Pathology Elective experience under the direction of Dr. Andrew Sciallis has undergone improvements tailored to the career goals of rotating students. I am pleased to announce that Drs. Nikolovska-Coleska (Director of our Molecular and Cellular Pathology Graduate Program) and A. Lieberman were successful in obtaining NIH T32 funding to educate next-generation Ph.D. scientists working at the interface of basic biomedical science and clinical research. The Molecular and Cellular Pathology (MCP) Graduate Program 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. Congratulations to Dr. Nikolovska-Coleska

for a successful Institutional graduate program review!

With all of the changes in UMHS leadership, the financial performance of the health system in FY16 remained strong compared to FY15. The Hospital and Health Centers (HHC) ended FY16 with an operating margin of $173.6M and finished well above the budgeted and forecasted amount of $116.1M. Ambulatory care continues to be a major and increasing source of revenue, with an operating margin of $251.7M compared to $184.6M in FY15. While the Medical School budgeted a predicted loss of $10.7M, recent one-time equity transfers including $110.3M related to the initial investment in the clinical investment fund catapulted the year-end total margin to a $56.8M loss. Without the $110.3M in clinical investment, the Medical School had a total positive margin of $53.5M. Overall, improved performance is attributable to strong patient care revenues, margin sharing, and philanthropy.

In closing, I would like to thank the faculty, trainees, and staff for helping to make this past year a huge success. None of this progress would have been possible without the hard work and team spirit of everyone in our department. This is one of the very top departments in the U-S and abroad, and a key ingredient to our success is the overarching spirit of collegiality and collaboration. Despite the departure of a few valued faculty members, our leadership team remains outstanding. Our vice chairs, Jeff Myers and Kathy Cho as well as our Division Directors (Drs. Keren, McKenna, Owens, Balis, Kunkel, Nusrat, Giordano, Lucas and Marty Lawlor) are second to none, and I look forward to working closely with all of them moving forward. We are also fortunate to have an outstanding Finance and Administration team and thank Marty Lawlor and David Golden for all of their hard work in managing a complex Division of Administration and Finance. Finally, I'd like to thank Vashni Santee, Angie Suliman, and Michal Warner, who have done an outstanding job providing administrative support in the Chair's office.



DIVISION OF ANATOMIC PATHOLOGY

David R. Lucas, MD

A. James French Professor and Director, Anatomic Pathology

OVERVIEW

Anatomic Pathology had a very productive and successful year across all three missions (patient care, research, and education). Demand for clinical services remained strong across the practice, accounting for record growths in surgical cases (exceeding 100,000 for the first time), outside consultation cases, and autopsies. 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 from University of Michigan medical and dental students, residents, fellows, graduate and post-graduate students, and continuing medical education participants.

Dr. Kristine Konopka joined the faculty in July 2015 as Assistant Professor in the clinical track with primary responsibilities in thoracic and surgical pathology. She also plays an important role in medical student education.

Dr. Kate McFadden joined the faculty in August 2015 as Associate Professor in the clinical track. Although her primary responsibility is neuropathology, she also participates in our pediatric and perinatal practice.

Dr. Leonardo Roquero joined the faculty in July 2015 as Clinical Lecturer in forensic pathology at Wayne Country Medical Examiner Office. He was hired on a temporary basis to cover **Dr. Avneesh Gupta,** who will complete a neuropathology fellowship in June 2017.

Dr. Jiaqi Shi joined the faculty in July 2015 as Assistant Professor in the clinical track. In addition to contributing to the GI practice and Room 1, she participates in pancreatic cancer research.

Dr. Rohit Mehra was promoted to Associate Professor (effective September 1).

Dr. Chantel Njiwaji was promoted to Assistant Professor (in effect).

Drs. Asma Nusrat, Tom Giordano, and Dave Lucas became endowed professors.

CLINICAL ACTIVITIES

Our AP services continue to realize strong year-over-year growth, increasing from a total of 97,543 surgical specimens in FY2015 to 107,705 in FY2016, an annual growth rate of 10.8%. Our extramural consultation practice continued to be a key area of practice growth with 13,449 consultation cases signed out in FY2016 compared to 11,245 in FY2015, an annual increase of 19.6%. 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 despite devaluations of key, high volume CPT codes (88305 and 88342) last year that affected pathology practices. Total RVUs/month increased to 19,087 in June 2016 from 17,772 in June 2015. Faculty productivity, measured as RVUs/FTE/month, increased to 555 in June 2016 expressed as a 12 month rolling average compared to 525 in June 2015; a 5.7% increase.

Surgical pathology services continued to demonstrate strong growth in nearly all services with a 12.1% annual year-over-year growth (see Table 1). The largest growth in numbers of accessioned cases was realized in our GI service which grew by over 3,000 cases.

Surgical pathology continued to support four separate frozen section labs: University Hospital, Cardiovascular

Center (CVC), East Ann Arbor (EAA), and Mott Hospital. Faculty participating in the Surgical Pathology Officer (SPO) rotation established in FY13 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

	FY12	FY13	FY14	FY15	FY16	YOY change
Breast	2,220	2,330	2,346	2,513	2,478	(1.4%)
Gastrointestinal	16,857	17,570	18,144	19,787	22,799	5.8%
Genitourinary	2,387	2,304	2,381	2,515	2,914	15.8%
Gynecological	5,988	6,166	6,013	6,217	6,765	8.8%
Surg path– Room 1	9,318	9,686	10,658	11,157	12,388	10.5%
TOTAL	36,770	38,056	39,542	42,189	47,294	12.1%

Dr. Karen Choi will join the GI section in July 2016, and **Dr. Aaron Udager** will join the GU, head and neck, and general surgical pathology teams in January 2017.

Pediatric and Perinatal Pathology

The pediatric and perinatal pathology practice continued to flourish in FY2016. As summarized in Table 2, the pediatric surgical service handled 3,288 cases from the CS Mott Hospital ORs. IP accessions were down slightly (4.0%). In addition, there were 1,822 placentas from the Von Voigtlander Women's Hospital, reflecting a 3.8% annual increase over FY2015.

Table 2: Pediatric Pathology Clinical Activity, FY12 – FY16

	FY12	FY13	FY14	FY15	FY16	YOY change
Peds (IP)	2,177	2,191	2,793	3,426	3,288	(4.0%)
Placentas (PL)	1,456	1,650	1,715	1,756	1,822	3.8%
Peds autopsies	29	25	37	32	38	18.8%
Fetal exams	36	115	129	149	151	1.3%

In addition to surgical cases and placentas, the pediatric team covers all pediatric autopsy cases from Mott Hospital. 38 autopsies were performed this year, and most of them were reviewed in grand rounds and morbidity/mortality meetings with various pediatric/perinatal subspecialties. The team participated in over 207 multidisciplinary and teaching conferences at Mott and Women's Hospital at which 1058 patients' cases were discussed.

Dermatopathology

The Dermatopathology Service receives diagnostic case material from four primary sources: (1) UMHS (ID) cases; (2) outside contractual (MD) cases; (3) outside cases reviewed for referred patients (TD); and (4) personal consultation cases. All showed YOY increases (overall 6.0%), except MDs which were down by 5.2%. We continue our active and integral involvement in the University of Michigan Multidisciplinary Melanoma Clinic (MDMC) and Tumor Board, Multidisciplinary Cutaneous Oncology Clinic (MCOC) and Tumor Board, and the Cutaneous Lymphoma Tumor Board.

Table 3: Dermatopathology Clinical Activity, FY14-FY16

	FY14	FY15	FY16	YOY Change	FY14-FY16
ID	13,906	14,562	16,212	10.10%	14.2%
MD	8,199	8,836	8,402	(5.2%)	2.4%
Consults	2323	2,390	2763	15.6%	18.9%
Transfer	3,856	3,925	4225	7.6%	9.6%
TOTALS	28,284	29,713	31,620	6.0%	10.6%

The past academic year has been a period of stability in the Dermatopathology Section under the direction of **Dr. Douglas Fullen**. **Dr. Lori Lowe** continues to provide excellent clinical service, senior leadership, and dermatology expertise to her colleagues. **Dr. Aleodor Andea** continues as Director of the Dermatopathology Molecular Research Laboratory (DMRL), which provides molecular testing on melanocytic tumors in support of clinical service, test development, and research investigation in cutaneous oncology. In addition to their primary roles in the dermatopathology service, **Drs. Rajiv Patel** and **May Chan** continue to participate in the soft tissue and orthopedic pathology and general surgical pathology (Room 1) services, respectively. In addition, **Dr. Patel** has taken on a greater role in support of the Sarcoma SPORE. In addition to her role in the dermatopathology service, **Dr. Alexandra Hristov** continues to provide invaluable hematopathology expertise to the service and the Cutaneous Lymphoma Tumor Board. **Dr. Paul Harms** has transitioned to clinical assistant professor with increased clinical service effort, while devoting the remainder of his effort to basic science research pertaining to cutaneous neoplasia under the mentorship of **Dr. Arul Chinnaiyan** and support of molecular testing in the DMRL.

This was another productive academic year for the dermatopathology faculty with high visibility of our faculty at national and international meetings. **Dr. Andea** began his tenure on the Program Committee for the United States and Canadian Academy of Pathology. **Dr. Harms** completed his final year of a three year *Dermatopathology Research Career Development Award* from the Dermatology Foundation. Despite the high clinical service volume on the clinical service, the dermatopathology faculty remain very productive. Collectively, the dermatopathology faculty had 52 peer-reviewed publications or articles in press, participated in 48 abstracts presented at local, national or international meetings, and moderated one oral abstract session at the United States and Canadian Academy of Pathology (**Dr. Chan**) during the past academic year. Ten research grants (3 external and 7 departmental) were awarded to dermatopathology faculty serving as principal or co-principal investigator on the studies. Dermatopathology faculty members were invited speakers at institutional, national or international meetings on 26 occasions. Three dermatopathology faculty members served on 8 editorial boards.

Neuropathology

Drs. Sandra Camelo-Piragua, Andrew Lieberman, Kate McFadden, Paul McKeever, and **Sriram Venneti** contributed to the neuropathology service. The service signed out 1317 cases this year (not including autopsy), similar to the 1335 cases signed out in FY15. There were 720 surgical specimens examined, comprising 55% of the case volume. This represents a 7.6% decline in case number from FY15. In contrast, consult cases increased from 177 cases in FY15 to 232 cases in FY16, an increase of 31%. The muscle and nerve biopsy service is staffed by **Drs. Camelo-Piragua, McFadden,** and **McKeever**. In FY16, they signed out 365 cases, representing 172 inside cases and 193 outside cases, a 3.7% decline in total cases from FY15. Brain cutting is staffed by **Drs. Camelo-Piragua, Lieberman, McFadden,** and **Venneti**. In FY16, 116 cases were examined at brain cutting, a 23% increase from FY15. This includes UH and Mott Hospital cases, ME cases, and cases acquired through the UM Alzheimer Center that required a more extensive evaluation.

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

Neuropathology faculty members teach M2 medical students during the neuroscience sequence (3 lectures, 3 laboratory sessions) and run a short course for residents as an introduction to diagnostic neuropathology. Educational activities included sponsorship of an ACGME approved two-year fellowship.

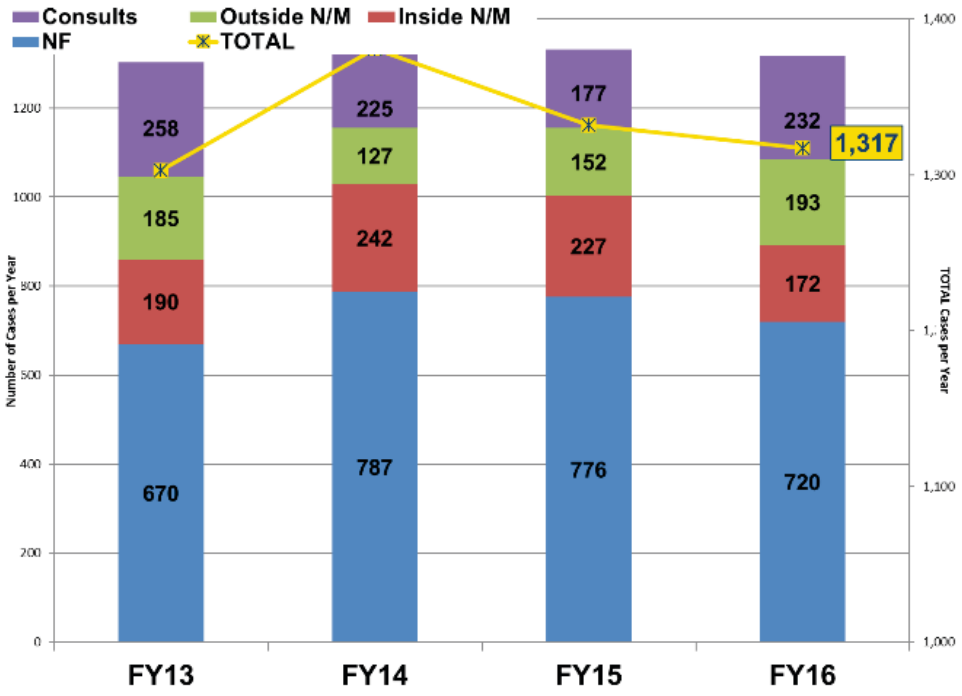


Figure 1 – Neuropathology Case Volumes, FY13-FY16

Overall neuropathology case volumes remained stable with notable YOY increases in outside consultations (31%) and outside muscle biopsies (27%), offsetting decreases in inside surgical and nerve and muscle cases.

Medical Renal Pathology

Drs. Paul Killen, **Jeffrey Hodgin**, **Evan Farkash,** and **Kent Johnson** supported our renal biopsy service in FY2106.

Our renal biopsy practice continued to stabilize in FY16; accessioning 1,171 cases compared to 1,121 in FY14 reflecting a 4.5% year-over-year increase (see Table 4). This is the fifth 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 4: Renal Biopsy Case Volumes, FY13 – FY16

FY13	FY14	FY15	FY16	YoY change	FY13–FY16
1,370	1,194	1,121	1,171	4.5%	(17.0%)

Cytopathology

FY16 saw a fully staffed cytopathology service comprising **Robert Davenport, Amer Heider, Xin Jing** (fellowship program director), **Madelyn Lew, Judy Pang, and Mike Roh**.

- Our cytopathology fellows, **Daisy Sun** and **Nilam Virani** successfully completed their fellowships in cytopathology.
- The Cytopathology Laboratory performed exceptionally well in this year's interim CAP inspection. 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 (CVC), Radiology (ultrasound and CT), and Mott.
- Pathologist-performed FNAs with and without ultrasound guidance (ASP4 and ASP3, respectively) continue to be performed at Cancer Center Room 32.

Table 5: Cytopathology Clinical Activity

	2008-09	2009-10	2010-11	2011-12	2012-13	2013-14	2014-15	2015-16
GYN TOTAL	40905	36392	34014	32866	26928	26078	24092	23578 (2.1%)
Non GYN EX-FOL	6830	6867	7123	7034	7483	8808	8392	6867 (18.2%)
ASP TOTAL	2415	2531	2604	2630	2836	3245	2853	3195 12%
-ASP1	*985*	*977*	*962*	*862*	*826*	*670*	*665*	*712 7.1%*
-ASP2	*1067*	*1276*	*1423*	*1526*	*1802*	*2345*	*1987*	*2299 15.7%*
-ASP3 (ASP4)	*363*	*278*	*219*	*242*	*208*	*230 (93)*	*201 (160)*	*184 (8.5%) (106)*

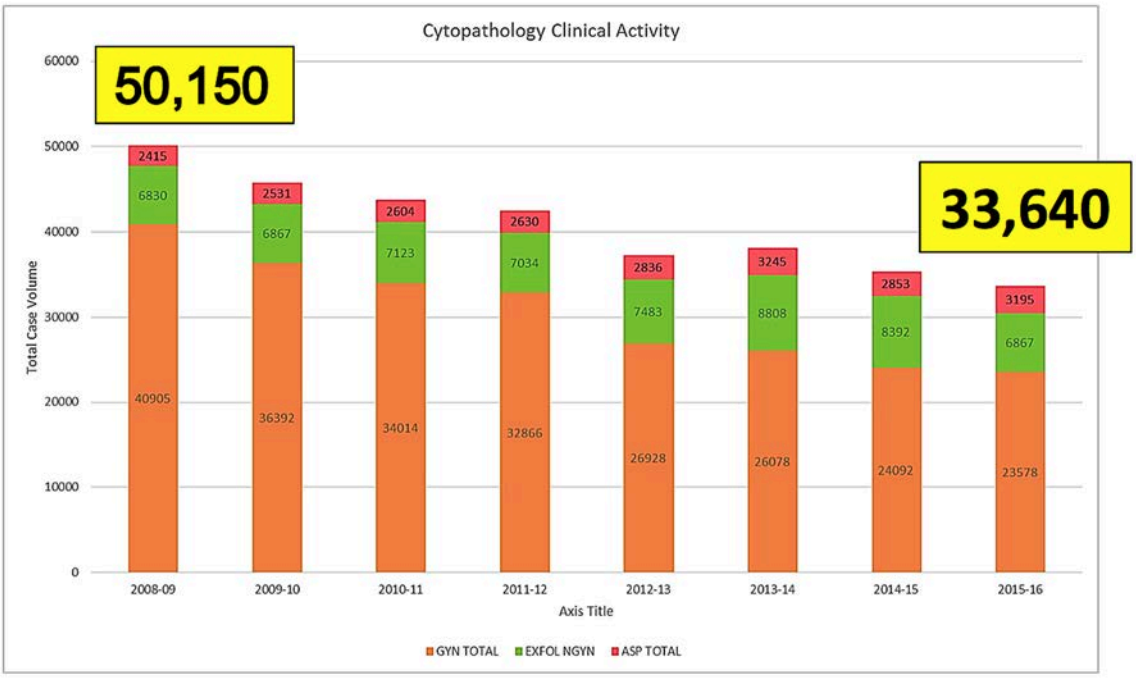


Figure 2- YOY Cytopathology case volume decreased by 4.8% due to decreases in GYN and non-GYN exfoliate specimens; while, aspiration cases increased by 12.0%.

The mean turnaround time for non-GYN cytology cases, including FNAs, was 1.57 days. The mean turnaround time for GYN cytology cases was 2.53 days for the year, and 1.47 following our process improvement project for Pap tests.

Summary of Service Initiatives and LEAN activities in Cytopathology

- Average turnaround times, and on-time results for Pap tests have dramatically improved from previous mean turnaround times following our process improvement that was implemented in October 2015 to reduce the average monthly TAT from 5 days to no more than 3 days. Prior to implementation, the overall TAT was 4.64 days with an on-time average of 60.46% (target = 5-day TAT). Following the implementation, the monthly average TAT was 1.47, with an on-time average of 87.2% (target = 3 days).

- Additional mobile telecytology carts have been constructed and successfully employed during this past year to assist with staffing of ASP2 FNA procedures. Telecytology is now routinely used for ASP2 FNA procedures taking place at Taubman Center, Radiology, and CVC.

- 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.

- Cytopathology has collaborated with Hematopathology to reduce duplicate processing of CSF cytology and fluid cytology samples. CSF samples from patients with history of lymphoma/leukemia are triaged to Hematopathology for processing with its concurrent flow cytometry and pathologist interpretation processes. Conversely, fluid samples received in Hematopathology are triaged to Cytopathology for processing along with its concurrent fluid samples.

- Cytopathology continues to collaborate with the Molecular Diagnostics Laboratory in their development of new assays. Cell blocks and Diff-Quik stained smears have been validated for use in next generation sequencing based assays for lung cancer and melanoma.

- 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 4 cytotechnologists are currently trained (**Binita Naylor, Kim Luckett, Brian Smola**, and **Kent Traylor**) and are performing scoring on approximately 750 breast biopsies annually. Additional cytotechnologists will be trained in the upcoming year.

- **Kalyani Naik, Dr. Pang**, and **Dr. Roh** have been a part of the MiP3 leadership group. **Dr. Lew, Dr. Pang**, and **Kalyani Naik** are serving on the newly formed Advisory Council for Patient and Family Centered Care.

- The cytopathology staff and faculty are actively involved in the NCRC relocation as well as the UH Renovation planning processes.

Autopsy and Forensic Services

The autopsy section provides staff and resident coverage for the performance of autopsies for UM and VA hospitals. The section also provides forensic pathology coverage for the Washtenaw and Wayne County medical examiner offices. The section has two forensic fellowship positions. Residents complete three one-month rotations on the autopsy service to comply with ACGME autopsy requirements. Medical students receive exposure to autopsies as requested. A one-month rotation dedicated to forensic medicine is offered to senior medical students.

Educational conferences in autopsy pathology include a weekly autopsy gross conference, weekly AP grand rounds emphasizing autopsy pathology clinicopathological correlations, and presentations in mortality conferences serving the clinical services within the hospital. A monthly didactic forensic pathology conference along with a multidisciplinary forensic sign-out conference also is provided by the staff.

The administrative staff supports an annual conference in *Advances in Forensic Medicine and Pathology* and the *Wayne County Death Investigation Seminar* sponsored by UM intended for physicians, death investigators, attorneys, and healthcare workers involved in the support of families.

Statistical Review

During the 2015-16 academic year the Autopsy and Forensic Service performed a total of 255 autopsies for UH and Mott Hospitals. The forensic service performed a total of 394 examinations for Washtenaw County (348 full autopsies, 5 limited and 41 external examinations), and 2827 examinations for Wayne County (2066 full autopsies, 470 limited and 709 external examinations).

Autopsy performance
The current initiatives of the section continue to revolve around continued improvements in autopsy turn-around time and communication with the clinical staff. Gross pathological diagnoses are routinely communicated to the clinical staff immediately following completion of the autopsy. The administrative and investigative functions of the medical examiner are located in offices in North Ingalls building, which allows for centralization of all medical examiner functions. The service supports two (2) forensic fellowship positions. The fellows obtain training and experience in all aspects of forensic medicine including: toxicology, criminology, forensic anthropology, forensic pathology, and courtroom testimony. The forensic autopsy experiences are augmented with cases from the office of the Wayne County Medical Examiner in nearby Detroit.

Accreditation
The Wayne County Medical Examiner Office obtained accredited by the *National Association of Medical Examiners* (NAME) for the first time in forty years. Washtenaw County will be preparing for a renewal of accreditation for the fall of 2016.

FY17 / Goals
The goals of the section remain essentially unchanged to provide a memorable educational experience for residents and medical students in autopsy pathology. Residents are provided a varied case volume of hospital and medicolegal cases to enhance their experience. An ongoing goal is to provide relevant pathology results to the clinical services at the University of Michigan. We expect to enhance the process of organ and tissue donation in the Wayne Office with Gift-of-Life Michigan to promote organ and tissue donation.

Research
The service expects to continue providing valuable assistance to local public health departments in areas of drug-related deaths, sudden deaths of children, and deaths due to violent injury. We plan to expand research opportunities into areas of forensic medicine and pathology, which currently include: Pedestrian deaths reviewed by ICAN (University of Michigan), Postmortem Microbiome (Michigan State University), Long Term Changes in Gene Expression During Chronic Drug Use (Wayne State University Department of Pharmacology), pharmacogenomics, and sudden cardiac death.

We are working to develop an interdepartmental MiP3 program with surgery to provide postmortem family care in the UM SICU, and an interdepartmental MiP3 program with the School of Social Work to provide social work services to benefit families and citizens of Wayne County.

Staffing
The current director, **Dr. Jeffrey Jentzen,** and Deputy Medical Examiner, **Dr. Allecia Wilson**, each provide hospital autopsy coverage for 30-40 percent of days with limited assistance from seven other AP faculty for the remainder. **Dr. Ted Brown** will join the section in July 2016, providing coverage for University of Michigan and Wayne County Offices. The coordinator of the autopsy service is assisted by autopsy assistant and investigator coverage. The Washtenaw Office includes 4.5 FTE positions.

With the addition of Wayne County Medical Examiner services, the staff has been expanded to assist with investigations and autopsies. The Wayne County office is staffed by a Chief Medical Examiner and seven additional forensic pathologists. **Dr. David Moons** will join the permanent staff beginning in July 2016. There is currently one clinical faculty appointment to cover a pathologist on a neuropathology fellowship. There are 6 autopsy assistants, 11 investigators, two senior administrators, and four clerical positions.

Challenges
The major challenge for the section will be to continue to provide timely autopsy results and response to scene investigations with the current staff; and to continue to change the professional culture in Wayne County and providing professional coverage. Morgue space continues to be a problem, especially cooler space for an increasing number of hospital deaths. We will continue to work within the department and outside partners (Gift of Life) to expand space.

Funding
The Wayne County contract was renewed for an additional three years 2014-2017.
The service will continue to investigate potential funding for another (third) fellow. The Washtenaw County contract is currently under review and expected for extension for 2015 through 2018.

RESEARCH ACTIVITIES
Success and vitality in our research activities remains 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) remained stable at 301 as did invited lectures at 186. Clearly our faculty remains top-of-mind when looking for cutting edge speakers in AP. Twenty-five different faculty were on editorial boards, an increase of 26% from 46 to 58 positions; an attestation to high national recognition by our faculty (see Table 6).

Table 6: Academic Productivity in AP, FY14 – FY16

	FY14	FY15	FY16	% Change
Publications	245	301	301	0%
Abstracts	120	168	115	(31.5%)
Invited lectures	157	187	186	(0.5%)
Editorial boards	33	46	58	26.1%
FTEs funded	5.35	7.01	6.42	(8.4)
Research expenditures	$3,449,157	$5,128,517	$5,893,331	14.9%

Research expenditures grew by $764,814, reflecting a year-over-year increase of 14.9% compared to FY2015 and a record level of extramural research support in AP (see Figure 7). Major contributions to this increase were from **Drs. Asma Nusrat** ($979,472; from 2 large NIH grants), **Scott Tomlins** ($339,704; from large grants from Astellas Pharma and the DOD), and **Kent Johnson** ($193,787 from renewal and incremental increased funding from Pfizer). Research expenditures in FY2016 increase by more than 80% over FY2008 and speak to the vitality of our research mission. The total number of FTEs funded through extramural sources decreased slightly from 7.0 to 6.4. 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 Hodgin**, **Rohit Mehra**, **Scott Tomlins, Sriram Venneti,** 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.

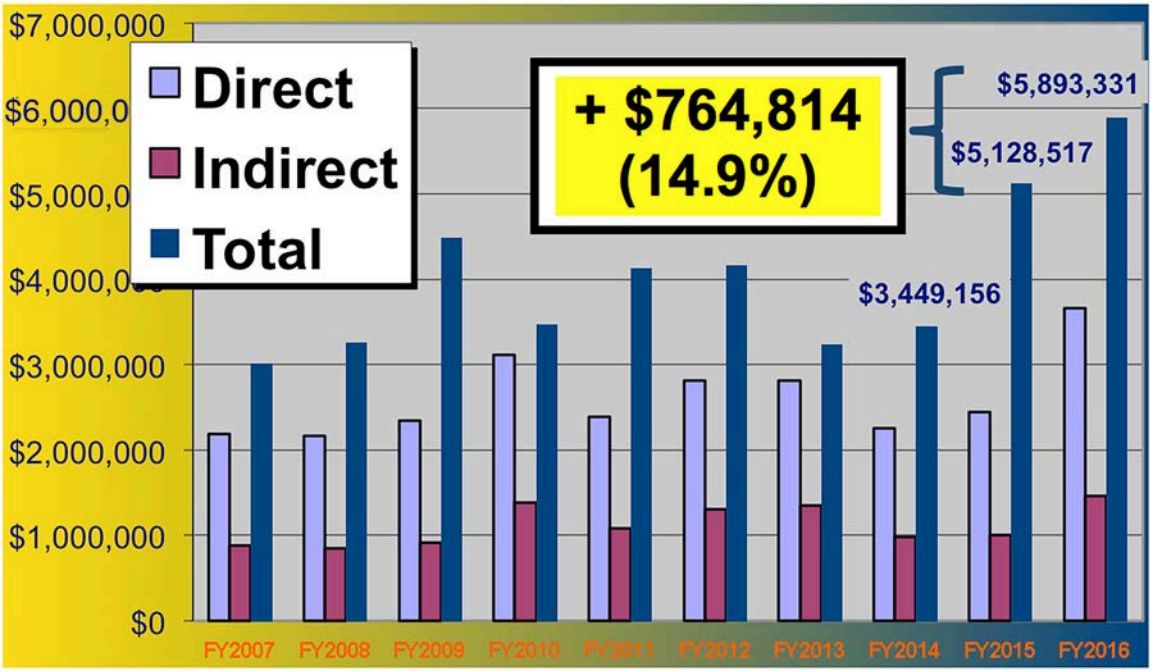


Figure 7 – AP Research Expenditures, FY07-FY16
Research expenditures grew by 764,814 (14.9%) compared to FY2015.

Intramural funding allocated by our *AP Projects Funding Committee* under the leadership of **Dr. Andrew Lieberman** reached a record high amount, which accounted for an additional $124,350 allocated in support of projects in which AP faculty and trainees served as primary investigators on 9 projects (see Figure 8). This reflects a 2.4% year-over-year increase and was a record high for intramural dollars spent in direct support of research projects.

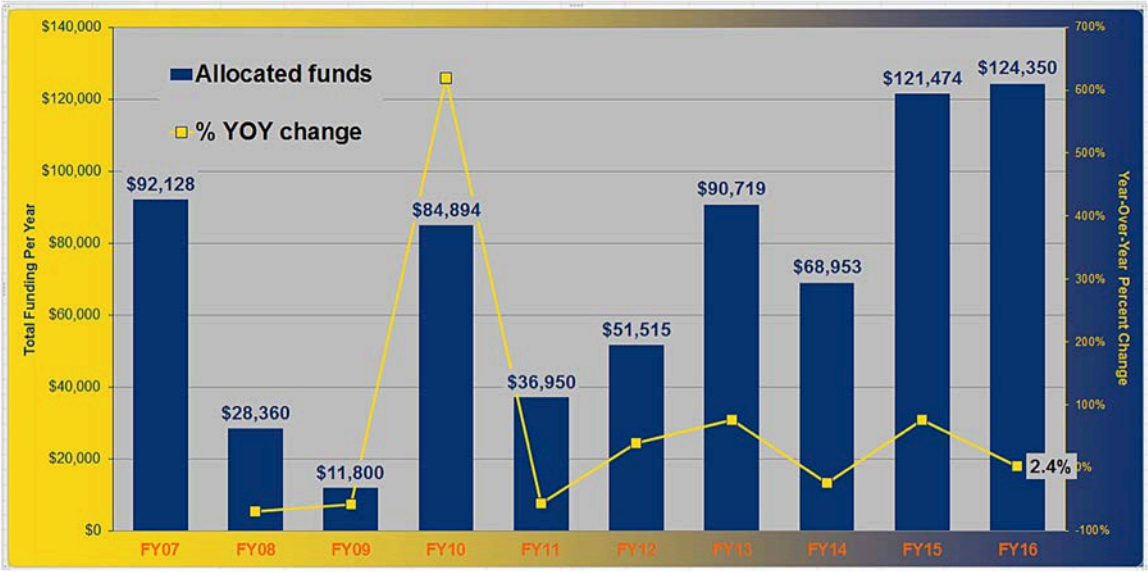


Figure 8 – AP Project Funding, FY07-FY16-Funding for AP Projects grew in FY16 grew to a total of $124,350, the highest allocation in the 10-year history of the program.

We hosted our **7th** *Annual Research Day* on February 13, 2016 in collaboration with Hematopathology and Molecular Pathology. The day included 32 abstracts presented as posters (24) and platforms (8). Our Keynote Speaker was our own **Dr. Kathy Cho**. The target audience was departmental trainees and faculty with the goal of increasing collaboration and projects. Next year we plan to add more Clinical Pathology abstracts to the agenda.

The *Molecular Pathology Research Laboratory (MPRL)*, under the direction of **Drs. Tom Giordano** and **Dafydd Thomas**, continues to be an important asset for faculty in AP. And finally, **Kathy Cho** was elected into the prestigious *National Academy of Medicine* for her work on ovarian cancer.

EDUCATIONAL ACTIVITIES

Education programs remained strong and included ongoing successes in existing fellowships. AP faculty continued to be highly ranked among our residents for their teaching, and played key roles in in medical 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 projects during the course of the year. Residents and fellows served as first authors on numerous abstracts at local and national meetings**. Dr. Allecia Wilson** was appointed Associate Director for the Residency Training Program. **Dr. Madelyn Lew** received the Residents' Teaching Award.

There were 16 AP fellows this year: Breast (1), Cytopathology (2), Dermatopathology (2), Forensic (2), Gastrointestinal (1), Genitourinary (1), Gynecological (1), Neuropathology (2), Pulmonary (1), and Surgical Pathology (3). Fellowships were filled by competitive candidates in the 2016-2017 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. **Drs.**

Michael Roh and **Scott Owens** co-directed the last iteration of the current pathology curriculum for first year medical students. 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 this 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** was appointed Director of Medical School Pathology Education Curriculum. **Dr. Henry Appelman** was honored with the Lifetime Achievement Award in Medical Education from the UMMS. **Dr. Scott Owens** was honored with the Elizabeth Crosby Award (Galens Medical Society) for medical student teaching.

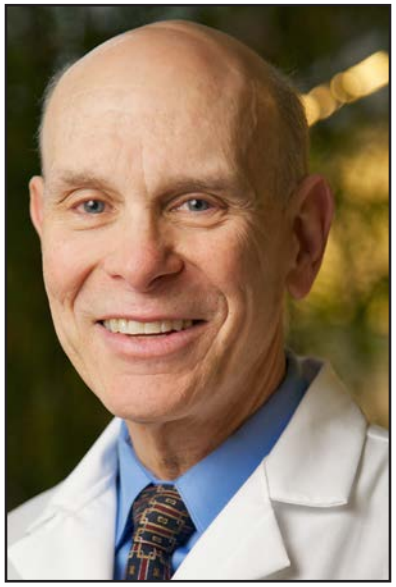
Nearly all AP faculty members participate in supporting an impressive array of multidisciplinary conferences including Tumor Boards for sarcoma, brain, breast, endocrine oncology, gastrointestinal, genitourinary, gynecologic, head and neck pathology, liver, pediatric, and lung tumors. Faculty also regularly 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. Educational conferences targeting primarily pathology trainees in which faculty participate include weekly slide and didactic teaching sessions.

Two Visiting Professors visited our department through the *A. James French Visiting Professorship*, each presenting a lecture and slide seminar, **Rupert Langer** (Bern University, Switzerland) and **David Grignon** (Indiana University). **Dr. Kristine Konopka** has assumed the role of running this important program.

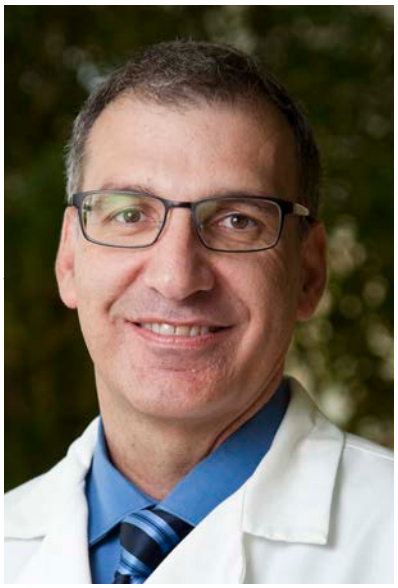
Multiple faculty members participated in our ninth annual CME workshop, *New Frontiers in Pathology,* presented in collaboration with the A. James French Society. The 2015 course was held at the Campus Inn and again yielded very strong attendee evaluations for the quality and content of the program. **Dr. David Elder** (University of Pennsylvania), **Dr. Laura Lamps** (University of Arkansas), and **Dr. Jennifer Hunt** (University of Arkansas) served as guest faculty. **Dr. Elder** was the A. James French Lecturer.

Our CME offerings included the sixth year of *Advances in Forensic Medicine and Pathology*, hosted in collaboration with the Washtenaw County Medical Examiner's Office in May 11-12, 2016 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, MD
Professor of Pathology
Director, Division of Clinical Pathology
CLIA Director for the Department of Pathology



Duane W. Newton, PhD
Associate Professor of Pathology
Associate Director, Division of Clinical Pathology
Director, Clinical Microbiology Laboratory
Chair, Service Excellence Committee

FACULTY UPDATES
New Faculty

Dr. Hema Ketha (Clinical Lecturer) joined the faculty on July 1, 2015 as Director of Toxicology and Drug Analysis, and as Associate Director of the Clinical Chemistry Laboratory. Dr. Ketha received a B.Sc (H) in chemistry and M.Sc in organic chemistry from University of Delhi, India in 2003 and a PhD in pharmaceutical and medicinal chemistry from University of Florida in Gainesville, FL in 2010. She completed her post-doctoral research training at the Mayo Clinic in Rochester, MN between 2010 and 2013. Her work was focused on areas exploring the role of vitamin D physiology in bone and kidney diseases, protein purification and protein interactions, mouse model studies of bone disease and development, validation and clinical implementation of LC-MS/MS analytical methods for vitamin D metabolic profiling. Then she pursued post-doctoral clinical training in clinical chemistry (2013-2015) at the Mayo Clinic before joining the Department of Pathology at the University of Michigan. She works on developing and implementing mass spectrometry based assays in the clinical laboratory and is actively involved in clinical pathology resident teaching. She has research interests in areas of clinical endocrinology, toxicology and clinical LC-MS/MS. She has authored several peer-reviewed publications on topics including clinical applications of LC-MS/MS and high-resolution mass spectrometry (HRMS) for steroids, drugs and proteins, role of vitamin D physiology in nephrolithiasis and hypercalcemia among others. She is the Secretary of Michigan Section of the American Association of Clinical Chemistry (2015-2016). She has received several awards, including the Paul E. Strandjord Young investigator award from ACLPS and the best oral poster at the American Association of Clinical Chemistry last summer.

Faculty Recruits

Dr. Shih-Hon (Sean) Li, M.D., Ph.D. joined the faculty as an Assistant Professor of Pathology on August 1, 2016. His major roles are as an Assistant Director of Transfusion Medicine and as Director of the Blood Bank Laboratory. Following his residency in Anatomic and Clinical Pathology at the University of Michigan, Sean spent a year as the Blood Bank/Transfusion Medicine Fellow, followed by a year as the Chemical Pathology Fellow, both at the University of Michigan. During the past year he delivered several presentations at local, national and international conferences including:
"Hemopure interference testing in routine chemistry assays," at the Michigan Chapter of the American Association for Clinical Chemistry, "Iatrogenic iron deficiency associated with automated red blood cell exchange in sickle cell disease," at the American Society for Apheresis 2016 Annual Meeting, a plenary oral presentation on "Evaluation of sickle cell trait by HPLC and capillary zone electrophoresis: The confounding effect of diabetes mellitus 2," at the XXIXth International Symposium on Technological Innovations in Laboratory Hematology in Milan, Italy, and "Dysregulation of iron metabolism in sickle cell disease: Special issues surrounding automated red blood cell exchange," at the 2016 Current Topics in Blood Banking in Ann Arbor.

Dr. Sarah Choi joined the Department as an Assistant Professor and member of the Hematopathology Section on September 1, 2016. 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

Dr. Lauren B. Smith was appointed as the new Director of Hematopathology on January 1, 2016. During the preceding nine months, Dr. Smith had delivered outstanding service as Acting Director of the Section of Hematopathology and Acting Director of the General Hematology Laboratory. Notably, these functions were in addition to her full time roles as Director of the Hematopathology Fellowship, Director of the Ethics Path of Excellence at the University of Michigan Medical School, Laboratory Director at Forest Health Hospital and Laboratory Director at the University of Michigan Student Health Service. Along with expertise in Hematopathology and Bioethics, she brings outstanding diagnostic skills, administrative experience, and local as well as national academic recognition to this position.
Dr. Smith received her undergraduate and medical degrees from the University of Michigan where she also completed her residency in Anatomic and Clinical Pathology and her Fellowship in Hematopathology. In June, 2008, Dr. Smith took an Intensive Bioethics Course at the Kennedy Institute of Ethics in Washington, D.C. She joined the University of Michigan Faculty in 2007 as an Assistant Professor, began her service as the Director of the Hematopathology Fellowship program in 2012 and was promoted to Associate Professor in 2013. On site, she has been our authority not only for Hematopathology, but also for advice on a wide range of Bioethics questions.
Dr. Smith has published over 40 peer-reviewed papers, 6 book chapters and presented talks at numerous national and international meetings and educational seminars in her research areas of interest, including Hodgkin and non-Hodgkin lymphoma and Ethical Issues in Pathology.

Congratulations to Dr. Bryan Betz, Technical Director of the Molecular Diagnostics Laboratory for his promotion to Clinical Associate Professor effective September 1, 2016. Dr. Betz received a B.S. in Biology from the University of Michigan (1996) and a Ph.D. in Molecular and Cellular Pathology from the University of North Carolina School of Medicine in Chapel Hill, North Carolina where he studied the molecular genetics of malignant rhabdoid tumor. He completed post-doctoral training at the University of North Carolina in 2002 and at the Laboratory of Molecular Toxicology, Cancer Biology Group, National Institute of Environmental Health Sciences, National Institutes of Health from 2003-2007 where he investigated the molecular basis of gastrointestinal stromal tumor (GIST). For the past nine years, he has lead much of the growth of the Molecular Diagnostics

Laboratory as its Technical Director. Dr. Betz has 35 publications in peer-reviewed literature and a long and distinguished record instructing our fellows and residents in Molecular diagnostic techniques.

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 600 staff during the year, not including those who viewed the Web versions. The Fifth annual Clinical Pathology Symposium again provided two half days of interactive presentations. Once again, the Quarterly joint Hematopathology-Anatomic Pathology case review evenings were attended by Pathology residents, fellows and faculty. 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, John Perrin, Kristina Martin, Jeff Sica, Elizabeth Walker, and Lisa Brown.

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 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. In addition, an educational component is presented encouraging the use of Lean techniques. The CPQA meetings are all videotaped and shown to the staff at Traverwood. Dr. Keren attended those meetings to respond to comments by staff. In addition, the videotapes are available at the Pathology Website.

July 14, 2015: UM Attendance 151

Speakers:
Try Not To Fall Off The Backwards Brain Bike - David Keren
Chemical Pathology Student Project - Tony Sinay
Huddle Dashboards - Brian Tolle
Applying Lean Tools in the Apheresis Service - Michael Meade
Financial Update – David Keren

October 13, 2015: UM Attendance 163

Speakers:
Video – Impact of Consumerism on How We Deliver Care - David A. Spahlinger
The Laboratory Formulary: Toward Rational Test Usage -Jeffrey Warren
Adult Blood Gas Lab: QA Game Plan -Heidi Fredenburg
Satellite Support: Streamlining Operations -Sue Clark and Laurie Sefton-Miller
Financial Update – David Keren

February 16, 2016: UM Attendance 141

Speakers:
UH Renovations PRR- Christine Baker
Random Urine Processing -Bonnie Grayson and Chanin Kelly
Macrodisection Workflow -Jennifer Bergendahl
Financial Update -David Keren

April 19, 2016: UM Attendance 165

CLIA & CAP, A Short Walk Down Memory Lane - Kellen Kangas
Service Excellence – Deirdre Fidler & Christine Meldrum
Lost Newborn Screens - Ann Rosin
Financial Quarterly Update – David Keren, MD

Clinical Pathology Symposium

CP Symposium Organizing Committee:
Suzanne Butch, Lori Blough, Kristina Martin, Pam Warwashana, Duane Newton, Carol Young, and Pamela Cornwell
In October, 2015, the Clinical Pathology Symposium provided two half-day grouping of laboratory medicine presentations featuring discussions on Safety and Compliance (Ms. Suzanne Butch), Pediatric Heart Failure (Dr. Ming-Sing Si), Emergency Planning for Transfusion Medicine (Dr. Barbara Bryant), IQCP: Individualized Quality Control Plan (Dr. Barbara Robinson-Dunn), Brain Bugs: Infections of the Central Nervous System (Dr. Amanda Fisher-Hubbard) and Navigating the Path of Point-of-Care Testing (Dr. Lee Schroeder).

Current Topics in Blood Banking 2016
Current Topics in Blood Banking Organizing Committee:
Robertson Davenport, Laura Cooling, Chisa Yamada, Suzanne Butch, Terry Downs, John Ko, Sandra Hoffmann, Holly Wilson
For the 2016 Current Topics in Blood Banking Conference, June, 2016, Joann Becker, M.D., the Clinical Chief of Laboratory Medicine at Roswell Park Cancer Institute, was the featured speaker. She presented the annual Harold A. Oberman, M.D. Memorial Lecture on “Platelets: Now Available in 38 Flavors.” In addition, there were presentations by Andrew Campbell, M.D. on “Challenges in the management of chronically transfused sickle cell patients,” Alvaro Rojas Pena, M.D. on “Ex situ perfusion of human limbs for 24 hours”, Robertson Davenport, M.D. and Sheri Hugan, MLS(ASCP)^{CM}, SBB on “Daratumumab: clinical and serologic perspectives”, Shih-Hon Li, M.D. on "Iron status and automated red cell exchange in sickle cell disease", Kelly Delany, MLS(ASCP)^{CM}, SBB and Pamela Cornmell MT(ASCP) on “Transfusion Service Case Studies”, Suzanne Butch, MLS(ASCP)^{CM}, SBB on “Table top exercises for disaster planning”, and Theresa Downs, MLS(ASCP)^{CM}, SBB on “cGMP for transfusion services”.
In FY 2016 the University of Michigan Department of Pathology Clinical Pathology Division was well represented at National and Regional meetings, including the American Society for Clinical Pathology, The American Association of Clinical Chemists, the Michigan meeting of the American Society of Clinical Laboratory Science in East Lansing, the Michigan meeting of the American Association of Clinical Chemists, and at the International Society for Laboratory Hematology meeting in Milan, Italy.

Academic Productivity
As shown in Table 1, the Clinical Pathology faculty had impressive academic productivity in FY2016. The twenty-five faculty averaged 3.8 publications (median 1.9) 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, Blood, Clinical Chemistry, Endocrine, International Journal of Laboratory Hematology, Journal of Clinical Apheresis, Journal of Clinical Microbiology, Journal of Infectious Diseases, Journal of Molecular Diagnosis, Nature, Nature Structural and Molecular Biology, and Transfusion. In addition, the faculty reported their work in 67 abstracts with 16 faculty serving as invited lecturers, speakers or visiting professors 71 times, for an average of 4.4 (median 2.2) per faculty. Finally, our faculty reported service on Editorial Boards or as reviewers for 71 journals including: American Journal of Clinical Pathology, Archives of Pathology and Laboratory Medicine, Cell, Clinical Chemistry, Cytometry, Human Pathology, Infection and Immunity, International Journal of Laboratory Hematology, Journal of Clinical and Experimental Pathology, Laboratory Investigation, Journal of Clinical Microbiology, Journal of Infectious Diseases, Journal of Molecular Diagnostics, Modern Pathology, Molecular Cell, Nature, New England Journal of Medicine PLOS, and Transfusion.
Table 1. Academic Productivity in CP FY2016

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

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 $70,000 annually. 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. Nathanael Bailey
    - Evaluation of TCF3 and ID3 expression in Burkitt Lymphoma and Diffuse large B-cell lymphoma
        i. Awarded 9/23/15
2. Brian Betz
    - Identification of Oncogenic Kinase-Fusions in Cutaneous Lymphoproliferative Disorders
        i. Awarded 1/26/15
3. David Lombard
    - Oncogenic role of SIRT5 in human melanoma
        i. Awarded 9/3/15
4. Michael Bachman
    - Molecular epidemiology of colonizing and infecting isolates of *Klebsiella pneumoniae*
        i. Awarded 2/16/16

Clinical Pathology Fellowships
Blood Bank Fellowship: Dr. Robertson Davenport served as the Director of the Blood Bank/Transfusion Medicine Fellowship. There was no fellow this year.

Chemical Pathology Fellowship: Dr. David Keren served as the Director of the Chemical Pathology Fellowship. This year our fellow was Shih-Hon (Sean) Li. The Chemical Pathology Fellowship filled for the 2016-17 session.

Hematopathology Fellowship: Dr. Lauren Smith served as the Director of the Hematopathology Fellowship. This year our 3 first year fellows were Pawel Mroz, M.D, Ph.D., Charles Harmon, M.D., and John Brazelton, M.D. The Hematopathology Fellowship program filled for the 2016-17 session.

Histocompatibility Fellowship: Dr. Daniel Ramon served as the Director of the Histocompatibility Fellowship. There was no Fellow this year.

Molecular Pathology Fellowship: Dr. Nathaneal Bailey served as the Director of the Molecular Pathology Fellowship. This year's fellows were Andrew McDaniel, M.D., Ph.D and David Steward, M.D. Ph.D. The Molecular Genetic Pathology Fellowship program filled for the 2016-17 session.

Formulary Committee
Dr. Jeff Warren originated 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 this year's PLUGS national meetings for his expertise on this method of vetting suggested additions to the University of Michigan Laboratory or its send out menu.

Informatics Support
This year, the staff and faculty of the Clinical Pathology laboratories continued to work with upgrades and challenges of coordinating the University of Michigan Health System MiChart (EPIC), the ongoing Soft laboratory information system and the upgrade to the our MasterControl system. The coordination of the MiChart and Soft implementation weighed heavily on the shoulders of Pathology Informatics (Dr. Ul Balis, Director; Kathy Davis, Manager; Cybil Rowerdink; Bill Hubbard and many others).

There have been extraordinary efforts by our laboratory mangers, supervisors and technologists to keep up with the upgrades and occasional unanticipated down times. These efforts included managers and supervisors being on-site at all hours for upgrades and numerous unforeseen challenges. While these efforts will eventually benefit our efficiency and our ability to effectively use the extraordinary amount of data generated daily, they require ongoing commitment from our staff for training and continuing refinement of the software itself. Over the three years since the SCC-Soft LIS was initially activated, these continuous software enhancement activities have allowed for the clinical lab and informatics teams to build an even stronger operational relationship, with the collective esprit de corps being as strong as it ever was. Over the period of the upcoming academic year, the Clinical Pathology Laboratories anticipates that many of the remaining LIS vulnerabilities and defects will be fully mitigated, owing to this mature and effective interdepartmental collaboration with Informatics.

Genetic Testing Resource and Quality Consortium (GTRQC) Pilot Project
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. 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. Our initial goals were too broad based and we had poor attendance by primary practitioners at our Kick-off meeting. We met with the Champions from UM, the Executive Committee, the Genetics Committee, the Clinical Committee and members of the Michigan Association for Genetic Counselors, as well as with teams from Henry Ford, West Michigan Cancer Center, and St. Joseph Mercy to gain insights on how to proceed. We also met with the BCBSM leadership team, Jack Billi and Joanne Kimata to examine the future of the GTRQC. The physicians we met with believe that the software tool we have envisioned, if it works as we intend, will be extremely valuable and useful to providers in a multitude of settings. They did not want us to give up on our more focused goal to develop a software tool that would efficiently collect data from patients to improve the detection of patients who would benefit from molecular screening tests for breast cancer.

With the significant changes in our purpose, we prepared and submitted a revised Proposal as a Pilot Project (GTRQC Pilot Proposal – July 2016 – June 2017 Submitted 2016.04.01). Our original Co-Director, Dr. Scott Owens, had to step down due to competing responsibilities. Lee Schroeder, MD, PhD, came on board effective March 1, 2016 and has provided us with exceptional insights and guidance as we planned our software tools and testing processes. Our new proposal was approved by BCBSM and a new Statement of Work and Budget was submitted, incorporating a 41% budget decrease over the prior year's budget. The new statement of work and budget are in the process of being signed by BCBSM and the University of Michigan. Moving forward with our pilot, we are working with Dr. Sofia Merajver, University of Michigan Breast and Ovarian Cancer Risk Evaluation Clinic, quite extensively and she has agreed to join our project as an Associate Director and to allow us to utilize her patient population for our early testing as well as to function as a pilot site. Her expertise in genetics and working with patients in the clinical setting is a significant improvement to our leadership structure. In addition, we added Kara Miliron, MS, CGC as a consultant to bring her expertise to bear on the testing and validation process for our software tools.

THE LABORATORIES

The University of Michigan Health System (UMHS) Clinical Pathology Laboratories encompass Specimen Processing and the Sendout Laboratory; more than twenty UMHS off-site limited function laboratories associated with ambulatory care units, phlebotomy stations and point-of-care testing facilities; a 24 hours per day/7 days per week inpatient Phlebotomy Service; and full service hospital-based laboratories that include 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 Laboratory personnel provide extensive testing capacity and consultative/logistical support to the MLabs Program. Pathology Informatics, Specimen Processing and Pathology Administration continue to provide logistical, operations, and regulatory support for the Pediatrics Michigan Molecular Genetics Laboratory (MMGL), Pediatrics Blood Gas Laboratories, and the CLIA laboratory component of the MCTP and Paradigm (an advanced molecular testing joint venture between the University of Michigan Department of Pathology, the International Genomics Consortium (Phoenix, AZ) and the UMHS).

Clinical Pathology Operations Manager

Ms. 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 gembas and coordination of subsequent projects resultant from these discussions. During 2015-2016 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 ASCLS professional society. She was the President-Elect for the Michigan chapter along with the ASCLS-Michigan Fab 5 Scientific Assembly chair and serves on various ad hoc committees. She assisted in organizing the creation of a short video to be used for recruitment of laboratory professionals with participating UM-Pathology staff. Over the past year Kristina has been recognized several times for her contributions. She has received the ASCLS-Michigan Omicron Sigma and Presidential award. She also received the ASCLS Voices under 40 award recognizing young professionals who have shown success early in their careers.

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) is complicated by changes in billing as well as in charges. The decrease in Billed tests recorded for Clinical Pathology in FY2014 reflected a significant change in the billing process. These effects are not present for FY2015 which became the baseline year for future comparisons. Notably, however, one can follow our gross charges that increased by almost $50,000,000 between FY2015 and FY 2016 and our expenses that increased by less than $1,000,000 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 a 4.5% increase in our FTE numbers in FY2016. We anticipate further increases to keep pace with our clinical needs for FY2017.

Table 2. Clinical Pathology Laboratories FY2013-2016

	FY2013	FY2014	FY2015	FY 2016	Change
Billed Tests	5,109,497	5,015,219	5,101,062	5,428,130	6.4%
Gross Charges	$490,563,953	$546,966,965	$579,988,161	$ 628,121,972	8.3%
Expenses	$72,163,336	$73,655,845	$75,673,407	$76,625,956	1.3%
Total FTEs	517.46	534.68	534.8	558.95	4.5%

Hematopathology Section (Hematology, Bone Marrow, Flow Cytometry, Coagulation)

I. OVERVIEW

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

Dr. Rajan Dewar began as faculty and hematology lab director in 9/2015. Dr. Lauren Smith was named Section Head effective 1/2016. Three candidates were interviewed for a junior incremental position. Dr. Sarah Choi was recruited from Northwestern University with a projected start date of 9/2016. A search is underway to replace Nate Bailey with a mid-career faculty member with a strong translational research background. Four candidates have interview dates scheduled or completed.

II. HEMATOPATHOLOGY FELLOWSHIP PROGRAM (Dr. Lauren Smith, Program Director)

Three fellows completed the ACGME-accredited training program this year (Charles Harmon, Jason Brazelton, and Pawel Mroz).

Fellow Abstracts and Publications

Pawel Mroz

1. TNFRS14 status in follicular hyperplasia
   Dr. Smith - follicular hyperplasia in pts with CML on Dasatinib induced follicular hyperplasia - case report - manuscript in preparation,
2. Dr. Schnitzer - EBV negative plasmablastic lymphoma in a 35 y.o. F involving myometrium
3. 2 projects completed (Dr. Bailey and Dr. Shao - both USCAP posters presented, one manuscript in preparation.)
4. High-Resolution, Genome-Wide Single Nucleotide Polymorphism Microarray Analysis of Abnormal Genomic Lesions in Patients with Myeloid Neoplasms and Normal Karyotype - manuscript in preparation
5. Design features for optimization of tetra pyrrole macrocycles as antimicrobial and anticancer photosensitizers - manuscript submitted
6. Dr. Bailey/Dr. Brown - Detection and quantification of BCR-ABL1 fusion transcripts in samples from patients with acute lymphoblastic leukemia and chronic myelogenous leukemia by digital PCR. - IRB accepted.
7. 2 weeks research rotation in Dr. Tewari lab scheduled for end of June, application for funding pending, case and sample selection in process.
8. Dr. Bailey - application of digital PCR in detection and monitoring of BCR/ABL1 transcript in CML and BLL - TCI3/ID3 IHC testing in DLBCL TCF3/ID3 IHC in DLBCL - USCAP abstract,
9. Drs. Shao and Smith - SNP microarray in normal karyotype patients with myeloid neoplasms - abstract accepted for USCAP

Charles Harmon

1. Harmon CM, Brown N. Langerhans cell histiocytosis: a clinicopathologic review and molecular pathogenetic update. Arch Pathol Lab Med. 2015;139(10):1211-4.
2. Harmon CM, Smith LB. B-cell non-Hodgkin lymphomas with plasmacytic differentiation. Surg Pathol Clin. 2016;9(1):11-28.
3. Pagano M, Harmon C, Cooling L Connelly-Smith L, Mann S, Pham H, Marques M, Schlueter A, Case R, King K, Cataife G, Wu Y, Wong E, Winters J. Use of hydroxyethyl starch in leukocytapheresis procedures does not increase renal toxicity. Transfusion (in press)
4. Harmon CM, Boyer D. Monomorphic post-transplant lymphoproliferative disorder, EBV+, morphologically consistent with plasma cell leukemia. Society for Hematopathology/European Association for Haematopathology Workshop; 2015 October; Long Beach, CA.
5. Cooling L, Harmon CM, Park YA, Dunbar N, Linenberger M, Kim HC, Murtaugh A, Schmidt A, Fernando LP, Draper N, O'Leary M, Horn B, Joshi S, Schwartz J. Frequent occurrence of procedure-associated thrombocytopenia in older related allogeneic peripheral blood stem cell donors: a donor safety pilot study by the ASFA subcommittee. American Society for Apheresis Annual Meeting; 2016 May; Palm

Springs, CA. (anticipated)

6. Plasmablastic lymphoma: a review of clinicopathologic features and differential diagnosis." New Frontiers case/review to be submitted to Archives of Pathology and Laboratory Medicine. Dr. Lauren Smith

Jason Brazelton

1. EAHP 2016 workshop : presented by moderator—blastic plasmacytoid dendritic cell neoplasm with Jason Brazelton and Lauren Smith
2. Multinucleated plasma cells. Submitted to Blood images with Dr. Smith

III. **CLINICAL HEMATOLOGY LABORATORY (Report from Usha Kota and Dr. Raj Dewar)**

Annual Report Information FY 2016
Significant changes in Hematology from first 10 months of FY2015 to first 10 months of FY2016 include:

• Reduced volume sickle cell screen, urine eosinophils, malaria screen testing-unknown reasons, low volume testing overall.
• Reduced volume reflexed urine microscopic testing (low volume testing)-but with increased UC orders (reflex to culture when needed). Increased UC orders reflect a positive change where urine cultures are reflexed in microbiology only when hematology finds a positive UA and reflexes urine microscopic. This effectively reduces unnecessary urine culture orders, and reduces the necessity to re-collect new specimens/add-on testing when urine cultures are needed.
• Major reduction in RBC morphology tests charged where technologist reflexed RBC morphology are still performed at the same or higher rates-but no longer charged, and it is only charged when a clinician orders the test.
• Definite increases in our highest volume testing including CBCD(6.5%), CBC(3.5%), UC(12.5%), ESRA(7.5%), CSFCD/BFFCD(1.6%), PLT(30.5%) without increase in staffing.
• Significant increase in testing billed with addition of ROTEM testing-this is a definite positive with decrease in blood product use in ORs and Trauma patients.

Personnel/Staffing/CE

Started the fiscal year with 4 open positions.
Hired and trained a total of 11 FTEs (9 MT, 2 LT), 3 more MTs starting in June 2016

Terminated-5
Promoted-3

- New section director for Hematology started in September.
- New dayshift supervisor started in October.
- New (incremental) flow supervisor started in November.
- We have come to the tail end of hiring the massive number of replacements we had this year. Most staff are now hired, trained, and in position. We have been able to substantially reduce overtime and additional regular time-we are at our lowest levels in the past few years.
- Submitted A3 to hire 2 lab technicians in the place of a part-time MT, a temp, and regular additional hours the lab had been using to patch our needs-this was approved in October.
    - This reduces wasted MT time, and allows for MTs to remain back in the lab to perform marrow diffs, and assist with other functions in the lab.
    - Allowed us to add another tech in differentials to help reduce TAT for stat ANCs which improves patient care/satisfaction.

- Began series of employee engagement meetings, worked on 2 of our worst scoring topics, including employees being treated fairly, and creating a climate of trust. We had several meetings to cross all shifts, and in addition had staff meetings within the lab to discuss. Some things we addressed:
    - Randomized our mandatory OT list (staff were extremely burned out doing so much OT when we had severe staffing shortage, and wanted a more fair system rather than alphabetical order).
    - Addressed flow lab, and why they are not on the M-list. Now that everyone knows the reasons-all are okay with this.
    - Addressed making sure that all openings (other than specialties) are filled by seniority of those who are interested in the shift.
    - Created a list of expectations in order to build trust between management and employees.
- Continuing Ed for staff
    - We sent around 12 staff members to Sysmex User's meeting in Ypsilanti.
    - Sent 2 staff members to WAM user's group meeting in Chicago.
    - Sent 2 staff members to ICCS conference in Denver (Clinical Cytometry).
    - Sent several staff to ASCLS-Michigan.
    - Monthly staff meetings are held for each section (Heme, Flow, Coag)
- Oriented 3 fellows, and provided one-week wet lab training for all three.
- Trained 7 MT interns, were able to hire 4 of them into our lab.

Equipment

- 4 Rotem units validated and implemented in OR, Lab and L&D-including training POC techs, Anesthesiologists, Lab Staff, and performing competencies, providing remote viewing, scanning records into MiChart, and writing IQAP for this testing.

  We validated and implemented Rotem for ICU units and ER in a very short amount of time in spite of decreased staffing-this was a very big project, requiring us to work out a system for ordering, transport, remote viewing, scanning records into MiChart, clinician training, tech training, and complete validation of 2 instruments. We accomplished all of this within a matter of weeks. In addition, we purchased and implemented another Rotem unit for L&D. We have received feedback regarding the great impact on patient care with the 5 units in use over the past 1.5 years. Anesthesiologists are able to make the best choices on blood product use, and eliminate waste of products that would not help.
    - We were approved for another FTE to cover Rotem work in our lab. This incremental, once hired and trained, will be added to evening shift.
- Completed Cellavision training for all day staff members and evening shift staff
- Sysmex/WAM upgrades for the lab-approved, and now in process of installation/implementation the new automation line/equipment, including satellite labs who will be receiving WAM upgrade, and Cellavision units to be interfaced.
- Evaluating Alcor Ised instrument. If found to be comparable to current technology or better, it:
    - will significantly reduce employee risk in trimming labels with blade to run on instrument
    - will reduce tech time to attend to mixing of the tubes, and constant attention to timers
    - will eliminate need for black top tubes which are often under filled, and cost the hospital approximately 47K/year

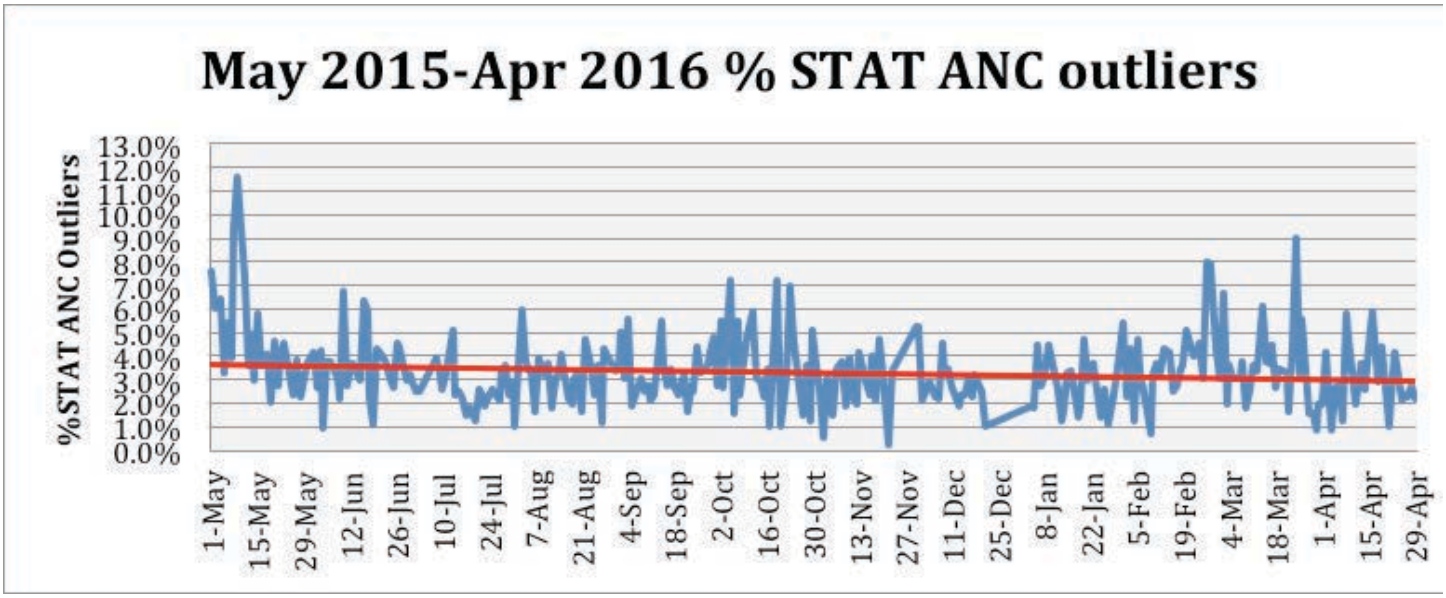
- Evaluated Urine analyzers, will be submitting request to purchase
- Evaluated coagulation analyzers for replacement, submitted request for purchase/lease
- Standardization and validation of new cytometer completed
- Evaluated flow prep instrument, submitted request for purchase

Testing

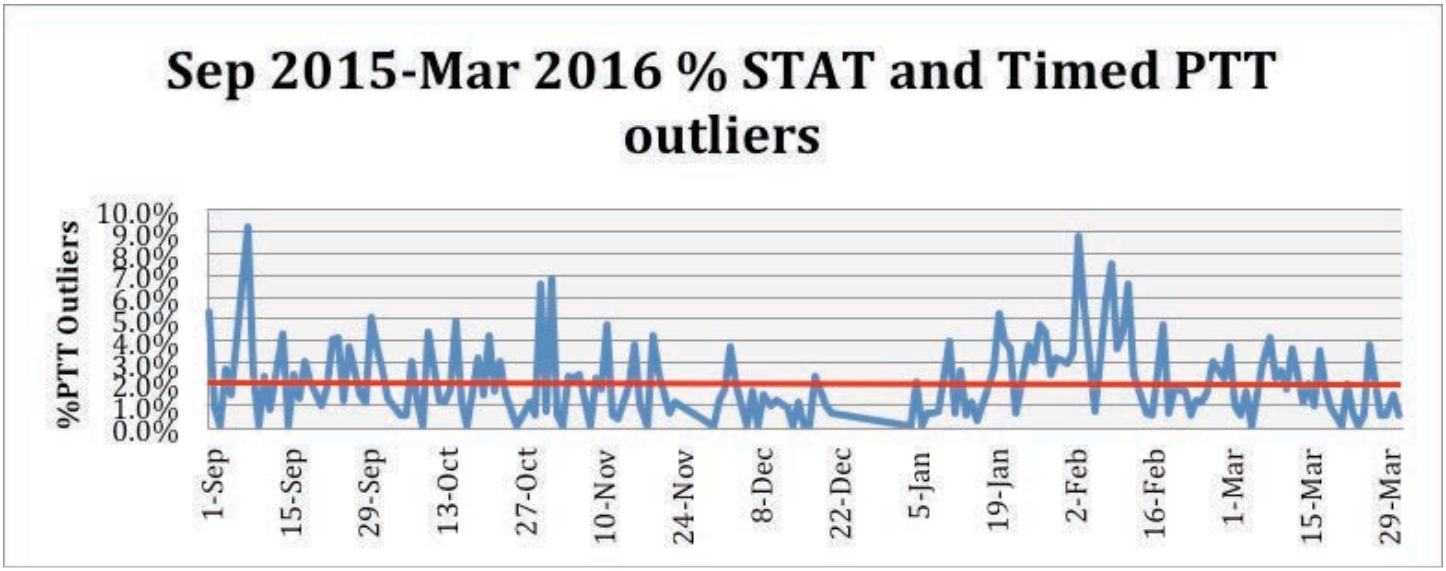
- New CBCPR test (CBCP with differential and path review test created in QA-to ultimately assist clinicians in finding those CBCs with pathologist review included in MiChart)
- Working on modifying stop-auto verification rules to decrease the number of slides that must be reviewed
- We responded to the patient safety report where a tech did not realize a sample was too old to run, by creating a “too old” flag in Soft. This ultimately caused a spike in canceled UNFH tests due to specimen expiring prior to reaching the lab. With communication efforts and education-we now have relatively few cancellations for this reason.
- With the addition of an incremental flow supervisor-many projects are now rolling
- Non 10 tube validated in flow (12 color lymphoid screening tube), and now in use-allows for complete analysis of previous QNS samples as well as multi-antigen analysis in a single dataset. This tube replaces the former 3 and 4 color chronic panel, and reduces that panel from 11 tubes to 1 tube, with no redundancy of non-billable antibodies used.
    - Evaluated dry mix tubes that will eliminate use of pipetting instrument (requires extra QC), and manual mixing (risk of error, and requires extra QC), and frequency of ordering antibodies. We are about to make this time-saving purchase.
- COG panel for ALL-MRD has been worked up, and in process of validation with reference laboratory
- Multi-color AML tubes are in evaluation phase to replace multi-tube acute panel

Policies/Projects

- Worked with various groups (nursing and house officers) to eliminate redundant critical value calls from hematology section. We were able to get consensus opinion from nursing management, House Officer Quality & Safety Council (HOQSC), and Hematology/Oncology clinicians regarding calling redundant critical values. We will be able to discontinue calling repeated critical values.
- Lab has been continuing to work on reducing Stat absolute neutrophil count (anc) ancTAT-most are engaged in this process for as much as can be done in the analytical phase-have had much success bringing 5-7% anc outliers down to 2-4% in spite of severe shortage in staffing and many newly trained techs.
    - Overall, between May and September, we have been able to maintain an average outlier rate of 3.5%, and a 95% confidence interval of 3.2% to 3.8% outlier rate. We’ve revised our new goal to <4% outliers.
    - Have worked with new lab techs to improve workflow and minimize anc TAT with manual work. We’ve maintained an overall outlier rate of between 3 and 4%-this in spite of a very heavy volume month (March).
    - Started working on relaxing some stop autoverification rules to decrease TAT by eliminating slide review of cases that do not need it.



- Added metric in Sep 2015 to track outlier rate for PTT, have been able to maintain an overall outlier rate of around 2% :



- Have participated in NCRC planning for hemepath support
- Working with Hem/Onc and infusion staff to improve anc TAT
- Participating with DQHI patient asset management project
- Participating in UH renovation project
- 2 abstracts submitted to ASCP regarding auto-receipt on the Sysmex line and implementation of iSED instrument
- Started a process for getting all hematological csf orders to hematology and flow lab instead of cytology, and forwarding non-heme cases to cytology

IV. **CLINICAL FLOW CYTOMETRY LABORATORY 2015 (report from Dr. Dan Boyer, MD, PhD, and Usha Kota, BS, MT (ASCP), Lab Manager**

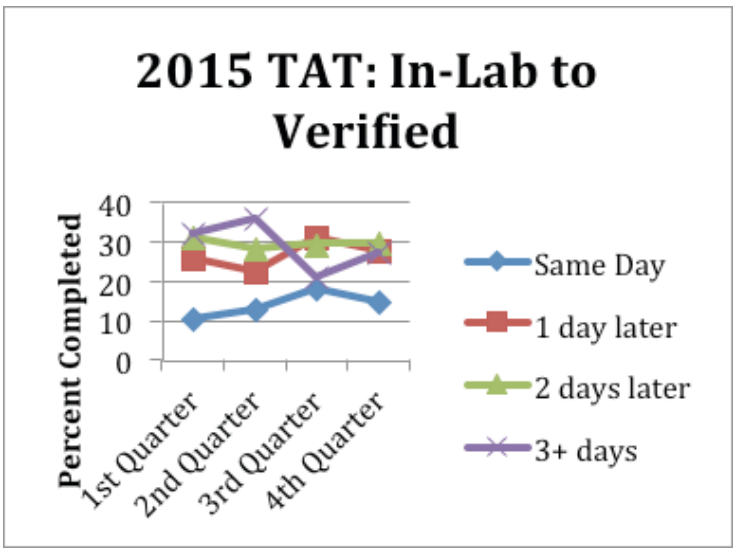
General Description

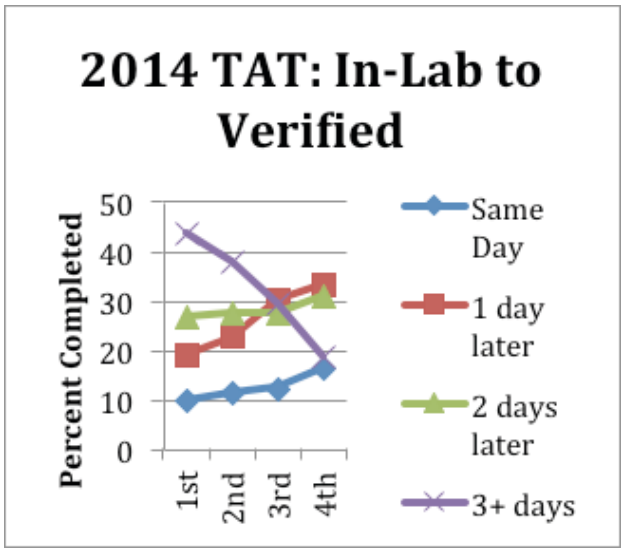
A. Instrumentation, Personnel and Space: The Clinical Flow Cytometry Laboratory is a division of the Consolidated Hematology Laboratory.

1. The laboratory purchased an additional Gallios flow cytometer this year. Current instrumentation includes three Gallios 3-laser, 10-color, 13-parameter Flow Cytometers, one FC-500 1-laser, 5-color, 7-parameter instrument, two Q-Prep Plus robotic pipette/lyse assist devices and support equipment housed in approximately 490 sq. ft. of space.
2. The division averaged 4.75 FTEs/week drawn from a group of 11 cross-trained technologists shared across the Consolidated Hematology Laboratory. This represents a decrease of approximately 0.5 FTEs/week in flow cytometry compared to FY2014.

B. Specimens: The laboratory projects a year-over-year increase of ~15% in complex cases (Pathologist verified), a 10% increase in antigen (Ag) "tests" (CDM), a 12% increase in revenue, and a 21% increase in Ag tests/FTE. Cost/test increased slightly from $11.56 to $12.33 (7%).

1. The increased test volume was accommodated despite a 0.5 FTE decrease in staffing, a testament to the bench technologists and lab manager.
2. Pathologist verified cases make up 53% of the volume (~5300 cases). These high-complexity tests require review of clinical records, specimen triage, panel selection and integration with other laboratory data for diagnosis.
3. Technologist-verified quantitative tests include lymphocyte subset analysis, stem cell counts, immunodeficiency testing, CD4 counts, CD4:CD8 ratio determination and PNH-testing (~4800 cases).
4. The major driver of increased costs was a 37% increase in expenditures on laboratory reagents, which was mainly due to purchasing new antibodies for development of 10-color assays. However, the development of 10-color assays will result in long-term savings because of a decreased number of tubes used per assay and decreased redundancy of antigens examined per assay.
5. Turn-around time for pathologist verified tests was virtually unchanged from the previous year (after stabilization of TAT post SoftFlw implementation). See graphs below:





C. 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.

Goals and Progress (highlights)

A. Modernize panels: Most panels in the laboratory consist of 3-5 color cocktails of monoclonal antibodies. These are sufficient for most diagnostic tests but the growth in minimal residual disease testing, cost benefits derived from consolidating panels into the fewest cocktails possible and the increased diagnostic power of "polychromatic" cocktails fueled interest in 8-10 color panels.

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 10-color, 15-parameter panel for B and T cell neoplasms was developed and validated on a set of clinical specimens, including: 24 peripheral bloods (13 abnormal), 36 bone marrows (11 abnormal), and 56 tissues (23 abnormal). This panel will replace the current "non-acute" leukemia/lymphoma panel, condensing a 10-tube assay to a single-tube assay. The newly validated panel will be implemented after the technologists have been trained on Kaluza analysis software, because the complexity of the panel is not amenable to analysis with the legacy CXP software currently used by the technologsts.
3. A single-tube assay for sezary cells and a two-tube assay for AML are in the planning stages, and we will begin validation on these panels after the B/T combo is implemented and the COG B-ALL panel validation is underway (see next item).

B. **B-ALL MRD assay**: We plan to implement 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 and is currently performed at Johns Hopkins and University of Washington for all patients on the trial.
2. U of M enrolls 15-20 patients on the trial each year.
3. In 2016, the COG will stop paying for reference testing for this trial and would prefer to have the assay performed as a billable test at local or regional laboratories.
4. Our application to be a site for MRD testing was approved, and we plan to process specimens in parallel with the University of Washington to validate the assay in our lab.
5. The necessary antibodies for the COG panels have been purchased and titrated.
6. We plan to begin validation this summer.

C. Flow cytometry supervisor search: The lab has not had a general supervisor since Usha's promotion to hematology lab manager. The lack of a designated supervisor has been an impediment to development of new assays and balancing the flow workload among a group of technologists who frequently rotate among different areas of the hematology lab and often divide their time between flow and other tasks within the same day. In addition, as part of our reference lab work, we would like to offer technical-component-only flow cytometry, which will require a senior technologist to oversee client support.

1. Approval for the position was obtained in February and the position was posted.
2. After review of CVs, two candidates were interviewed in June.
3. Neither candidate was thought to be ideal due to limited supervisory experience and little experience with multi-laser cytometers.
4. The position has been re-posted and we are continuing the search.

D. Upgrade specimen preparation assist devices: The lab currently uses two PrepPlus instruments from Coulter; however, these instruments can only make cocktails with a maximum of 7 antibodies, while our newer panels use 9 – 13 antibodies. We are testing a newly developed instrument from a Norwegian

company (InstruNor), which can cocktail up to 100 antibodies and automates the entire stain-lyse-wash-fix procedure for up to 18 patient samples at a time. We are currently one month into a two-month testing period. Our technologists have been pleased with the instrument so far, especially the cocktailing capabilities.

E. Refine triage criteria for CSF: Most CSF specimens that we receive for flow cytometry are paucicellular and low volume (less than 5 ml received for >70% of specimens; 40% of specimens contain 2 ml or less). These specimens are rarely positive, and we would like to develop criteria for cancelling specimens that are likely to be inadequate.
   1. Mary Dhesi, Josh Jacques and Lloyd Stoolman are reviewing archival flow data. 708 CSF cases analyzed so far. Data set will eventually include > 1000 cases. Largest comparable series in the literature is 500 cases.
   2. Of 708 cases reviewed so far, 129 were positive (18%).
   3. Only 3 positive samples (1.5%) among 200 submitted from patients without prior history of malignancy.
   4. Although it has been documented that flow cytometry can successfully detect rare CNS lymphoma cells that are not evident on cytospins, we hypothesize that there is a lower limit of specimen cellularity below which flow cytometry is insensitive.
   5. Our goal is to use the data from this retrospective review to identify a set of criteria, including patient history and specimen cellularity, that will enable us to prevent wasteful testing of uninformative specimens.

SPECIAL COAGULATION LABORATORY: Report from Steven Pipe, M.D.

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 to scholarly activity:

Cost Reduction
Following correspondence from Dr. Keren, met with Brian Tolle from DQHI to discuss test utilization in Coagulation. Department will track reflex testing of HIT's to BCSRA (Serotonin Release Assay); volume of DIC's ordered as standing orders, order errors (i.e. Factor 5 that should be Factor V Leiden, Factor 10 that should be Anti-Xa); and tests screened by Special coags (Aggies ordered inappropriately, PSACTs)

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.

Completed a retrospective evaluation of use of anti-Xa assays, compared PTT for monitoring heparin in the Children's Hospital with Pharmacy. Manuscript has been completed and will be submitted.

November started staff meetings to provide education to bench staff and improve employee surveys, very positive response from staff.

Evaluated Stago vs IL/Werfen vs Siemens analyzers and reagent platform for new analyzer acquisition; including site visits and information from Tech Specialists.

Feb 2016 in response to patient safety report, implemented strict policy for monitoring collection-to-receipt time for Heparin levels. Supported development of Soft Computer rule that alerts bench technologist of delivery delay. This caused some concern from nursing units, but they complied when they realized this was in the handbook and required by CAP.

Started Chromogenic Factor 9 assays; continuing to gather data for implementation.

Scholarly Activity

Argatroban/anti-IIa manuscript published in Am J Hematol.
Poster presented at ISTH on our evaluation of a new coagulation analyzer (Siemens).

Clinical Research

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 Wave A and Wave B and are about to start Wave C of these research studies. We also completed a study funded to evaluate a new INNOVANCE Heparin assay.

We completed another field study for a PTT and chromogenic factor VIII assays on a new bioengineered factor VIII product from Novo Nordisk.

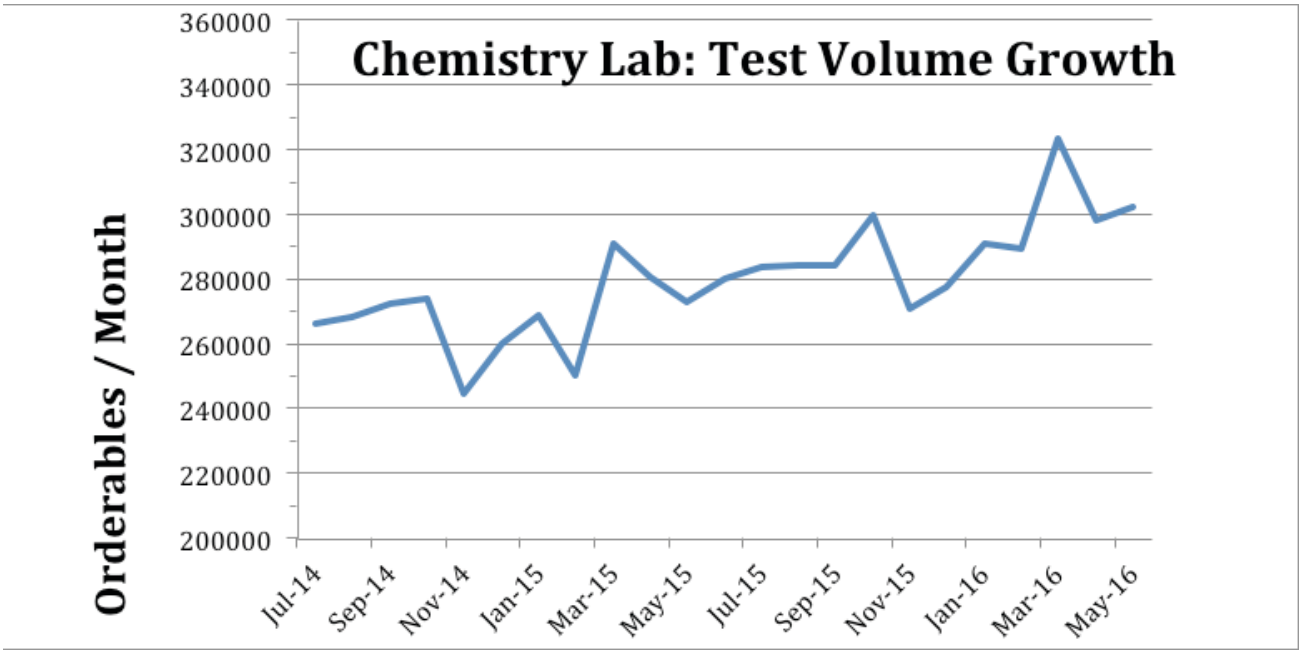
Education

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 presented at the ASCLS-Michigan annual meeting on coagulation testing. He provides lectures to the Hematopathology Conferences and supervises special coagulation testing interpretations with the pathology residents, Blood Bank fellows and Clinical Hematology fellows. He provides oversight for a Coagulation Rotation for the Hemepath Fellows.

CHEMICAL PATHOLOGY SECTION LABORATORIES

The Chemistry Section, under the leadership of Dr. Donald Giacherio, and the administrative management of Sue Stern MS, MT(ASCP), experienced an approximate 8.2 % increase in overall testing volume this year. Associate Lab Directors Dr. Lee Schroeder and Dr. Hemamalini Ketha both saw significant growth in their specialty areas of Point-of-Care Testing and Toxicology, respectively, and Dr. Jeff Warren oversaw changes in the Immunology Laboratory. Lab test volumes continue to grow at a fairly consistent rate, as demonstrated in FIGURE 1. The outstanding efforts of Sue Stern, Merry Muilenberg, 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.

FIGURE 1



The continued increases in sample volumes have put pressure on the lab to maintain rapid turn-around times, particularly on STAT samples. Currently, approximately 30 % of orders are STAT. The lab has consistently met its goals of greater than 98 % of STAT's being verified within 45 minutes (FIGURE 2). Over 99 % of STATS are verified within 1 hour of receipt, and 99.5% of routine samples are verified within 120 minutes of receipt. The lab has also begun working with DQHI on a number of possible utilization control projects for the upcoming year.

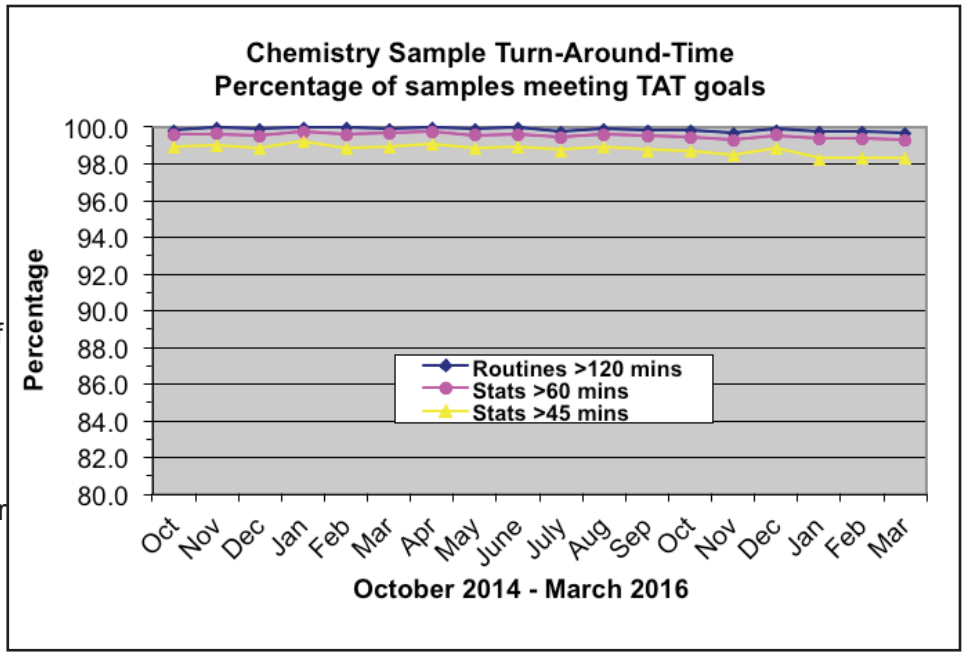


FIGURE 2

The Chemistry Section has once again made significant progress towards it goals of bringing in new tests and automating more manual testing methods. The automation section of the lab under the supervision of Eric VasBinder continued to add new tests to the Siemens Chemistry / Immunoassay automation track system. A new fourth generation HIV antigen plus antibody test was validated and implemented this past fall. Testing for Hepatitis B envelope antigen was switched from a manual ELISA assay to the Siemens Centaur this winter. Urine free cortisol testing was moved from an RIA assay to an automated chemiluminescent immunoassay on the automation line, moving the lab one step closer to its goal of eliminating all radioactivity based assays. Responding to requests from Cancer Center physicians, Eric VasBinder took the lead in validating testing for betaHCG and AFP on CSF samples. Chemical Pathology Fellow Dr. Shih-Hon (Sean) Li completed an elegant validation of exactly which chemistry tests could be accurately performed on patients receiving the blood substitute Hemopure.

Two other major focus areas of the automation section were the planning for a new core laboratory function in the hospital and the active search for replacement instrumentation. Multiple members of the lab staff met with the Pathology Relocation and Renovation (PRR) staff and architects to thoroughly elucidate the current state of the laboratory and prioritize key future state objectives. Continued refinement of core laboratory structure will be a major focus of the coming year. Dr Giacherio, Sue Stern and Eric VasBinder led negotiations with Siemens to acquire new chemistry and immunoassay analyzers to replace aging equipment. This recently agreed upon unique 3 year contract will help bridge the time gap until the core lab renovation project is finished. The automation section leadership has also put together a bid packet seeking proposals to replace other aging specialty analyzers in the section. This bid packet goes out in June 2016 and the lab expects to award contracts for new analyzers in the fall of 2016.

The Special Chemistry section of the laboratory had a very busy year. The Sebia Capillarys analyzer was acquired and validated for performing confirmation testing on patients with hemoglobin variants. Dr Sean Li, David Harro, and John Alfsen were all instrumental in the thorough validation of this system, which allowed the lab to discontinue sending out confirmatory hemoglobin testing. The lab acquired a Diasorin Liason XL immunoassay analyzer, and switched multiple infectious serology assays over to this platform. In addition, the Liason XL enables the performance of 1,25 dihydroxyVitamin D in an automated fashion, replacing a very laborious RIA assay. Drs. Ketha, Giacherio, and pathology resident Martin Magers have demonstrated the feasibility of calculating bioavailable testosterone from the measurement of total testosterone by immunoassay, sex hormone binding globulin, and albumin. This lab developed test is in the final stages of validation of reference intervals, and should be implemented by fall. Bioavailable testosterone is currently the highest volume send out test from UMHS. Work is progressing on 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 Drs, Giacherio and Li have worked with Tony Sinay on the complex task of validating the fecal calprotectin assay. Because these are considered lab developed tests (LDT's), validation requirements are significantly more rigorous. Both are expected to be implemented by this fall. AMH is a top ten volume send out test, and Fecal Calprotectin is currently the highest dollar volume send out test from UMHS. The special chemistry section began offering a more sensitive thyroglobulin assay to aid Endocrinology and Nuclear Medicine physicians in monitoring post-thyroidectomy thyroid cancer patients for recurrence. This more sensitive assay will help with earlier detection of recurrence and reduce the need for use of recombinant TSH stimulation in these patients. Anti-thyroglobulin testing was moved from the Immunology Lab to a more automated chemiluminescent immunoassay platform in Special Chemistry. Sue Stern and Merry Muilenberg were instrumental in deploying a SOFT interface so that testing on the Beckman Access analyzer for Erythropoietin, SHBG, AMH, Thyroglobulin, and anti-Thyroglobulin test results could be uploaded to the SOFT LIS system rather than be manually entered by technologists. Finally, Nick Wesener, IT specialist for the point-of-care testing group was instrumental in setting up a SOFT interface for ionized calcium testing performed in the lab. This will significantly reduce the incidence of transcription errors for iCal testing.

The Drug Analysis and Toxicology section of the laboratory focused on LC-MS assay development this past year. The lab was very happy to welcome Dr. Hema Ketha to the faculty as director of the toxicology lab. Dr. Ketha, lab supervisor Sheridan Mattson, Sr Technologist Larry Clayton, and all the medical technologists in the Tox section have been actively involved in new assay development. The lab finished the validation and implemented an LC-MSMS assay for testosterone that is utilized for samples from children and women to provide a far more accurate measurement than the current immunoassay methodology. Dr. Ketha was instrumental in the development and implementation of an assay for DHEA that replaces the previously used radioimmuno-assay. The ability to measure 17 hydroxyprogesterone, DHEA, androstenedione, and testosterone from the same serum extraction has been demonstrated by Dr. Ketha and Theresa Swift. Brian Wright has nearly finished validation of an LC-MSMS assay for fentanyl, which is becoming increasingly more prevalent as an abused drug in the area. Dr. Ketha continues to do validation work on GC-MS detection and identification of synthetic designer drugs such as substituted phenyethylamines. Larry Clayton has been instrumental in developing LC-MSMS assays for quantitation of Lamotrigine and other seizure control medications, and has begun the development of an assay for plasma metanephrines. This will complete the laboratory's comprehensive list of tests now available for diagnosis of pheochromocytoma, and bring in-house one more of the top ten send out volume tests. Because all LC-MSMS assays are now considered LDT's, the development / validation times can be significant. Drs. Giacherio and Ketha put together a proposal for acquisition of an LC-MS-QTOF analyzer for enhanced urine drug screening capabilities, and presented it to the hospital committee for capital projects over $500,000. The proposal was approved and the new instrument should be installed this summer.

The Immunology section of the laboratory acquired a 2nd BioRad BioPlex multiplex immunoassay analyzer and finished all the correlation studies needed to move testing for both cardiolipin antibody panel and beta-2 glycoprotein 1 antibody panel from a manual ELISA procedure to the automated BioPlex multiplex assay. The lab acquired a new Sebia Capillarys II system for serum protein electrophoresis, and implemented testing on this platform last fall. The Immunology Lab completed an RFP bid process and selected the Image Navigator system automated ANA fluorescent microscope slide reader which was installed and validation studies for this LDT were begun this winter. Donna Bush and Chris Offord trained on the system and performed all the validation studies. Immunology should begin using this system for ANA by IFA, Crithidia anti-dsDNA by IFA, and ANCA testing in the next two months. Sue Stern worked with The Binding Site to implement a SOFT interface for the SPA serum protein analyzer, and built the reflex test panel for Celiac Disease diagnosis that is now up and operational. Mary Lou Erber, supervisor of Immunology, spearheaded a project to scan all paper protein electrophoresis chromatograms and interpretations so they can be viewed electronically rather than maintaining individual folders of testing records for each patient.

The laboratory continued its tradition of focusing on lean strategies aimed at improving efficiency. A redesign of special chemistry space to accommodate new Point-of-Care staff was accomplished with minimal disruption. The senior technologist work area was redesigned to allow for one more work space. Dr. Ketha and Nicole Sobolak led a lean team effort to redesign work stations in the Toxicology section to shorten walk distances be-

tween prep and analysis areas. Eric VasBinder led two small redesign efforts in the automation area that had significant positive impact. The sample manger/ loaders for the automation track were reconfigured to perform both loading and unloading functions, thus improving sample handling at peak workflow times. After review of specialty clinic ordering patterns, the maintenance schedules for the Centaur immunoassay analyzers were changed to improve instrument availability during early morning heavy patient blood draw time periods. Multiple lab staff worked with Lean Coach Brendan Weil and PRR Project Manager Christine Baker to define and describe current operations and important adjacencies that would be desirable to maintain as planning for the core lab begins. The lab continues the use of daily huddles and lean idea suggestion forms to promote technologist suggestions for improvement ideas. Thanks to the dedicated efforts of Sue Stern, the lab continues its practice of daily posting of turn-around time statistics for both automation line and COBAS Integra work bench assays in the effort to maintain the trend of continuous improvement in those areas.

The Chemistry section labs continue their significant role in education. Dr Sean Li is completing his yearlong fellowship, and has been a tremendously positive asset for the lab. Pathology residents on a monthly rotation through the laboratory met daily with Drs. Giacherio, Schroeder, Ketha, and Keren and spent additional time with the supervisory staff and senior clinical technologists. Lab manager Sue Stern was the keynote speaker for a Siemens healthcare diagnostics employee meeting on Voice of the Customer. Six medical technology students spent 4 weeks each rotating through the lab sections. In addition, the lab hosted Pediatric Endocrinology (Special Chemistry) fellows for one week of laboratory testing exposure, and two Allergy Fellows for a two day exposure to IgE allergy testing and serum protein electrophoresis interpretations. 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 lab will be actively involved in planning for the hospital renovation and core laboratory design. We expect to upgrade the seven analyzers on the automation track, as well as acquire several new replacement analyzers for specialty testing. This installation and validation will require a significant amount of effort from all laboratory staff. The installation of a new LC-MS/QTOF system will open up numerous possibilities for quality improvements of urine drug screening and detection of opiate use and abuse. The lab will also welcome a new Chemical pathology fellow in July, Dr. Forest Huls.

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 12 positions due to transfers or retirements (2 senior techs, 7 med techs and 3 lab techs), and are anticipating 7 more retirements or reduction in hours in the first half of 2016-17 (2 senior techs and 5 med techs). Many of these vacancies are due to retirement of very senior employees whose technical expertise is impossible to replace. Several approaches are being taken to try to fill these emerging gaps:

- Targeted approach to hiring of experienced technologists with specialized expertise
- Using LEAN 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

With regard to the approach mentioned above, we are creating new operational positions from vacated senior technologist positions that will allow us to dedicate resources to Quality Assurance, Teaching/Training, and Project Management. These positions will complement ST positions which will be targeted to high impact technical areas. In addition, refinement of the supervisors' roles and responsibilities are ongoing. In particular, they are functioning in a more integrated manner with overlapping coverage of technical areas and work shifts in order to improve connection with staff.

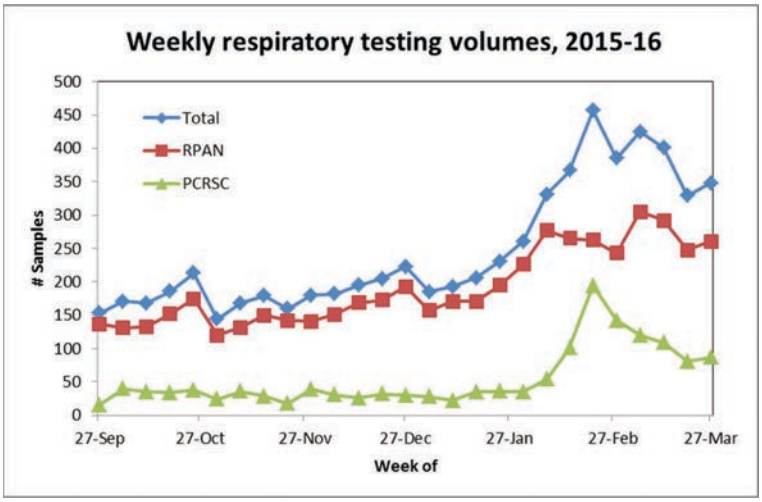
Major clinical activities over the last year:

- Rapid identification of blood cultures
    - Completed evaluation of performance of BioFire and Nanosphere multiplex panels
        - For rapid identification of bacteria/yeast and critical antibiotic resistance markers directly from positive blood cultures
        - Results are linked to antibiotic stewardship guidelines to expand or narrow to effective and appropriate therapy
    - Implemented Nanosphere system
        - Worked with antimicrobial stewardship team to develop reporting language and educational information for providers
        - Maintained dialogue post-implementation

- Rapid identification of gastrointestinal pathogens
    - Evaluated performance of BioFire multiplex panel
        - Direct detection of bacterial, parasitic and viral pathogens from stool
        - Potential consolidation of methods and elimination of conventional methods
        - Planned implementation for inpatients (especially immunocompromised)
        - Working with ambulatory care to determine appropriate utilization

FilmArray system from BioFire:

- 24/7 testing for respiratory pathogens
    - Expanded testing to midnight shift in response to requests from Emergency Department and Infection Prevention to enhance admission and bed placement process
    - Increased education to improve test utilization so that BioFire multiplex panel (RPAN, 17 targets) is used for inpatients and Focus Flu A/B/RSV assay (PCRSC) is used for outpatients or inpatients when Influenza vs. RSV is the primary differential diagnosis. We felt that these efforts were successful. RPAN orders remained consistent through the respiratory virus season (reflecting primarily inpatient orders) while PCRSC volumes increased coincident with influenza activity (reflecting primarily outpatient orders, see graph below)



- Zika virus preparedness and response
    - Worked with multiple clinical areas (OB/GYN, Ambulatory Care, Infectious Diseases, Infection Control) to develop response plan
        - Coordinated development of test ordering process with MiChart
        - Coordinated specimen collection protocols and sendout with MDCH and Specimen Processing
    - Activity was high over the winter as media attention was high and travelers were returning from endemic areas (approx. 75 patients tested to date)
    - Preparations are ongoing in anticipation of summer mosquito season

- UM campus norovirus outbreak
    - In Feb. 2016, approximately 500 students were affected by acute gastroenteritis that was ultimately determined to be due to norovirus
    - Communicated with MDCH, local health departments, University Health Services, Occupational Safety and Environmental Health
        - Coordinated specimen collection protocols, transport to MDCH, and result reporting

- 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
        - Site visits were conducted to evaluate laboratory automation systems

- RFP process completed for sexually transmitted infection testing platform:
    - Panther (GenProbe/Hologic) system selected
        - Instrument install, staff training, and system validation will occur during summer of 2016

- RFP submissions for new automated systems recently initiated:
    - Automated specimen processing/plate handling systems
        - Products being considered: Kiestra and WASP
    - Automated blood culture incubation systems
        - Products being considered: Bactec, BacT/Alert, Trek
    - Anticipate selections for each in the first half of FY17

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. Planning for potential Ebola virus patients has shifted from being Ebola-specific, to developing a system whereby patients with any novel serious communicable disease could be managed safely and effectively, and the Clinical Microbiology Laboratories have played an integral role in this planning. Furthermore, 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; implementation of blood culture ID panel testing and reporting phrases; implementation of GI panel testing and reporting phrases.

In addition to the clinical duties, the laboratory continues to be active in multiple research projects which involve many bench-level technologists and provide them with opportunities to attend scientific meetings, which additionally enhances the academic visibility of the laboratory and department. Ongoing research projects include: MRSA surveillance in radiology patients; Surveillance for multidrug-resistant organisms in nursing home patients; Enterovirus D68 in pediatric patients; Changing susceptibility to daptomycin in vancomycin-resistant enterococci; Clinical trial for MRSA Select II in surveillance specimens; Characterization of viral pathogens and subsequent immune response in children with clinical respiratory tract infections; *H. influenzae* genes associated with COPD; Cryptococcosis in patients with end-stage liver disease and liver transplants; 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, led a multi-disciplinary research team of infectious disease physicians, bioinformaticians, a biostatistician and a molecular epidemiologist in a MICHR-funded project to identify bacterial and patient factors associated with *Klebsiella pneumoniae* infections from a cohort of nearly 2,000 patients. He is currently 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. Two Molecular Genetic Pathology fellows, Andrew McDaniel and David Seward, each completed six-week rotations that included assay development projects. 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.

MOLECULAR PATHOLOGY DIVISION

Dr. Tom Giordano was appointed as the Director of the Division of Molecular Pathology this year. In that role, he now 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, Histocompatibility and Microbiology. The vision statement indicates that the University of Michigan Hospital and Health Systems will be a principal provider of 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 which 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 that has had extensive involvement in planning the new Molecular Laboratory at the NCRC.

The Molecular Group of laboratories newly under the leadership of Dr. Tom Giordano, has made great strides engaging its various staff members so 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. Tom Giordano)

Laboratory	Director	Technical Director/ Manager	Manager/Supervisor
Molecular Diagnostics	Dr. Noah Brown	Dr. Bryan Betz	Jennifer Bergendahl
Michigan Molecular Genetic Laboratory	Dr. Jeff Innis	Marwan Tayeh	Todd Ackley
Cytogenetics	Dr. Lina Shao	Beth Cox	Leslie Ernst
Michigan Center for Translational Pathology	Dr. Priya Kunju	Javed Siddiqui	Debbie Snyder
Histocompatibility	Dr. Daniel Ramon	Kathryn Daavettila	Cynthia Shall
Dermatology Molecular	Dr. Aleodor Andea	Min Wang	

MOLECULAR DIAGNOSTICS LABORATORY

Overview

The laboratory is directed by Dr. Noah Brown. The laboratory's Technical Director is Dr. Bryan Betz. The Associate Medical Director is Dr. Thomas Wilson. The technical supervisor/laboratory manager is Jennifer Bergendahl. Laboratory Supervisor is Nanci Lefebvre. 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 directors, technical director, attendings, supervisors, R&D 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.

Bimonthly operation meetings are now conducted with the director, on-site director, associate director, technical director, lab manager and supervisor. Discussions focus on operations of the laboratory.

Monthly Manager/Supervisor meetings are now conducted with the lab 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

Drs. David Seward and Andrew McDaniel graduated as Molecular Genetic Pathology Fellows of the University of Michigan Department of Pathology fellowship program's seventh class (2015-2016 academic year).

New Molecular Genetic Pathology Fellow (2016-2017):

Dr. Pawel Mroz

New Tests

09/08/2015: KRAS Exon 4 mutation analysis
01/27/2016: TRB Gene Rearrangement
02/10/2016: MGMT Promoter Methylation
02/24/2016: IGK Gene Rearrangement
03/30/2016: Comprehensive NSCLC Mutation Panel (NGS)
03/30/2016: Comprehensive CRC Mutation Panel (NGS)
03/30/2016: Comprehensive Melanoma Mutation Panel (NGS)
04/06/2016: Luminex xTAG Cystic Fibrosis Carrier Screening
05/02/2016: MLH1 Promoter Methylation

Future Tests in Development - (all to be completed by June 30, 2017):

- Comprehensive Solid Tumor Panels – Expansion of solid tumor Next-Generation Sequencing (Ion Torrent) panels to detect clinically actionable mutations, copy number variants and fusions:
    - Non-Small Cell Lung Cancer Panel
    - Colorectal Cancer Panel
    - Melanoma Panel
    - Comprehensive Solid Tumor Panel

- BRAF Rearrangement by FISH – Break-apart FISH assay to detect BRAF translocations in gliomas, melanomas and other tumors.

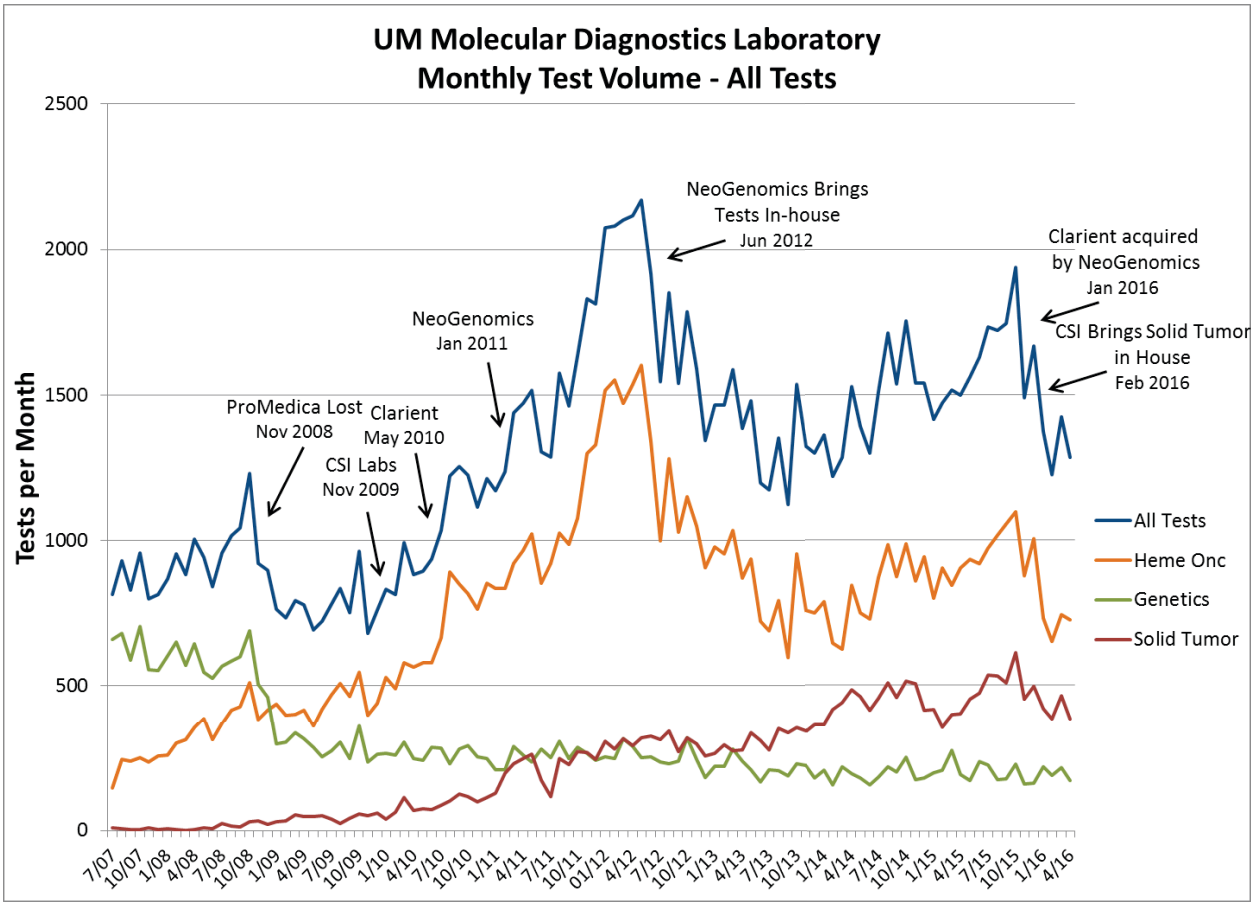
- TERT Promoter Mutation – Allele-specific PCR assay to aid in the diagnosis of melanocytic lesions and to detect urothelial carcinoma in urine.

- Bone Marrow Engraftment Analysis – Conversion to a new testing platform, in part due to licensing requirements with additional markers and more automated data analysis

- Myeloid / T-ALL 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, MDS and T-ALL
    - Acute Myeloid Leukemia Panel
    - Myelodysplastic Syndrome Panel
    - Myeloproliferative Neoplasm Panel
    - T Acute Lymphoblastic Leukemia Panel
    - Comprehensive Myeloid Panel

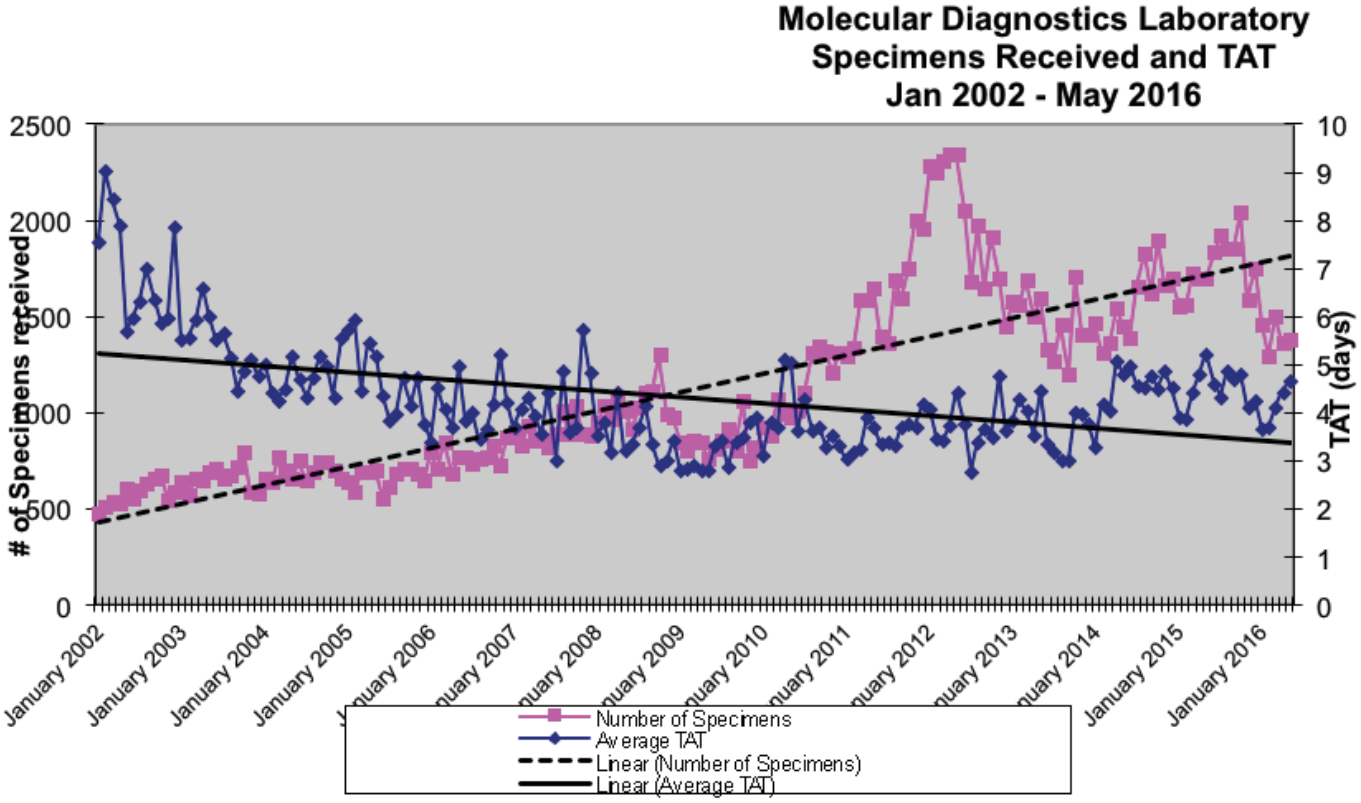
Specimen Volume

Specimen Volume 1/1/2015 – 12/31/2015: 19840 (This is a 9.75% increase from the previous year). Much of the increase is attributable to increased utilization of testing for solid tumors.



Test Turn-Around-Time

The average turn-around-time for all assays was 4.48 days. This is a decrease of 0.82 days from the previous year. We actively worked to streamline test procedures and tissue microdissection workflow to facilitate faster review of H&E's to aid in samples getting to technologists more quickly.



Educational Improvements

We created a more rigorous Resident Training program. Our Medical Director, Dr. Noah Brown, wanted to have a training program where the residents are more involved in learning our procedures. Dr. Brown developed, and with the help of our Supervisors and technologists implemented a new in-lab procedure-based training program in October. 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. A problem-based teaching portfolio is currently being created.

Operational Improvements

Additional Staff (1FTE)

Our staffing increased by one 40-hour position with the addition of a lab technician. We now have two lab technicians to assist with processing our samples and to assist in our histology department. Our Lab technicians now process all sample drops and process all of our Histology requests. Our Medical Technologists are now more available for assay setup and have quicker TAT's due to not having to process the sample drop. We also added one work study position. Our work study employee only works on Saturday to help process our sample drop. The laboratory employs 22 full-time employees and one part- time employee. Two, out of the 22, full-time employees are dedicated research and development.

Additional Instrumentation

Capital equipment for 2015 included 12 new thermal cyclers. Our current 9700 thermal cycler lids were breaking due to age. The cost to repair the lid was $5,000 dollars. We received a discount through Life Technologies to purchase Veriti thermal cyclers for under $5,000 dollars each. The decision was made to replace the old 9700 thermal cyclers with the new Veriti's since Life Technologies will be discontinuing the 9700 thermal cycler. The new thermal cyclers need to be validated for all of our assays. Validation is still ongoing.

Clinical Testing Improvements

A Quality Announcement Dashboard was created and maintained. Within this we showcase and trend select examples of Pre-analytical, Analytical, and Post-Analytical data. We also have a section for announcements. This section is utilized to inform staff of new tests that are in development, kudos, continuing education opportunities, and welcoming new staff.

We co-developed the Molecular All Staff meeting, with all molecular laboratories that will be sharing space at our future laboratory at the NCRC. This will help technologists get to know other staff members within the Molecular Diagnostics, Medical Genetics, Translational Pathology, HLA, and Cytogenetics laboratories before moving into shared space at NCRC. These meetings are held quarterly until we move to NCRC in 2018.

We implemented a new slide storage system within the lab. Through this new process we can utilize the slide barcodes and file the slides in distinct slots so the slides do not touch or lean against other slides. We also have an inventory management system that allows us to track what space a certain slide is in. This also facilitates easy retrieval of slides and filing of slides. This has resulted in a reduction of time to file and find slides by 10 mins.

We implemented Rounding with our employees in November 2015. Ideas generated from these sessions have been implemented and have had a positive impact on the laboratory. Rounding sessions occur quarterly.

We implemented a Luminex assay for Cystic Fibrosis Carrier Screening which is FDA approved and which increased the number of tested mutations from 43 to 60. By transitioning to a Luminex test platform and working with the HLA laboratory we were able to use existing equipment instead of purchasing new.

We implemented a new refrigerator/freezer organization system to reduce reagent waste and cost due to reagents becoming outdated.

CYTOGENETICS

Overview

The laboratory Director is Lina Shao, M.D., Ph.D., and the Director Emeritus is Diane Roulston, Ph.D. Thomas Glover, Ph.D. (Professor, Department of Human Genetics, Department of Pathology) continued to provide invaluable expertise and sign-out coverage, primarily for constitutional genetic cases and oncology FISH cases. Over the past fiscal year, the Cytogenetics Laboratory made several important improvements. A Leica CytoVision GSL scanner was validated and used in scanning metaphase cells, resulting in less analysis time per case and improved turn-around-time (TAT) for oncology cases; Thermotron chamber was validated and replaced cold room in preparation of oncology chromosome and all FISH slides, resulting in improved safety to technologists, consistency and quality of slides, and also efficiency (0.375-0.5 FTE saved); a new hybridization buffer, FAST buffer, was validated and replaced the standard buffer in CLL FISH panel and STAT FISH testing procedure, resulting in improved quality and shortened TAT. A series of employee engagement classes were carried out with DQHI manager Brian Tolle, resulting in improved communication and decreased negativity.

Clinical Services

In FY2016, the Cytogenetics Laboratory had a slight decrease in overall sample volume compared to FY2015 (Table 4). A total of 3,715 tests were performed, representing a decrease of 3.1%. Most of the sample types showed a decline to some extent; a continued increase in Cancer Cytogenomic Array test helped offset some of the decline.

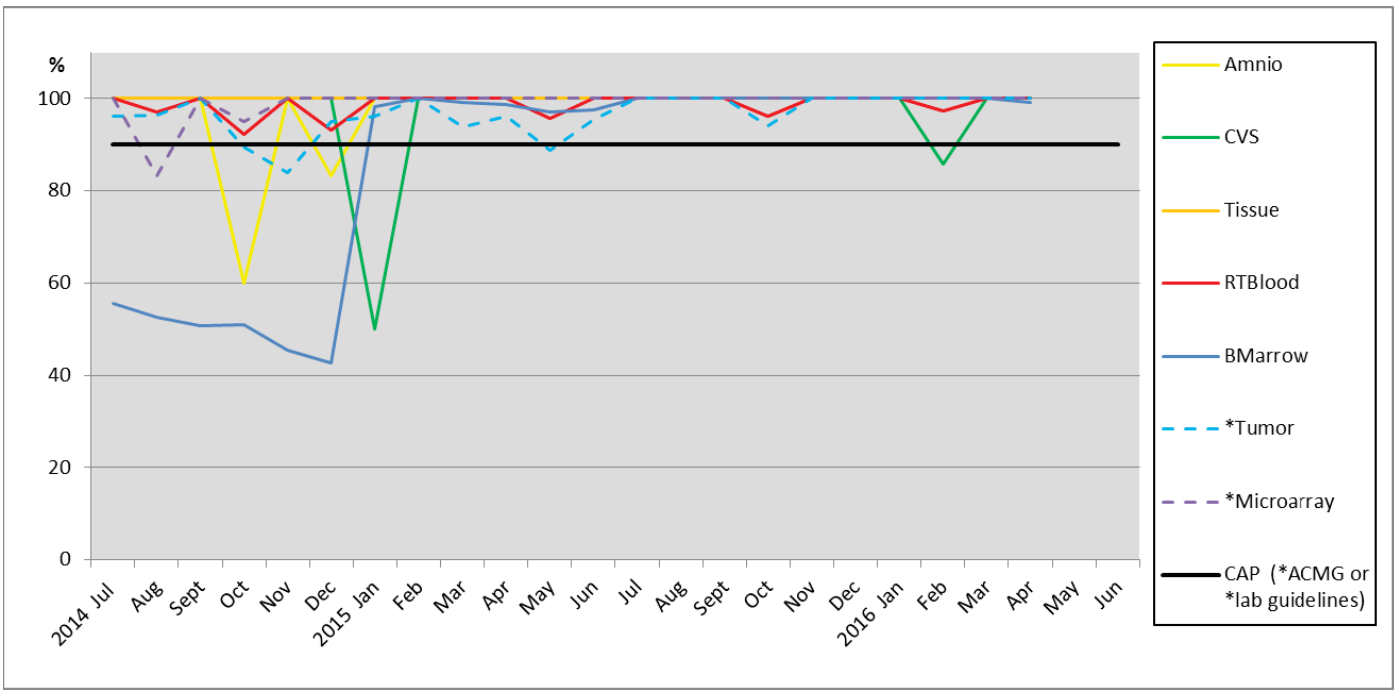
Table 4. Projected Sample Volumes in Clinical Cytogenetics Laboratory (FY2016)

Sample type	**N**	**Change from FY2015**
Bone marrows	1,698	-88 (-4.9%)
Tumor/Lymph node	288	-30 (-9.4%)
PB constitutional	336	-25 (-6.9%)
Prenatal		
Amnios	67	+8 (+13.6%)
CVS	67	+8 (+13.6%)
Tissues (POC)	42	-63 (-60.0%)
Total (chroms):	**2,498**	**-188 (-7.0%)**
Tissue culture only	13	+5 (+62.5%)
Add tissue culture for AM, CV or TI	18	+0 (+0 %)
Total	**31**	**+5 (19.2%)**
FISH		
Constitutional genetics	109	+44 (+67.6%)
Oncology		
Single probe	542	-104 (-16.1%)
Panels*	162	+37 (+29.6%)
FFPE	53	+11 (+26.2%)
Total (FISH):	**866**	**-12 (-1.4%)**
Microarray		
Hem- onc	242	+24 (+11.0%)
Solid tumor	78	+53 (212%)
Total (microarray):	**320**	**+77 (+31.7%)**
Total tests:	**3,715**	**-118 (-3.1%)**

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

The total volumes for karyotype had a moderate decrease of 7% (-188 cases) compared to FY2015. Volume of products of conception declined significantly (-60%, -63 cases) due to a switch from chromosome analysis to a sendout SNP array test. Moderate decreases were also observed in tumor/lymph node samples (-9.4%, -30 cases), constitutional blood samples (-6.9%, -25 cases), and bone marrow samples (-4.9%, -88 cases). Prenatal sample volumes (amniocentesis and chorionic villus) had moderate increase (+13.6%, +16 cases). Under the leadership of supervisor Turquessa Brown-Krajewski and senior technologist Lynn Knudson-Horneber, the laboratory consistently met the CAP required TAT for each sample type (Figure 1).

Figure 1. Percentage of chromosome cases meeting CAP-compliant turn-around-time between July 2014 and April 2016



The volume for single probe FISH tests kept declining (-104, -16.1%) following the trend starting in FY2013; the significant increase in each of the other categories including constitutional FISH (+44, +67.6%), oncology FISH panel (+37, +29.6%), and FFPE FISH (+11, +26.2%) helped to offset the decline in the total volume of FISH tests (-12, -1.4%) compared to FY15. The decrease in single probe test volume was ultimately due to improvements in the quantitative PCR assay for BCR/ABL1, such that fewer FISH tests are required to monitor response to TKI therapy. Under the leadership of senior technologist Hong Xiao, the section streamlined workflow and shortened TAT from 10-14 days to 7 days. A FAST hybridization buffer from Abbott was validated, better or at least equivalent results were achieved with 2-hour hybridization time compared with standard overnight hybridization, this solution has been used for the CLL FISH panel with an improved quality and decreased failure rate, also for STAT cases to shorten the TAT.

The volume for Cancer Cytogenomic Array continued to increase in FY16 (+31.7%, +77 cases), mainly due to a steady increase in pediatric solid tumor samples after the tumor array test was offered clinically in March 2015. The Cancer Cytogenomic Array test has improved diagnosis, prognosis, and treatment in hematological malignancies and pediatric solid tumors, and has become standard of care for acute lymphoblastic leukemia and pediatric solid tumor patients at diagnosis.

We acquired a Leica CytoVision auto-scanner in May 2015, it was validated and used for scanning and capturing oncology metaphase cells. It significantly increases efficiency, speeds up the analysis process, and improves productivity. Two additional CytoVision analysis stations were acquired, so technologists have easy access to the analysis software. We validated and put into full use of the Thermotron chamber for preparation of oncology chromosome and all FISH slides, this change improves safety to slide droppers, consistency and quality of slides, and also efficiency (0.375-0.5 FTE saved). An additional Affymetrix Fluidics station was acquired to meet

the increasing volume in Cancer Cytogenomic Array testing.

With regard to staffing, the laboratory administrators replaced two departing technologists, and a previously recruited technician was promoted to technologist position to replace another departing technologist. One technologist and one technician position are in the interview stage currently. Locum tenens contracts were renewed and have proven extremely helpful for coverage of sign-out duties during director absences.

With regard to employee engagement, under the leadership of Margaret Rayer and Beth Cox, the laboratory launched a self-designed trust survey in September 2015 and identified areas to work on this year. Two technologists were sent to a Gossip Stopper workshop. Brian Tolle gave a series of classes to the laboratory leadership, and a series of workshops on DISC communication style to the entire laboratory. A post-survey conducted in June 2016 demonstrated improved scores in almost all the areas in the trust survey compared with the pre-survey.

Other significant activities included a successful internal CAP inspection without citation or recommendation and continued effort in the PRR project.

Education

Residents and fellows from a wide range of specialties performed rotations in the laboratory. These included Pathology residents (10), fellows from training programs in Molecular Genetics in Pathology (2), and Hematopathology (2). The residents and fellows presented brief talks on relevant topics in cytogenetics for the technologists, making a much-appreciated contribution to continuing education.

The laboratory implemented a monthly continuing education program under the leadership of Beth Cox and Leisa Stempek. Continuing education activities include presentations from residents/fellows during their rotation, didactics from directors, special topics and abnormal cases from laboratory staff. 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 regional conferences, two technologists attended the annual Great Lakes Chromosome Conference in Toronto. Two other technologists attended the 24th Annual Symposium on Molecular Pathology at Beaumont Hospital. Two senior technologists will go to the national Association for Genetic Technologists conference in Orange County, California.

The laboratory continued to benchmark well and maintained Approved Laboratory status for participation in clinical trials for the Children's Oncology Group (COG); 8 case studies were submitted. Dr. Roulston served on the Cytogenetics Committee for COG, and served as co-chair of the SWOG Cytogenetics Committee (see individual report). Dr. Shao was invited to give two talks: one on "Whole genome SNP array improves prognostication in acute lymphoblastic leukemia" at the 9th Annual World Cancer Congress-2016 in Shanghai and the other on "Whole genome array improves diagnosis and prognostication in hematological malignancy and pediatric brain tumor" at Zhejiang University in Hangzhou, China. Dr. Shao was recruited to the ACMG/CGC workgroup to develop "Standards & Guidelines for interpretation and reporting of copy number changes & copy-neutral LOH in neoplastic disorders" and nominated for the director position on the Board of Cancer Genomic Consortium.

Future Plans

The University of Michigan Health System sent out over 200 multiple myeloma FISH panel tests last year. We plan to complete the validation of the in-house FISH panel which includes 10 probes. The recently acquired scanner already demonstrated that it can improve efficiency and productivity in oncology samples; validation of constitutional blood samples using the scanner is planned. Thermotron provides consistent results on oncology chromosome slides, optimization of Thermotron with peripheral blood slide preparation is also in the plan. We'll renew efforts to address areas identified by employee engagement survey, and continue to improve communication and patient care in the laboratory.

HISTOCOMPATIBILITY AND IMMUNOGENETICS LABORATORY

Dr. Daniel Ramon is the Director of the Histocompatibility Laboratory. This year has been another very industrious year for the lab. The goals envisioned during the previous year have been implemented and have vastly improved laboratory operations and the services we provide.

Operational improvements:

One of our most notable achievements this year was the change made to receiving our "mailed-in" patient samples. Monthly samples are required from patients who are wait-listed for an organ, for the purpose of monitoring HLA antibodies and for the mandatory pre-transplant cross match. Our lab sends the tubes and packaging to the patients for the collection of these samples. In advance, we notified patients that we would switch from using the United States Post Office, to now using the United Parcel Service (UPS). In previous years, many of these mailed patient samples were arriving as hemolyzed, delayed/too old or in some cases, the sample was mailed by the patient but not received at all. With the expert help of our Pathology Administration team, we were able to acquire a contract with UPS and make a smooth change to this new system. We now prepare the outgoing mailing twice per year, by sending a package of 6 kits, so that our patients have supplies for 6 months. Since using UPS, we have nearly eliminated the problems of hemolyzed samples, delayed samples and lost samples. In addition, using UPS has increased the overall return sample rate as well. This change in the mailing system has been extremely beneficial for our patients.

Another great accomplishment for this past year, was the completion of the Patient Document Digitizing project. Just recently, with the use of the Automatic Imaging team, we completed digitizing all of our on-site documents related to Kidney patients, HCT patients, Heart and Lung patients. Some of these documents dated back decades and contain critical information such as raw test data, organ donor information, HLA reports, etc. It is important to keep access to these documents for a variety of medical reasons, in addition to regulatory requirements. Approximately 272,730 pages have been digitized. All of the digitized documents are stored on a hard drive which is kept in the HLA laboratory and easily accessible to the staff. Soon the documents will be uploaded onto a subset of the Traverwood Drive. In addition, we are very effective in managing our incoming patient digital data. We have accomplished our goal of digitizing all of these files before we move into the new Pathology Laboratory location at NCRC.

The **TempTrak Monitoring System** has been installed, validated and is operative for all of our temperature controlled instruments, equipment and freezers. Within our laboratory, the TempTrak system now monitors 31 freezers, 6 refrigerators, 3 different rooms for ambient temperature, the walk-in refrigerator and various incubators. Our patient care technical associate staff has done a monumental job of performing the monitor set-up, temperature trials, performance validation, maintenance and reviewing the alerts for this monitoring system. Furthermore, this team has done a tireless and flawless job of teaching and training the entire lab regarding TempTrak. Since our lab collects an enormous amount of patient sera, which is stored frozen on a long term basis, implementation of the TempTrak System is of incredible value to us.

As a result of setting up our **Cell Culture Laboratory**, we have now spent over one full year freezing donor cells and have trained 3 additional technologists in this area. We have stored over 22 different donor's lymphocytes. This process enables us to perform cross matches immediately upon request from our transplant staff. This procedure will significantly help the Paired Donor Programs as well as providing cross matches for our living and deceased donors, aiding the clinicians in diagnosis and treatment.

The **JANUS Automated Workstation**, validated last year, has been remarkably useful for us. The JANUS is used to aliquot the large number of serum samples from our solid organ transplant patients. Our first annual evaluation of this automated workstation confirms that it is economical, laborsaving, cost-effective, not wasteful, consistently dispenses and requires very low maintenance.

Our **Bioinformatics Specialist** continues to develop valuable methods to automate data collection in addition to other bioinformatics tools to aid in antibody analysis. She created a more efficient system for documenting

Donor Specific Antibody (DSA) results by developing an access database to incorporate results. In addition, she developed a mechanism in HistoTrac to incorporate our internal proficiency testing results, which will now allow us to track activity and create reports. She has successfully implemented the "FORM 22" for the electronic HLA data transfer to the National Marrow Donor Program (NMDP).

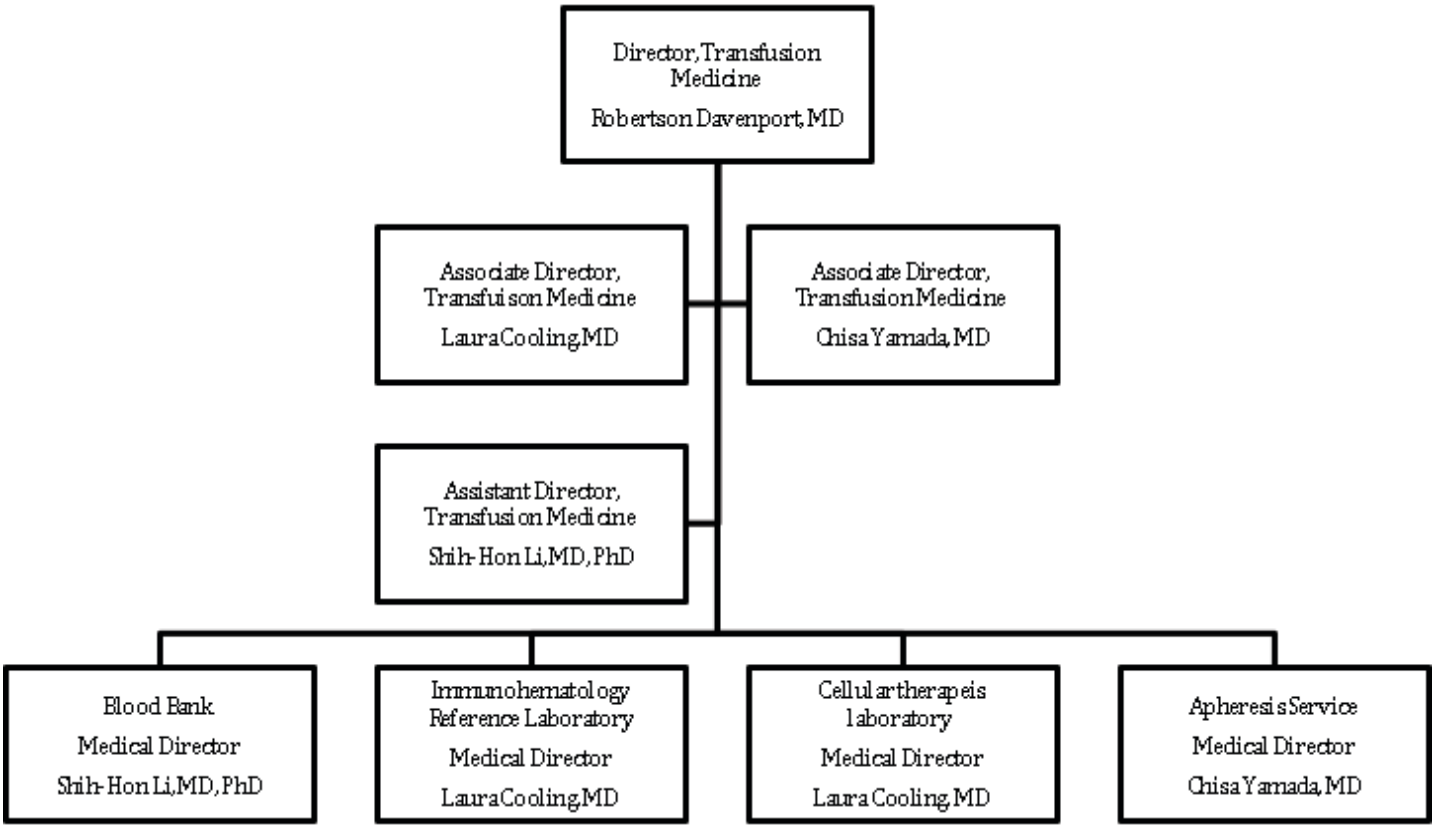
The HLA **molecular team** is now performing HLA-DP typing for all of our HCT recipients and unrelated donors. This additional molecular test enables our HCT Transplant team to select better matched donors for our patients. The HLA molecular team also continues to investigate the various Next Generation Sequencing (NGS) instruments to be used by our lab and attends NGS workshops.

The HLA **serology/flow team** is always looking for ways to become "paperless" and has made great strides in this area. They now scan patient records such as UNET listing forms, accuracy reports and UNET list changes. This team is extremely cognizant of becoming LEAN and as efficient as possible.

Staff development and engagement activities

- Presentation by Lena Kleyman made at the Clinical Pathology Quarterly All Staff Meeting: Process Automation of Turnaround Time & Test Statistics Data Export and Reporting
- Presentation by Scott Parker made at the Clinical Pathology Quarterly All Staff Meeting: UPS Mailer Procedure - Changes in the Way We Send/Receive Mailers
- Two of our Medical Technologists were promoted to Medical Technologist Specialists
- Sent a total of 9 staff to national and regional meetings and specialized workshops
- Oral presentation at the annual AST conference in June 2016: Positive Lymphocyte Flow Cytometry Cross Match Due to AT1r Antibodies in Absence of HLA-DSA

SECTION OF TRANSFUSION MEDICINE



The section of transfusion medicine, under the leadership of Robertson Davenport, MD, is comprised of the blood bank, the immunohematology reference laboratory, the cellular therapies laboratory, and the apheresis service. We welcome the addition of Shih-Hon Li, MD, PhD, to the faculty as Assistant Director of Transfusion Medicine and Medical Director of the Blood Bank.

BLOOD BANK

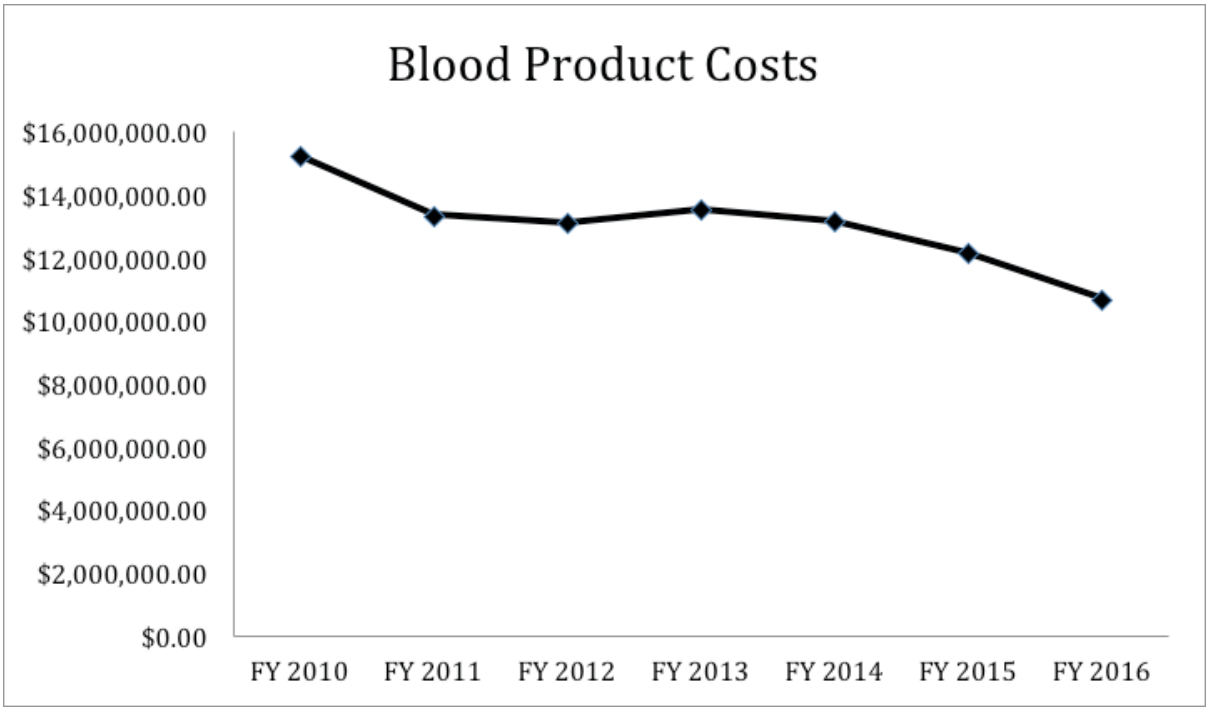
Total utilization of blood products decreased significantly. In part, this is attributable to a switch in platelet supply at midyear from primarily pooled random donor platelets to apheresis platelets. For typical adult dosing a pool of 5 random donor platelets is equivalent to an apheresis platelet unit. In addition there was a decrease in utilization of red blood cells and plasma reflecting the continuing trend in more conservative transfusion practices. There was an increase in cryoprecipitate utilization, driven primarily by the increasing use of point of care coagulation testing (ROTEM) in cardiac surgery, which can rapidly identify hypofibinogenemia.

	FY 2015	FY 2016	Percent Change
Red Blood Cells	28667	26515	-7.5
Random/Pooled Platelets	47264	20959	-55.9
Apheresis Platelets	873	6394	632.4
Plasma	8688	6642	-23.5
Cryoprecipitate	4979	6011	20.7
Total Components Transfused	90471	66521	-26.5
Total Cross matches Performed	25770	24026	-6.8

When apheresis platelet utilization is expressed as random donor unit equivalents, the adjusted platelet utilization increased slightly, while the adjusted total blood components decreased slightly.

	FY 2015	FY 2016	Percent Change
Adjusted Platelet Units	51629	52929	2.5%
Adjusted Total Components	93963	92097	-2.0%

Total expenditures for blood products decreased by 11.7% from the previous year. This continues a trend that is the result of both favorable pricing obtained from the primary blood supplier and utilization control efforts led by the Transfusion Committee.



Immunohematology Reference Laboratory

Overall activity in the Reference laboratory increased slightly. While antibody identifications were down slightly, there was an increase in the most complex tests, particularly adsorptions and titers.

	FY 2015	FY 2016	Percent Change
Antibody identifications	1107	1081	-2.3
ABO resolution	150	156	4.0
M-Labs/referrals	18	8	-55.5
BMT	322	247	-23.3
Eulates	184	174	-5.4
Adsorptions	241	317	31.5
Titers	259	303	17.0
Total activity[1]	2763	2801	1.4

[1] Includes procedures not listed above

Cellular Therapies Laboratory

Activity in the Cellular Therapies laboratory showed an overall decrease. This is attributable to faculty turnover in both the adult and pediatric transplant programs.

	FY 2015	FY 2016	Percent Change
Collections processed	518	415	-19.8
Bags frozen	614	542	-11.7
Transplants, autologous	137	116	-15.3
Transplants, allogeneic	45	45	0
Transplants, unrelated	69	61	-11.6
Transplants, total	251	222	-11.5

Apheresis Service

Overall activity in the Apheresis Procedure Unit increased, driven by the core activity in therapeutic plasmapheresis and HPC collection. A marked decline occurred in therapeutic phlebotomy, as the result of shifting these low value procedures to other outpatient settings. LDL apheresis activity continues to be impacted by recently approved cholesterol lowering drugs. The activity in red cell exchange procedures reflects the strength of the hemoglobinopathy clinics in adult and pediatric hematology.

	FY 2015	FY 2016	Percent Change
Therapeutic plasmapheresis	1313	1389	5.8
HPC collections	386	416	7.8
Donor pre evaluations	258	243	-5.8
Therapeutic phlebotomy	163	40	-75.5
LDL apheresis	212	124	-41.5
RBC exchange	96	120	25.0
Total Procedures	2218	2407	8.5

Professional billing activity decreased slightly in gross charges and charge units.

	FY 2015	FY 2016	Percent Change
Gross charges	$748,855	$745,071	-0.5
Charge units	2,461	2,443	-0.7

Significant quality improvement initiatives undertaken by the section of Transfusion Medicine included implementation of the mobile emergency blood refrigerator in C&W to hold a massive transfusion pack that reduces time to obtain blood in emergency situations, implementation of group A plasma in acute trauma resuscitation to conserve limited groups AB plasma, and adjustment of the massive transfusion pack ratio of blood products

changed to meet current thinking.
Research projects in which the section of Transfusion Medicine had significant participation included Ortho instrument evaluation to collect data for FDA submission, cell collection and processing support for CART-19 trials in pediatric acute lymphoblastic leukemia and adult defuse large B-cell lymphoma, comparing the efficacy and safety of high-titer versus low-titer anti-influenza immune plasma for the treatment of severe influenza A, and age of blood in children in pediatric intensive care units (ABC PICU).
The staff was active in presenting at the regional and national levels. Terry Downs, Kelly Delaney, Sheri Hugan, and Kelly Roxbury had presentations at AABB. Terry Downs served as Treasurer of MABB. Terry Downs presented at ASCLS-MI. John Ko served as District Representative for ASCLS-MI. Terry Downs and Sandra Hoffmann served as AABB Assessors.

SPECIMEN PROCUREMENT

Specimen Procurement consists of Specimen Processing and Phlebotomy. Dr. Don Giacherio is the Director of Specimen Processing and Dr. David Keren is the Director of Phlebotomy. Harry Neusius is the Manager of both services with Bonnie Grayson being the supervisor of Specimen Processing.

Specimen Procurement is the front-end specimen collection and processing area for the Department of Pathology. This area includes Inpatient Phlebotomy (University Hospital, University Hospital South, Cardiovascular Center, and C&W Mott Children's Hospital), Outpatient Phlebotomy (Cancer/Geriatric Center, the Taubman Center and C&W Mott Children's Hospital Blood Draw Station), and Central Distribution/Referral Laboratory. A total of approximately 184 FTEs staff the three areas, responsible for 24-hour/7 day a week operations. The departments are directed by 1FTE manager, 4 FTE supervisors and 11.5 FTE Associate Supervisors. The complex and specialized areas in Central Distribution, including Referral Laboratory Services also employ a Senior Medical Technologist and a Medical Technologist Training Coordinator.

SPECIMEN PROCESSING

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. It is a requirement that Specimen Processing staff be well versed in all testing methodologies in pathology.
Specimen Processing receives and triages between 9,000 and 12,000 tests 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.

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.
An example of this are the following activities completed this year:

- Saving of the Urine Cups aliquoted and adding the yellow dot on top with the number of test to be aliquoted to capture missed aliquots and for use of add-on testing. This process change helped immensely to improve missed test and to have urine available for add-on testing. This was presented at the Q.A. meeting and was then selected to be presented at the CP all Staff Quarterly Meeting.
- Implemented change to the daily Order Entry Q.A. – Refinement of the process to printing of a label for the error and placement on a log. This greatly decreased the amount of time staff were spending performing the daily OE Q.A., allowing for more time to complete tasks on bench.
- Implemented change in staging of MiChart specimens at the front counter. The change was to triage all blood specimens to a separate bin to avoid delay in processing with an emphasis on placing all blue tops forward as received. The urine and non-blood specimens are binned together. This change has

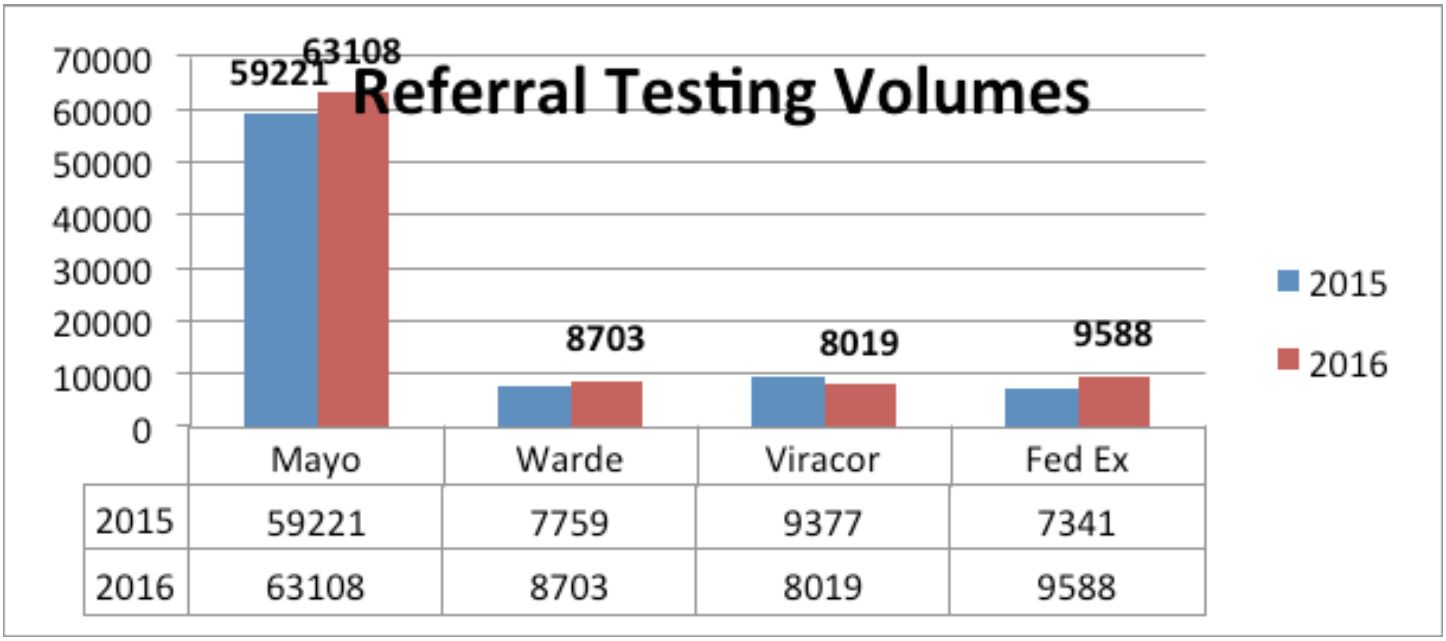
had a good outcome – having less delay with the processing of medical staff collected bloods from our critical patient care areas like infusion. There is still some work to be done with MiChart work but this change has had a positive effect.

- Refined the training for the Customer Service and MiChart processing benches – adding one additional week to each. Recognizing that these areas are very detailed and some errors had resulted from staff processing MiChart specimens – more time training would help staff to gain more experience and become more efficient. This proved to be true – showing the results of newer staff and their ability to maneuver the benches when they have completed training.
- New Staff Weekly Training Meetings added at my direction. The meetings were to give new staff opportunity to speak with the Training Specialist and myself about their training and how they were progressing. The meeting allowed the trainee time to share concerns of any kind, including if their trainer may not be the best match. These meetings have revealed need to re-match the trainee and also discovery of when a trainee thought they needed more time on the bench. These meetings have been successful by creating a more successful employee at the end of their training period.
- FedEx Check and Refinement: This change involved how consults are logged with the change in the log sheet to capture the FedEx tracking number to assist with problem solving, adding of a problem log/form to go to Surg Accessioning when we spot a problem so there is instant notification. Holding and checking of all FedEx mailers, boxes and containers for a final check before anything is tossed, then a hold for one day. Beth and I shared this project.
- Q.A. of MLabs Daily Problems: This area recently presented a huge problem, and I quickly recognized that there was no Q.A. for these problems – when previously there had been. This is a targeted area for the next 2 months.
- Implemented use of Green Bags for Time Sensitive Send outs: This change helped draw staff to clearly identify time sensitive specimens and SP staff to recognize these bags to direct delivery to centrifuge for processing. This change has saved a number of specimens.
- Developed New Holiday Rotation System for SP: Previous system was time consuming and not effective in ensuring all staff had an opportunity to get prime holidays off. I developed a system that grouped staff together by skill (ensuring coverage for specialized benches) and these groups rotate together covering holidays by rotation. This system not only freed up time for monitoring sheets by staff seniority but also gave newer staff the assurance that eventually they would have a Christmas or other prime holiday off.
- Implemented the Test Label “Cancel” requested form: With the SOFT system some cancels can be tricky. The labs requested SP staff pass all labels to the lab for review and they would cancel testing as requested. Previously we simply placed the label in the bag and often would get lab staff who questioned why they were receiving the label. This was the assurance that loose labels received from medical staff, requesting Cancel of the test(s) on the label was not missed/tossed. The half sheet form is a clear indicator to alert lab staff there is a request for cancel of test.
- Redesign of the Front Counter: New Bins clearly labeled and defined to expedite priority work. Visually able to know what is in each bin and how to distribute. Bench has been labeled to show “keep clear” areas to advert walk by drops into bins by med staff or others. Also, there is a clear area for couriers to drop their samples. This work continues.
- Change from the Large Brown paper bags to Large Clear Bio-Hazard bags: Health Centers were using the large paper bags for specimen transport. This produced a large amount of trash and presented problems for opening and placing in the dry ice cooler. I presented the request to Sue Clark and Tom Morrow. They have begun this change. The change will not only help with clear view of bags, but also no specimens will be stuck to the staple in the brown bag. Less trash - no bulk from plastic bags. This will also help with sorting and getting specimens to processing staff in a timely manner.
- Sendout Q.A. – full Q.A. of all work was implemented – supporting finding of errors in real time for ease of correction with our reference labs.
- MLabs Bench Cleanup: Removal of shelving, cleaning up space at front counter and lowering of bench to desk height to define work area. Work space was previously part of the Specimen receiving and sorting. Moving the work bench to desk height clearly defines receiving and staging of work from the processing bench.
- CAP Package Receipt for All Labs: We were asked to be the primary delivery location due to our 24/7

operating hours to ensure that someone would always be present for deliveries. SP now receives all CAP packages for the department. Responsibilities include xeroxing of paperwork received with specimens– forward to Jeanette Jeffreys. We also receive mailed CAP paperwork which is also sent to Jeanette. Delivery to labs and calling labs to come and pickup from SP.

REFERRAL TESTING

Referral laboratory testing continues to be an expensive, yet necessary service.
FY 2016 showed slight increases in test volumes, 7% over FY 2015. We continue to use Mayo Medical Laboratories as our primary reference laboratory, with increased use of Warde Medical Laboratory.
An electronic interface with Warde Medical Laboratory was developed and implemented in March, 2016.
This will be helpful in the efficient processing or result entry into our electronic medical record.
The referral laboratory continues to utilize 90 plus boutique labs as a result of the unique testing requirements of providers and specialists utilizing the Department of Pathology for testing.



	Mayo	Warde	Viracor	Fed Ex
2015	59221	7759	9377	7341
2016	63108	8703	8019	9588

INPATIENT PHLEBOTOMY

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.

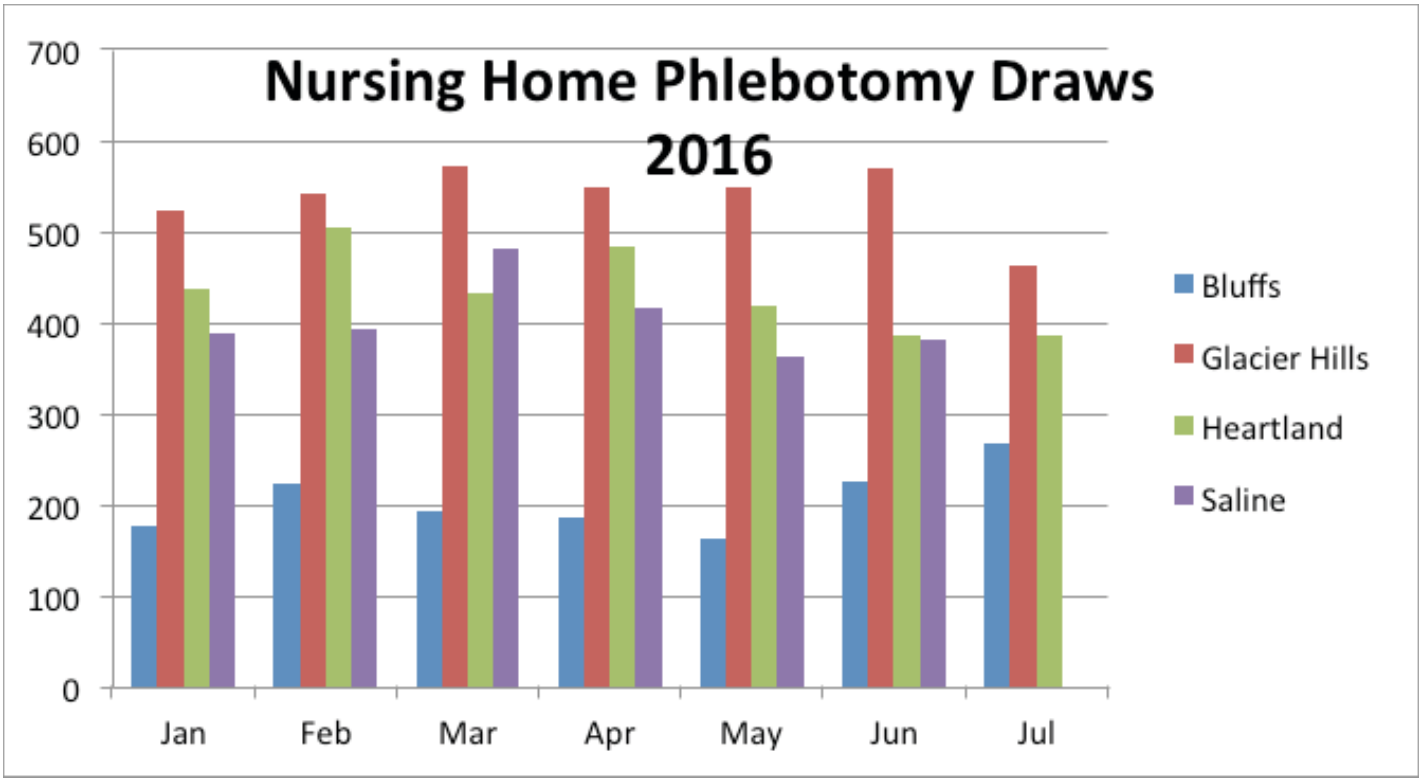
1. MLabs Client Nursing Homes
Inpatient phlebotomy continues to service MLab client nursing care facilities.
Phlebotomists are dispatched Monday through Friday to:

- 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

<u>Volumes:</u>
Specimen volumes have remained consistent over the last fiscal year.
Staffing includes 3.5 FTE's, scheduled amongst the 4 nursing home locations.

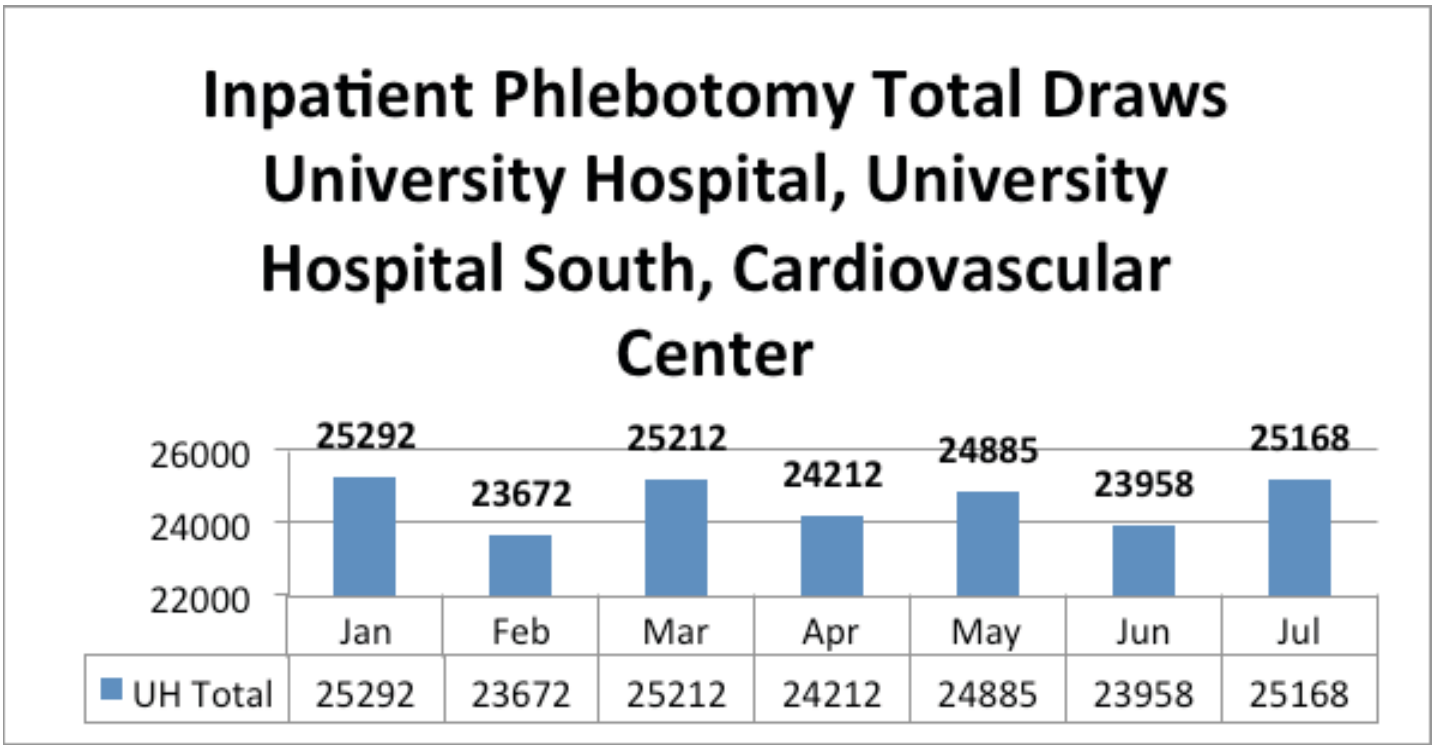


2. University Hospital, University Hospital South, Cardiovascular Center:

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.

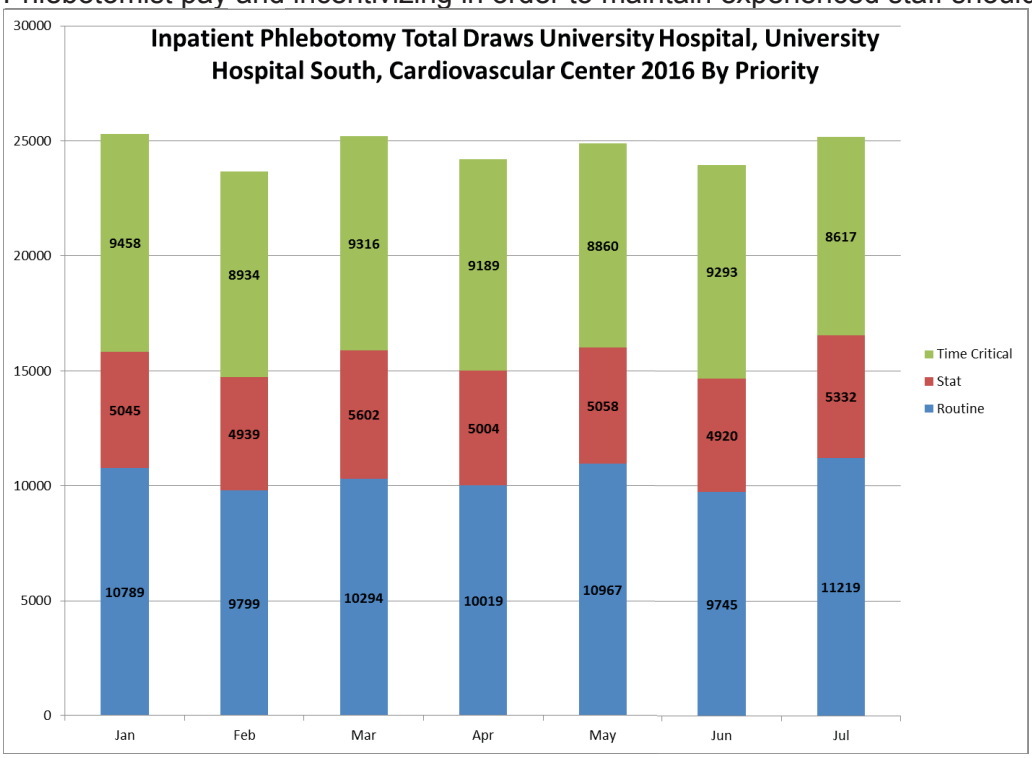
Volumes:

Volumes for the inpatient team remain relatively stable.

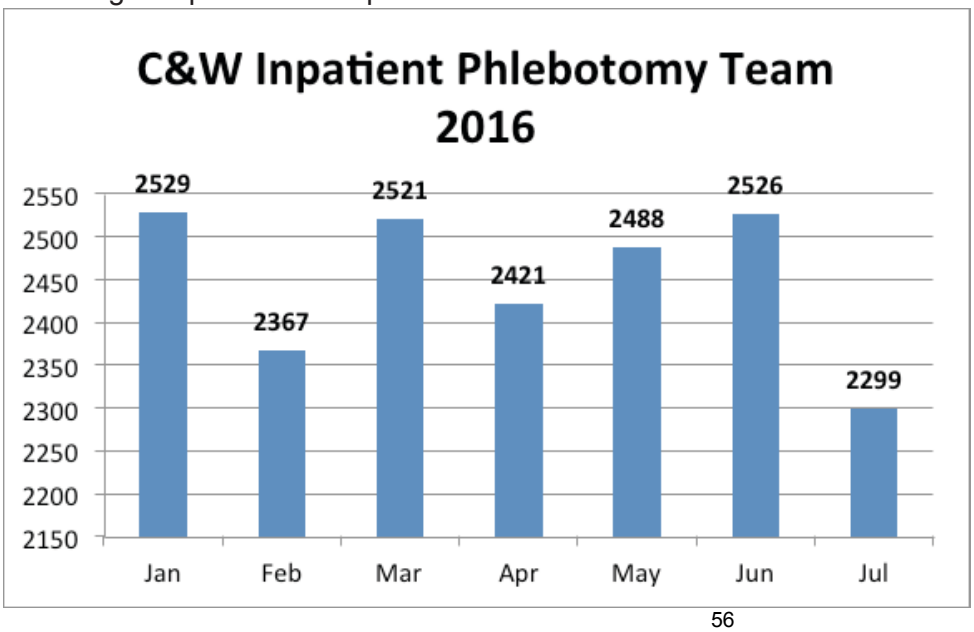


Significant impact on the team occurs from the high numbers of stat and time critical orders.
More stat and time critical orders are realized than routine draws.
This significantly impacts the ability of the team to meet clinician expectations for timely collection and resulting. Several groups have assessed the phlebotomy process, including in 2008, 2011, 2015 and 2016. An action plan to help support the team to be able to meet expectations is being developed.

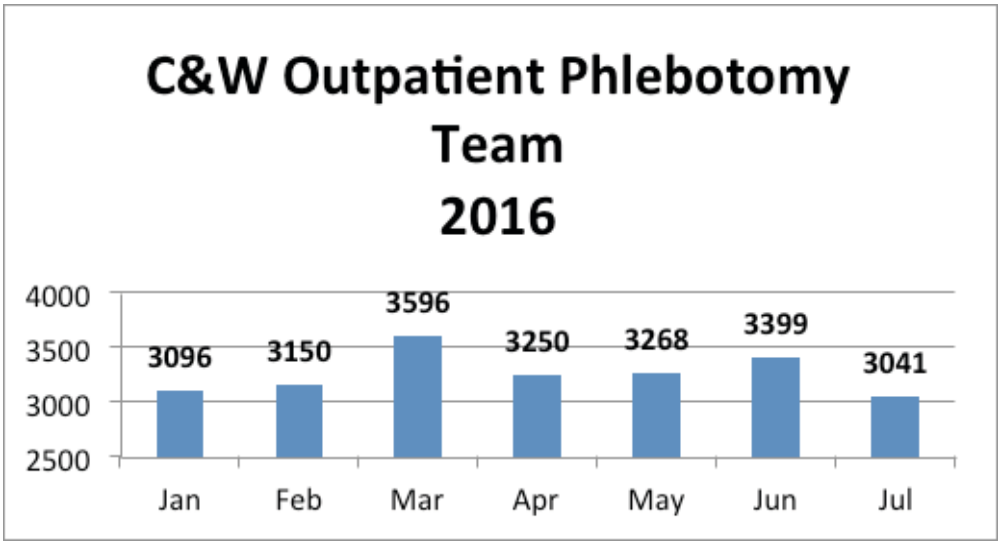
High turnover of staff is another contributor and should be addressed.
Phlebotomist pay and incentivizing in order to maintain experienced staff should be implemented.



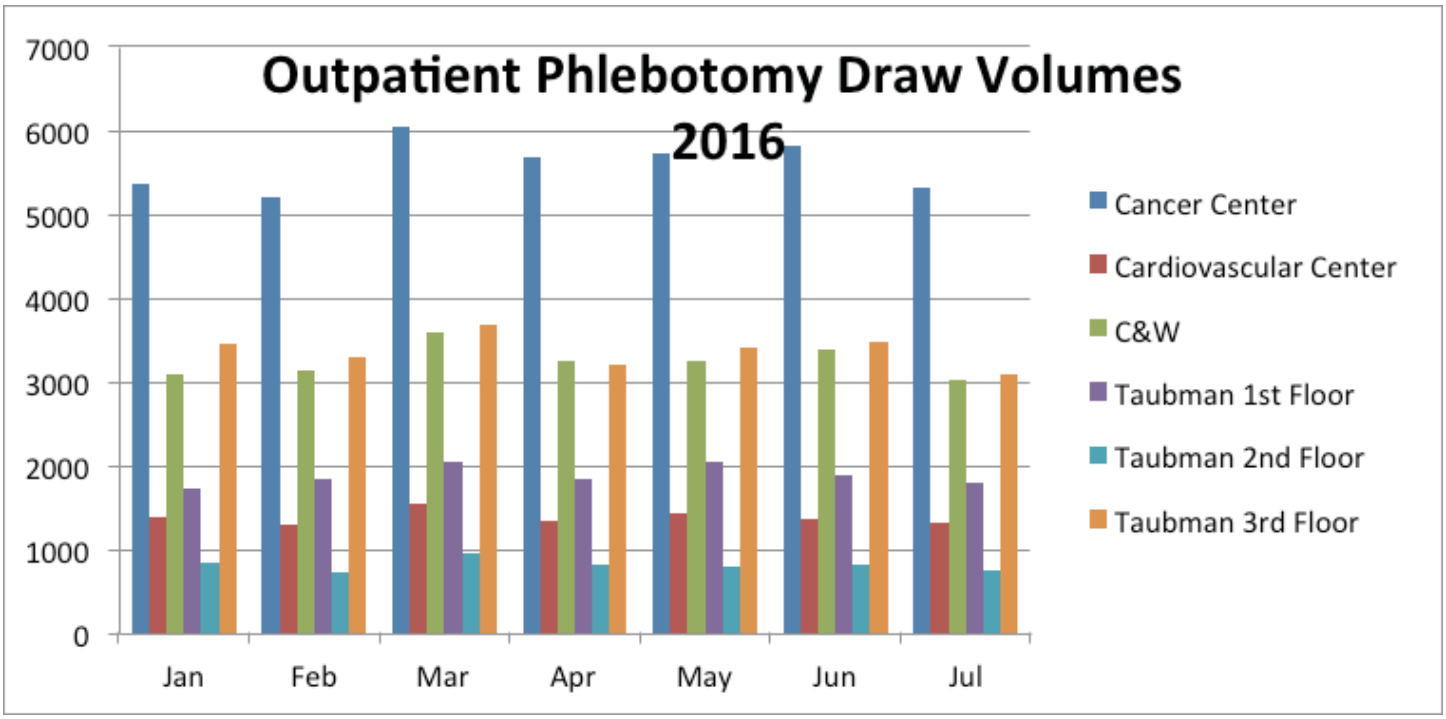
3. C&W Mott Children's Hospital Inpatient Phlebotomy Team:
The inpatient phlebotomy team in C&W Mott Children's Hospital is comprised of a skilled team of phlebotomists with significant pediatric phlebotomy experience. Staff are advocates of minimizing pain and anxiety for pediatric patients and have worked closely with the Child Life department to hone those practices. This year they have 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 presentation.



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, 2016 flu season) and summer vacation fluctuations (July, 2016).



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



The outpatient phlebotomy team continues to be a busy group. The area of responsibility has increased in scope in the Taubman Center to include servicing an Ambulatory Diagnostic Treatment Unit (ADTU) on the first floor of the Taubman Center.
The clinic was established to diagnose and treat acute conditions or acute exacerbations of chronic conditions that may require extended time for appropriate diagnosis and treatment. The ADTU helps to ensure there is a coordinated plan for clinical and diagnostic services (including priority lab tests and imaging studies) to enhance patient access and convenience for a variety of complex patient conditions requiring care that extends beyond that provided in a typical clinic visit. This added responsibility has required the front desk staff to arrive

Vascular Access Patients, for central line placement, the non-cancer infusion clinic patients, and the ADTU patients. This has proven to be a challenge to manage along with our phlebotomy patients, but staff continues to resolve issues and improve the process.
The outpatient blood draw stations have also been involved in rolling out the chairside label printing process to comply with regulatory requirements from several accrediting and regulatory agencies regarding the collection of blood bank specimens. The new standard is now requiring that any new patient, without historical testing records in the blood bank who will be utilizing blood bank services must have electronic documentation of the collector of blood bank specimens or have 2 separate specimen collections if this electronic documentation requirement is not met. Current state process does not electronically document the collector of blood bank specimens in the ambulatory care setting. An opportunity to evaluate and modify the current state to meet this new AABB standard and prevent the need for 2 separate collected specimens from this patient population is desirable. In addition, opportunities exist to improve safety issues associated with specimen label “hand offs” and accurate documentation of collector identification and actual specimen collection time. This new process began rolling out in the outpatient blood draw stations in March, 2016.

Kudos to our Administrative Assistants

Finally, a hearty thank you is due to the extraordinary efforts of our Administrative Assistants who provide support to the Director and his colleagues:

Pam Warwashana, Lori Blough, and Bill Sherman

DIVISION OF PATHOLOGY EDUCATION

Barbara J. McKenna, MD
Godfrey D. Stobbe Professor in Pathology Education
Director, Division of Education Programs
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 2015-16 academic year was marked by significant achievements, as outlined below. The leadership and administrative team consists of Program Director Barbara J. McKenna, MD, Associate Program Director Allecia Wilson, MD, Fellowship Coordinator Marie Goldner, Residency Program Coordinator Pamela Howard, and Medical Student Program Coordinator and Conference Coordinator Desire' Baessler. The Residency Program GME Committee included Allecia Wilson, MD, Michael Bachman, MD, PhD, Jonathan McHugh, MD, David Keren, MD, Daniel Boyer, MD, David Lucas, MD, and the Chief and Assistant Chief Residents Reena Singh, MD and Cody Carter, MD.

Recruitment: We continue to recruit high caliber residents from a wide geographic region. Choosing from among the over 400 applicants to the residency program is an exciting challenge, and we were highly successful. All incoming first year residents for 2015-16 were highly ranked by UM in the NRMP match. The group includes graduates of medical schools in California, Ohio, Iowa, North Carolina, and Louisiana.

Achievements: Our residents and fellows were very active academically, with a total of 49 publications during 2015-16, 58 abstracts/meeting presentations, one book chapter, and 4 additional papers submitted and under review.

Engagement: Our residents and fellows are active members of the medical and pathology communities, with many engaged in local, regional, and national organizational service, including 9 departmental committees, 9 institutional committees, 1 USCAP committee, 2 CAP committees, 1 Michigan Society of Pathologists committee, and 2 ASCP committees. In addition, 6 residents and fellows served on the UMHS House Officer Quality and Safety Committee. In addition, they were awarded 4 travel awards from various pathology organizations.

Our residents were also highly 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, a new Quality Improvement curriculum was initiated in the residency training program. Residents worked through web-based learning modules, attended lectures and discussions, and worked in teams on quality projects that included:

- Appropriate utilization of peripheral blood smear reviews
- A novel method for labeling frozen section specimens that would reduce mislabeling
- Optimization of platelet refractoriness evaluation workflow and communication
- Asset tracking for cases as they move throughout the department, to prevent lost cases and improve turnaround time
- Improving appropriate ordering of hemoglobin electrophoresis assays
- Improving workflow processes for slides and blocks sent from other institutions to the Hematopathology consultation service

Resident performance improved significantly from the pre-course to the post-course assessment. A poster outlining the project has been accepted for presentation at the UMHS Quality Month event in October, 2016.

In 2016, the Pathology Residency Program at the University of Michigan was ranked #2 in the United States among large public hospitals, and #7 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 gradates of our residency over the past 5 years indicates that 100% of respondents rate the training they received as “excellent.”

American Board of Pathology Certification: 100% of the graduating class of 2015 passed the ABP certification examination on the first attempt.

Graduates: Six residents completed training in 2016. All are proceeding to fellowships, 3 of them here at Michigan, one at the Mayo Clinic, one at the Beth Israel Deaconess Medical Center in Boston, and one at the Denver, CO Medical Examiner Office.

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. Our fellowship banner and links on the Pathology Outlines website receive between 200 and 350 hits per month, generating traffic to our own department website, and reflecting the interest in our programs.

In May and June of 2016, the Forensic Pathology Fellowship, under the direction of Dr. Jeff Jentzen and the Chemical Pathology Fellowship, under the direction of Dr. Dave Keren, underwent accreditation site visits from ACGME field staff members. While official notification has not been received, both site visitors commended the programs for their excellent curriculum and documentation as well as positive feedback from program faculty and fellows.

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 (9), jobs in private practice (5), 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 their area 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. In this regard, pathology faculty are working in conjunction with faculty from Surgery, Anesthesiology, 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 it 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 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 PhD thesis research.

Statistics of our current students

Candidacy exam:

In this year, five students (5 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 2015/2016:

- Shirley Lee (Dou lab)
- Chan Chung (A. Lieberman lab)
- Jonathan Pollock (Cierpicki/Grembecka labs)

MSTP students graduated in 2015-2016:

- Elisabeth Pedersen (Lawlor lab)
- David Rogawski (Grembecka lab)

Productivity of MCP students

Individual extramural and intramural fellowship (7)

- Sierrah Grigsby (NSF fellowship for 2nd year)
- Talha Anwar (F30 for 2nd year, received 2 internal grants from The Dept. of Pathology)
- Ulas Ozkurede (Munger-Coleman Fellowship)
- Shayna Bradford (Research Supplement to Promote Diversity in Health Related Research-NIH)
- Yuqing Sun (Rackham Research Grant)

Travel awards (13)

- Elisabeth Pedersen, Lorena Lazo de la Vega, Rebekah Martin, Mary Morgan, James Ropa, Amy Han, Emmalee Adelman, Anna Ting, Yuqing Sun and Talha Anwar(Rackham & MCP travel awards (10))
- Rebekah Martin (American Society for Microbiology Travel Award)
- Anna Ting (Society of Leukocyte Biology 2015 Travel Award (Oral+Poster))
- Edward Grimley (AAPS Drug Discovery and Development Interface Section Travelship)

Training grants (5):

- Emmalee Adelman (Training in the Biomedical Research of Aging for 2nd year)
- Amy Han (Training in the Biomedical Research of Aging for 2nd year)
- Carrie-Anne Malinczak (Immunology Training Grant)
- Jacqueline Mann (PICTP Training Grant)
- James Ropa (PICTP Training Grant)

Other awards (3):

- Talha Anwar (AACR scholar-in-training award, Munger Case Competition)
- Jonathan Pollock (AACR scholar-in-training award)

Published papers by our students as first authors: 3

- First author (3): Cani, Ozkurede, Pollock

Papers published by our students as co-authors: 9

- Co-authors (9): Garcia, Johnson, Ozkurede, Pollock, Sun x4 and Zhang

Recruitment activities

New class 2016/2017:

In April we finished the recruiting for the fall 2016 class for the Program in Biological Sciences (PIBS) and successfully recruited 4 high quality students

Following the progress of the current students and their satisfaction of the MCP Program

- Student's annual reports (due June 30th) - during July and August the Director of MCP students met individually with all students and discussed their progress.
- Annual meeting with MCP student council to hear students' opinions and suggestions
- Mentorship plan – introduced 2016 for 2nd year students
- The format for the first committee meeting is updated - students write proposal in R21 format
- The format for the annual dissertation committee meetings is updated – short summary of the progress needs to be prepared and submitted to the members of the committee
- Dissertation committee form updated – signed by both mentor and student to ensure student is aware of the committee's final evaluation
- Professional development opportunities
  - The Director of MCP invited the VP of Cayman Chemicals, Dr. Jeff Johnson, to discuss the careers in industry.
  - Each year during the Research Symposium the career panel discussion is organized

Students' activities

- Academic activities, including mentoring of younger students and undergraduates.
- Organizing the annual Department Research Symposium.
  - This year the seminar was scheduled for November 1st-2nd 2016 when we will celebrate our 15th anniversary.
  - Last year the Outstanding Research Award was given to Hung-An "Anna" Ting; Best oral presentation went to Elisabeth Pedersen and best poster awards went to Chan Chung and Rebekah Martin.

Social events supported by MCP Program 2015/2016

9/10/15 Annual MCP student/faculty picnic – Island Lake Park

12/15/15 Happy hour student/faculty mixer – HopCat

5/12/16 Happy hour student/faculty mixer – Dominick's

8/6/16 Student camping trip – Waterloo Recreation Area

8/16/16 MCP Ice Cream Social – Med Sci I

Translational Pathology training grant

- Translational Pathology pilot grant supported by the Department – in total 5 students participated in this program which was a foundation for our T32 awarded program

- The NIH T32 training program in Translational Research, directed by Drs. Lieberman and Nikolovska-Coleska, was funded and started on July 1, 2016. The first 4 students were selected: 2 students from MCP, 1 from Microbiology and Immunology and 1 student from Neuroscience.

Rackham Program Review
In 2015 the fifth year Rackham Review of our Program was held. The feedback received after the review process was very positive and identified multiple strengths of our Program including: admissions and enrollment, time to candidacy and degree, completion rate, publications and student professional development and placement.

To further improve our Program, several recommendations were received and based on them we have already introduced changes for:

- Improving the mentoring of the students

- Improving the sense of community between our faculty and students

- Recruiting underrepresented students

- Career professional development

Pathology Education Series

A vibrant and varied morning Pathology Educational Series takes place most mornings at 8 am, from September through mid-June. In 2015-16 there were 120 conferences, each offering CME credit. Four were presented by visiting faculty from other institutions, 40 by residents, 20 by fellows, and the remaining 60 were presented by departmental faculty members. In addition, 10 Gross Conferences were conducted by surgical pathology faculty and fellows. Also presented during the morning conference series is a unique graduate course, Pathology 862, Translational Pathology, that brings graduate students, residents and fellows together to learn about techniques and factors involved in conducting translational research, and includes teams of students, residents, and fellows preparing research proposals around clinical pathology questions. Thirteen hours of the morning conference series was devoted to this course. Eleven hours of the series was devoted to the Quality Improvement curriculum, described above.

The morning conference series may be the one venue that most often draws together residents, fellows, AP faculty and CP faculty.

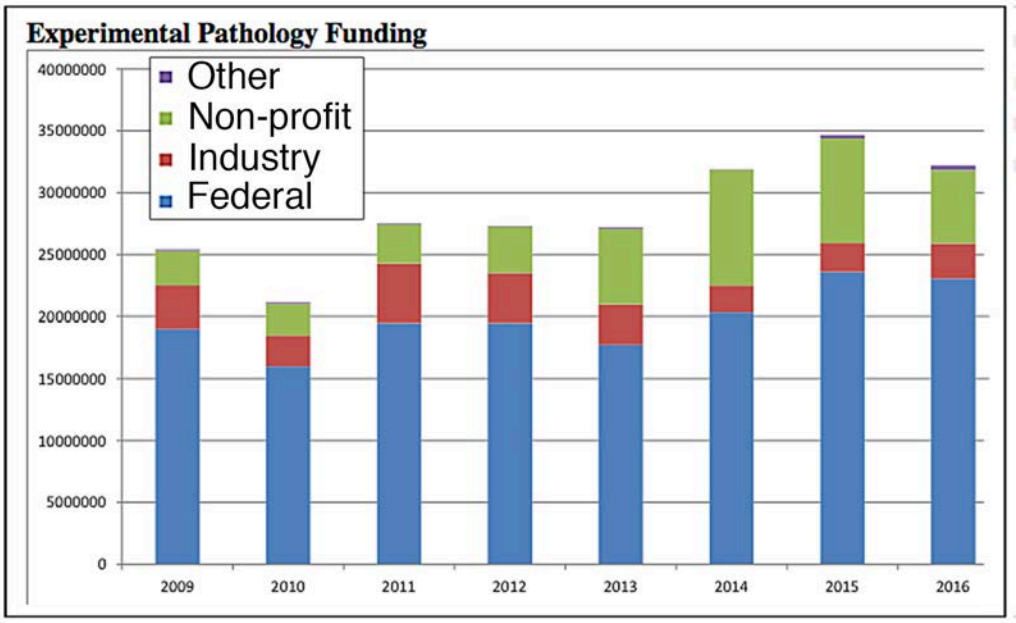
DIVISION OF EXPERIMENTAL PATHOLOGY

Asma Nusrat, MD
Aldred S. Warthin Professor of Pathology
Director, Experimental Pathology

OVERVIEW

The past academic cycle was another productive year for faculty in the division of Experimental Pathology (EP). The EP faculty research focus encompasses basic science projects aimed at understanding pathobiologic basis of human disease, as well as translational projects and development of therapeutics. The research focus of EP faculty have been thematically unified into Cancer Biology, Development, Neuroscience, Epigenetics, Aging, Epithelial and Mucosal biology, Immunology and Inflammation, and Experimental Therapeutics. Funds provided by Dr. Parkos were utilized to purchase and upgrade shared equipment which has not only facilitated individual research programs, but these facilities have also fostered scientific collaborations and grant applications.

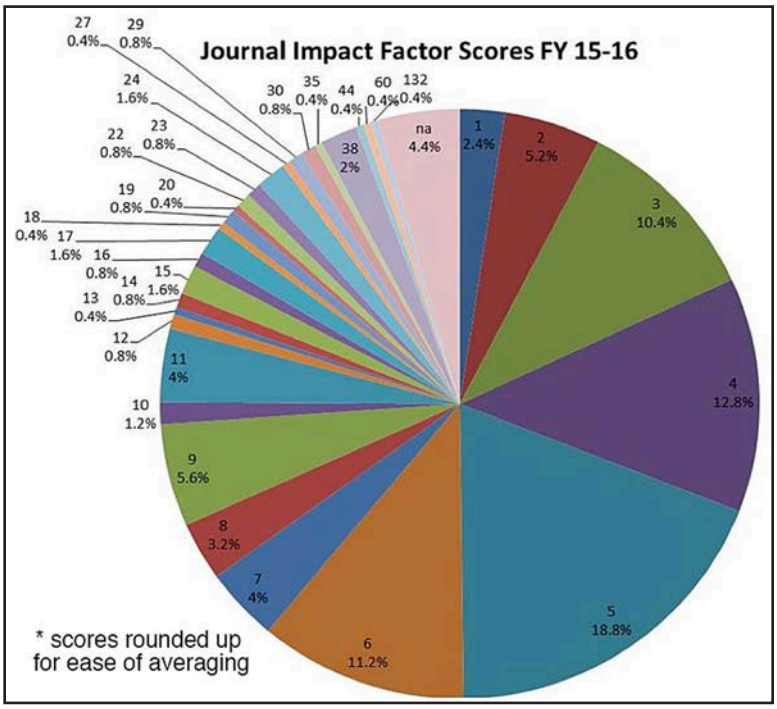
The research funding continues to be high with $32.2 million in current committed EP pathology grants. The vast majority of this funding is from federal sources with an additional component of funds from non-profit organizations and industry. In the current challenging federal funding climate, these successful grants represent a significant achievement.



The EP resource intensive space is 62,217.6 sq. ft. and the average indirect cost (IDC/square feet) of research space in Pathology is $113/sq. ft. These high numbers are reflective of successful EP research programs and funding. The continued success of research faculty is also reflected in the current national Pathology NIH ranking which is #7 nationally.

Included in the many exceptional faculty achievements is the funding of three NIH T32 training grants awarded to Pathology. Drs. Andrew Lieberman and Zaneta Nikolovska-Coleska successfully obtained a new NIH T32 training grant for PhD students in the MCP program. Drs. Steven Kunkel and Bethany Moore head a T32 funded multi-disciplinary program for Research Training in Experimental Immunology which is currently in its 20th year. Furthermore, Dr. Nicholas Lukacs is the PI of a long standing postdoctoral fellowship lung Immunopathology Training grant which is now in its 30th year of funding. Dr. Lukacs also continues to serve as the Scientific Director of the Mary H. Weiser Food Allergy Center (MHWFAC). The philanthropic goal of the center is made possible by $42 million in funding and thanks to the tireless advocacy from Ambassador Ron Weiser and his wife Eileen, as well as their daughter-in-law Mary Weiser. The Food Allergy Center has acquired three-fourth of these funds which have in part been utilized to recruit two new endowed Professors. The MHWFAC mission is to continue to recruit highly accomplished basic science and clinical faculty with focus on food allergy research.

The Michigan Center for Translational Pathology (MCTP) directed by Dr. Arul Chinnaiyan continues to successfully develop molecular tests and identify new human cancer therapeutic targets. The MCTP also maintains its remarkable track record of scientific success which is evidenced by high profile publications and successful funding. In 2016 Dr. Chinnaiyan and a group of distinguished scientists visited Washington DC to provide advice on research strategies aimed at advancing cancer research which is in line with Vice President Biden's hope for a "moon shot vision to cure cancer".



In the past fiscal year, Experimental Pathology faculty published over 250 manuscripts, including papers in high-impact journals such as *Cell*, *Science, Nature, Immunity* 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.

In addition to successful funding, EP faculty members have also received a number of prestigious awards. A few examples of special achievement by EP faculty members are worthy of special notice. Drs. Kathleen Cho and Laurie McCauley were recognized for their dedication to research, and were elected into the National Academy of Medicine. Dr. Asma Nusrat was elected as the Vice President and then President of the American Society for Investigative Pathology starting in July of 2016. Dr. Sriram Venneti received the Kimmel Scholar award for his contribution to brain tumor research and Dr. David Lombard was inducted into the American Society for Clinical Investigation. Dr. Jeffrey Hodgin received the Gloria Gallo Research Award from the Renal Pathology Society for the most impactful research in November. Dr. Ulysses Balis was appointed to the Database and Information Technology Advisory Committee of the American Board of Medical Specialties. In addition to these prestigious external awards, Dr. Alexey Nesvizhskii was one of eight outstanding faculty honored in January by the University of Michigan Endowment for Basic Sciences for excellence in classroom teaching, mentoring, and leadership in the advancement of the teaching mission.

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 a robust strategic research plan. This initiative, branded as "Fast Forward to Tomorrow's Cures," is bound together by three integrated parts: targeted innovative science, infrastructure to enable science broadly, and a research board of directors to provide leadership. The Fast Forward program has been instrumental in developing support for three research themes over a 5-year period: Epigenetics, the Host Microbiome and Protein Folding Diseases (co-directed by Dr. Andrew Lieberman.) In this past year stronger managerial and operational principles were implemented in the Biomedical Research Core Facilities to ensure short- and long-term responsiveness to the needs and competitiveness of researchers. Additionally this strategy has facilitated a number of research programs that include but are not limited to a Central Biorepository, Research data warehouse (DataDirect), Data office for clinical and translational research, Medical innovation initiative, R01 Boot Camp, and reinvigoration of the Clinical trials system.

DIVISION OF PATHOLOGY INFORMATICS

Ulysses G.J. Balis, MD

Professor of Pathology
Director, Pathology 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, 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 as a wholly contained division within the department that is independent of central enterprise IT stewardship. This autonomy affords the division both the ability to carry out internal prioritization of departmental projects, as well as the ability to independently carry out original IT initiatives. In addition, the division hosts its own active thrusts in fundamental areas of information technology, including: computational imaging of WSI subject matter, asset tracking solutions, computational pathology, and interoperability.

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

In contrast to the prior 2014-2015 academic year, over the most recent interval, the Division has been able to significantly expand its scope of optimization activities, as compared to the prior major focus on stabilization. For example, of the over 1500 modifications that were applied to our Lab Information System suite of solutions in the last year, nearly half of these were enhancements, with them collectively contributing to many workflow areas throughout the department. In most instances, owing to extensive pre-deployment testing, each of these enhancements ultimately equates to substantive productivity gains in actual real-world settings, with this observation reaffirming the Division's current strategy of validation testing. However, it should also be recognized that this year marks the three-year anniversary since the current LIS solution, SoftLab, was activated, and despite this interval specific modules such as Anatomic Pathology are still only fractionally complete. This is a significant deviation from what was promised by the vendor for go-live functionality and the Division continues to address this functional deficit as one of its highest internal priorities. In response to this continuing challenge, the division has implemented a new issue tracking strategy and associated issue database system that allows for real-time tracking of all active issues along with a simplified model by which we can track realization of corrections or enhancement from the vendor. Through the use of these solutions, it has become far easier for the division to effectively hold the vendor accountable for under-performance of our ongoing issue mitigation efforts.

Evolution of the Division's Data Stewardship Model

While the Division continues to maintain oversight of two geographically distinct data centers, the 2015-16 interval was noteworthy for significant activity between the Informatics Division and Health Informatics Technology Services (HITS) in terms of identifying opportunities for both a closer partnership model and additionally, for leveraging of extant IT infrastructure already in place within the enterprise at-large. Specifically, with the completion of the North Campus Data Center (NCDC), it became possible for the Informatics Division to transition from use of an aging Tier-1 secondary data center (our long-standing use of the radiation oncology server facility in the lower level of University Hospital) to use of a state-of-the-art Tier-4 type facility, as made available by the offering of space at the NCDC. After an extensive planning phase, the division was able to identify a functionally workable transition plan and associated long-term partners stewardship model by which

one-half of informatics' enterprise storage and virtualized server facilities could be permanently moved to the enterprise facility, and in so doing, leverage the significant economies of scale and intrinsic support services available at that facility. At the same time, Informatics continues to maintain its own primary data center at University Hospital, ensuring a continuance of the department's current capability of expediting disaster recovery by virtue of a walking-distance primary LIS computational facility juxtaposing the central laboratory. Now, with several months of experience operating in this new stewardship model, there is ample confirmatory evidence that the transition of our secondary data center was a strategically opportune choice and as a result, both levels of service and total operating cost will show improvements in their standard metrics of performance.

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. These enhancements included both the elimination of multiple major functional defects/deficits as well as the addition of long-awaited workflow and user interface enhancements. The anatomic pathology module remains an ongoing challenge. In this prior year, the division was able to definitively ascertain that SCC at present does not maintain a complete application-wide dependency map. This realization on our team's part allowed for our finally understanding the etiology of the large number of defects that would typically accompany any scheduled upgrade or service patch installation. With this knowledge in hand, the division successfully petitioned SCC to initiate an application-wide program of documenting all application dependencies within the next 12 calendar months. This process is already underway at the vendor's development offices and will be instrumental in allowing SCC to reunify the current 10 or more separate development forks into a single master application build version (a software stewardship practice that is absolutely essential for an application of this size and complexity, especially so in the setting of its supporting multiple clients). 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 over 28 projects that were initiated and completed:

- Upgraded to Gene Version 3.2.6.16
- Tested, validated, and implemented several packets of major AP module corrections, an addition to a major AP Module upgrade
- Implemented major improvements of the report delivery model for consult reports
- Implemented a functional call list solution for microbiology
- Activated a daily Soft audits reports to detect errors in real time
- Diagnosed and tracking hundreds of SCC operational / user interface issues
- Implemented numerous custom SoftReports:
    - Specimen count by ward
    - Monthly CP orders
    - AP orders by specimen type
    - Turn-around-time for chemistry, hematology, cytology, flow, and many other laboratory sections
    - Reference lab test volume by test type and by lab section
    - Phlebotomy patient volume per site
    - Performing location implementation for CAP reporting
    - Many others
- Implemented a sustainable FTP shuttle process for SoftReports
- Expanded the repertoire of electronically orderable sendout tests
- Completed major portions of the long-standing Cerner-to-Soft final cross-load project – allowing the capture of Cerner-Pathnet accession numbers in outbound messages. This will ultimately improve workflow in Soft and allow the department to fully decommission use of Cerner Pathnet (currently, AP addenda on historical cases are managed through Cerner and not SCC).

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 expeditiously configuring and attaching instruments to the laboratory network and to the LIS application. The 2015 – 2016 year was particularly brisk 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 factored as a significant source of projects for the division. The most important of these activities are enumerated below:

- Upgrade of Atlas LabWorks from version 11 to 19
- Implementation of the Agility interface
- Upgrade of the Rals interface
- Upgrade of the Cytovision solution – hardware and software
- Implementation of the GLS slide scanning robot in the HLA Laboratory
- Implementation of an interface from the HLA laboratory to UPS, enabling automated pre-ordering of supplies for transplant patients specimen kits
- Implementation of POCT connections with multiple new instruments being activated (e.g. GEMS, Clinitek)
- Implementation of Integrated FISH studies with the Cytovision server application
- Continued Preparation of the Ventana Immunostainer bi-directional interface (so far, a multi-year project)
- Implementation of Virtual Server support for the ROTEM instrument solution
- Enhancement of Irradiated Blood Product electronic workflow
- JVHL compliance improvements – now 98.5% compliant
- Continued testing and maintenance of all extant interfaces, per CAP requirements

Major IT Projects and Enhancements

The preceding year was exceptionally busy from a major-projects perspective, given that major constituent elements of our hardware abstraction layer were at end-of-life and in need of immediate replacement. Additionally, these upgrade activities were encountered at the exact time of a number of high-profile multi-department/enterprise-wide orchestrated interface projects, making the challenges on our implementation teams even more significant. In the specific case of orchestrated interfaces, these projects are particularly challenging, owing to the often-present external dependencies in the form of both foreign systems and external information technology divisions, with these representing an expanded scope for initial specification and subsequent partnered validation and implementation. Calling out a few projects from the overall efforts carried out, the MPU/Provation project singularly stands out as a major accomplishment, in that its activation allowed for the comprehensive programmatic elimination of a long-standing reporting challenge for the department, where clinicians would not be made aware of important anatomic pathology results in a timely fashion, owing to unresolvable limitations in the Epic ordering and results interfaces. To identify a solution, the informatics division worked closely with the division of gastroenterology in tandem with the newly-formed DQHI division of the pathology department, to create a purpose-built real-time interface between GI's Provation application solution and the Informatics Division's integrated message bus. Overall, this solution allowed for the programmatic capture of all performing and requesting physician identities, such that they could be recorded and documented on outbound anatomic pathology reports, and similarly, electronically directed to the in-baskets of these individuals, without fail. With this integrated solution now being active, it is estimated that over 10 reports per week that would otherwise proceed to being in an undelivered status, are now uniformly being directed to their intended recipients. This project was deemed as a major success by the enterprise at large and has resulted in a combined quality poster submission for the 2016 – 2017 academic year. An additional significant project completed was the activation of the Warde Laboratories reverse reference lab interface. This project was particularly noteworthy for it being completed well ahead of schedule and under the typical six-month timeline typical of most foreign system interfaces. This expedited implementation is a reflection of the mature and sophisticated capabilities of the well-seasoned interface team now supporting the Pathology Informatics division. The additional major IT projects completed in the preceding academic year are enumerated below:

- Activation of the MPU/Provation interface
- Activation of the Warde Laboratory reverse reference lab interface

- Upgrade of the Oracle layer supporting the division's EMPI server
- HP digital scanner server consolidation and upgrade
- Participation in WBI interface engine upgrades and router upgrades
- Continued development of an electronic Quest interface for inbound patient laboratory results
- Completion of the Sysmex/WAM interface upgrade
- Preparation of a clustered interface for Athena Laboratories in support of a group of 16 clients

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 continues, with the following activities of 2015 – 2016 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 academic year was particularly challenging for the division in terms of maintaining a full complement of staffing for all major operational sections. For example, the concurrent loss of our website's team lead and network engineering and security team lead to a single external campus division represented a semi-urgent development requiring expedited identification of suitable replacement expertise. Fortunately, the division was able to transition its current contract application programmer into the role of lead website architect and efforts are well underway to identify a second web application programmer. Similarly, the loss of one of the division's two anatomic pathology application specialists represented a short-term functional deficit that was fortunately resolved with the identification of a superb anatomic pathology LIS specialist. A complete overview of the preceding year's staffing changes is included below:

- Cole Smith replacing PathDx business analyst Rachel Roach
- Chris Sobeck replacing Senior Web Architect Jeff Sica
- Jorge Livingston replacing Senior Virtualization Architect Bob Killen
- Addition of Liz Walker as a Communications Specialist to the Web team
- Ongoing restructuring of Pathology Imaging workflow in the setting of Mark Deming's departure and Liz Walker's transition to the Web team
- Andrea Hawk replacing MLabs interface specialist Marianne Mara, upon Marianne's transition to her new role at DQHI
- Improvements to the division's on-boarding and off boarding policies
- Implementation of a web-based electronic user account request form for new hires

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:

- MU2 Reporting Project
- Epic 2105 version October 1 readiness
- ICD10 implementation
- IE 11 roll-out
- MCIT (HITS) committee memberships
    - MLT (now 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
- Pathology Datacenter Inventory Project - ready for gap analysis
- Continued client interface work with EHRs:
    - Answers On Demand
    - 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 4 readiness
- VMI project participation
    - End User Devices
    - Applications
    - Data Center Consolidation initiative

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 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.

Intramural Infrastructure Updates
In any given academic year, the Pathology Informatics Division embarks on a large number of infrastructure update projects, reflecting the contemporary reality that most if not all IT solutions provide an ephemeral-at-best value proposition for their use. Typical longevity of hardware-based solutions ranges from 5 to 10 years with the average being seven years. Software solutions, if properly maintained, can exhibit a lengthened longevity from these values, but are nonetheless also subject to periodic turnover. In the 2015 – 2016 academic year, a number of high profile infrastructure elements were enhanced or otherwise updated with the following list being a subset of the more substantial activities carried out:

- External device encryption project
- Transition of File System Administration to the Pathology Operations/Desktop Team
- Upgrade of Firmware of SAN fabric
- Upgrade of SAN fabric to 16Gbps speed
- Migration of antiquated Novell server technology for both Clinical and Research Pathology
- Continued updates of Reading Room hardware with large monitor configurations
- Upgrade of Data Center Switches
- Enhancement of Wayne County Medical Office networking/connectivity
- Wiping and disposal of old equipment, with forwarding to property redistribution
- Upgrade of Battery Farm in the primary Pathology Datacenter

Departmental Website Enhancements
The Department of Pathology's contemporary website is now in its seventh generation of major design, with the preceding year being noteworthy for a major overhaul of the architecture of the top-level pages as well as the underlying content management system that operates in the background. Specifically, the new architecture imparted on the content management system now allows for "responsive" webpage performance, where different browser technology form factors (workstation versus tablet versus smart phone) automatically activate media-specific rendering of content which is optimally suited for the available window size form factor. Additionally, major functional sections within the departments website were enhanced to allow for simplified navigation and access of commonly requested information, including the faculty and staff listings, departmental structure, departmental calendars, and timely news items. Specifically concerning the news items, significant developmental effort was carried out to implement a new and streamlined departmental news dissemination process along with a sliding marquee at the top of the master webpage, where timely news articles can be depicted in rotating fashion. The process leading to these multiple enhancements was facilitated by a market-wide review of other leading pathology department websites, with the goal of identifying a select list of desirable functionalities not currently on hand. At present, three quarters of these desirable attributes have been implemented and it is anticipated that in the 2016 – 2017 academic year, the remainder of these

functional enhancements will be placed on the live website. Complementing these technical enhancements was the addition of a content generation/media Specialist to the web team (Liz Walker) who now assists with the timely generation of news articles concerning the department. Specific enhancements to the website of note, implemented in the prior year, are enumerated below:

- Top-level Web page redesign
- Implementation of a standing pathology Newsletter
- Implementation of an Experimental Pathology Webpage section
- Implementation of a DQHI Pathology Webpage section
- Improvement of the HR Tools process and website
- Overhaul of the custom billing process and web program
- Implementation of Departmental Administrative Structure Tools and Webpages

MICHIGAN CENTER FOR TRANSLATIONAL PATHOLOGY

Arul M. Chinnaiyan, MD, PhD

S. P. Hicks Endowed Professor of Pathology
Director, Michigan Center for Translational Pathology
Investigator, Howard Hughes Medical Institute
American Cancer Society Research Professor
Professor of Urology

OVERVIEW

The Michigan Center for Translational Pathology (MCTP) was formed in 2007 as a focused initiative to bring basic research discoveries from molecular medicine to clinical applications for the identification of biomarkers and therapeutic targets for cancer diagnosis and treatment. This endeavor was supported by the Department of Pathology, the University of Michigan Health System, the Medical School, and the University President's Office. The goals of MCTP were not only to improve clinical care for cancer patients, but also to complement the academic goals of the University of Michigan Medical Center.

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.

The Center continues to expand and evolve and a solid foundation has enabled us to become well-positioned to pursue cutting-edge research to advance the discovery of important biomarkers of cancer as well as novel therapeutic targets. The Center has established strong partnerships with industries such as Agilent Technologies, Ventana, and GenProbe to translate basic research discoveries into clinical applications.

Earlier we reported the development and release of a new clinical-grade assay, Mi-Prostate Score (MiPS), an early detection test for prostate cancer that incorporates three specific markers, TMPRSS2:ERG (T2:ERG) gene fusion, PCA3 (prostate cancer antigen-3) and PSA (prostate specific antigen). This test is currently on offer through Pathology's MLabs.

Our clinical sequencing study, Michigan Oncology Sequencing Center (MI-ONCOSEQ), continues to experience a tremendous rate of growth since its inception in 2011; over 1000 adult and pediatric (under PEDS-ONCOSEQ study) patients have undergone clinical sequence analysis thus far, for many of whom actionable mutations were identified and suggested therapies that would otherwise not be considered. Overall, clinically

relevant results were identified in approximately 60% of patients and clinically significant germline aberrations were identified in 50 patients.

In collaboration with Dr. Rajen Mody from Pediatric Oncology, we published the results from the first 102 pediatric patients enrolled in the PEDS-ONCOSEQ clinical sequencing study (*JAMA*, Vol. 314, No. 9, Sept. 1, 2015). A total of 91 pediatric patients with advanced or relapsed cancer underwent complete sequence analysis. Forty-two patients (46%) had actionable findings that changed their cancer management and individualized actions were taken in 23 patients based on actionable integrative clinical sequencing findings, including change in treatment for 14 patients and genetic counseling for future risk for 9 patients. Nine of the personalized clinical interventions resulted in ongoing partial clinical remission of 8 to 16 months or helped sustain complete clinical remission of 6 to 21 months. All 9 patients and families with actionable incidental genetic findings agreed to genetic counseling and screening. The study is the first to report on combined multiple genome sequencing approaches (tumor as well as normal DNA and tumor RNA) in real-time, in children and young adults with relapsed cancers.

Finally, as part of the SU2C-PCF International Dream team effort, we reported that treatment with the PARP inhibitor olaparib in patients whose prostate cancers were no longer responding to standard treatments and who had defects in DNA-repair genes led to a high response rate (*N Engl J Med*. 2015 Oct 29;373(18):1697-708). Out of all enrolled patients (49/50) who had evaluable data, 16 had a response to olaparib, including 6 patients having a radiological response and 4 patients having responses lasting more than a year. In addition, NGS sequencing study in these patient samples detected mutations in genes associated with DNA repair in 16 of 49 patients. Of those, 13 of 16 patients responded to olaparib. The most common aberrations were BRCA2 biallelic loss (either somatic or germline) but we also identified ATM, PALB2, HDAC2 and BRCA1 genomic aberrations associated with responses, among others.

Recently, we developed a targeted panel called OncoSeq that utilizes in solution hybrid-capture methods focusing “sequencing bandwidth” on the protein coding exons in ~1700 target gene set. The OncoSeq gene set is designed to efficiently identify genetic aberrations in both highly recurrent cancer genes as well as a larger additional panel of candidate genes with suggestive links to cancer. This approach enables a faster turn-around time that is more feasible for routine clinical use. Recently, this approach is being used predominantly and our average turnaround time (TAT) for adult patients decreased to 34 days from ~60 days previously; we were able to achieve a TAT as low as 18 days. Our target TAT goal is three weeks, which we are rapidly approaching for nearly all samples.

With these accomplishments, we are well positioned to successfully compete for the Clinical Sequencing Evidence-Generating Research (CSER2) funding that transitions from an exploratory phase (CSER1 that we were previously awarded) to an expansion phase to apply clinical sequencing more broadly in the medical community.

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 include:
1) The landscape of antisense gene expression in human cancers (*Genome Res.* 2015 Jul;25(7):1068-79);
2) Overexpression of the long non-coding RNA SChLAP1 independently predicts lethal prostate cancer (*Eur Urol*. 2015 Dec 23. pii: S0302-2838(15)01211-7)
3) BET bromodomain inhibitors enhance efficacy and disrupt resistance to AR antagonists in the treatment of prostate cancer (*Mol Cancer Res*. 2016 Apr;14(4):324-31) and;
4) KRAS engages AGO2 to enhance cellular transformation (*Cell Rep*. 2016 Feb 16;14(6):1448-61). Overall, Dr. Chinnaiyan and colleagues published 41 papers in FY 2016, including in high-impact journals (*N Engl J Med, JAMA*).

MCTP continues to engage in both national and international collaborations with other research groups and industry partners. The Center has a longstanding collaboration with the Early Detection Research Network (EDRN). Even as the international SU2C-PCF Dream Team’s grant has ended, the group continues their collaborative research under a new PCF grant. Studies are underway to leverage the “CRPC500” SU2C

patient cohort and samples to molecularly track the various courses of disease progression by re-biopsy, and characterize novel aberrations we identified- AR splice variants, DNA repair genes and germline variants. We also have plans to study “exceptional responders” from the associated clinical studies. Further, the data generated here is deposited into a web-based portal (http://www.cbioportal.org) along with associated clinical data and made available to the research community to enable novel discoveries and associations in prostate cancer progression.

Other collaborations include Metabolon, Ventana, GenProbe, GenomeDx and WaferGen to develop 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.

On January 8, 2016, fifteen distinguished American Association for Cancer Research (AACR) leadership and members, including Dr. Arul Chinnaiyan, from 10 cancer centers and medical institutions all across the U.S. (from nine different states) participated in meetings with top officials from the Food and Drug Administration (FDA) to discuss FDA’s current thinking on how the agency might regulate NGS-based tests, as well as interrelated topics, such as laboratory developed tests (LDTs) and companion diagnostics for cancer therapies. The AACR used the meeting as an opportunity to provide information and important perspectives to the FDA as it begins developing NGS-related guidance for the scientific community. In addition, the AACR team was invited to a separate meeting with senior staffers for Vice President Joe Biden to discuss ways the Vice President can further his commitment to cancer research. The Vice President believes that his power is in: 1) serving as a convener; 2) influencing Federal agencies; and 3) spurring public-private partnerships; he is specifically interested in determining how to incentivize collaboration and breaking down barriers. The AACR Team was well-received by both the FDA officials as well as the Vice President’s staff, the meetings were productive and encouraging.

Our publications in high impact journals and media exposure were coupled with the recognition of MCTP scientists by their scientific peers. Dr. Arul Chinnaiyan, an Investigator, Howard Hughes Medical Institute and an American Cancer Society Research Professor, was named a member of the University of Michigan Precision Medicine Task Force.

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

- Yashar Nikfas was awarded the AACR-Bristol-Myers Squibb Oncology Scholar-in-Training Award. The Award recognizes outstanding young investigators for their meritorious work in cancer research. He also was awarded the Rackham Predoctoral Fellowship.

- Sethu Pitchiaya received the 2016 AACR-Bayer Prostate Cancer Research Fellowship for his project entitled, “Androgen receptor regulation by lncRNA PRCAT47 in prostate cancer”.

- Rohit Malik received the DOD Prostate Cancer Research Program (PCRP) Idea Development New Investigator Award for his project entitled, “Discovery and Characterization of PRCAT47: A Novel Prostate Lineage and Cancer-Specific Long Noncoding RNA”.

- Lanbo Xiao received the FY2015 DOD Prostate Cancer Research Program (PCRP) Fellowship entitled, “Biological characterization and clinical utilization of metastatic prostate cancer-associated lincRNA SchLAP1”.

- Sunita Shankar received 1st place for her abstract presentation entitled, “KRAS Engages AGO2 for Cellular Transformation” at the APHPMP Research Day held at BRSB, University of Michigan on Feb 13th 2016.

- MCTP was awarded the Occupational Safety & Environmental Health Safety First Recognition Award. This award is presented to individuals or workgroups within the University of Michigan community who are committed to making the University of Michigan a safer place.

MCTP funding continues to be strong despite the challenging funding climate. This past fiscal year, the Center obtained $7,402,791 in committed awards. In addition, MCTP discoveries generated $ 791,781 of royalties to UM in FY 2016. The total gross charges continue to increase each fiscal year for our CLIA testing. Fiscal year 2016 saw total gross charges of $1,645,012. The majority of the charges were due to the PCA3 technical component ($1,321,924).

MCTP continues to be successful on all fronts and make progress towards our goal of translating basic laboratory discoveries into clinical applications. We strive to remain at the forefront of and make a significant impact on cancer biology, bioinformatics and the emerging field of precision medicine. In the coming year, particularly as our clinical sequencing program experiences increase demand, we hope to offer the OncoSeq test formally and more broadly through Pathology's MLabs, similar to our other clinical tests.

DIVISION OF MLABS

Jeffrey L. Myers, MD
A. James French Professor of 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 University of Michigan Health System (UMHS). As we celebrate our 31st anniversary in the reference laboratory business with another successful year of growth, 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 are 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 of Pathology, 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 Division Director: Jeffrey L. Myers, 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 unit 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 does not utilize a phone tree menu approach to call triage; each call is answered personally. Our trained client service representatives are available to answer questions related to specimen procurement and handling, look up 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:
The UMHS Department of Pathology Laboratories (*i.e.,* 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 695 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 UMHS. MLabs extends molecular testing and 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 366 physician offices (all subspecialties) within geographic catchment of UMHS. Some patient specimens are collected at the physician offices (*e.g.,* 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 UMHS 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 (JVHL). 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 HL clients include hospitals 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 80 hospitals throughout the state and the country.

HPG reflects 202 hospital-based pathology groups 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 hematologic and lymphoproliferative 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 via MiShare (a secure email delivery platform), and most recently through MLabs Connect, our internet-based secure web portal.

Reference Lab/Commercial Accounts - MLabs leverages the clinical, educational, and research missions of UMHS 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 currently under development 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 inher-

ited 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, Mi-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 regional nursing home and acute care facilities of strategic interest to UMHS. 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 UMHS' clinical data repository (MiChart) if that patient is known to UMHS. This allows both hospital and nursing home electronic medical records access to the same laboratory information, improving quality and continuity of care for our UMHS patients.

FINANCIAL METRICS – TOTAL BUSINESS

MLabs maintains steady growth year over year in a competitive reference laboratory industry. FY16 Total Gross Charges increased by 2.0 million dollars over FY15, allowing MLabs to make significant contribution to the margin that supports all of the missions of UMHS and the Department of Pathology. This increase reflects organic growth in our reference laboratory services, including a significant increase in consult cases (24%) and nursing home testing (22%) along with acquisition of 70 new clients across all market segments.

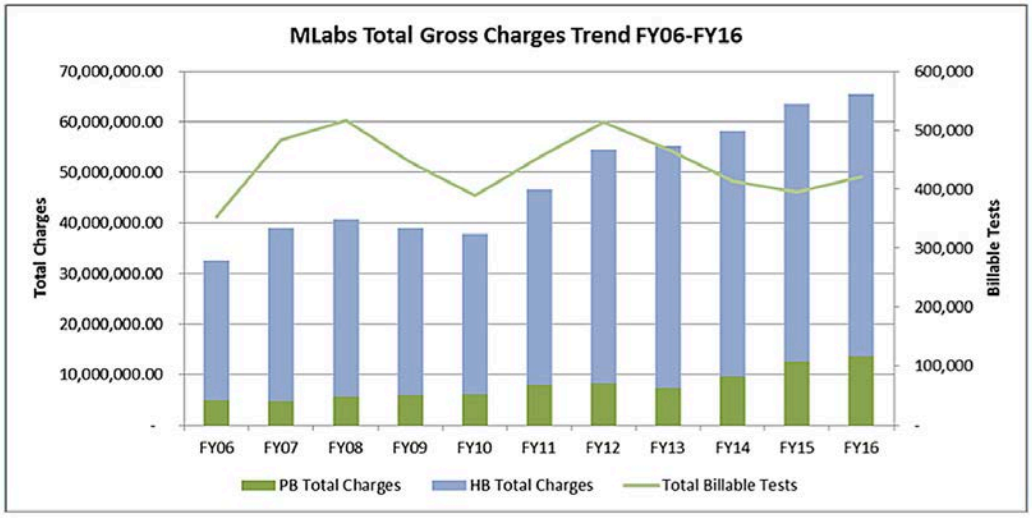


Figure 1: MLabs Total Gross Charges (Professional and Technical) Trend FY06 - FY16 with PB (professional) and HB (facility) detail.

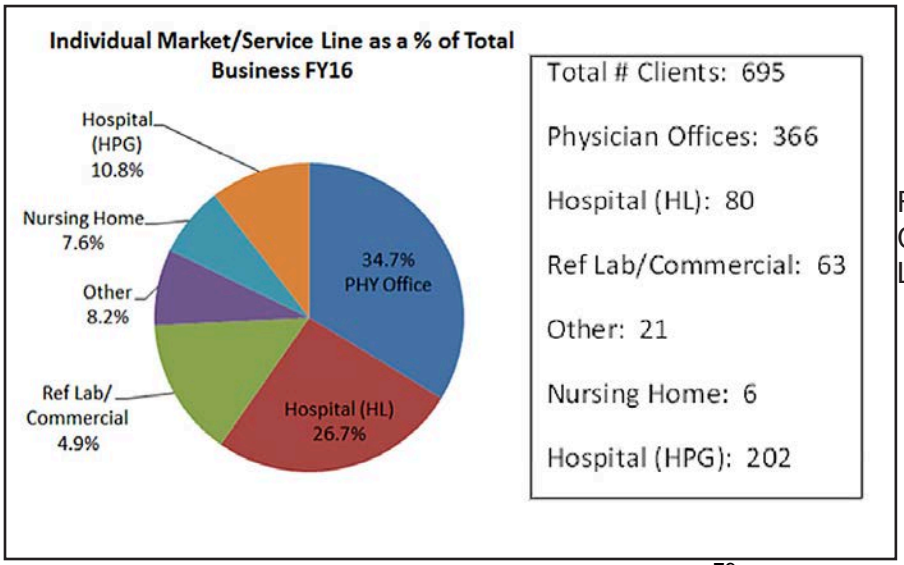


Figure 2: Percentage of Total Gross Charges by Individual Market/Service Line

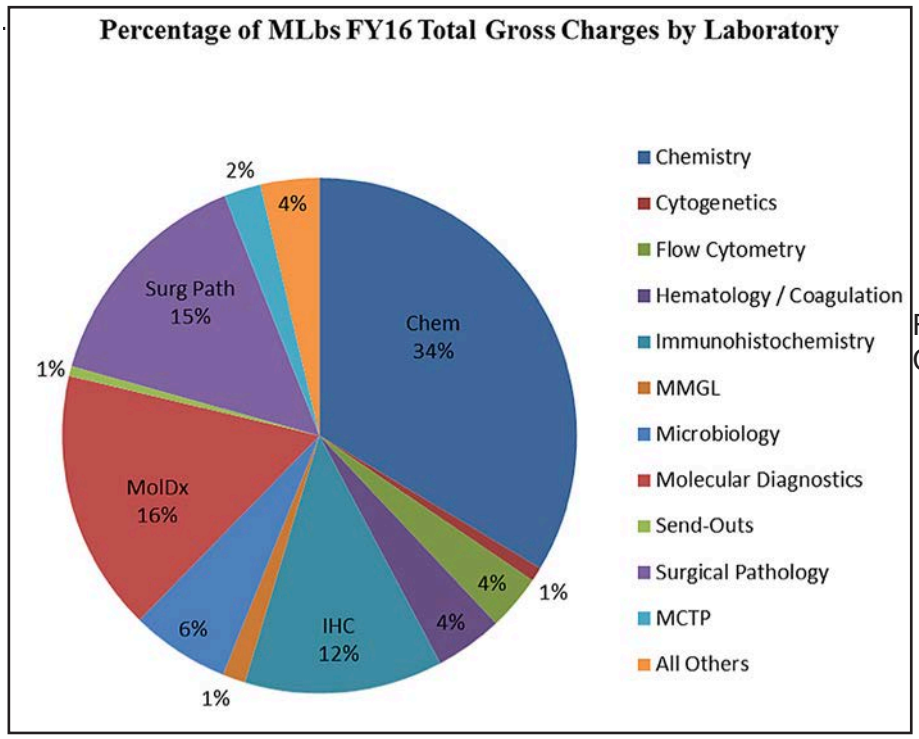


Figure 3: Percentage of Total Gross Charges by Laboratory

FY16 KEY ACCOMPLISHMENTS

- 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.
- State of New York Licensure for PCA3 testing.
- Increased market share nationally in anatomic and hematopathology consultations.
- Successful recruitment of 3 Client Service Representatives, IT Analyst and Senior Brand Analyst.
- Increased national awareness of MLabs brand as provider of choice for subspecialty services.

SALES AND MARKETING

MLabs primary sales and marketing effort remains focused on making certain that pathologists, hospitals, and reference laboratories everywhere recognize The University of Michigan MLabs as the center of excellence for specialized laboratory testing, especially molecular diagnostics, subspecialty and consultative services. Exhibiting at regional and national meetings affords us an opportunity to be visible and recognized as a national provider of high quality laboratory services. During FY16, MLabs exhibited at three national meetings (USCAP, CAP and ASCP) and five regional pathology meetings across the country.

MLabs Statewide Laboratory Network Participation – JVHL and GLN

JVHL is the largest laboratory network in Michigan and is organized as a limited liability company, equally owned by its hospital laboratory members. UMHS (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 UMHS Managed Care Operations Office with lab related issues.

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, MD, PhD

Henry Clay Bryant Professor of Pathology
Director, Division of Molecular and Genomic Pathology
Professor of Pathology and Internal Medicine

OVERVIEW

The Division of Molecular and Genomic Pathology (DMGP) was created one year ago with a vision to integrate and unite the department's various clinical molecular pathology laboratories as well as transitioning the precision oncology assays developed by the Michigan Center for Translational Pathology (MCTP) from research to clinical assays, in support of its vision to establish a new model of precision oncology. The primary components of the DMGP consists of the Molecular Diagnostics Laboratory (MDL) under the direction of Drs. Noah Brown, Thomas Wilson, Bryan Betz, the Cytogenetics Laboratory under the direction of Dr. Lina Shao, the Dermatology Molecular Diagnostics laboratory under the direction of Dr. Aleodor Andea, and the MCTP under the direction of Dr. Arul Chinnaiyan. The DMGP also works very closely with the Michigan Medical Genetics Laboratories (MMGL) in the department of Pediatrics, under the direction of Dr. Jeff Innis.

In its inaugural year, (DMGP) has made good overall progress in coordinating the department's various molecular activities. The Division has focused its efforts on developing an overarching strategy for precision oncology, especially in light of the institutional decision regarding Paradigm. This strategy consists of offering a package of assays that range from single gene tests to comprehensive assessment of nearly all known cancer-related genes.

Divisional Activities

Survey of UM Oncology

One of the first activities of the past year, in collaboration with Dr. Kathy Cooney (former Director of UM Hematology/Oncology), was to design and execute a survey of UM Oncologists regarding their future needs and vision for molecular and genomic testing in oncology. While the survey revealed a wide diversity of opinion among UM oncologists, a strong and overarching theme that emerged was that more genetic information in the form of large panel testing would be needed over time as the field matured and more targeted therapies were developed and approved.

The results of the survey were shared with directors of the various UM molecular laboratories and helped shape the current precision oncology strategy (see below).

Monitoring FDA regulation of LDTs

In October 2014, the FDA issued draft guidance for a new regulatory framework for Laboratories Developed Tests (LDTs) entitled *Framework for Regulatory Oversight of Laboratory Developed Tests (LDTs)* (see http://www.fda.gov/downloads/medicaldevices/deviceregulationandguidance/guidancedocuments/ucm416685.pdf). Since nearly all tests performed by academic molecular diagnostic laboratories are LDTs, this guidance has the potential to significantly alter the regulatory framework under which we operate. This guidance would add a new layer of regulations in addition to those of CLIA and CAP. Many individual thought leaders and associations, such as the Association for Molecular Pathology (AMP), have expressed strong and formal reservations about the FDA entering this area, warning about redundancy with other regulations, inhibition of innovation by academic laboratories, and inadequate FDA oversight bandwidth.

The US Commerce and Energy Committee, chaired by Congressman Fred Upton of Michigan, has a role in laboratory oversight. Because of this alignment, Dr. Giordano was encouraged by various leaders in molecular diagnostics to engage with Congressman Upton's office. Dr. Giordano engaged Rick Bossard, Government Relations Representative for the UM Health System. At the request of Dr. Giordano, Mr. Bossard did discuss the LDT issue and how FDA oversight would negatively impact UM laboratories. However, Mr. Bossard learned that FDA and CMS have made convincing arguments to the E&C committee for additional regulation.

Many counter proposals have been offered by various professional organizations. Several members of the Department of Pathology have provided comments to the FDA about LDT draft guidance, encouraging updating of existing CLIA regulations as a preferred method of modernizing oversight.

Dr. Giordano has also been in regular contact with Tiana Korley, Associate General Counsel, Office of the Vice President and General Counsel, who is following the LDT issue closely and is of the opinion that FDA is continuing to move forward with its LDT guidance and targeting the end of the year for issuing final guidance.

If and when the FDA issues final guidance, the DMGP will assess the final regulations and adjust our strategies accordingly as much as possible, recognizing this has the potential to fundamentally change and disrupt much of what we do.

Team Building Efforts Across UM Laboratories

Many of the molecular pathology laboratories, including those at the Traverwood complex, will be relocating to the North Campus Research Complex (NCRC) in early 2018. The NCRC design process has placed the various laboratories in close proximity and working together as much as possible, with shared spaces as appropriate. In an effort to provide a smooth transition, the DMGP in collaboration with Dr. David Keren and Brian Tolle, has started quarterly team building meetings with laboratory personnel from the various laboratories. These meetings have been successful in many ways, from providing opportunities to meet co-workers in other labs to answering questions about how the laboratories will function after the move to NCRC. Parking at NCRC remains an important issue for laboratory staff, given that parking at Traverwood is currently free and amply available.

Standardizing Laboratory Work Culture

Given the planned move to NCRC, Dr. Giordano met with the various laboratory supervisors of the DMGP laboratories to better understand their operations and work cultures and how they might differ between laboratories. During the meeting, it was apparent that the laboratories do not implement uniform policies. In an effort to address this, Dr. Giordano has engaged departmental administration and Human Resources in an effort to create standardized policies for laboratories operations. This process is just underway.

Search for a new Assistant Director of Cytogenetics

At the end of the academic year, Dr. Diane Ralston announced her decision to retire. Arrangements have been made for Dr. Ralston to provide a 20% effort the next academic year to support educational efforts and to provide clinical relief for Dr. Lina Shao for meetings and vacation. Accordingly, Dr. Giordano is leading the search for a new Assistant Director and several candidates have been identified.

Collaboration with MLabs

Molecular Pathology has been a significant source of activity and growth for the department's outreach initiative, MLabs. Over the course of the academic year, discussions have occurred on how to optimally market UM molecular pathology test offerings to MLabs clients and how to leverage our laboratories to derive new clients. One example of such collaboration is the developing arrangement with Tempus, via MLabs, to license and market the MCTP's OncoSeq1500 assay.

Collaboration with Commercial Laboratories

Some UM oncologists have been making increasing use of commercial genomic assays for cancer testing, such as *FoundationOne* offered by Foundation Medicine. While we intend to be supportive to UM oncologists, we also intend to offer equivalent tests internally, such as *OncoSeq1500*, and hope to direct their testing activities to our own laboratories as appropriate and feasible.

Current Strategy for Precision Oncology Testing

Much of the DMGP's efforts have been to determine an overarching strategy for providing testing in support of precision oncology and to support clinical trial enrollment in the UM Comprehensive Cancer Center. Developments in this regard in the MDL and the MCTP are outlined below.

Molecular Diagnostics Laboratory (MDL)

At the beginning of the year, the MDL offered a large menu of individual gene tests and was developing three panels of 6 to 8 genes, one each for melanoma, lung cancer and colon cancer. These panels launched in the spring of 2016. However, the pricing on these assays as set by UMHS administration was $5,550, approximately equal to very large panel assays offered by Foundation Medicine and other commercial laboratories. Given this discrepancy in pricing, Dr. Giordano, working with David Golden in Pathology administration, was able to achieve a price reduction to $1500 in collaboration with UMHS billing administration. This pricing is much more logical and should help to establish these assays with UMHS oncologists.

Towards the end of the year, the MDL decided to transition to the Oncomine Focus Panel as their foundational platform going forward. This assay evaluates for the presence of genetic alterations, including gene fusions, in a 52-gene set that is linked to existing targeted therapeutics or likely clinical trials with targeted approaches. The current plan was to divide the OFP assay into several large cancer-specific panels. At the end of the year, a capital equipment purchase was achieved, which will allow development and validation of the OFP assay for launch in the spring of 2017.

Michigan Center for Translational Pathology (MCTP)

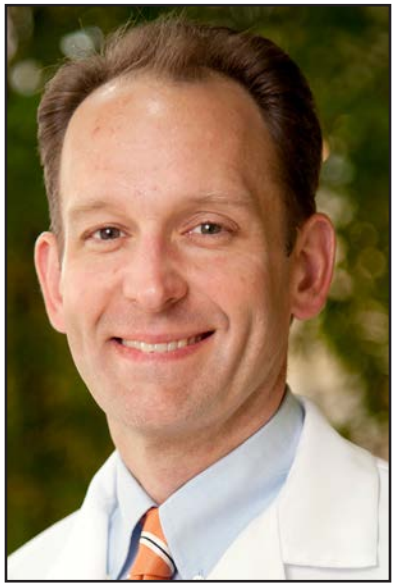
To date, the MCTP has genomically profiled over a 1,000 UM cancer patients. Most of these were done using a combination of whole exome sequencing plus RNA sequencing. During this past year, this assay was migrated to a targeted assay of over 1,700 cancer genes plus RNA sequencing. One of the benefits of the current assay, called OncoSeq1700, is a quicker turn-around time and deeper sequencing, resulting in a quicker and more accurate assay.

In addition to OncoSeq1700, the MCTP with direction from Dr. Scott Tomlins is developing the Oncomine Comprehensive Panel (OCP), a 142-gene assay that includes the components of the Oncomine Focus Panel plus a larger set of potentially actionable genes. This assay will be offered to UM oncologists starting in the fall of 2016. If successfully implemented and in demand by UM oncologists over time, the OCP assay can be migrated to the MDL after their move to the NCRC.

In conjunction with the MCTP, the DMGP is working towards full clinical implementation of the OncoSeq1700 and OCP assays. Working with UMHS billing administration, we have determined the clinical charge of OncoSeq1500 to be $5,500, in an attempt to be competitive with other commercial assays such as FoundationOne.

Summary

The DMGP is well positioned to offer a range of testing options for precision oncology, evaluate their implementation and clinical utility, and make adjustments to the testing portfolio going forward once the laboratories make the transition to the NCRC. These efforts will benefit UMHS patients.



DIVISION OF QUALITY AND HEALTH IMPROVEMENT

Scott R. Owens, MD

Associate Professor
Medical Director, Professional Practice Evaluation
Director, Division of Quality and Health Improveme

OVERVIEW

During its first full fiscal year of operation, the Division of Quality and Health Improvement (DQHI) has accomplished several important goals and has honed its activity to focus efforts on a handful of major projects aimed at transforming the patient experience at the University of Michigan Health System (UMHS) and beyond, from a pathology-based platform. This work included:

- An inaugural Quality Improvement Curriculum for our residents was introduced and successfully completed in partnership with the Division of Pathology Education
- DQHI launched its coordination of the Patient Asset Management Initiative (PAMI) a Department-wide program aimed at an approach to asset stewardship that will ultimately affect and guide management of our patients' physical and digital resources from the time testing is initiated through archiving of assets
- DQHI staff partnered with other Departmental key players and UMHS personnel to develop an interface between Provation – the electronic solution for documentation and specimen identification in the Medical Procedure Unit – and SoftPathDx, which will help to streamline the way specimens are recorded and tracked as they pass from the clinical/procedural setting into Pathology
- Several patient- and family-centered care initiatives were facilitated with the help of DQHI personnel
- DQHI personnel were instrumental in a number of important compliance, accreditation, and regulatory activities
- DQHI personnel facilitated and coordinated several technological improvements including the installation of TempTrak software and hardware in the majority of laboratories throughout Pathology, and the improvement of the slide library request tool on the Departmental website
- DQHI interfaced with and supported operational quality activities throughout the Department, including adoption of an overarching quality management framework (CLSI Quality System Essentials) to unify Departmental quality efforts, as well as support of operational quality dashboards/metrics
- DQHI partnered with members of the University of Michigan's Department of Computer Science and Engineering as well as the Division of Pathology Informatics to begin a project aimed at utilizing machine learning technology and "big data" to approach the topics of test utilization and predictive modeling from a pathology platform

A more detailed description of these activities follows in the subsequent sections of this report.

Quality Improvement Curriculum

In collaboration with Drs. Allecia (Lisa) Wilson and Barbara McKenna from the Division of Pathology Education, as well as representatives from within the group of residents, Jeff Lott served a project manager role to provide our pathology house staff formal education on quality improvement methodologies and tools, primarily based on the "Toyota System", also known as "Lean" thinking. This program was aimed at meeting ACGME requirements, but was also believed by DQHI to be an opportunity for pathology residents to take an integral role in the fundamental and "front-line" quality activity in the Department. Prior to this project, departmental offerings for QI education to Pathology residents were inconsistent and unstructured, with some house staff

being heavily involved in quality initiatives and others essentially abstaining from this type of work, based solely on individual interest. Using (with modification) methodology already piloted by the resident education team in the Department of Dermatology, we managed a five-month, team- and project-based education program for our first-, second-, and third-year residents. As part of this curriculum, our team of 21 residents, as well as the three 2015-2016 hematopathology fellows, worked on six projects:

- Reduction of lost and damaged Descemet's membrane specimens from ophthalmology
- Reducing inadequate formalin fixation of key surgical pathology specimens
- An identification scheme for frozen section "chucks" aimed at reducing specimen misidentification in the busy frozen section room
- Standardization of "platelet-refractory" workups in the blood bank
- Streamlining of hemoglobin electrophoresis test utilization in the setting of pregnancy
- Optimization of peripheral blood smear review vs. automated red blood cell morphology ordering practices in the hematology lab

In addition to the outcomes of these individual projects, which DQHI personnel will help to prepare for presentation at the annual UMHS "Quality Month" poster session as well as for submission to national meeting venues such as the United States and Canadian Academy of Pathology Annual Meeting, pre- and post-test assessments indicated an overall 34% increase in knowledge by the participants, ranging individually from 7% to 122%. Using feedback from the participants, DQHI and Education personnel led by Project Manager Jeff Lott are working to make improvements to the curriculum for next year's installment, in which first- and second-year residents will participate.

Patient Asset Management Initiative

DQHI Project Manager Amy Mapili serves as overall program manager for this Departmental initiative focused on ensuring Pathology's ability to manage and control the physical and electronic life of patients' specimens from ordering to disposition. In a variety of ways, Amy's work is supported by the remaining personnel in the Division for this large and ambitious program. It is crucial to be clear that this is a Departmental-level program that is being spearheaded and coordinated by DQHI, whose vision for this work involves embedding test utilization and decision support activities, because we hope ultimately to formally leverage expertise in Pathology to support our colleagues in face-to-face patient care activities as they consider, order and interpret tests for their patients. The initial scope of this large project, however, will focus on the life of physical patient assets ("specimens") from the moment of their creation through the documentation and transmission of results to our customers (both health care professionals and patients). Our goal is to create a system of specimen tracking that provides information and a level of granularity similar to what can be obtained when tracking the life of a package using the major transportation and delivery organizations, such that every patient asset can be uniquely identified and located at key points in its travels through the system. In addition to streamlining workflow, this should allow for early identification, and thus an improved chance of recovery, for assets that "go missing" as they traverse the operation. The initial phase of documenting the overall method of obtaining, transporting, processing, and tracking patient specimens is 90% completed as of the end of FY 2015-2016. This effort includes working with clinical partners to assess current test utilization practices, as well as how orders are placed and results communicated back to them. The program management strategy includes prioritization in phases which positions us to execute projects of a manageable size while managing the interdependencies of these endeavors based on our understanding of the overall system.

Provation-SoftPathDx-MiChart (Epic) Interface

Amy Mapili served as project coordinator in collaboration with the Division of Pathology Informatics (PI), the Histology laboratory, and Faculty and Nursing staff from the Medical Procedure Unit (MPU) to create an interface between Provation (the program used by MPU staff to document procedure notes as well as specimens collected during endoscopic examinations) and Soft, that allows for an order to be automatically created in Soft as specimens are identified and entered into Provation. Prior to this interface, the process did not guarantee that the appropriate clinical physician would receive the result associated with each specimen generated in

Provation, as there was a manual entry step when assets were transferred from the hands of the MPU staff to Pathology. This created inefficiencies and potential delays in patient care as the correct physician was identified and results sent to MiChart. The new interface, created with the extensive efforts of Bill Hubbard and Kathy Davis from PI, now allows the unique physician identifier ("doctor number") indicated in Provation to be a direct and automated input into SoftPathDx, thereby ensuring the appropriate physician receives the appropriate reports each and every time. This was the primary problem at which the work was aimed, but there are ancillary benefits that we believe DQHI's participation identified and helped to create. Because the interface creates an order number at the time of specimen collection, Pathology personnel now have knowledge regarding which specimens are being generated in the MPU, with the ability to reconcile the list of specimens as they are received in real time to reduce the chances of specimens being unaccounted for or missing. In this way, the process supports the activities of the PAMI described above. Furthermore, while the process is primarily focused on endoscopic biopsies from the gastrointestinal tract generated by our colleagues in Gastroenterology, its use can easily be broadened to encompass specimens generated from endobronchial examinations and various cytology preparations generated in the MPU as well.

Patient- and Family-Centered Care Initiatives

As part of DQHI's support from an "execution" standpoint for several initiatives first begun in the "Michigan Innovative, Personalized, Patient-centered Pathology" (MiP3) initiative in Anatomic Pathology, Brian Tolle is leading, in collaboration with Pathology medical and operational leadership and the staff of the Neonatal Intensive Care Unit (NICU), a project to identify opportunities for pediatric pathologists to serve with the NICU clinical staff as a resource to provide value-added autopsy information to both providers and families experiencing the loss of a child in the NICU. Initial response to this program has been very positive.

In another MiP3-related project, Brian also works in collaboration with personnel from the Wayne County Medical Examiner's Office (WCMEO) and UM's School of Social Work to provide social work services to families experiencing emotional trauma from the loss of loved ones who undergo forensic examination at WCMEO. Prior to this pilot, WCMEO staff and faculty needed to address the emotional needs of visitors without having been provided the necessary skill set for such encounters. This important, but ancillary, activity would also interrupt the WCMEO staff's primary work responsibilities. Preliminary assessment of this pilot has indicated that interaction with a social worker has a positive impact on ensuring that WCMEO staff members provide the appropriate service in which they are competent, while providing a value-added service to Wayne County residents and others who interact with WCMEO under difficult circumstances.

Compliance, Accreditation, and Regulatory Activities

In his role as Compliance Manager, Kellen Kangas, with the support of several other DQHI staff, has undertaken a number of important projects.

College of American Pathologists Accreditation

- Kellen facilitated, in collaboration with the CLIA Laboratory Director Dr. David Keren, a peer-institution CAP inspection of the University of Florida Health System Department of Pathology in November 2015. The team for this inspection consisted of 21 members from the Department who inspected nine pathology laboratories over two days.

- Kellen also guided a project in collaboration with the Department's laboratory leadership and management to conduct an interim mock inspection of the Department's labs in April 2016 to comply with the CAP self-inspection requirement. While previous self-inspections have been less rigorous, the decision was made in DQHI to make this interim inspection more of a "dress rehearsal" for a true biennial CAP inspection, as part of an effort to maintain daily inspection-readiness. Thus, this self-inspection involved staff, residents, and fellows to raise awareness, develop quality competency, and lessen anxiety surrounding future CAP inspections. The majority of responses to a follow-up survey given to lab personnel were very positive and all feedback will be taken into account during planning for upcoming spring 2017 CAP inspection.

New York State Licensure

- Kellen served as a facilitator in collaboration with Michigan Center for Translational Pathology to achieve New York State licensure for Laboratory Developed testing. Approval was granted by New York State in December 2015.
- Kellen is serving as a facilitator in collaboration with the Molecular Diagnostics laboratory to submit licensure application for *JAK2* testing.

Document Control System

Kellen managed a project in November 2015 in collaboration with lab management staff and Pathology Informatics personnel to implement an upgrade to the Departmental document control system (MasterControl) to ensure that a UMHS enterprise upgrade to a new internet browser did not disrupt use of the critical MasterControl system.

Additional Technological Advances

Jeff Lott served as project manager for the installation of the TempTrak temperature monitoring system (hardware and software) in the majority of laboratories throughout Pathology. Prior to this work, the Department was cited during its 2015 CAP inspection for failing to monitor ambient temperature and humidity in some of our clinical lab spaces. This prompted an investigation into how we monitor both our labs' ambient temperature and humidity and the temperatures in our clinical refrigerators, freezers, and incubators used to house and process patient samples. After Jeff's work, sensors are now installed in every clinical lab space, refrigerator, freezer, and incubator, and lab managers and designated "super users" have been educated on how to use the system, as well as how to integrate with Hospital Facilities and Systems Monitoring to provide afterhours alarm coverage for non-24 hour-staffed labs. As Jeff's management work on this project comes to a close, DQHI is in the process of transferring the day-to-day management of the system to a laboratory operations staff member.

Support of Departmental Operational Quality

Departmental Quality Framework

With work by Suzanne Butch, John Perrin, and others, the Clinical Laboratory Standards Institute's Quality System Essentials (QSE) was adopted as the quality model for the entire Department of Pathology. Before adoption of this framework, the approach to quality activities in the Department varied among the laboratories and between Anatomic and Clinical Pathology, with fragmentation and organizational challenges. The adoption of this framework allows for regularly scheduled audits of laboratories, focusing on a specific essential aspect or process during each round of audits. The area of focus is communicated to laboratory managers ahead of the formal audit to allow them to self-audit and make changes prior to the process. These "essentials" also allow for laboratory leaders and managers to have clear expectations of what a comprehensive quality management program requires. Through the QSE process, several opportunities for process improvement have already been identified. One example of such an improvement is the identification of review notifications through our document control system (MasterControl) that were "orphaned", leading to missed reviews of critical Departmental documentation. As a result of this identification, the appropriate laboratory managers could re-assign these tasks to ensure compliance with document control requirements.

Deviation Management

Related to the work described above, Suzanne Butch also served as facilitator in collaboration with laboratory personnel to enhance the Department's ability to meet the expectations of the "Deviation Management" Quality Service Essential by working with laboratory managers to ensure that patient safety events are entered into the UMHS event management system (RMPro). Additional analysis and trending of event occurrences logged in RMPro is planned for the coming year to identify potential opportunities for quality improvement.

CP Quality Dashboard

Suzanne further served as a facilitator in collaboration with the clinical pathology laboratories to develop additional critical indicators of performance, with a preparation of appropriate graphs to display the relevant data. This process has enhanced the information provided in the quality dashboard and has made quality assurance activities more visible to hospital administrators and laboratory staff.

Investigational and Scholarly Activity

Collaboration with Other Members of UMHS Community
Brian Tolle is heading a collaboration with Pathology laboratory leadership and residency program leadership in the Department of Internal Medicine to identify opportunities to define value-added testing and its requisite clinical and operational workflow changes. This work is in its early phases, but a project carried out by Internal Medicine residents with collaboration and support from DQHI recently resulted in identification of ways in which the ordering of "time-critical" laboratory studies affects the efficiency of the Phlebotomy team and, ultimately, timely patient care. As an initial foray into test utilization activities, several recommendations were made for ways to increase and ensure the efficient and rational use of this ordering method.

Predictive Modeling for Test Utilization
Brian is also coordinating collaboration with a Computer Science and Engineering professor (Jenna Wiens, PhD) and student (Eli Sherman), Pathology Informatics, and the Department of Cardiology (Hitinder Gurm, MD) to develop a predictive model using machine learning and "big data" techniques to understand when laboratory testing adds value to managing electrolyte levels of cardiac intensive care unit patients. This work should provide publishable results, while helping to optimize care for critically ill patients and to provide a framework for the use of machine learning in other test utilization work to which DQHI aspires. This project and its content also dovetail with work currently being undertaken by Dr. Ul Balis with partners throughout the health system as part of the new Computational Pathology laboratory.

Summary

DQHI has had a fruitful FY2015-2016, resulting in a focused approach to tackle several important initiatives that should have far-reaching effects on the patient experience throughout UMHS, and provide examples of Pathology's contribution to patient care in the coming value-based era of health care.

VA ANN ARBOR HEALTHCARE SYSTEM

Stephen W. Chensue, MD, PhD

Professor of Pathology
Chief, Pathology and Laboratory Medicine Service
VA Ann Arbor Healthcare System

The VA Ann Arbor VA Healthcare System (VAAAHS) is a University of Michigan affilated tertiary health care provider for veterans. In FY2016 the VAAAHS was consolidated into a new Veterans Integrated Service Network (VISN) #10 serving the veteran population of Michigan, Ohio and Indiana. It is one of five VHA tertiary care centers in this region. The VAAAHS Pathology and Laboratory Medicine Service (PALMS) maintains a close relationship with the University Department of Pathology at every level. There are currently five full-time, one part-time plus a fee basis consulting dermatopathologist on faculty. All pathologists in the VAAAHS have medical school appointments and participate in university activities in a manner similar to other departmental sections. Recruitment for VAAAHS 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 VAAAHS laboratory retains full accreditation by the College of American Pathologists. Likewise, its satellite laboratory at the Toledo Oupatient Clinic is currently fully CAP accredited. The VAAAHS 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).

Service	Volume	Target	% meeting	Average TAT	QC diagnostic concordance rate
Surgical Pathology	14,185	Diagnostic report < 2 days	98.2	1.4 days	98.9
Frozen section	613	Diagnistic Report < 20 min	100	8.6 min	99.0
Autopsy	13	Report complete < 30 days	100	8.7 days	N/A
Gyn & Non-gyn cytology	4,887	Diagnostic report non-gyn < 2 days gyn ≤ 10 days	99.2	4.3 days	99.4

In addition to serving its local hospital and clinics, the VAAAHS 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.

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 comprehesive quality assurance review with analyses of frozen section accuracy, amended diagnoses, surgical appropriateness, turnaround times, report quality, random restropective review, and follow-up of positive cancer diagnoses. In addition, the VAAAHS 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 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.

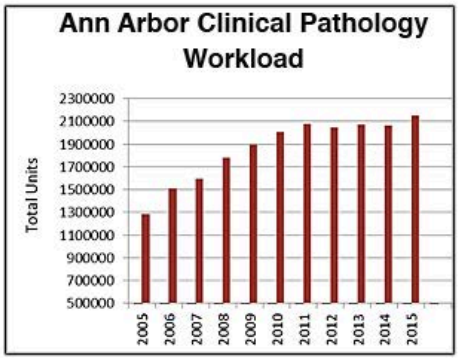
Both non-gynecologic and gynecologic diagnostic cytology is provided. Due to the increasing population of women veterans, gynecologic pathology is becoming an important compontent of the VAAAHS workload. The VAAAHS performs all PAP screening cytologies for the northern tier of VISN 10. The Ann Arbor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

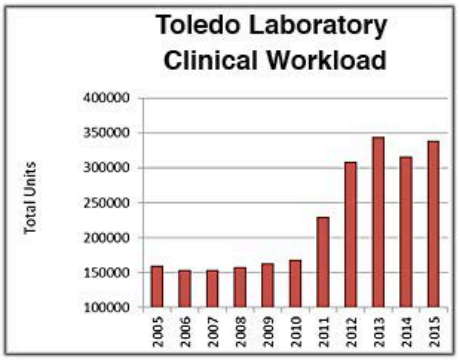
Clinical Pathology Workload	
Chemistry	1,891,752
Hematology/Coagulation/Urinalysis	511,226
Microbiology	115,666
Blood Bank	53,523
Phelbotomy	126,269
Point of Care	105,392
Toledo Outpatient Clinic Laboratory	311,367
Total	3,115,195

During the period of this report 3,115,195 clinical pathology tests were performed in the Ann Arbor and Toledo laboratories. 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.

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 webased VistAWeb 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 VAAAHS laboratories have continued to incorporate as much automation as possible employing state-of-the-art technologies to improve efficiency and informatics management.

Ten 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. All residents serve monthly 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 VAAAHS is physically close to the University, the residents are expected to attend the appropriate teaching conferences at the University. VAAAHS 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 VAAAHS 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 VAAAHS, the pathology staff members serve on all major committees involved with institutional policies and procedures.

In summary, the VAAAHS 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 VAAAHS 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

OVERVIEW

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, University of Michigan Health System (Medical School and Hospitals), and the University. In addition to directing this Division, Mr. Lawlor served on various departmental, Health System and University committees, including the Financial Advisory Committee, and is co-Chair of the Cancer Center Ambulatory Care Coordinating Group. Mr. Lawlor served as a Team Executive for the VMI IT and a team member of the VMI Research Services Team. 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:

- Worked with the Wayne County Faculty and Staff to transition county employees to the UMHS Department of Pathology.
- Our team successfully completed the departmental audit and WCMEO audit.
- Served on the search committee for the Radiology Clinical Department Administrator as well as the search committee for the Executive Vice Dean for Academic Affairs.
- Served on the committee for the Dean's Staff Awards.
- Presented financial management talks to the new residents and presented at the Pathology Education series.
- Established a weekly Open Position Review process to review all replacement and new positions.
- Oversaw a decrease in blood costs, with an overall reduction of 12% from FY2015-2016 and a 30% reduction in annual costs over five years.
- Continued planning space solutions for NCRC Buildings 30, 35, 36 and 60, incorporating LEAN facility design principles.
- Received Regental approval for Dr. David Lucas to be appointed as the A. James French Professor of Anatomic Pathology.
- Received Regental approval for Dr. Thomas Giordano to be appointed as the Henry Clay Bryant Professor of Pathology.
- Successfully supported faculty and staff in the implementation of the Department's Point of Care testing menu at off-site clinics.

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 FY16 revenue for component billing was $796,318. UMHS 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 $116.6 Million. Pathology is responsible for 10.0% of total Hospital Gross Revenue and 4.1% 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.

Mr. Thomas Morrow oversaw the Clinical Pathology Laboratories. 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. 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 focused sessions. She has also assisted in the planning for the Pathology Relocation and Renovation project. Kristina is responsible for the Clinical Pathology Operations meetings and coordination of subsequent projects resultant from these discussions. Kristina also serves as the department liaison with nursing.

Ms. Christine Rigney, Anatomic Pathology Operations Administrator, oversees the Anatomic Pathology Laboratories. Services are provided in 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 many 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 building project which is breaking ground this September 2016.

Ms. Rigney continues to participate and represent Anatomic Pathology with patient safety issues, Lean projects or process improvement initiatives with partners such as the Cancer Center, Operating Rooms, and medical procedure units, Office of Clinical Safety, Biomedical Engineering and Hospital Finance. She represents Pathology on the Quality Month Committee and is a representative on Pathology's Diversity, Equity and Inclusion Committee.

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 UMHS 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 UMHS. 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 January 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. This role was integrated into the Quality Division this year.

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 UMHS and All Funds expenditures and forecast processes. Total Medical School All Funds expenditures for FY 2016 (Pathology and MCTP) were $69,362,290 and Hospital expenditures were $116.6 Million. He also developed the 2017 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 184 research proposals submitted to external sponsors this year. 67 of these proposals were submitted to the NIH. Committed awards for FY 2016 were $32,209,926. A decrease of 7.1% compared to FY 2015 committed awards. This is the result of declines in committed awards for the MCTP in FY 2016. Actual sponsored research expenditures were $31,568,098. A 1.6% decrease when compared to FY 2015 actual research expenditures. Overall, the academic side of the Department saw a 3.2% increase ($1,694,414) 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 2015 to FY 2016. Overall gross charges for Pathology's group practice were up 10.8% ($6.82M). 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 FY2016 was $697.0M, compared to $640.27M in FY2015, an increase of 8.9%. Professional fee gross charges were $70.0M. 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 FY2016 amounted to $31,568,098. Mr. Harris manages a staff of two accountants and two procurement specialists. 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. Along with other members of Mr. Harris' staff, Mr. Thad Schork has begun to transition from pre award to pre- and post-award management for our research program for the Department of Pathology. In addition, Mr. Schork also serves 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 2017.

Mr. McVicker is responsible for Medical School financial reporting as well as 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 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, 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 690 FTEs) and Medical School support staff, including our research programs (approximately 240 FTEs).

Faculty Affairs is the responsibility of Ms. Sarah Dudley-Short, who coordinates appointments, reappointments and promotions for our 160 active faculty. She also has responsibility 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 23 fellows in 8 ACGME and 6 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 25 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 two NIH training grants (PIs Steven Kunkel, Ph.D. and Nicholas Lukacs, Ph.D.) which support 4 pre- and 8 post-doctoral trainees. Ms. Labut performs the human resource functions for the department's graduate students (35 including 10 non-MCP students with Pathology mentors) and training grant trainees (6).

Office of the Chair

Ms. Angela Suliman 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 been the facilitator for the Cancer Center Ambulatory Care Coordinating Group and has also served as the conference coordinator for the Advances in Forensic Medicine & Pathology Conference, which was held for its sixth year.

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.