

AMERICAN ACADEMY OF CRANIOMAXILLOFACIAL SURGEONS

Keynote Speaker





Transforming the practice of oncology

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The practice of oncology is undergoing a transformation! This change is fueled by the clinical success of novel immunotherapies in tumors other than melanoma and the recognition that a strong T cell infiltrate (Immunoscore+) is a good prognostic factor independent of tumor stage. While the strongest data supporting these claims is in a small number of cancers, there are data for an immune infiltrate being a good prognostic factor in 18 cancer histologies and that number is likely to expand as technologies to objectively assess immunity improve. Present efforts are applying advanced digital imaging and objective assessment tools to augment current abilities to quantitate the immune-tumor interplay. But this is just the start. Alternative lines of investigation are continuing to probe the tumor microenvironment with improved technologies and are examining factors, other than the checkpoint inhibitors, that may prevent or suppress immune activation and the accompanying regression of metastatic deposits. Knowledge of these inhibitors will provide opportunities to tailor combination therapy, to include agents that counteract identified inhibitors in specific patients, and ultimately improve the efficacy of treatment and patient outcome.

In 2014, it is imperative that the field address the following questions:

- 1) What drives different anti-cancer immune responses in patients that appear otherwise similar for disease stage, age, gender?
- 2) What is the pattern or patterns of immune inhibitors expressed in tumors that are the “Bad actors”?
- 3) How can we effectively induce immunity in patients that appear to lack it?

In my opinion it is possible to answer these questions. Given the remarkable success of checkpoint blockade and adoptive immunotherapy with chimeric antigen receptor (CAR) modified T cells, fewer people doubt the potential curative power of an anti-cancer immune response. What we need now are large scale collaborations to address these questions and then the access to appropriate agents so that we can implement tailored/personalized combination therapies in multicenter clinical trials.

OncologyMeetsImmunology: The Cancer-Immunity Cycle
Daniel S. Chen and Ira Mellman, *Immunity* 39, July 25, 2013

Cancer Immunoediting: Integrating Immunity's Roles in Cancer Suppression and Promotion. Robert D. Schreiber et al. *Science* 331, 1565 (2011)

The additional facet of immunoscore: immunoprofiling as a possible predictive tool for cancer treatment. Ascierto, PA, et al. *J Transl Med*, 2013 Mar 11(1):54.

Towards the introduction of the Immunoscore in the classification of malignant tumors. Galon J et al. *J Pathol*. 2014 Jan;232(2):199-209.



Development of an ACSCOT Verified Level One Trauma Center in a Private Community Hospital

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Background Information

Most ACSCOT verified Level 1 Trauma Centers are located at University Medical Centers or at county hospitals, staffed by university faculty. The ACSCOT requirements for Level 1 Trauma Centers focus on the education and training of surgical residents in trauma and surgical critical care and trauma related research, the commitment of which separate Level 1 Trauma Centers from Level 2 Trauma Centers.

Many community hospitals with a large volume of elective and emergency surgical cases can attract the attention of residency program directors at academic medical centers, seeking to find case volumes for their residents to be able to meet the standards for resident experience, as defined by the Residency Review Commission. For an approved trauma experience, the general surgical resident must not only acquire surgical experience in trauma, but also learn how to lead a trauma team in the resuscitation areas in the Emergency Department, but also in the Operating Room, the ICU Trauma Team, the care of the trauma patient on the acute care floor, and in the trauma clinic following patient discharge from the trauma center. The trauma leadership training requires a PCY 4 or 5 or higher general surgical resident to be continuously staffing a Level 1 Trauma Service. Most community hospitals cannot meet the commitment to training PGY 4 or 5 surgical residents, or the university won't assign the PGY 4 or 5 surgical residents to a community hospital competing for trauma patients with a university trauma center.

The trauma-related research requirement for Level 1 Trauma Centers places an additional burden on community hospitals, with no laboratory space and staff for basic science research, nor a clinical research program staffed with trained clinical research nurses to gather the data, and a database to store the data. Most community hospitals have few senior administrative executives with a research background to understand the logistics and costs of supporting a clinical research program provided by physicians interested in and capable of doing clinical research, but not having the financial backing outside of incomes from patient care revenues to support the time to do clinical research.

The following is a story of how a private community hospital located in a poor urban neighborhood rose to the level of a tertiary medical center and the first trauma center in the Pacific Northwest to be verified by the ACSCOT:

Emanuel Hospital was founded about 100 years ago by the Lutheran Church and eventually located in North Portland, Oregon. Surrounded by a poor neighborhood, the hospital struggled to take care of the poor and to remain financially solvent.

Fellows and residents completing training at academic medical centers and county hospitals looked for opportunities to make a living and practice their specialty. Diseases of the poor involve social problems leading to need for high-risk obstetrical care, pediatric emergency and critical care, pediatric subspecialty care, trauma and burn care, and surgical subspecialties. Many of these young specialists migrated to Emanuel Hospital in North Portland. Because the care of the critically is so demanding, many of these young specialists realized the need for skilled help and sought and obtained support from the Graduate Medical Education Committees and Residency Review Commission to establish hospital-based residencies in obstetrics, perinatology, neonatology, pediatric critical care, internal medicine, general surgery, including burn and trauma rotations. Some of these residency training programs were the first offered in Oregon.

The Emanuel neighborhood provided a lot of trauma patients, mostly penetrating trauma from acts of violence, and usually unfunded from a lack of insurance. Compared to suburban hospitals in more affluent neighborhoods, Emanuel had a hard time retaining teaching faculty and staff for the resident training programs.

Oregon EMS laws in 1977 required land ambulances to take accident patients to the nearest hospital, no matter what the hospital's capability.

In 1977 some general surgeons in private practice at Emanuel Hospital proposed to the Emanuel Hospital administrator that the hospital acquire an EMS helicopter to be a community resource for rapid response to an accident scene (suburban and

rural) and bring these patients to Emanuel where urgent surgery to stop bleeding could occur almost immediately. The general surgeons promised to be in the hospital 24 hours a day to provide emergency and trauma surgery. Administration leased an EMS helicopter from a local vendor and thus started the 4th hospital-based EMS helicopter service in the USA. The Emanuel Trauma service began when the general surgeons committed themselves to be available in the hospital at all times. No other hospital in the Pacific Northwest provided that level of service at that time.

The volume of trauma patients grew over time. The Emanuel general surgeons realized that the trauma program needed a leader with credentials in trauma and surgical critical care, if the program was to grow and gain regional recognition and acceptance. The general surgeons recruited Dr. Long from UCSD to become the first Trauma Medical Director at Emanuel Hospital.

Dr. Long empowered the ICU nurses by creating a nursing educational program leading to a trauma nursing career ladder. He developed high impact programs with trauma nurses playing key roles:

- Massive Transfusion Protocol (MTP) with nurses provided active blood component therapy by a set protocol or guidelines.
- Direct to OR for unstable surgical patients for immediate surgery. For this service, he needed anesthesiologists in-house 24/7 to provide the immediate anesthesia needed for these patients.
- Hypothermia treatment protocol for severe accidental hypothermia patients, use of CPB.
- ECMO for advanced shock patients who might also be in severe pulmonary failure.
- Mobile surgical transport team (MSTT), a surgical team that would fly to rural hospitals and operate there on trauma patients too sick to transfer to Emanuel Hospital.
- Designed a special trauma center where all the critical needs of severe trauma patients are met.
- Provided an education program for doctors and nurses at rural hospitals, unaware of the new resources available to them.

The growing trauma patient volume produced conflicts within Emanuel Hospital over access to resources, and surgical expertise and skills:

- Should arriving trauma patient “bump” elective surgery patients from scheduled OR times?
- Increasing complexity of trauma patients demands increasing specialty skills in trauma care.
Should the hospital or private practice groups recruit these trauma trained specialists?
Solution: Specialty groups were encouraged to hire trauma trained specialists in each subspecialty.
- Need for trauma leadership in each specialty for call coverage, CQI, CME and research to focus on and meet the standards of the ACSCOT for level one trauma centers.
- The special programs with head and neck subspecialties to cover a level one trauma program:
Office based, high volume surgeons: Oral Surgery, ENT, Plastic Surgery
Too many call schedules for too few head and neck trauma patients
Fighting over facial territory among the specialists vs. total disinterest by most
Super-educated and trained head and neck specialists: Do they exist?
Are there enough to contract with several of them to do the whole face and neck call coverage for the trauma program and the Emergency Department?
The use of RFP process to grant an exclusive contract to make head and neck call coverage worthwhile financially for one particular group to commit to the call and to the ACSCOT requirements of level one trauma care.

Getting the ACSCOT to verify Emanuel Hospital as a level one trauma center:

Development of Trauma Research in a private community hospital

- Need for a formal research center with a leader in charge (Lutz Kiesow, MD, PhD)
- Conversion of an old HCA 150-bed hospital into a research center
- Creation of basic science labs for certain interested specialties wanting to do research
- Hiring of clinical research nurses to help gather the data

Coordinating the efforts of all specialty groups provided trauma care: Creation of Trauma Specialists, LLP

- A business entity comprised of five specialty groups committed to level one trauma care:
 - OAG (anesthesiology group based at Emanuel Hospital)
 - Head and Neck Surgical Associates
 - Pacific Surgical, PC (trauma, surgical critical care, general and thoracic surgeons)
 - Summit Orthopedics
 - Radiology Consultants
- Independent contractors include Neurosurgeons, The Urology Clinic
- Creation of one tax ID number for trauma billing
- Contract with Emanuel Hospital to guarantee ACSCOT level one professional services
- Contracts with medical insurers for “pay for performance”

Development of three specialty models for academic research, meeting standards of the ACSCOT for level one:

- Neurosurgery: Jeff Chen, MD, PhD, sole researcher, working with Trauma ICU nurses
- Orthopedic Surgery: Steve Madey, MD and Michael Bottland, PhD
 - Legacy Biomechanics Research Laboratory for basic science
 - Research productivity: Seven patents
 - Doug Beaman, MD and Richad Gellman, MD: Foot & Ankle Specialists
 - Research productivity: List
- Head & Neck Associates: Clinical patient volume: Trauma, Cancer, Emergency, Cosmesis
 - Development of mentorship program for residents and fellows
 - Research productivity: List
 - Placement of fellows in academic leadership positions

Conflicts with hospital administration and medical staff in developing and maintaining an ACSCOT Verified Level 1 Trauma Center:

- Intellectual property: whom does it belong to? Hospital/physician/inventor/author
- Trauma patients brought to LEMC: who owns them? Hospital or responsible physician?
- Encouraging referrals to program: Hospital or physician providers?
- Revenues generated from Trauma program: validity of data, use of trauma revenues to enhance trauma service?
- Trauma Fundraising: who decides what happens to the money raised? Can physician groups earmark their donations?
- Pay for performance for physicians: Whose database do we use?
 - CMS?
 - Insurance Companies
 - Hospital Databases
 - Professional Society Databases
 - Individual Physician Databases

Summary:

Legacy Emanuel Trauma Program is unique, according to data from TCAA.

External validation of success “trumps” internal recognition, most times.

- TQUIP data from NTDB
- Research papers in peer reviewed journals
- Site Surveys by professional societies and organizations
- Fundraising for trauma program
- Support from Residency program directors and professional societies.