

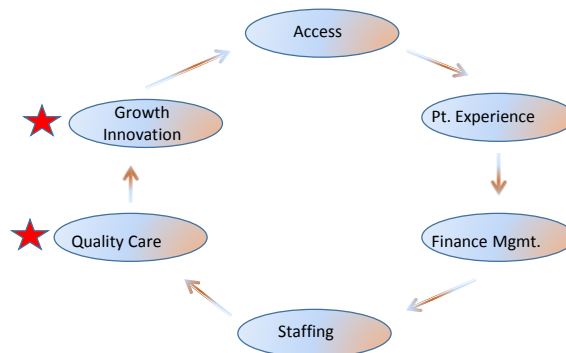
Demonstrating the Value of the Allergist in Academics and Private Practice

Aidan Long, MD
Nick Hernandez, MBA, FACHE

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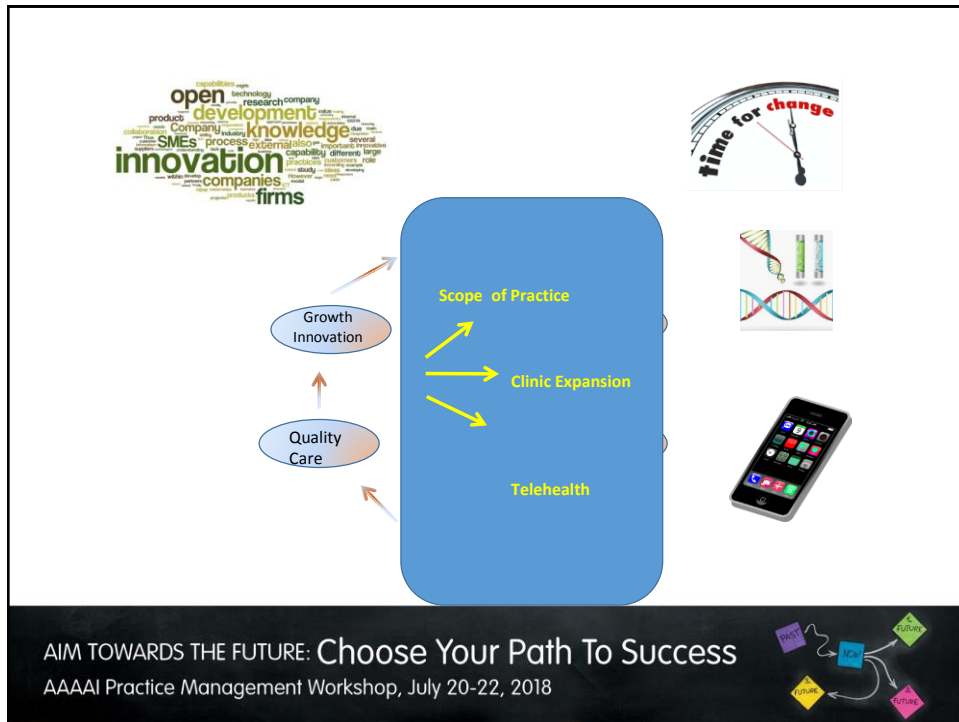


Important Domains of Clinical Practice Management



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Some Potential Domains of Practice Expansion

Adverse reactions to medications

Adverse reactions to other chemicals

Adverse reactions to foods

Other immune dysfunction including immunodeficiency

BRINGING ADDED VALUE TO YOUR CONSTITUENCY

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Domains of Practice Expansion

Adverse reactions to medications

Antibiotic stewardship and safer antibiotic prescribing
 Cancer chemotherapy adverse reactions (allergic and other immune-related)
 ASA use in preventive cardiology and neurovascular disease
 Anesthesia related and other intra-op. adverse drug reactions
 Other



Development of a comprehensive Drug Allergy program

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Antibiotic Stewardship and Safer Antibiotic Prescribing

By providing comprehensive programs of evaluation for suspected penicillin allergy, Allergy and Immunology specialists are uniquely positioned to significantly “move the needle” with respect to appropriate antibiotic selection. Estimated to be the biggest single factor in progress with antibiotic stewardship.

Separately, but no less important such a program has significant impacts on patient safety and quality assurance.

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Comprehensive Penicillin Allergy Evaluation Program

- Guideline development for prescribing or seeking consultation for general physicians
- Standardized approach to triage and testing
- Creation of urgent availability and standing slots on the weekly schedules
- Comprehensive engagement of our patients
- Systematic roll-out to other services
 - Surgical
 - Orthopedic
 - Gynecology
 - Medicine
- Roll-out across the health care system
- Population Health Management initiative
- Public Health Initiative
 - The FDA ... stated that appropriate screening of people with vague histories of penicillin allergy "would also provide a public health benefit by facilitating good antimicrobial stewardship."

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Antibiotic Resistance Solutions Initiative

Improve Antibiotic Prescribing Practices



Summary of Core Elements of Hospital Antibiotic Stewardship Programs

- **Leadership Commitment:** Dedicating necessary human, financial and information technology resources.
- **Accountability:** Appointing a single leader responsible for program outcomes. Experience with successful programs show that a physician leader is effective.
- **Drug Expertise:** Appointing a single pharmacist leader responsible for working to improve antibiotic use.
- **Action:** Implementing at least one recommended action, such as systemic evaluation of ongoing treatment need after a set period of initial treatment (i.e. "antibiotic time out" after 48 hours).
- **Tracking:** Monitoring antibiotic prescribing and resistance patterns.
- **Reporting:** Regular reporting information on antibiotic use and resistance to doctors, nurses and relevant staff.
- **Education:** Educating clinicians about resistance and optimal prescribing.

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Guideline for Prescribing Antibiotics to Inpatients with Penicillin Allergy

Penicillin Hypersensitivity Pathway

Type I (IgE-mediated) HSR	Type I (IgE-mediated) HSR	Mild reaction
<p>Type I (IgE-mediated) HSR</p> <p>Serum sickness</p> <p>Stevens-Johnson Syndrome</p> <p>Toxic Epidermal Necrolysis</p> <p>Acute Interstitial Nephritis (AIN)</p> <p>Drug Rash Eosinophilia</p> <p>Systemic Symptoms (DRESS) Syndrome</p> <p>Hemolytic anemia</p> <p>Drug Fever</p>	<p>Type I (IgE-mediated) HSR</p> <p>Anaphylaxis</p> <p>Angioedema</p> <p>Wheezing</p> <p>Laryngeal edema</p> <p>Hypotension</p> <p>Hives/urticaria</p> <p>OR</p> <p>Unknown reaction WITHOUT mucosal involvement, skin desquamation or organ involvement</p>	<p>Mild reaction</p> <p>Minor rash</p> <p>(not itchy)</p> <p>Maculopapular rash (mild Type IV HSR)</p> <p>Record test allergy, but patient denies</p>

OR to:

Use 3rd/4th gen cephalosporins or carbapenems*
Test Dose Procedure

OR

Use alternative agent by microbial coverage†

OR

Autism†

OR

Use carbapenem*

OR to:

Use penicils or 1st/2nd generation cephalosporins by Test Dose Procedure

OR

Use penicils or 1st/2nd generation cephalosporins by Test Dose Procedure

OR

Use carbapenem*

† ALTERNATIVE AGENTS BY MICROBIAL COVERAGE (see Table 1 for additional details):

Gram positive coverage: Vancomycin, linezolid*, daptomycin*, doxycycline, TMP/SMX

Gram negative coverage: Ciprofloxacin, sulfamethoxazole/trimethoprim, aminoglycosides, carbapenems*, aztreonam*

Cephalosporins by generation:

1st: cephalexin, cephazolin

2nd: cefuroxime, cefotaxime

3rd: ceftazidime, ceftiofur, cefepime, ceftazidime/avibactam

4th: ceftaroline

5th: ceftaroline

HSR: Hypersensitivity Reaction
*Optimal regimen

Guideline for Prescribing Antibiotics to Inpatients with Penicillin Allergy

Why use it? The purpose of this [guideline](#) is to provide allergy history-taking support and antibiotic prescribing recommendations for patients reporting penicillin allergy.

How do I access the guideline?

- Via your smartphone or tablet:**
 - Connect to Partners wifi (phs wifi3). You will not be able to access the app via unsecured wifi (phs wifi1).
 - Access the app at <http://id.partners.org/allergy>. You'll be prompted for your Partners username and password.
- Via a Partners PC:** just go to <http://id.partners.org/allergy/>

What's the evidence base? This decision support tool and guideline, based on a pathway that has been in use with success hospital-wide at MGH since 2013^{2,4} is supported by drug allergy literature and the practice parameters created by the American Academy of Allergy, Asthma and Immunology.⁵

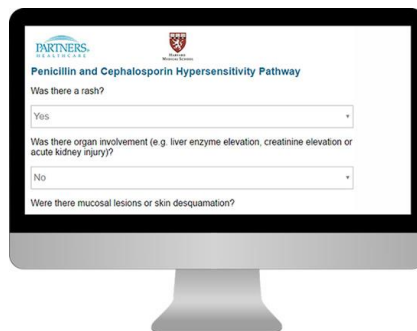
What if I still have questions?

Please involve Infectious Disease and refer to these informational videos:

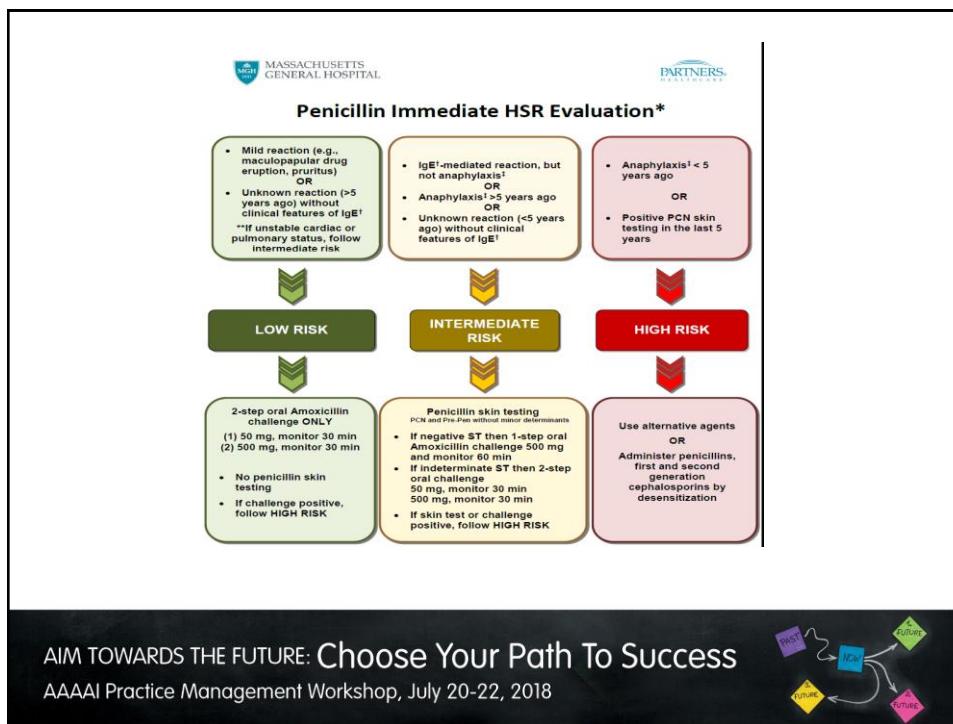
- Introduction to pathway and app: <http://www.videoscp.com/kimberthal/videoscript1-partners-penicillin-and-cephalosporin-hypersensitivity-pathway-orientation/>
- Pathway patient cases: <http://www.videoscp.com/kimberthal/videoscript2-partners-penicillin-and-cephalosporin-hypersensitivity-pathway-case-review/>
- General education about beta-lactam antibiotic allergy and procedures: <http://www.videoscp.com/kimberthal/videoscript3-video-orientation-to-penicillin-and-cephalosporin-allergy/>

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Computerized Guideline/ App



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Standardized Skin Testing and Oral Challenge Procedures

MASSACHUSETTS GENERAL HOSPITAL
MGH ALLERGY ASSOCIATES

Patient name _____
MGH # _____
DOB _____

Beta-Lactam (Penicillin) SKIN TEST Date: ____/____/____

Discussions _____

- Place test on arm.
- For intracutaneous testing, inject 0.1ml of testing drug at each site.
- Monitor for sites 15 minutes after placement.
- Record largest diameter wheel 15 min or test site in millimeters.
- Test a positive if test site results in wheel and flare within 15 minutes of placement. Stop testing reactive drug immediately.
- Continue testing the drug until reactive or test completed.

Drug	Preick	10:0.02 ml	10:0.2 ml
1. Penicillin G	10,000 units/ml	1000 units/ml	10,000 units/ml
2. Pen-Proc	Undiluted	Undiluted	
3. Penicillate	Undiluted	Undiluted	
4. Penicillate	Undiluted	Undiluted	
5. Other Beta-Lactam Name of agent _____	1:10	1:1000	1:100
6. Bistamine prick (drug not)	Saline prick	Bistamine ID (8.1 mg/ml)	Saline ID

Comments _____

Tester: _____ Physician: _____

MASSACHUSETTS GENERAL HOSPITAL
MGH ALLERGY ASSOCIATES

Patient name _____ Date: ____/____/____

MGH # _____

DOB _____

Oral Challenge for Amoxicillin

General Directions:

- Review BP, pulse, respirations and O2 sat prior to start.
- Check skin for wheals or hives. Record any findings.
- Report oral signs with O2 sat prior to every dose. Record any symptoms of allergic reaction.
- Perform oral challenge ordered by physician. Stop test immediately if symptoms of allergic reaction observed.
- If no reaction, continue oral challenge until completion.

Physician direction for Oral challenge: Check all that apply:

☐ Administer Amoxicillin 500 mg by mouth.
Observe ☐ 30 minutes ☐ 60 minutes for symptoms of allergic reaction.

☐ Administer Amoxicillin 500 mg by mouth.
Observe ☐ 30 minutes ☐ 60 minutes for symptoms of allergic reaction.

Physician signature: _____


Start time: _____ Finish time: _____

Time	BP/Pulse/RR	Symptoms Check	Amoxicillin given


Comments: _____

Tester signature: _____ Physician signature: _____

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MASSACHUSETTS
GENERAL HOSPITAL



HARVARD
MEDICAL SCHOOL

Evaluate Your "Penicillin Allergy" Now

10% of patients report a penicillin allergy

95% of them are not allergic

This negatively impacts antibiotic choice and patient safety

If you are hospitalized and labeled "penicillin allergic," you are at increased risk for **worse** outcomes, including:


- Increased length of hospital stay
- 23% increased risk of developing a severe form of colitis (diarrhea) due to a bug called *Clostridium difficile*, which can be long-lasting and difficult to treat.
- 14% increased risk of developing MRSA and 30% increased risk of developing VRE (drug resistant bacteria)
- Increased risk of adverse events overall and higher treatment failures for some types of blood stream infections.

Penicillin Allergy Testing at MGH Allergy Associates

At penicillin allergy appointments, you will undergo skin testing by an experienced allergy nurse, if appropriate. Penicillin skin testing is a procedure performed in sequential steps with small plastic "torks" followed by intradermal needles and takes about 45 minutes. If skin testing is negative, you will be given a test dose of amoxicillin and observed for 30 to 60 minutes. We anticipate the entire appointment to be approximately 3 hours. If tolerated, the penicillin allergy will be removed from your medical record.

While **all** patients with suspected penicillin allergy should undergo evaluation, patients who would specifically benefit from immediate evaluation include those with:


- Planned surgical or dental procedure
- Recurrent infections or hospitalization
- Upcoming chemotherapy or bone marrow transplantation



Last updated: 11/15/2016

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Partners Penicillin Allergy Pathway


Special Article

Addressing Inpatient Beta-Lactam Allergies: A Multihospital Implementation




Kimberly G. Blumenthal, MD, MSc^{a,b,c,d}, Erica S. Shenoy, MD, PhD^{b,d,e,f}, Anna R. Wolfson, MD^{a,d}, David N. Berkowitz, PharmD^g, Victoria A. Carballo, MPH^h, Diana S. Balekian, MD, MPH^{i,j}, Kathleen A. Margolis, PhD, PharmD^j, Rany Elshaboury, PharmD, BCPS, AQID^g, Ronak G. Gandhi, PharmD, BCPS^g, Paveen Meka, MD, MBA^g, David W. Kuback, PharmD, BCPS, AQID^{g,k}, Jennifer Catella, PharmD, BCPS^g, Barbara S. Lambi, MD, MPH^g, Joyce T. Hsu, MD^g, Monique M. Freese, RPh^g, Alana Gruszecki, PharmD, RPh, BCPS^g, and Paige G. Wickner, MD, MPH^g *Boston, Mass*

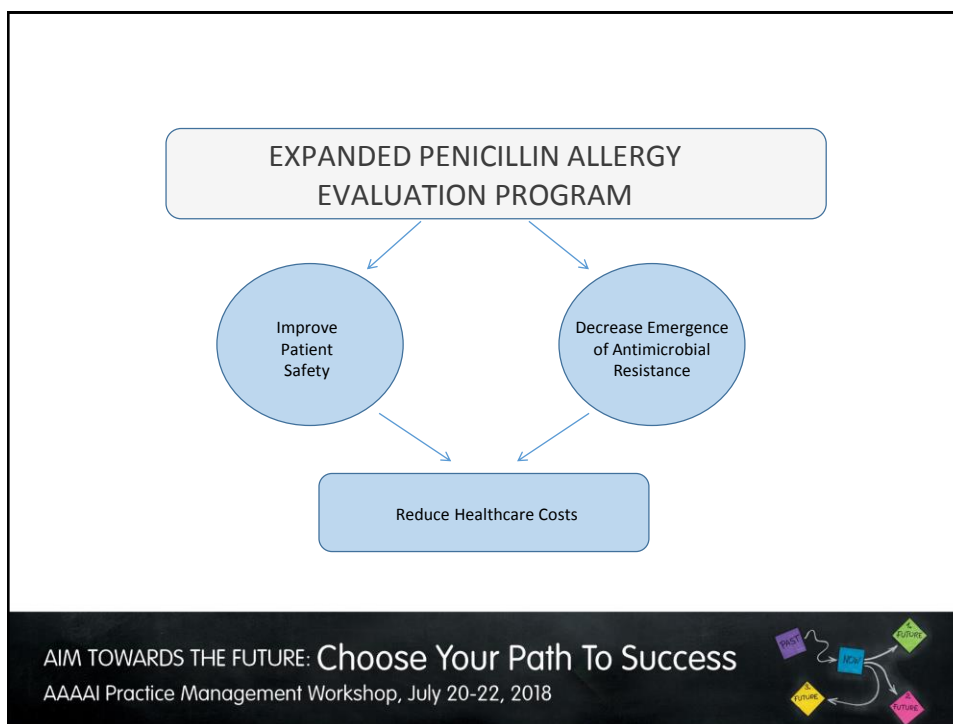
- Additional planned research:
 - Pre/Post impact on antibiotic use
 - Safety analysis
- SMART app: professionally created for open source download by Persistent Healthcare



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The Penicillin Allergy Label

10% of patients report a penicillin allergy

95% of them are not allergic

This negatively impacts antibiotic choice and patient safety.

We have not only the ability to change this but we have a moral obligation to do so!

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Core Measures in a Value Based Health System

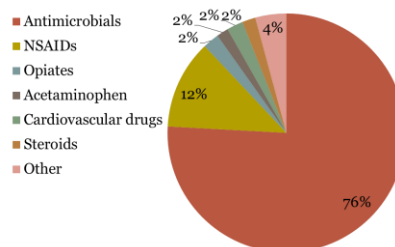
- Quality +
- Utilization +
- Expenditure +
- Medical Error +
- Social
- Economic
- Behavioral

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Drug Classes Prompting Test Doses

- Between 2008 and 2013, 456 patients underwent 497 test dose protocols with 1-2 steps

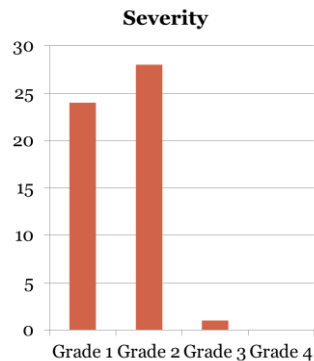


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Adverse reactions during test doses ?

- Only 53/482 test doses (11%) were associated with adverse reactions



	1-2 Step (n=53)	3-4 Step (n=10)
Reaction Rate	11%	12%
Grade		
1	24 (45.3%)	6 (60%)
2	28 (52.8%)	4 (40%)
3	1 (1.9%)	0 (0%)
4	0 (0%)	0 (0%)

With these reassuring data have been able to persuade the institutional powers to permit test doses on the floors without need for ICU monitoring.

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Master List Drug for Allergy Evaluation at MGH Allergy and Immunology

- Database of published protocols
- Determination of non-irritating skin test concentrations
- Protocols for preparation agreed upon with hospital pharmacy
- Most commonly needed agents are stocked within the clinic area
- Others are available from pharmacy with 48 hours advanced notification
- Standardized testing sheets for recording results with each agent
- Test dose protocols for follow up after skin testing (where appropriate)

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Master List Drug Allergy Evaluation at MGH Allergy and Immunology

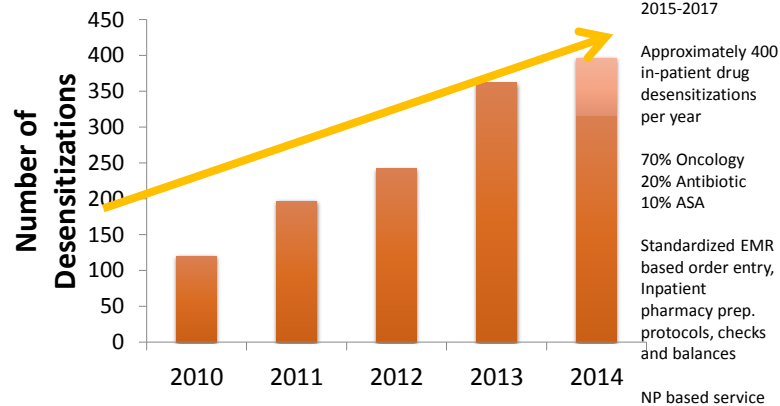
ANTIBIOTICS
ANTIFUNGALS
CHEMOTHERAPY DRUGS
MONOCLONAL ANTIBODIES
GENERAL ANAESTHETIC AGENTS
LOCAL ANAESTHETIC

DIURETICS
H2 BLOCKERS
PPIs
HEPARINS
STEROIDS
INSULINS

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Clinical Care: Volume of Drug Desensitizations



DRUG ALLERGY PROGRAM
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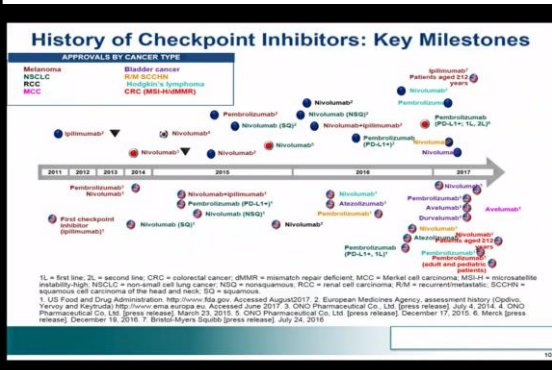
Immune Related Adverse Events to Checkpoint Inhibitors

There is a storm brewing all around us right now ...and it's a rich opportunity for expansion and learning!

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FDA Approval of Checkpoint Antibodies



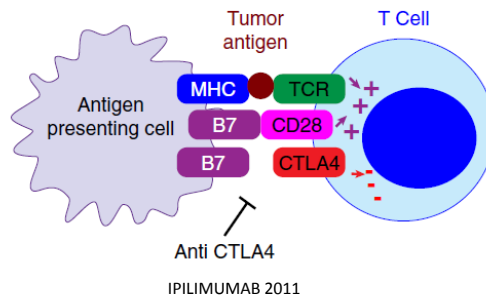
- October 2017
- YTD – 11 FDA approvals
- 6 “approved” drugs
- 20 PD1 or PDL1 antibodies under study
- >1300 ongoing clinical trials
- > 200, 000 patient slots

TSUNAMI

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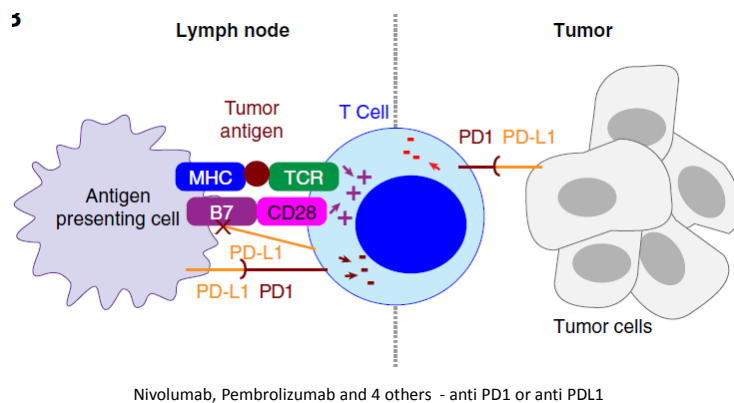
Mechanism of Action of Checkpoint Inhibitors



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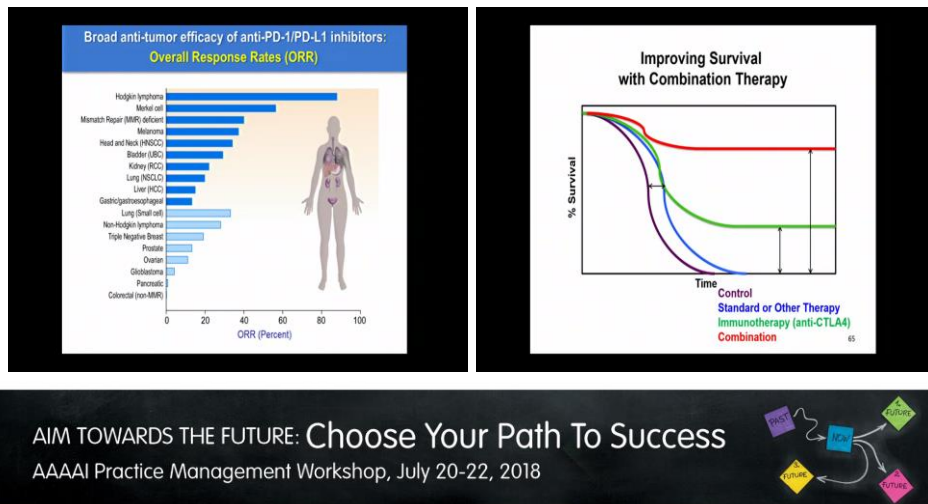
Mechanism of Action of Checkpoint Inhibitors



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Why the Enthusiasm?



Immune Related Adverse Events Related to Checkpoint Inhibitors

- By activating broad populations of T cells with checkpoint inhibitors, a wide swath of auto-immune type phenomena are being observed
- There is a high frequency of immune related adverse effects

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Frequency of cutaneous IrAEs with CPI

Table 1. All-grade and high-grade skin toxicities of anti-PD-1 and anti-CTLA-4 immune checkpoint antibodies reported in pivotal studies conducted in melanoma patients^a

Treatment-related select skin adverse events (% grade 3)	Pembrolizumab	Nivolumab	Ipilimumab	Nivolumab/ipilimumab in combination
Skin select adverse events	Data missing	37.4–41.9% (1.5–1.6)	43.5–58.7% (0–2.9)	58.7–71.3% (4–9.6)
Rash	13.4–20.7% (0–2)	15–21.7% (0.3–0.5)	14.5–26.1% (0–1.6)	28.4–55% (2.9–5.3)
Rash maculopapular	1.5–3.6% (0–0.4)	2.5–4.2% (0.3)	2.7–17.4% (0–0.4)	11.8–16% (1.6–3.2)
Pruritus	14.1–20.7% (0–1)	17–18.8% (0–0.5)	24.4–35.4% (0–0.4)	33.2–47% (0–1.9)
Vitiligo	8.9–11% (0)	7.3–10.7% (0–0.3)	1.6–8.7% (0)	6.7–11% (0)

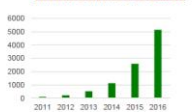
Sibaud et al Current Opinion in Oncology 2016

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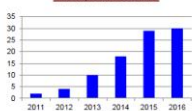


MGH Experience Immune-Related AEs (irAEs)

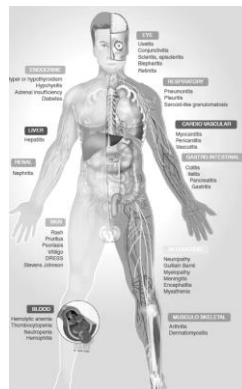
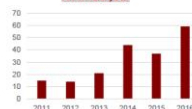
Number of Doses of Immune Checkpoint Inhibitor Administered at MGH



Number of Clinical Trials with Immune Checkpoint Blockade

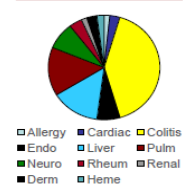


Number of Hospital Admissions for irAEs/year



- Colitis – 44%
- Hepatitis -15%
- Pneumonitis – 16%
- Myocarditis – 3%
- Neurological Conditions – 9%
- Endocrinopathies -7%
- Renal – 2%
- Rheumatology 4%

Distribution of irAEs



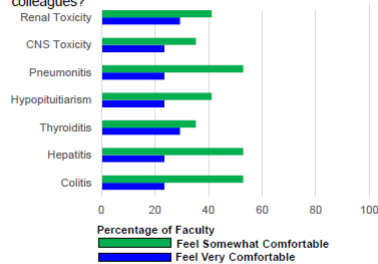
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Additional Immunosuppressive Therapies in use for IrAEs

FACULTY SURVEY DATA

- How comfortable do you feel managing toxicity with consultants and outpatient colleagues?



- Do you think patients with immunotherapy complications should be managed by a specialized service?

48% Yes, 52% No

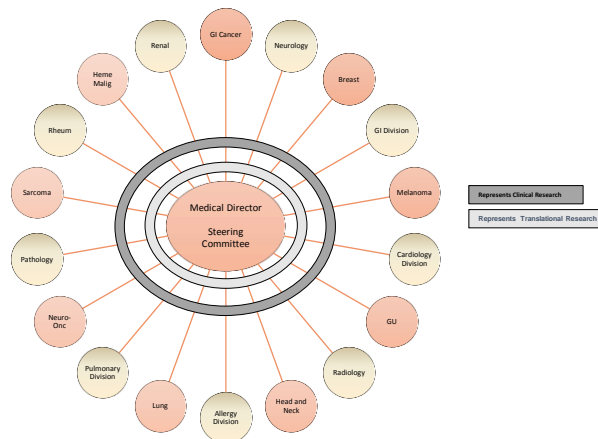
Mechanism of action of immune modulating medications.

Drug	Key mechanism of action
Steroids	Multiple effects on T cells, B cells and phagocytes through inhibition of transcription of interleukins, reduction in synthesis of cytokines, inhibition of neutrophil apoptosis and reduced macrophage function
Infliximab	Antibody that inhibits binding of the inflammatory cytokine tumour necrosis factor alpha (TNF- α) to its receptors
Mycophenylate mofetil	Inhibits inosine monophosphate dehydrogenase (IMPDH), an enzyme involved in nucleotide production, particularly in activated lymphocytes
Tacrolimus and Cyclosporine	Calcineurin inhibitors that limit transcription of interleukin 2 (IL-2), involved in T cell proliferation

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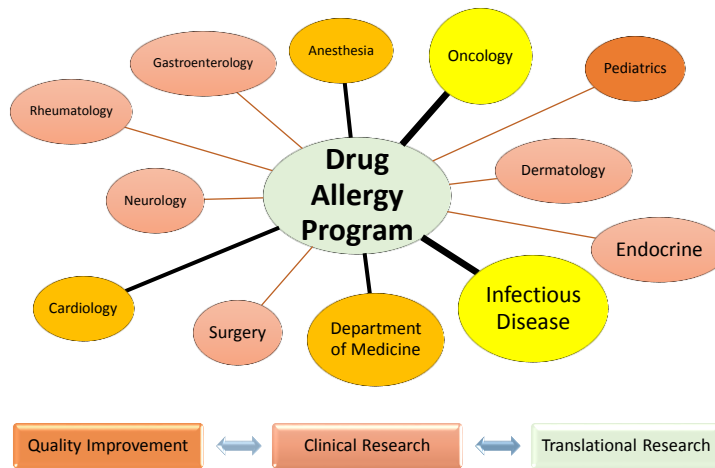
Immunotherapy Toxicity Service



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Drug Allergy Program



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The screenshot shows a web browser displaying a news release from Mass General Hospital. The URL is www.massgeneral.org/News/pressrelease.aspx?id=1859. The article is dated Sunday, October 25, 2015, and is titled "Mass. General study finds medication error or adverse event associated with 5 percent of perioperative drug administrations". The text describes a study of more than 275 operations at Mass General Hospital (MGH) published in *Anesthesiology*. It states that the first study to measure the incidence of medication errors and adverse drug events during the perioperative period found that some sort of mistake or adverse event occurred in every second operation and in 5 percent of observed drug administrations. The study also found that a third of the errors resulted in adverse drug events or harm to patients. The report is being published online to coincide with a presentation at the ANESTHESIOLOGY® 2015 annual meeting in San Diego. A quote from Karen C. Nanji, MD, MPH, of the MGH Department of Anesthesia, Critical Care & Pain Medicine, is included: "We found that just over 1 in 20 perioperative medication administrations resulted in a medication error or an adverse drug event," says Karen C. Nanji, MD, MPH, of the MGH Department of Anesthesia, Critical Care & Pain Medicine, lead author of the report. "Given that Mass. General is a national leader in patient safety and had already implemented approaches to improve safety in the...". A "Contact Public Affairs" button and social media links are also visible.

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Domains of Practice Expansion

Adverse reactions to other chemicals

Allergic contact dermatitis

Irritant contact dermatitis

Surgical metal implants
(prosthetic joints and endovascular stents)

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Expanded Range of Testing for Allergic Contact Dermatitis

MOH Allergy Associates
Patch Placement for riverty patches;
North American Comprehensive Series and plus Metal Group

ROW 1															
A				B				C				D			
1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16
1	7			12	17			22	27			32	37		
3	11			13	18			23	*28			33	38		
4	8			14	19			24	29			34	*39		
5	10			15	20			25	30			35	40		

Contact Dermatitis



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Metal Patch Testing

Metal Patch Testing

MGH Allergy Associates now offers metal patch testing to patients prior to joint replacement surgery, cardiac device implantation (not cardiac stents), dental surgery or dental prosthetic implants. To be eligible for patch testing to metals, patients must meet the following criteria (1 and either 2 or 3):

1. Planned joint replacement, cardiac pacemaker or defibrillator implantation or dental surgery/prosthetics.

- AND -

2. Reported history of allergic reaction to metals (i.e. nickel hypersensitivity).
3. History of premature joint replacement failure.

- OR -

M01	Aluminum chloride hexahydrate			
M02	Copper sulfate			
M03	Ferric chloride			
M04	Molybdenum			
M05	Palladium Chloride			
M06	Titanium Powder			
M07	Vanadium trichloride			
M08	Zirconium chloride			
M09	N, N-Dimethyl-4-toluidine			
M90	Mercury (only pts. presenting for dental testing)			

UpToDate - Nickel Hypersensitivity and Coronary Artery Stents **Sarita Patil and Aidan Long**

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Domains of Practice Expansion

Adverse reactions to foods

Peanut allergy prevention

Oral immunotherapy

Oral food challenges for diagnostic evaluation

Joint management of EoE

Large perception of food related symptoms
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Domains of Practice Expansion

Other immune dysfunction including immunodeficiency

- Non-infectious complications of CVID and other PIDs
 GLILD, cytopenias, granulomatous diseases and malignancies
- Adverse reactions to immunomodulatory biologicals
 see publication by Ballas et al.
- Immune related AEs to checkpoint inhibitors
- Novel PIDS
 Whole exome sequencing

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Clinical Immunology – Its time come at last....

AAAAI and ACAAI



AAIAA and ACIAA

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Integration of Allergy and Immunology (MGH)

- Interdigitations of the drug allergy program
- SIC service
- Directorship of MGH Medical Infusion Center
- Diagnostic Immunology Laboratory
- Administrative roles within DOM
- QI directorship – “allergy field” within EHR
- Internship recruitment committee
- House staff teaching
- MSTP mentorship
- Medical student training in “immunology”

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Hospital Based vs Community Based?

- Not as obvious an answer as one might first think.....

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Whither Allergy and Immunology?

- The future is very bright
- Scope of practice expansion possibilities are truly vast
- We need to continue to recruit and appropriately train
- We have extraordinary opportunities to demonstrate our value to our several constituencies

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Value Creation in Private Practice

- Operational efficiency
- Reduced costs
- Reporting quality metrics

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PEPC Overview

- Partnership to Empower Physician-Led Care
- Advocate value-based care models
- Support independent physician practices with transition
- Use regulatory/legislative levers to advance agendas
- First: opportunities in payment rules and analyzing risk

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PEPC Founding Members

- Aledade
- American Academy of Family Physicians
- California Medical Association
- Florida Medical Association
- Medical Group Management Association
- Texas Medical Association

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PEPC's Four Priorities

- Advance physician-led APMs
- Ensure equitable policy framework that promotes choice and provider competition
- Create new opportunities for physicians in commercial markets (i.e. Medicare Advantage)
- Support consumer-directed care

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Independent Physician Association (IPA)

- Exists primarily for negotiating managed care contracts
- “Messenger Model” in negotiating contracts
- Separate TINs; no operational cost efficiencies, no economies of scale

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Clinically Integrated Network (CIN)

- Express purpose of improving quality and cost efficiency in healthcare delivery
- Contracts on behalf of members, unlike IPA
- Separate TINs; no operational cost efficiencies, no economies of scale

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Management Services Organization (MSO)

- Separate TINs, but host of management services and economies of scale
- Centralized billing and collections
- Negotiating leverage with payors and vendors
- Human resources and personnel management

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Mergers and Acquisitions (M&A)

- 2 or more groups coming together
- Single TIN
- Greatest potential for economies of scale in practice operations, contract leverage with hospitals, and negotiating power with payors

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Joint Venture (JV)

- 2 or more entities
- Shared resources
- Some specific specialties with hospital or large multispecialty

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Questions?

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