Demonstrating the Value of the Allergist in Academics and Private Practice

Aidan Long, MD
Nick Hernandez, MBA, FACHE

Important Domains of Clinical Practice Management
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
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

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.
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."

Summary of Core Elements of Hospital Antibiotic Stewardship Programs

- Leadership Commitment: Dedicate 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 systematic evaluation of ongoing treatment need after a specific period of initial treatment (i.e., "antibiotic time out" after 48 hours).
- Tracking: Monitoring antibiotic prescribing and resistance patterns.
- Reporting: Regular reporting on antibiotic use and resistance to doctors, nurses and relevant staff.
- Education: Educating clinicians about resistance and optimal prescribing.
Partners Penicillin Allergy Pathway

Special Article

Addressing Inpatient Beta-Lactam Allergies: A Multihospital Implementation

Kimberly G. Bornenthal, MD, MSc**, Eric S. Stence, MD, PhD**, Anna R. Wilcox, MD*,
David N. Berkwitz, PharmD, Victoria A. Cotella, MPH**, Dana S. Babalis, MD, MPH*
Kathleen A. Marcu, PhD, PharmD**, Perri Oshinsky, PharmD, BCPH, BID**, Pamela O. Grentz, PharmD, BCPH**
Poonam Malik, MD, MIA**, David W. Kubik, PharmD, BCPH, BID**, Jennifer Catula, PharmD, BCPH*
Sara R. Lanki, MD, WM**, Joyce T. Hu, MD, MSc, Simon M. Fader, MPH*
Alana Grunfeld, PharmD, MPH, BCPH, and Page G. Wilcox, MD, MPH**. Boston, Mass

- Additional planned research:
  - Pre/Post impact on antibiotic use
  - Safety analysis

- SMART app: professionally created for open source download by Persistent Healthcare
EXPANDED PENICILLIN ALLERGY EVALUATION PROGRAM

- Improve Patient Safety
- Decrease Emergence of Antimicrobial Resistance
- Reduce Healthcare Costs

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!
Core Measures in a Value Based Health System

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

Drug Classes Prompting Test Doses

- Between 2008 and 2013, 456 patients underwent 497 test dose protocols with 1-2 steps
Adverse reactions during test doses?

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

<table>
<thead>
<tr>
<th>Severity</th>
<th>Grade</th>
<th>Reaction Rate</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>1</td>
<td>11%</td>
</tr>
<tr>
<td></td>
<td>2</td>
<td>12%</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Grade</th>
<th>Reaction Rate</th>
<th>1-2 Step (n=53)</th>
<th>3-4 Step (n=10)</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td></td>
<td>24 (45.3%)</td>
<td>6 (60%)</td>
</tr>
<tr>
<td>2</td>
<td></td>
<td>28 (52.8%)</td>
<td>4 (40%)</td>
</tr>
<tr>
<td>3</td>
<td>1 (1.9%)</td>
<td></td>
<td>0 (0%)</td>
</tr>
<tr>
<td>4</td>
<td>0 (0%)</td>
<td></td>
<td>0 (0%)</td>
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</table>

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

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)
Clinical Care: Volume of Drug Desensitizations

MGH experience
2015-2017
Approximately 400 in-patient drug desensitizations per year
70% Oncology
20% Antibiotic
10% ASA
Standardized EMR based order entry, Inpatient pharmacy prep. protocols, checks and balances
NP based service
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!

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
Mechanism of Action of Checkpoint Inhibitors

IPILIMUMAB 2011

Nivolumab, Pembrolizumab and 4 others - anti PD1 or anti PDL1
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
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

<table>
<thead>
<tr>
<th>Treatment-related select skin adverse events (%) grade 3</th>
<th>Pembrolizumab</th>
<th>Nivolumab</th>
<th>Ipilimumab</th>
<th>Nivolumab/ipilimumab in combination</th>
</tr>
</thead>
<tbody>
<tr>
<td>Skin select adverse events Data missing</td>
<td>38.4–41.9% (1.5–1.6)</td>
<td>43.5–58.7% (0–2.9)</td>
<td>58.7–71.3% (4–9.6)</td>
<td></td>
</tr>
<tr>
<td>Rash</td>
<td>13.4–20.7% (0–2)</td>
<td>15.3–21.7% (0.3–0.5)</td>
<td>14.5–26.1% (0–1.6)</td>
<td>28.4–55% (2.9–5.3)</td>
</tr>
<tr>
<td>Rash maculopapular</td>
<td>1.5–3.6% (0–0.4)</td>
<td>2.5–4.2% (0.3)</td>
<td>2.7–17.4% (0–0.4)</td>
<td>11.8–16% (1.6–3.2)</td>
</tr>
<tr>
<td>Pruritus</td>
<td>14.1–20.7% (0–1)</td>
<td>17.1–18.8% (0–0.5)</td>
<td>24.4–35.4% (0–0.4)</td>
<td>33.2–47% (0–1.9)</td>
</tr>
<tr>
<td>Vellus</td>
<td>8.9–11% [0]</td>
<td>7.3–10.7% (0–0.3)</td>
<td>1.6–8.7% [0]</td>
<td>6.7–11% [0]</td>
</tr>
</tbody>
</table>

Sibaud et al Current Opinion in Oncology 2016

MGH Experience Immune-Related AEs (irAEs)

- Colitis – 44%
- Hepatitis -15%
- Pneumonitis – 16%
- Myocarditis – 3%
- Neurological Conditions – 9%
- Endocrinopathies -7%
- Renal – 2%
- Rheumatology 4%
Additional Immunosuppressive Therapies in use for IrAEs

**FACULTY SURVEY DATA**

- **How comfortable do you feel managing toxicity with consultants and outpatient colleagues?**
  - CNS Toxicity
  - Pneumonitis
  - Hypophosphatemia
  - Thyroiditis
  - Hepatitis
  - Cellulitis

<table>
<thead>
<tr>
<th>Percentage of Faculty</th>
<th>Feel Very Comfortable</th>
<th>Feel Somewhat Comfortable</th>
</tr>
</thead>
<tbody>
<tr>
<td>0</td>
<td>20</td>
<td>40</td>
</tr>
<tr>
<td>60</td>
<td>80</td>
<td>100</td>
</tr>
</tbody>
</table>

- **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.**

<table>
<thead>
<tr>
<th>Drug</th>
<th>Key mechanism of action</th>
</tr>
</thead>
<tbody>
<tr>
<td>Steroids</td>
<td>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</td>
</tr>
<tr>
<td>Infliximab</td>
<td>Antibody that inhibits binding of the inflammatory cytokine tumour necrosis factor alpha (TNF-α) to its receptors</td>
</tr>
<tr>
<td>Mycophenolate mofetil (MMF)</td>
<td>Inhibits inosine monophosphate dehydrogenase (IMPDH), an enzyme involved in nucleotide production, particularly in activated lymphocytes</td>
</tr>
<tr>
<td>Tacrolimus and Cyclosporine</td>
<td>Calcineurin inhibitors that limit transcription of interleukin 2 (IL-2), involved in T cell proliferation</td>
</tr>
</tbody>
</table>

**Immunotherapy Toxicity Service**

AIM TOWARDS THE FUTURE: Choose Your Path To Success
AAAAAI Practice Management Workshop, July 20-22, 2018
Mass. General study finds medication error or adverse event associated with 5 percent of perioperative drug administrations

The first study to measure the incidence of medication errors and adverse drug events during the perioperative period — immediately before, during and right after a surgical procedure — has found that some sort of mistake or adverse event occurred in every second operation and in 5 percent of observed drug administrations. The study, of more than 275 operations at Massachusetts General Hospital (MGH), which will appear in Anesthesiology, the official medical journal of the American Society of Anesthesiologists, 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.

"We found that just over 1 in 20 perioperative medication administrations resulted in a medication error or an adverse drug event," says Karen C. Nairn, RN, MPP, 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..."
Domains of Practice Expansion

Adverse reactions to other chemicals

Allergic contact dermatitis

Irritant contact dermatitis

Surgical metal implants
(prosthetic joints and endovascular stents)

Expanded Range of Testing for Allergic Contact Dermatitis

North American Series Patch Testing

ACDS CAMP SOFTWARE AND APP

Collaborative with ACD—specializing dermatologists in the city

Patient-centric smart phone app
Contact Dermatitis

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).  
   **- OR -**  
3. History of premature joint replacement failure.

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

AIM TOWARDS THE FUTURE: Choose Your Path To Success

AAAAI Practice Management Workshop, July 20-22, 2018

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
Clinical Immunology –
It’s time come at last....

AAAAI and ACAAI

AAIAA and ACIAA

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”
Hospital Based vs Community Based?

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

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
Acknowledgements

- **Drug Allergy Program**
  - Aleena Banerji
  - Johnson Wong
- **PCN program**
  - Kim Blumenthal
  - Anna Wolfson
- **Patch testing program**
  - Michael Wilson
- **Peanut allergy prevention program**
  - Michelle Conroy and Paul Hesterberg
- **EoE Clinic (joint with GI)**
  - Sarita Patil
- **Immune dysregulation**
  - Jocelyn Farmer
  - Sarah Barmettler
- **Chronic Sinus disease**
  - Daniel Hamilos
- **Diagnostic Clinical Immunology Lab**
  - Mandakoluthar Murali
  - Morris Ling
- **Angioedema program**
  - Aleena Banerji
- **Medical Infusion Center**
  - Aidan Long and Aleena Banerji

Value Creation in Private Practice

- Operational efficiency
- Reduced costs
- Reporting quality metrics
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

PEPC Founding Members

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

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
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

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
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

Joint Venture (JV)

• 2 or more entities
• Shared resources
• Some specific specialties with hospital or large multispecialty
Questions?

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