Health PEI
One Island Health System

QEH Grand Rounds

Beta-Lactam Allergy Management and PEI Provincial Guidelines

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Stewardship Champions

- “High Dose ; Short course”
- Offer Local Guidelines
- SAVE CIPRO
- AVOID COLLATERAL DAMAGE
  - STOP CLINDA / SWAP MOXI
  - Sort out the allergy, previous Cdiff
  - Probiotic
- IMMUNIZE

Antimicrobial Stewardship Program Survey Results – Fall 2016

Fall Survey Response Rate

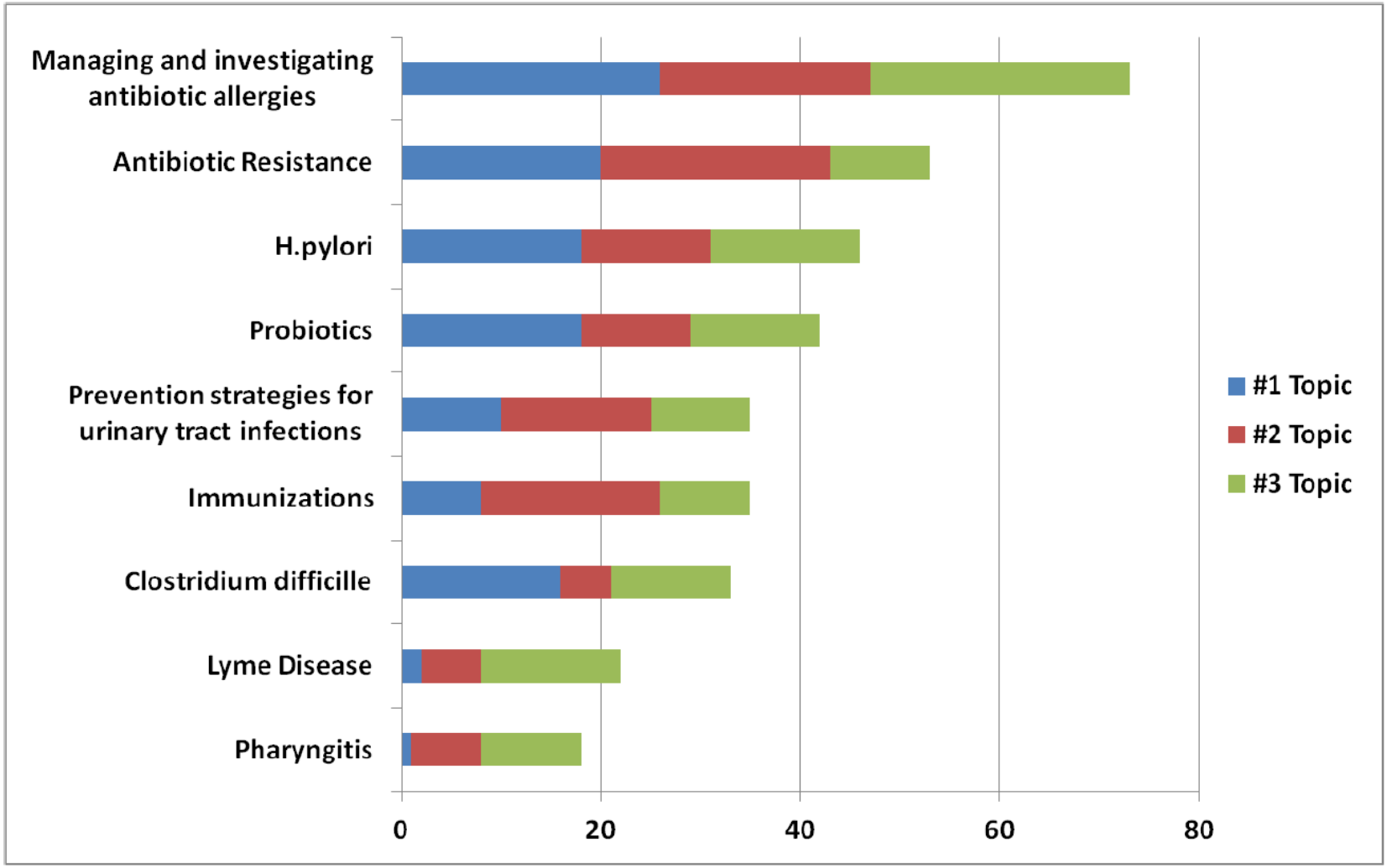
Profession	# Individuals Survey Sent to	# of Responses	Response Rate
Physician	250	49	20%
Pharmacist	186	40*	22%
Nurse Practitioner	21	8	38%
Nurse	45	20	44%
Total	**502**	**117**	**23%**

* 40 = 20 Hospital or Provincial Pharmacy Pharmacists, 20 Community Pharmacists

Survey Response Percentages by Profession

Profession	# of Responses	% of Total Survey Responses
Physician	49	42%
Pharmacist	40	34%
Nurse Practitioner	8	7%
Nurse	20	17%

Rank up to 3 infectious diseases / antimicrobial topics for a possible education event.



No Disclosures

Objectives:

1. Review the epidemiology and classification of Penicillin allergy
2. Illustrate the patient impact of having an antibiotic drug allergy.
3. Study the new Penicillin allergy guidelines
4. Discuss implementation of the guidelines on your practice…

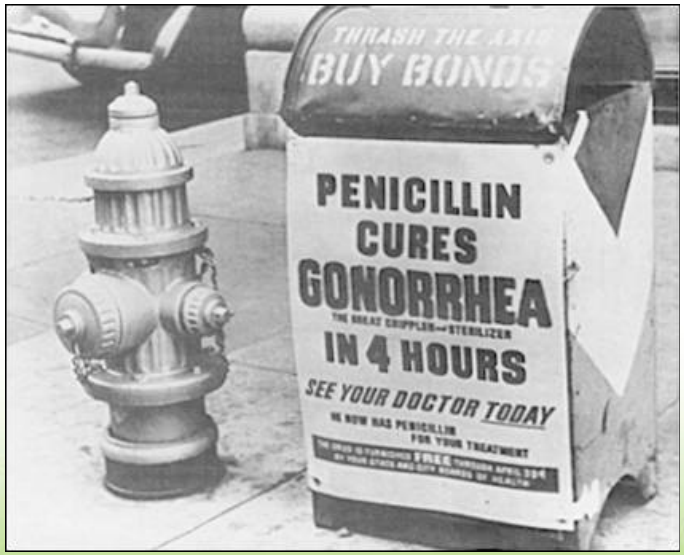
CASE

- 30 yo Female Smoker with psychiatric issues
- Right medial Maleous abscess growing from possible MSSA Septra S, and later *Pseudomonas aeurginosa* Cipro R, and *Enterobacter cloacae* Septra R.
- I & D 2x by ortho, little improvement with vac dressing and skin flap.
- pMHX: Asthma, atopic dermititis, frequent MSSA/MRSA cellulitits, post traumatic infected spinal hardware, frequent Pseudomonas line infections.
- On bendryl IV q4h for chronic urticaria Allergic to "All Antibiotics" MSSA tx with Vancomycin, what to treat GNBs?

- "All Antibiotics" = Penicillin, Amoxicillin, Cloxacillin, Septra, Biaxin, Clindamycin, Erythromycin, Haldol, Latex, Fucidin, Flamazine, Ancef, Keflex, Cipro, Gentamycin, Tetracycline, Flagyl, Sulfa drugs, Polysporin, Bacitracin, Betadine, Iodine containing solution, shellfish.

Case #2

- 34 yo Lady 7 weeks gestation positive gonorrhea nucleic acid testing otherwise well with pMHX of a severe rash like reaction after penicillin remotely.



The Mechanisms of PCN allergy

it all started when i had an ear infection as a nine-year-old. since then i have gone on to try many other drugs. please outlaw penicillin before it's too late.

PENICILLIN
the gateway drug™

Back to Basics…

- Immunology (yuck?)
- then biochemistry (double yuck??)

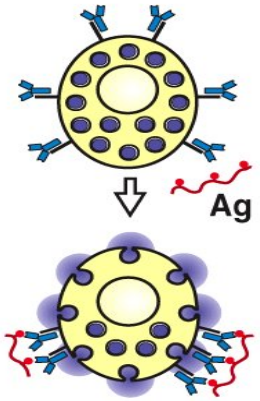
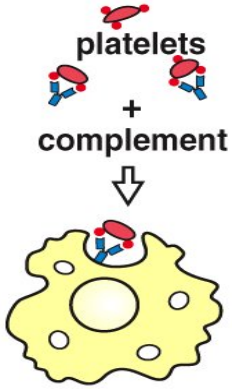
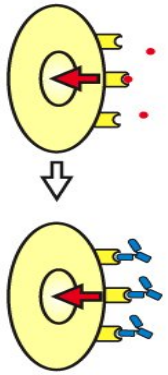
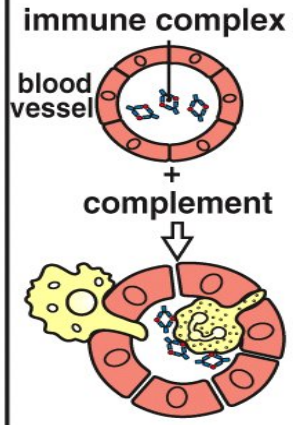
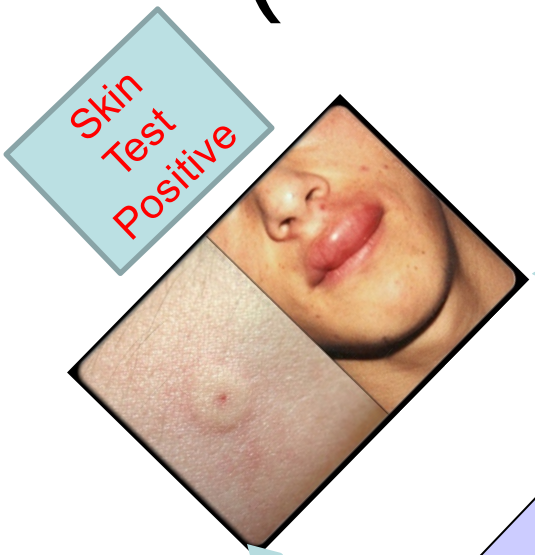
	Type I	Type II		Type III
Immune reactant	IgE	IgG		IgG
Antigen	Soluble antigen	Cell- or matrix-associated antigen	Cell-surface receptor	Soluble antigen
Effector mechanism	Mast-cell activation	Complement, FcR^+ cells (phagocytes, NK cells)	Antibody alters signaling	Complement, Phagocytes
				
Example of hypersensitivity reaction	Allergic rhinitis, asthma, systemic anaphylaxis	Some drug allergies (eg, penicillin)	**Myasthenia gravis**	Serum sickness, Arthus reaction

Figure 12-2 part 1 of 2 Immunobiology, 6/e. (© Garland Science 2005)

Response Time	**15-30 minutes**	**minutes to hours**	**hours**

What is a reported PCN Allergy (1-10% of your Patients)



Death
0.001-0.005%

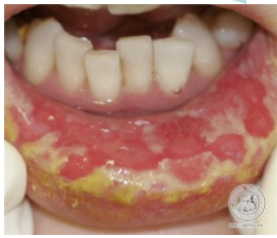
Anaphylactic, angioedema*
0.01-0.05%

Type II, III or Type IV reactions including Maculopapular rash, Hemolytic anemia, cytopenia interstitial nephritis, drug fever, serum sickness

IgE mediated Dermatologic urticaria / Hives
10-20% of reported PCN Allergy

Non-Allergic adverse effects (40%>): Nausea, Fatigue, Antibiotic associated Diarrhea, Seizures, Exanthema associated, Jarisch-Herxheimer reaction, coinciding Rx

idiosyncratic
*Some Maculopapular rash
*Stevens-Johnson Syndrome
*Some Eosinophilia

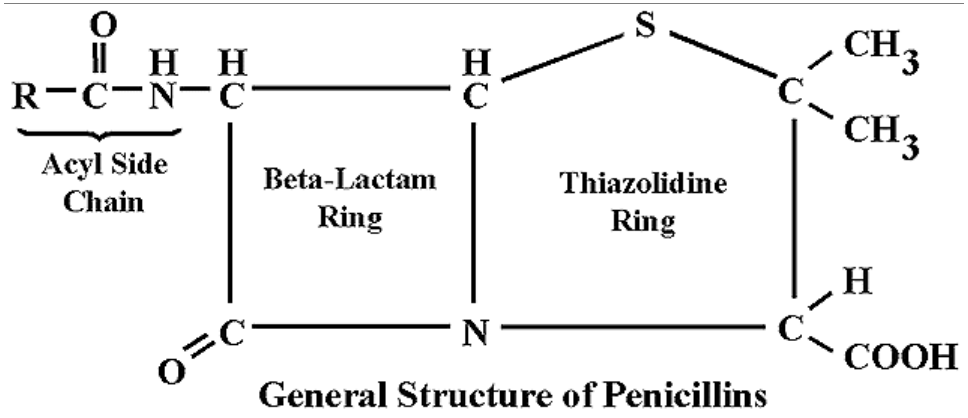


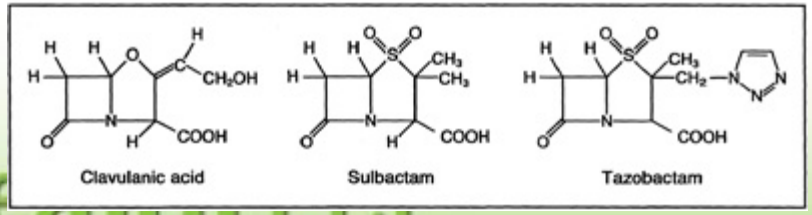
(*PCN Anaphylaxis 1 in 5K to 10K (STD clinics, Rhodolph and Price JAMA 1973)

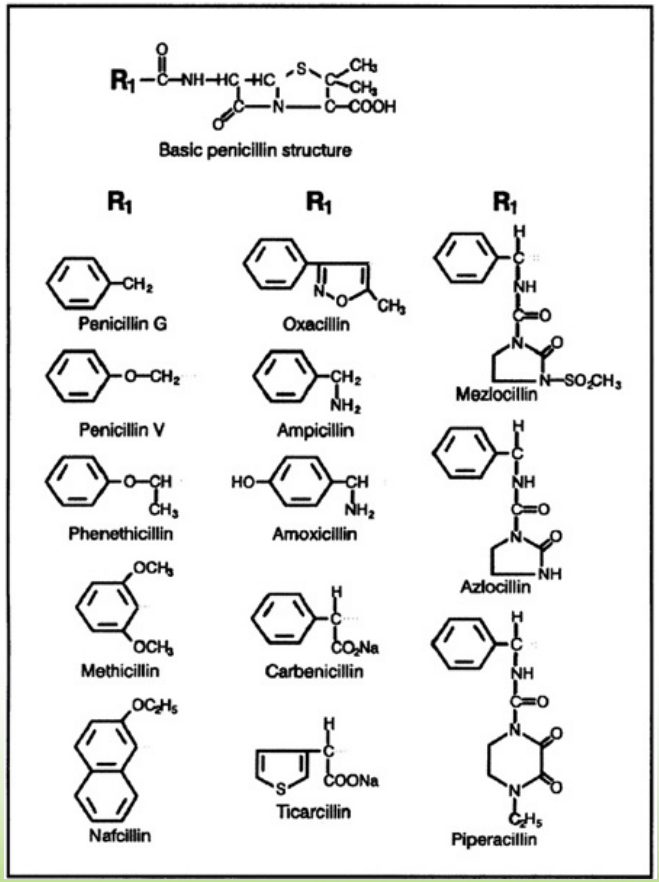
A few slides on Biochemistry

PCN Structure

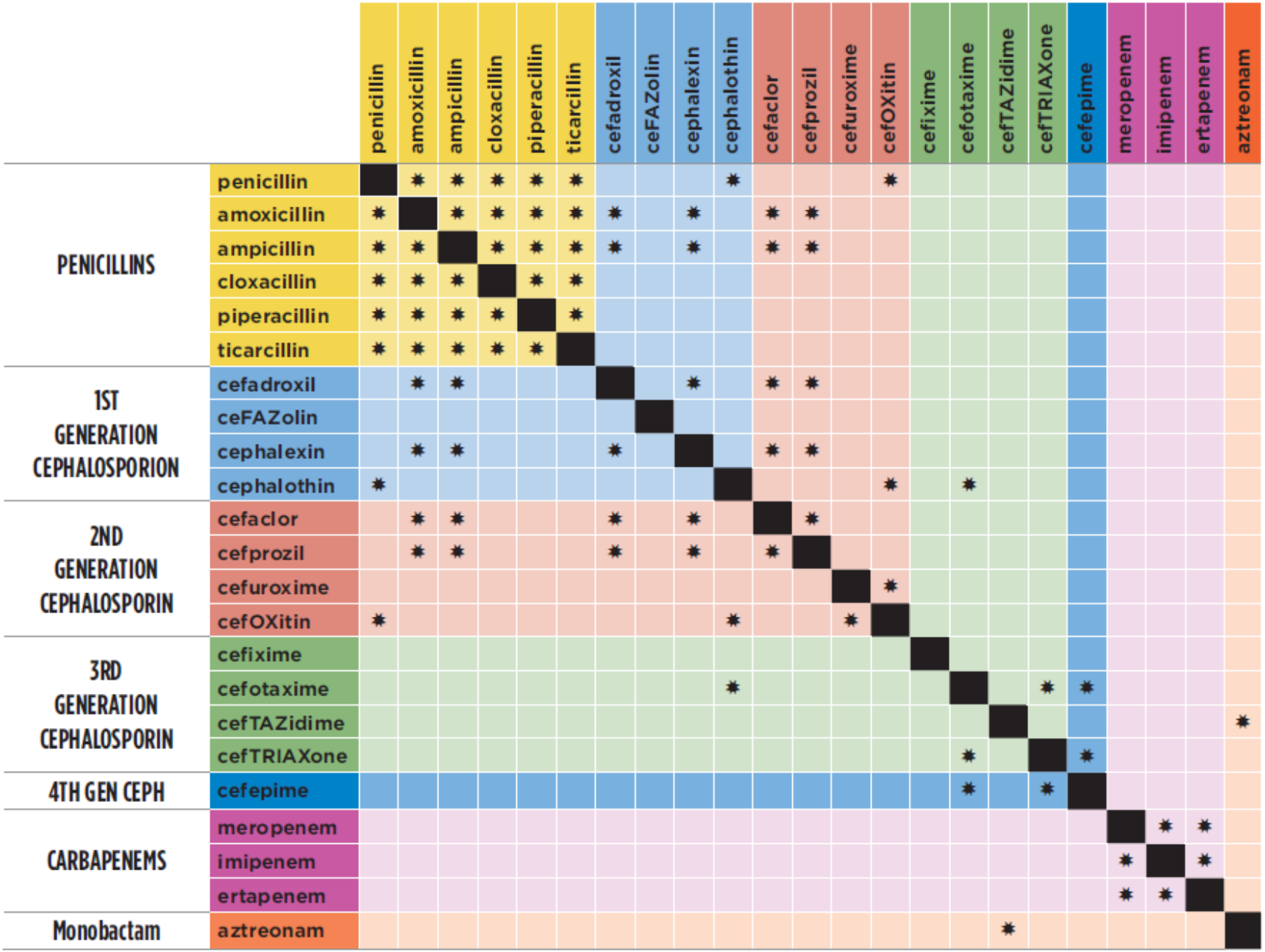
- Penicillin is broken down but not that well conserving the beta lactam or Thiazolidine Ring







Matrix of Beta-Lactam Cross Allergy

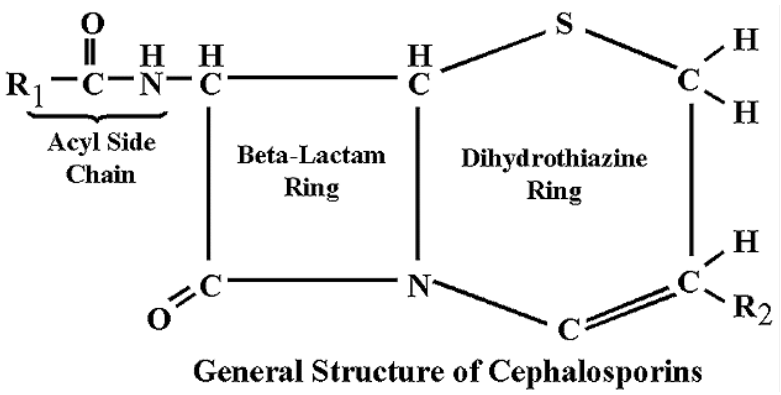


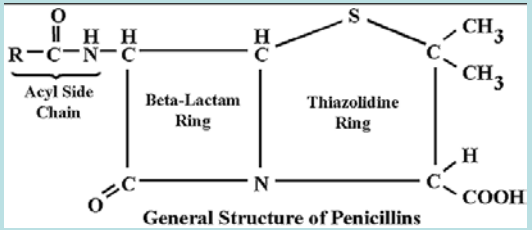
PCN allergens

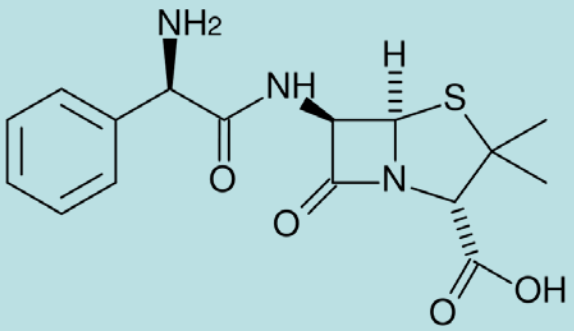
- Major Determinate
  - 95% is metabolized into benzylpenicillol-polylysine
- Minor Determinates
  - Penilloate
  - Penicilloate
  - Native benyzlepenicillin

- For modified PCN the Side Chains or unique metabolities can serve as allergens through haptenization
- For skin testing both the Major and Minor determinates should be used*

Cephalosporin structure

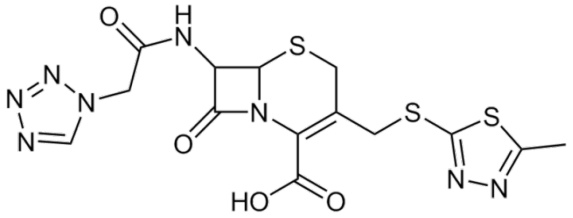




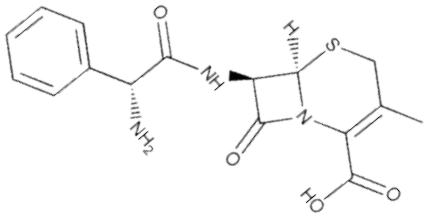


Ampicillin

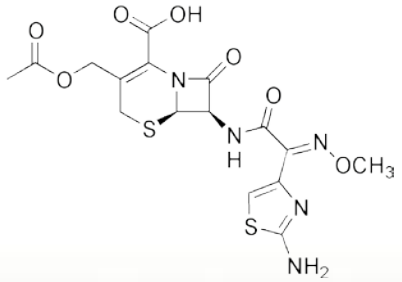
Cefazolin / Ancef / Vitamin "A"



Cephalexin / Keflex



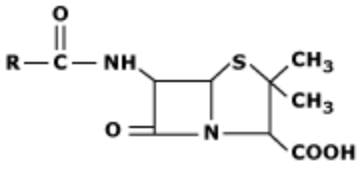
Cefotaxime



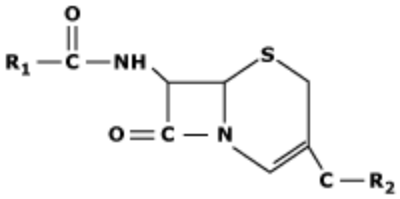
-Beta lactam plays less central role because breakdown does not preserve ring structures

-Side Chains can be identical to Penicillins like Cephalexin and Ampicillin

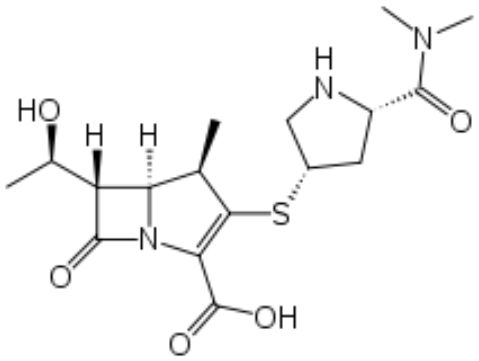
Carbapenem / monobactam



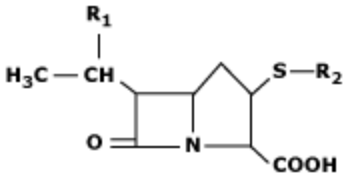
Penicillins



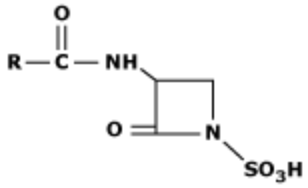
Cephalosporins



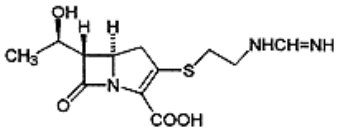
Meropenem



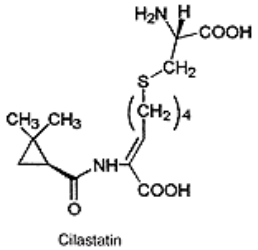
Carbapenems



Monobactams



Imipenem



Cilastatin

What is the real rate of cross reactivity???

Adverse Reactions Associated with Oral and Parenteral Use of Cephalosporins: A Retrospective Population-Based Analysis

(Macy & Contreras. J Allergy Clin Immunol 2015;135:745-752)

- Retrospective Population-Based Analysis (3.9 million patients)
- Objective: Descriptive report of "real-world" frequency of new reports of cephalosporin-associated "allergies" in 30 days or serious ADRs (anaphylaxis, severe cutaneous ADRs, hemolytic anemia, nephropathy, *C.diff* infection, all-cause death within 1 day) – 3 years
  - 622,456 pts exposed to 901,908 courses of PO cephalosporins
  - 326,867 pts exposed to 487,630 courses of IV cephalosporins
  - 65,915 pts with history of penicillin "allergy" received 127,125 courses of cephalosporins

Adverse Reactions Associated with Oral and Parenteral Use of Cephalosporins: A Retrospective Population-Based Analysis

(Macy & Contreras. J Allergy Clin Immunol 2015;135:745-752)

- Results:
  - New cephalosporin "allergy" report within 30 days
    - Women – 0.56%
    - Men – 0.43%
    - Penicillin "allergy" – 1.13%*
    - Cephalosporin "allergy" – 0.70%
    - Other drug "allergy" – 0.50%
    - No drug allergy – 0.37%
  - Anaphylaxis
    - 5 of 901,908 oral courses; 8 of 487,630 IV courses (0.00055% – 0.0016%)
    - No significant difference between those with and without penicillin or cephalosporin "allergy"

1 in 135 patients had a new cephalosporin "allergy" who have previously reported a penicillin "allergy"

9 cases out of 1,000,000 lead to anaphylaxis. Penicillin "allergy" not scientifically linked.

Clostridium difficile infection at least 100 times more lethal than anaphylaxis when using a broader spectrum cephalosporin IV

Clostridium difficile infection in 90 days

- Case fatality for Cdiff is at least 6% at 30 days*
- Overall per treatment course: 0.91%
  - (expected mortality 546 per 1,000,000)
- 1st generation parenteral: 1.3% per treatment course
  - (Deaths of 780 per M)
- 3rd generation or higher parenteral: 2.9% per course
  - (Deaths of 1,750 per M)
- Difference Between 1st and 3rd(Mortality of 970 per milllion)
- Versus Anaphylaxis risk of 9 per one million
  - Versus Anaphylaxis death of ~1 per million

(Macy & Contreras. J Allergy Clin Immunol 2015;135:745-752)
*(Hota et al 2012 EID)

Other results

- Nephropathy in 30 days – 0.15%
- 3 documented cases (out of ~ 1.4 million courses) of serious cutaneous adverse reactions, all associated with the use of another antibiotic at the same time as the cephalosporin

Adverse Reactions Associated with Oral and Parenteral Use of Cephalosporins: A Retrospective Population-Based Analysis

(Macy & Contreras. J Allergy Clin Immunol 2015;135:745-752)

- Conclusions:
  - Cephalosporins are widely and safely used in patients with unconfirmed allergies to penicillin and other cephalosporins
  - Anaphylaxis associated with cephalosporin use is rare and no higher in patients with an unconfirmed penicillin "allergy"
  - Severe cutaneous ADRs are even more rare
  - *C. difficile* infection was the most common serious ADR identified
    - Avoiding 1st and 2nd generation cephalosporins in penicillin "allergic" patients and using 3rd generation instead does not improve patient safety
    - Avoiding unnecessary use of 3rd or higher generation cephalosporins may reduce rate and improve safety
  - "Warnings against the administration of cephalosporins to patients with unconfirmed penicillin allergy should be removed from the electronic medical record system"

The effects of having a label…

Impact of an Antimicrobial Allergy Label in the Medical Record on Clinical Outcomes in Hospitalized Patients

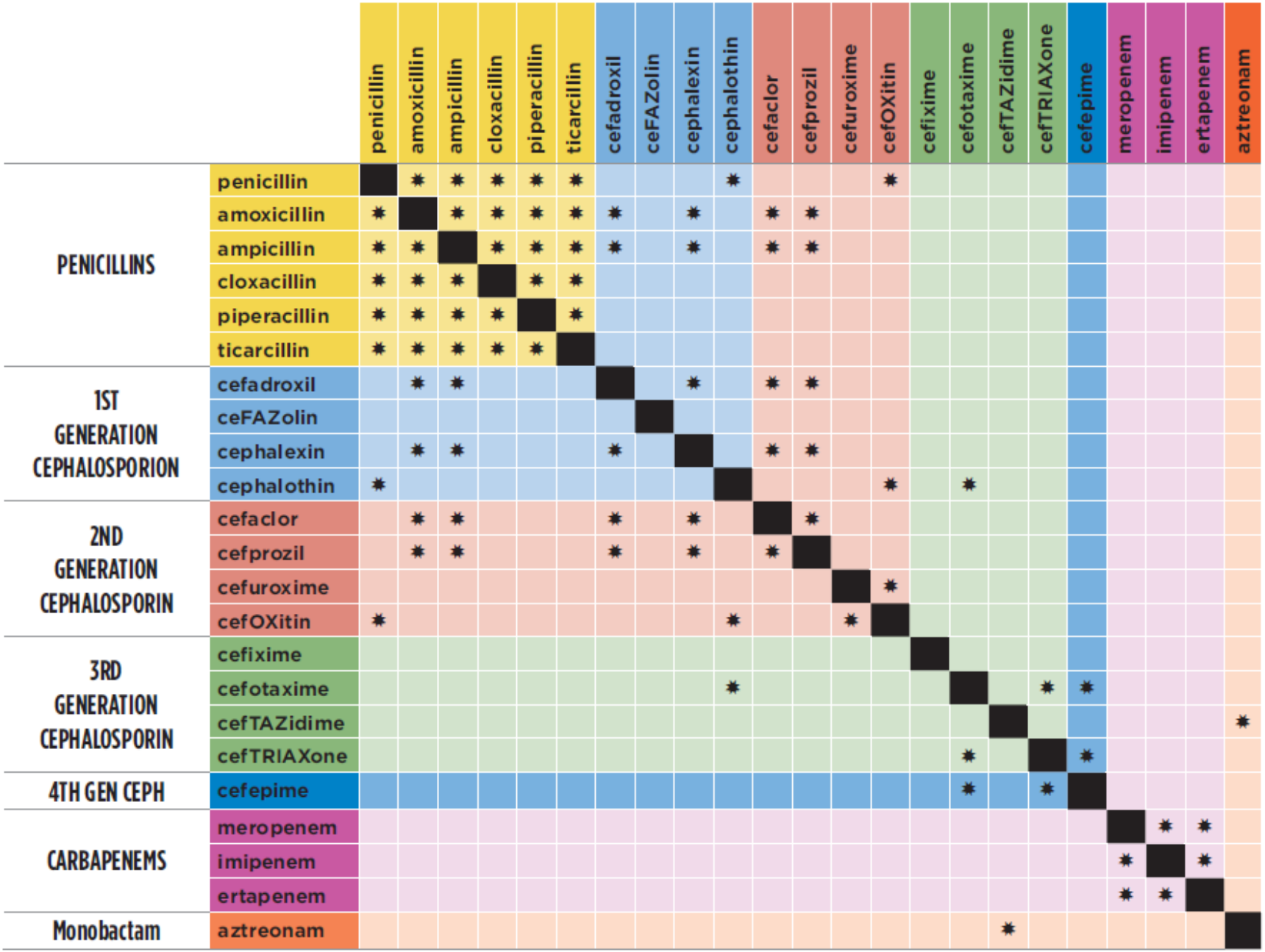
(Charneski *et al.* Pharmacotherapy 2011; 31(8):742)

- Retrospective Cohort Study
- Objective: To determine the impact of having an antimicrobial "allergy" label in the medical record on clinical outcome in hospitalized patients
- Adjusted for age, sex, season and surgery during admission
- 11,872 adult pt's who received at least one antimicrobial
  - 1324 (11.2%) had an "allergy" label; 10,548 (88.8%) had "no allergy" label
- Results:
  - **Patients with an "allergy" label to ANY antimicrobial:**
    - Have longer hospital stays (average 1.16 days longer; adjusted)
    - Are more likely to be admitted to an ICU (adjusted OR 1.61, 95% CI 1.21 – 1.67)
    - Are more likely to receive more than one antibiotic during hospitalization (adjusted OR 1.51; 95% CI 1.20 – 2.04)
    - Are more likely to die during hospitalization (OR 1.56; 95% CI 1.20 – 2.04)

Health care use and serious infection prevalence associated with penicillin "allergy" in hospitalized patients: A cohort study

- Retrospective, matched cohort study
- Objective: To determine total hospital days, antibiotic exposure and rates of *C.diff*, MRSA and VRE in pts with and without penicillin "allergy"
- 51,582 cases, 99.6% matched at time of admission to 2 controls (diagnostic category, sex, age, date of admission)
- Results:
  - **Patients with a PENICILLIN allergy label:**
    - Have longer hospital stays (avg. 0.59; 95% CI 0.47 – 0.71)
    - Have higher rates of infections due to:
      - *Clostridium difficile* (23.4% more; 95% CI 15.6 – 31.7%)
      - Methicillin-resistant *Staphylococcus aureus* (MRSA) (14.1% more; 95% CI 7.1 – 21.6%)
      - Vancomycin-resistant *Enterococcus* (VRE) (30.1% more; 95% CI 12.5 – 50.4%)
    - Are treated with more fluoroquinolones, clindamycin and vancomycin ($P < 0.001$)

Matrix of Beta-Lactam Cross Allergy



Beta-Lactam Cross Allergy Matrix (based on similar core and/or side chain structures)

(Health PEI Provincial Drugs & Therapeutics Antimicrobial Stewardship Subcommittee)

		penicillin*	amoxicillin/ampicillin	cloxacillin	piperacillin (pip/tazo)	cefADROxil	cephALEXin	ceFAZolin	cefPROZil	cefUROXime	cefOXitin	ceFIXime	cefoTAXime	cefTAZidime	cefTRIAXone	meropenem	ertapenem
PENICILLINS*	penicillin*	■	X	X	X	*	*		*		X						
	amoxicillin/ampicillin	X	■	X	X	X	X		X								
	cloxacillin	X	X	■	X												
	piperacillin (pip/tazo)	X	X	X	■												
1ST GENERATION CEPHALOSPORIN	cefADROxil	*	X			■	X		X								
	cephALEXin	*	X			X	■		X								
	ceFAZolin							■									
2ND GENERATION CEPHALOSPORIN	cefPROZil	*	X			X	X		■								
	cefUROXime									■	X						
	cefOXitin	X								X	■						
3RD GENERATION CEPHALOSPORIN	ceFIXime											■					
	cefoTAXime												■		X		
	cefTAZidime													■			
	cefTRIAXone												X		■		
CARBAPENEMS	meropenem															■	X
	ertapenem															X	■

X - Each 'X' in the matrix indicates side-chain and/or major/minor antigenic similarity between two antibiotics. For type-1 immediate hypersensitivity including anaphylaxis there is a risk of cross-allergenicity between pairs marked with 'X'. This is due to similar side-chains and/or major/minor antigenic determinants, use NOT recommended without desensitization.

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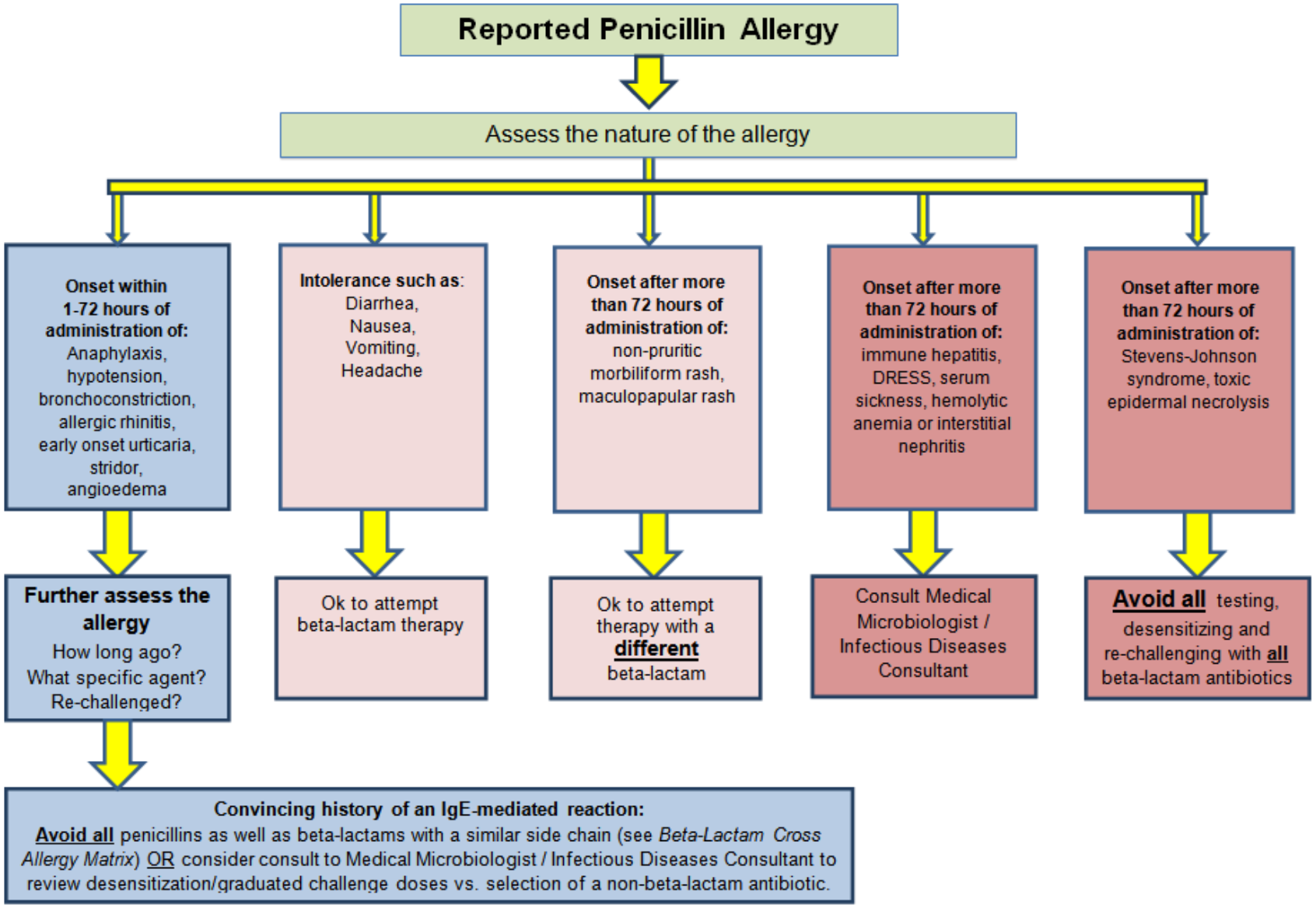
* Caution! Before using cephALEXin, cefADROxil, or cefPROZil in a patient with an allergy to "penicillins" as a group, clarify or confirm the patient is NOT allergic to amoxicillin or ampicillin.

Penicillin Allergy Management Algorithm

(Health PEI Provincial Drugs & Therapeutics Antimicrobial Stewardship Subcommitte)



Penicillin, Amoxicillin, "Keflex" or other beta-lactam antibiotic allergy
Patient Questionnaire
Please complete one form for each antibiotic you are allergic to

Nine out of 10 of Canadians who think they have a penicillin allergy do NOT actually have a true allergy to the antibiotic. It is important to know if you have a true allergy, if you have an intolerance (not a true allergy) or if there was another reason for your reaction, so that your health care team can make sure you are treated with the safest and best antibiotics if you become ill.

If you have been told you have a penicillin allergy or allergy to another similar antibiotic, complete this form and take it to your family doctor or nurse practitioner or community pharmacist to review.

1) Which antibiotic was it?

☐ Penicillin ☐ Amoxicillin ☐ "Keflex"

Other: (please write its name here) _____

How was the antibiotic given: ☐ oral ☐injection ☐ cream ☐ other

2a) What was your reaction to the medication (In your own words)?

_____

3) Did your reaction include any of the following symptoms
(check if yes or circle if maybe / not sure):

☐ Swelling of the lips, tongue or airways
☐ Trouble breathing
☐ Wheezing
☐ Low blood pressure
☐ Hives
☐ An Itchy Rash
☐ An anaphylactic reaction
☐ Other: _____

3) How long after your first dose of the medication did the reaction start?

- ☐ Immediately (a few minutes)
- ☐ Within a couple of hours to one day
- ☐ Within one day (24 hours) to three days (72 hours)
- ☐ After three days

4) How many years ago was this reaction?

- ☐ Within the last 5 years (be specific)_____
- ☐ 5-10 years ago
- ☐ Over 10 years ago

Were you able to treat the reaction yourself or at home OR did you go to your family doctor/walk-in clinic OR the Emergency Department OR seek help from another healthcare worker? OR Admitted to a regular Hospital bed OR Admitted to an ICU Bed? (Circle all appropriate answers)

Please take this form with you to your next appointment with your family doctor or nurse practitioner. S/he will complete the back side of this page to help determine if you have a true allergy.

Health Care Professional (HCP) Section:

To be completed by the patient's family doctor, nurse practitioner, or other HCP.

1) **Medication** name, route of administration: _____

a. Indication for medication:

2) **Reaction details**

a. Confirm symptoms and onset of first symptoms in relation to first dose

b. When did the reaction take place / how old was the patient at the time of the reaction?

_____

_____

c. What other medications was the patient taking at that time?

_____

3) **Medical care sought after reaction**– type of treatments received for reaction

_____

_____

_____

a. Was the patient

Hospitalized? Yes / No Intubated? Yes / No In ICU? Yes / No

4) **Has the patient experienced a reaction like this without intake of the suspected medication? Describe reaction and identify possible triggers.**

_____

_____

_____

5) Has the patient taken any other beta lactam antibiotics anytime before or after the reaction?

_____

_____

6) Patient's past medical history including illnesses at the time of reaction

_____

_____

_____

7) Has the patient have any of the following at anytime in their lives?

☐ Asthma
☐ Autoimmune disease
☐ Atopic dermatitis
☐ Prior anaphylaxis
☐ Other medication allergies: (please specify) _____
☐ Multiple drug intolerance syndrome
☐ Multiple drug allergy syndrome
☐ Latex allergy
☐ Food allergies: (please specify) _____

Completed by: _____, _____ on _____, 20____
(Please print Name Profession Date Year)

Assessment (to be completed by family physician or Dr. German)
☐Probable Type 1 immediate hypersensitivity reaction (IgE mediated)
☐Probable severe delayed hypersensitivity reaction (non IgE mediated)
☐Probable non-severe delayed hypersensitivity reaction (non-IgE mediated)
☐Probable non-allergic adverse reaction or intolerance

Please provide a copy of this form to:
The patient Family physician _____
Community pharmacy_____
Nearest Major Hospital: PCH or QEH
Dr. Greg German, Health PEI. Fax 902 – 620 –0483

Clinical Decision Support

- Enhancing antibiotic stewardship by tackling 'spurious' penicillin allergy.
- Computerised clinical decision support system to enable nonspecialists rapidly identify and de-label 'low risk' hospitalised patients with a label of PenA thereby obviating the need for allergy tests.
- This approach however needs rigorous evaluation for feasibility, safety, patient & physician acceptability, cost effectiveness and its compatibility with information technology systems currently employed in the health service.

Clin Exp Allergy. 2017 Oct 13. doi: 10.1111/cea.13044.

A practical approach…

Convince yourself

- How long ago
- Who (MD documented, occupation of patient)
- What (GI vs rash vs Hives, vs respiratory concern)
- Where (had to go to ER or ICU)
- When (years ago, days into therapy, minutes after dose)
- Why
  - Allergic to everything (minor vs severe)
  - Hasn't had same or similar antibiotic since.
  - Fam Hx of penicillin allergy (more a social issue)

Clarify allergy in the Hospital

- PCN*
  - not sick but convincing and recent history
    - Use non-penicillin Beta-lactam antibiotic with a different side chain (I use cefuroxime and basically avoid keflex) first dose in ER
    - If you or patient unsure use: for PO use Test dose 5mg (in 5m) then 50mg (in 5 ml) wait 30-60 minutes wait between then use full dose.
    - Modify pcn allergy notes to indicate XXX drug ok
  - Sick patient but convincing and recent history
    - Severe sepsis or greater meropenem or imipenim.
    - In Sepsis cefazolin now ok with close attention
    - Azeotrenam IV is not available in Canada
    - Avoid clindamycin unless needed for synergy

Clarify allergy in the Hospital

- Cephlosporin* (a much rarer event)
  - not sick and convincing and recent history
    - Use cephalosporin, penicillin class, with a different side chain or non-clindamycin alternative.
    - If you or patient unsure use: for PO use Test dose 5mg (in 5m) then 50mg (in 5 ml) wait 30-60 minutes wait between then use full dose.
    - I have given ceftriaxone 50mg po in 5ml solution.
    - Modify pcn allergy notes to indicate XXX drug ok
  - Sick patient and convincing and recent history
    - Severe sepsis or greater meropenem or imipenim or consult ID (Me/Moncton/Halifax)
    - Avoid clindamycin unless needed for synergy

Back to Cases

- Case #1

  30 yo Female Smoker with psychiatric issues
  Right medial Maleous abscess growing from possible MSSA Septra S, and later *Pseudomonas aeurginosa* Cipro R, and *Enterobacter cloacae* Septra R.
  I & D 2x by ortho, little improvement with vac dressing and skin flap.
  pMHX: Asthma, atopic dermititis, frequent MSSA/MRSA cellulitits, post traumatic infected spinal hardware, frequent Pseudomonas line infections.
  On bendryl IV q4h for chronic urticaria Allergic to "All Antibiotics" MSSA tx with Vancomycin, what to treat GNBs?

  "All Antibiotics" = Penicillin, Amoxicillin, Cloxacillin, Septra, Biaxin, Clindamycin, Erythromycin, Haldol, Latex, Fucidin, Flamazine, Ancef, Keflex, Cipro, Gentamycin, Tetracycline, Flagyl, Sulfa drugs, Polysporin, Bacitracin, Betadine, Iodine containing solution, shellfish.

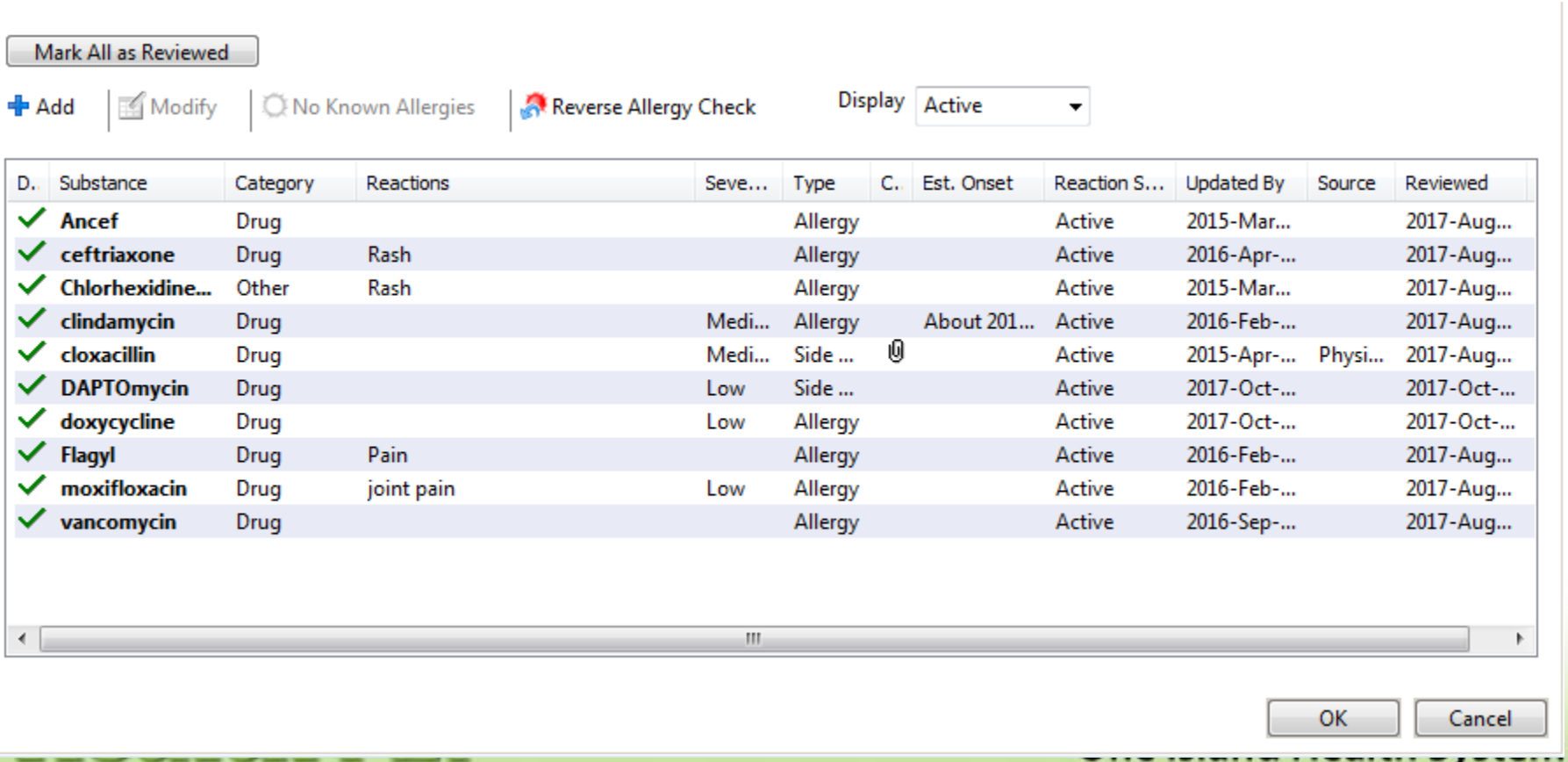
Case # 2

- 34 yo Lady 7 weeks gestation positive gonorrhea nucleic acid testing otherwise well with pMHX of a severe rash after penicillin remotely.

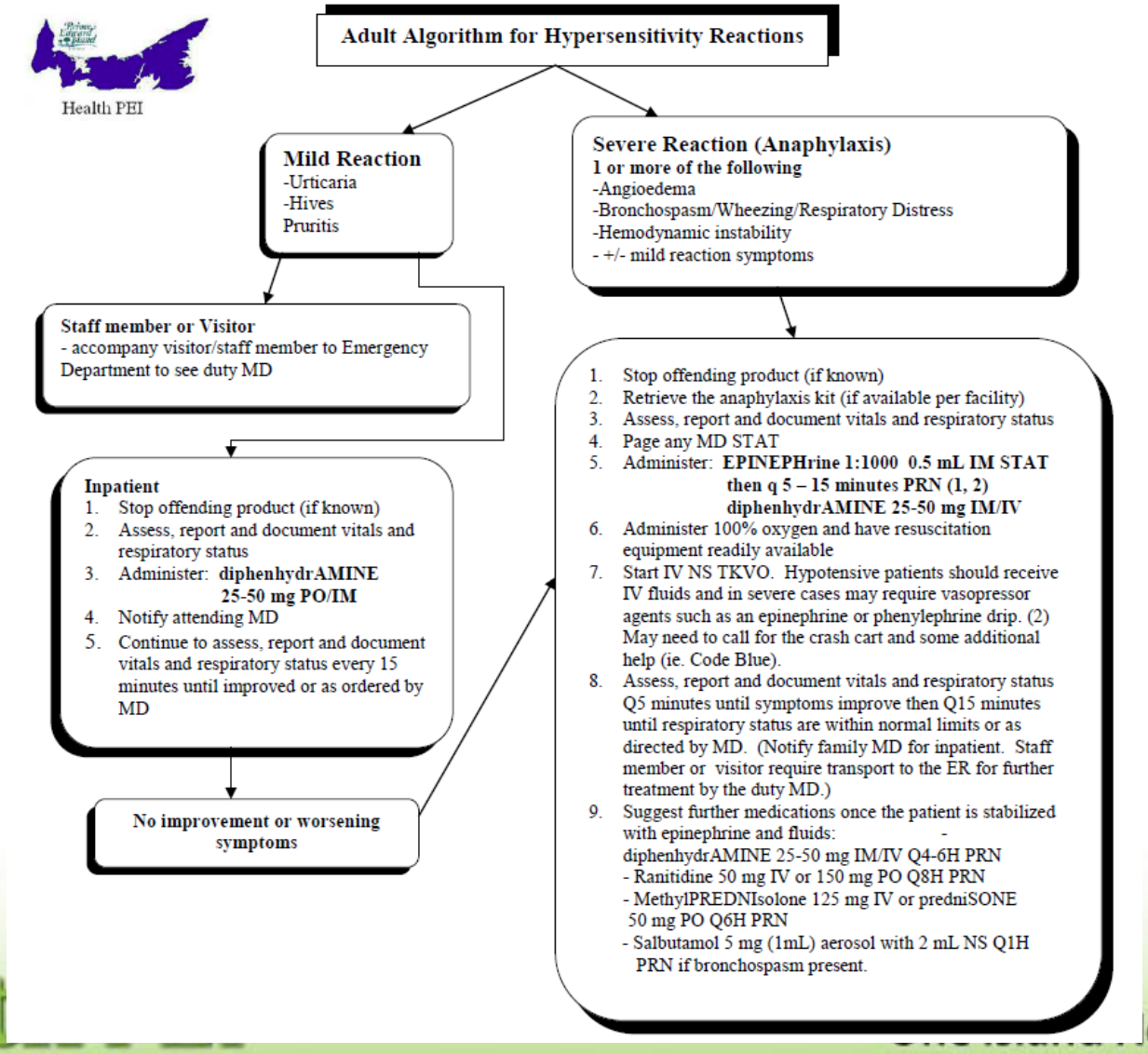
- Given Ceftriaxone IV one dose, watched carefully for 1 hour

- Consider Jarisch-Herxheimer Reaction

Bonus case…
35 yo F with ankle hardware infection



Just in case…


Health PEI
Adult Algorithm for Hypersensitivity Reactions
Mild Reaction
-Urticaria
-Hives
Pruritis
Severe Reaction (Anaphylaxis)
1 or more of the following
-Angioedema
-Bronchospasm/Wheezing/Respiratory Distress
-Hemodynamic instability
- +/- mild reaction symptoms
Staff member or Visitor
- accompany visitor/staff member to Emergency Department to see duty MD
Inpatient
1. Stop offending product (if known)
2. Assess, report and document vitals and respiratory status
3. Administer: diphenhydrAMINE 25-50 mg PO/IM
4. Notify attending MD
5. Continue to assess, report and document vitals and respiratory status every 15 minutes until improved or as ordered by MD
No improvement or worsening symptoms
1. Stop offending product (if known)
2. Retrieve the anaphylaxis kit (if available per facility)
3. Assess, report and document vitals and respiratory status
4. Page any MD STAT
5. Administer: EPINEPHrine 1:1000 0.5 mL IM STAT then q 5 – 15 minutes PRN (1, 2) diphenhydrAMINE 25-50 mg IM/IV
6. Administer 100% oxygen and have resuscitation equipment readily available
7. Start IV NS TKVO. Hypotensive patients should receive IV fluids and in severe cases may require vasopressor agents such as an epinephrine or phenylephrine drip. (2) May need to call for the crash cart and some additional help (ie. Code Blue).
8. Assess, report and document vitals and respiratory status Q5 minutes until symptoms improve then Q15 minutes until respiratory status are within normal limits or as directed by MD. (Notify family MD for inpatient. Staff member or visitor require transport to the ER for further treatment by the duty MD.)
9. Suggest further medications once the patient is stabilized with epinephrine and fluids:
- diphenhydrAMINE 25-50 mg IM/IV Q4-6H PRN
- Ranitidine 50 mg IV or 150 mg PO Q8H PRN
- MethylPREDNIsolone 125 mg IV or predniSONE 50 mg PO Q6H PRN
- Salbutamol 5 mg (1mL) aerosol with 2 mL NS Q1H PRN if bronchospasm present.

Health PEI

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No improvement or worsening symptoms

Severe Reaction (Anaphylaxis)
1 or more of the following
-Angioedema
-Bronchospasm/Wheezing/Respiratory Distress
-Hemodynamic instability
- +/- mild reaction symptoms

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Even though anaphylaxis events are rare management can be optimized

- Consideration for graded challenges
- Standard of care for desensitization
  - Consent Form
  - Beta blocker discontinuation (if possible)
  - Epinephrine 1: 1000 0.5ml IM predrawn
  - Diphenydramine 50mg IM/IV predrawn
  - Good IV access established if in acute care

Stewardship Champions

- “High Dose ; Short course”
- Offer Local Guidelines
- SAVE CIPRO
- AVOID COLLATERAL DAMAGE
  - STOP CLINDA / SWAP MOXI
  - Sort out the allergy, previous Cdiff
  - Probiotic
- IMMUNIZE

Review What is in the tool kit?

1. Using a different antibiotic side chain then PCN
   - Cefazolin, cefuroxime, ceftriaxone, meropenem
   - Future: Changes to CIS, ordersets
2. Graded dose challenges
3. Temporary Desensitization in ICU for type 1 allergies
4. Alternative non-beta lactam antibiotics
   - Use of fluoroquinolones or linezolid for gram positives
5. Allergy testing (if absolutely necessary)
6. A process for delisting allergies (Soon…)

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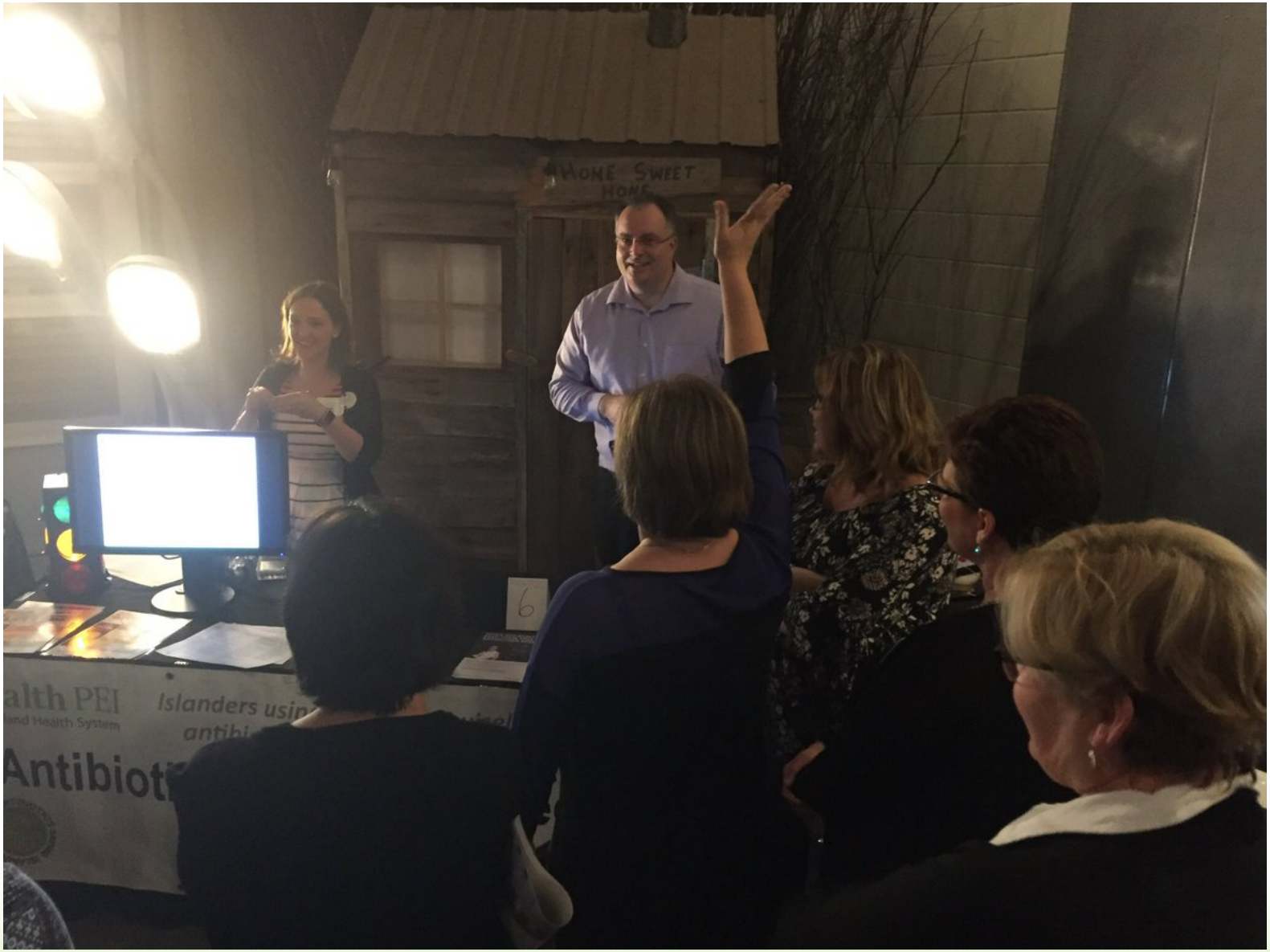
- Members of the NB Health Authorities Anti-Infective Stewardship Committee Working Group



Health PEI

One Island Health System