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This lesson is a knowledge-based CPE activity and is targeted to pharmacists and technicians in all practice settings.

Learning Objectives

At the completion of this activity, the participant will be able to:

1. State two positive changes you can make to your practice following participation in this series.
2. Summarize three practice updates or changes you acquired while participating in this series.

Disclosure

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Subcutaneous Immunoglobulin Infusions in the Treatment of Primary Immunodeficiencies

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There are over 400 different types of primary immunodeficiencies (PID) currently documented, with more being discovered each year[1]. Patients with this condition are much more likely to develop severe infections, autoimmune diseases, and inflammatory disorders when compared to the general population. One of the cornerstones of treatment for PID revolves around the replacement of immune globulins that these patients are missing. In the 1950's, this replacement was accomplished via intramuscular injection. The problem with this particular route of administration was that the injection was quite painful, and it was difficult to control the patient's serum immunoglobulin levels. In the 1980's subcutaneous immunoglobulin (SCIG) injections were being used as an alternative to this method, as it was less painful for patients and allowed for better control of serum levels. However, intravenous immunoglobulin (IVIG) would eventually replace SCIG therapy as larger volumes of immunoglobulin could be given to patients and could be completed faster. Now, with the addition of new SCIG medications and delivery systems, SCIG is becoming more common[2].

Depending on the situation and patient preferences, there are multiple advantages and disadvantages for using SCIG compared to IVIG (Table 1)[3]. Of particular note is the ability for patients to administer doses outside of a treatment facility. Depending on the level of comfort of the patient/caregiver there is little need for a patient to receive the infusions in a healthcare facility once tolerability results and proper techniques are addressed. Conversely, for patients who cannot tolerate the multiple infusion sites that can accompany SCIG administration, or who do not feel comfortable administering at home, IVIG still remains a viable alternative with advantages of its own. Some common side effects of SCIG include, but are not limited to, redness, swelling, and itching, all of which typically decrease after each subsequent infusion. More rare but serious side effects include serious

allergic reactions, kidney problems, or blood clots that would require immediate medical intervention[4].

Table 1: Advantages and Disadvantages of SCIG and IVIG

Advantages	**Disadvantages**
SCIG • Possible self-administration for patient freedom • Steady-state IgG levels easier to achieve • No venous access • Localized AE most common	SCIG • More frequent infusions which can lower patient adherence • Less monitoring available when used at home for adverse effects • Multiple injection sites usually required • Patient and parent hesitancy for in-home infusions
IVIG • Longer gaps between infusions • Well-studied safety profile • Mitigation strategies are well known	IVIG • Requires venous access • Systemic adverse reactions possible, like anaphylaxis • High pharmacokinetic variability • Cannot be done at home easily

There are 3 main types of infusion techniques of SCIG: infusion pumps, rapid push, and hyaluronidase-facilitated infusions. Infusion pumps allow for the delivery of large volumes to multiple sites in equal and simultaneous quantities. Typical infusion quantities will range from 5 – 60 mL per site (without hyaluronidase) at a rate of 20 – 50 mL/hour. Rapid push infusions, on the other hand, use only a syringe and needle to administer the immunoglobulin to patients. While some products are available in prefilled syringes, others require the patient or provider to draw up the dose. This method allows for 20 mL to be injected per site with administration time varying between 3 – 20 minutes depending on patient tolerability[5]. Lastly, the addition of hyaluronidase facilitated infusions (fSCIG) allowed for the delivery of larger quantities of immunoglobulin at dosing nearly the same as IVIG. The process involves the infusion of hyaluronidase at 1 – 2 mL/min followed directly by the infusion of immunoglobulin. Starting patients on fSCIG requires a ramp-up period of seven weeks to achieve maximum patient tolerability (Table 2). Once complete, patients can see infusion rates of up to 300 mL/hr[5,6]. Acceptable injection sites for all techniques are illustrated in Figure 1.

Table 2: fSCIG Ramp-Up Schedule

Week	Infusion Number	Dose Interval (dose example)
1	First infusion	One week dose (7.5 g)
2	Second infusion	Two week dose (15 g)
3		No infusion
4	Third infusion	Three week dose (22.5 g)
5		No infusion
6		No infusion
7	Fourth infusion	Four week dose (30 g)

HYQVIA. US Food & Drug Administration (FDA) approved product information. Revised September, 2014. US National Library of Medicine. Available online at www.dailymed.nlm.nih.gov (Accessed December 3, 2015)

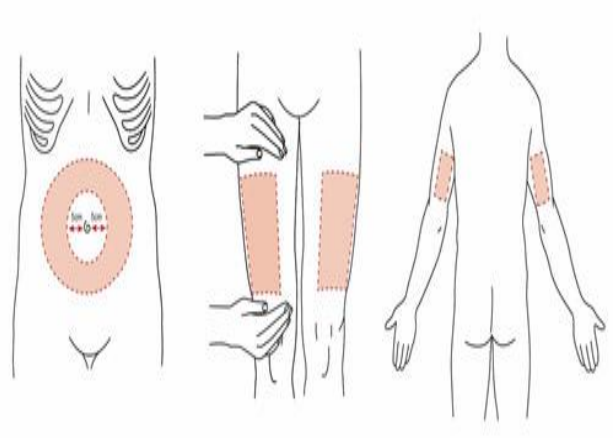

Figure 1: Acceptable Subcutaneous Injection Sites

Subcutaneous immunoglobulin (scig) therapy. https://www.allergy.org.au/patients/immunodeficiencies/scig-therapy-general-information. Published June 19, 2018. Accessed April 19, 2021.

Overall, SCIG offers a viable and sustainable alternative to IVIG infusions for patients with primary immunodeficiencies. With pros and cons to both administration techniques, providers will need to determine the most appropriate administration method for their patients. Specifically, SCIG provides increased patient freedom, multiple techniques, and decreased systemic reactions which gives providers the opportunity to tailor treatment specifically to patient preferences. As additional medications and techniques are released in the future, SCIG could continue to improve patient care.

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Oral Relugolix for Advanced Prostate Cancer

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The Center for Disease Control reports that 13 out of every 100 men will develop prostate cancer during their lifetime.[1] Of those 13 men, 2 to 3 of them will die from prostate cancer.[1] Not including skin cancer, prostate cancer is the most common cancer in American men.[1] Medical or surgical castration is often the choice for patients with prostate cancer to prevent disease progression. Castration levels (testosterone <50 ng/dL) are commonly achieved by using long-acting injectable luteinizing hormone releasing hormone agonists (LHRH) in the treatment of advanced prostate cancer.[2] However, LHRH agonists cause an initial surge in testosterone that sometimes leads to a clinical flare up with symptoms of bone pain, obstructive urinary symptoms and rarely, spinal cord compression.[2] The down regulation of luteinizing hormone-gonadal axis takes weeks, causing a delayed suppression of testosterone levels.[2] In some circumstances, the National Comprehensive Cancer Network (NCCN) recommends the use of antiandrogen therapy for the first few weeks after starting LHRH agonists to prevent the testosterone surge.[3]

Degarelix is a monthly depot injection gonadotropin-releasing hormone (GnRH) antagonist and is approved for androgen deprivation therapy (ADT).[4] It works by suppressing luteinizing hormone and follicle-stimulating hormone (FSH) and results in rapid testosterone suppression without an initial surge.[4] A major problem in its use is the incidence of injection site reactions in nearly 40% of patients.[4] New therapy is needed for patients with advanced prostate cancer, who do not want monthly or every three month injections and want to minimize adverse reactions.

New Therapy

Relugolix (Orgovyx™) was developed as the first oral, highly selective, GnRH antagonist that is given once daily. Relugolix is a nonpeptide GnRH antagonist that competitively binds to pituitary GnRH receptors, thus decreasing secretion of luteinizing hormone and FSH, resulting in a decreased testosterone levels.[5] The Food and Drug Administration approved relugolix for the treatment of advanced prostate cancer in December 2020 following the results of the phase III, multinational, HERO trial.[6]

Clinical Trial[7,8]

The HERO trial compared relugolix 120 mg orally daily (with a loading dose of 360 mg on day 1) to leuprolide acetate 22.5 mg by subcutaneous injection every 3 months, for 48 weeks. Patients were randomized 2:1 into the relugolix (n=622) and leuprolide (n=308) groups. The main efficacy outcome measure was sustained medical castration rate defined as achieving and maintaining serum testosterone levels <50 ng/dL by day 29 through 48 weeks.

In patients who received relugolix, maintained castration was seen in 96.7% of patients (95% CI, 94.9 to 97.9) compared to leuprolide with 88.8% (95% CI, 84.6 to 91.8). Relugolix demonstrated noninferiority with respect to sustained castration rate, within the noninferiority margin of -10 percentage points, so a superiority test was done. In the superiority test, relugolix was found to be superior over leuprolide with a difference of 7.9 percentage points (95% CI, 4.1 to 11.8, $p<0.001$). 56% of patients in the relugolix group obtained castration levels by day 4 and 98.7% of patients

by day 15, compared to 0% and 12% in the leuprolide group, respectively. Mean testosterone levels at day 90 after treatment discontinuation in the subgroup (184 patients) were 288.4 ng/dL in the relugolix group and 58.6 ng/dL for leuprolide patients.

The incidence of adverse events were similar between groups. Hot flash was the most common with 54.3% in the relugolix group and 51.6% in the leuprolide group. Diarrhea was higher in the relugolix group than leuprolide group at 12.2% and 6.8%, respectively. After 48 weeks of treatment, relugolix showed a 54% lower risk of major adverse cardiovascular events (MACE) compared to leuprolide (HR, 0.46; 95% CI 0.24 to 0.88).

Role in Therapy

Relugolix provides several advantages compared to leuprolide. The first advantage is how fast testosterone can be suppressed and there is no initial surge of testosterone, leading to fewer initial side effects.[7] The second advantage is for patients receiving intermittent therapy. After 90 days after discontinuation of treatment, 54% of men had recovery of testosterone within normal limits compared to only 3% men in the leuprolide group.[7] With cardiovascular events being a leading cause of death in patients with prostate cancer, another advantage of relugolix is the decreased incidence of MACE compared to leuprolide.[7,9]

Relugolix has not been studied in combination with other androgen receptors antagonist, or in combination with docetaxel or cabazitaxel chemotherapy. Potential interactions include the induction of cytochrome P450 enzymes and cardiac QTc interactions with abiraterone.[3] Current NCCN guidelines state that further studies of relugolix dosing and drug interactions with commonly used drugs in advanced prostate cancer are needed.[3]

Relugolix has shown benefits for men with confirmed adenocarcinoma of the prostate and are candidates for at least 1 year of continuous ADT.[7] Pharmacists can play a role in helping determine if a patient is eligible to receive relugolix and provide counseling.

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Community-Acquired Pneumonia Adult Treatment Guidelines and Alaska State Antibiogram Update

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Background:

Community acquired pneumonia (CAP) is the second most common causative infectious disease that leads to hospitalization in the United States and accounts for approximately 650 admissions per 100,000 adults per year.[1-3] The Infectious Diseases Society of America (IDSA) reports the most infectious bugs leading to infection include *Streptococcus pneumonia*, *Haemophilus influenza*, *Mycoplasma pneumonia*, *Staphylococcus aureus*, *Legionella* species, *Chlamydia pneumonia*, and *Moraxella catarrhalis*.[4] Virological causes of pneumonia are also possible including influenza A &B, adenovirus, respiratory syncytial virus, parainfluenza, and the novel coronavirus (COVID-19).

Treatment recommendations are initially based on the patient's severity on presentation to determine if they should be managed in the inpatient setting or if it is safe to manage in the outpatient setting. The diagnostic tool of choice for this decision is the Pneumonia Severity Index, recommended by the IDSA. Patients who present within Risk Class I or II can be managed outpatient,

Risk Class III can be managed either inpatient or outpatient, while Risk Class IV and V should be managed inpatient as they carry the highest risk of mortality (8.2-29.2%).[4]

The treatment of any infectious disease should be tailored to a specific patient population with the most common bacteria as the primary target, however, rates of resistance and prevalence of infections can vary based on physical location. For this reason, reference to the most up to date antibiogram will help empirically treat patients based on accumulated evidence and can help decrease rates of resistance by narrowing the treatment spectrum.

The Alaska Antimicrobial Stewardship Collaborative (A2SC) has published updated treatment guidelines that are specific to the patient population within Alaska. This update is accompanied by an update to the 2019 Alaska State Antibiogram.

Treatment: For those patients in Risk Class I-III who can be managed in the outpatient setting, treatment should be based on the patient's risk factors for MRSA or *Pseudomonas aeruginosa* infection. As supported by the IDSA 2019 CAP treatment guidelines, patients without these risk factors can be treated with amoxicillin 1gm PO TID for 5-7 days as monotherapy, or doxycycline 100mg PO BID for 5-7 days if penicillin allergic. This is a change from previous recommendations which previously included concomitant azithromycin.[4] It should be noted that azithromycin monotherapy is no longer recommended as the rates of resistance exceed 25% within our population.

Should the patient have risk comorbidities such as heart, lung, liver, or renal disease, diabetes mellitus, asplenia, malignancy, or chronic alcoholism the recommended treatment is amoxicillin/clavulanate 875/125mg PO BID for 5-7 days with azithromycin 500mg PO daily for 3 days. Penicillin allergic patients can be treatment with cefuroxime plus azithromycin or levofloxacin monotherapy depending on their allergy.

Patients that have risk factors for MRSA or pseudomonas aeruginosa, such as prior isolation of either pathogen or hospitalization within the last 90 days with antibiotic administration, should be treated based on previous culture and susceptibility data and patient specific data.

Inpatient management and empiric treatment will rely on the patient's severity of infection (severe vs. non-severe). Major and minor criteria that will affect this decision are listed in Table 1. Severe pneumonia is classified as a patient who has either 1 major criterion or $\geq$ 3 minor criteria at one time; all other patients who do not fit this presentation are considered to have non-severe pneumonia.

Preferred therapy for both severe and non-severe CAP includes ceftriaxone 1g plus azithromycin 500mg daily. Of note, for patients with non-severe CAP who have been hospitalized within the last 90 days and have received IV antibiotics it is no longer recommended to empirically cover for MRSA or *Pseudomonas aeruginosa*. This recommendation for empiric coverage is only recommended for those patients who have severe CAP. Anaphylactic reactions to beta-lactam antibiotics can be managed with levofloxacin 750mg daily with an option to add vancomycin 15mg/kg if the infection is classified as severe. As always, prior cultures and susceptibilities should be referenced in order to make the most informed decision. Prior infection with MRSA or *Pseudomonas aeruginosa* should include vancomycin or cefepime, respectively.

Duration of therapy will generally depend on the patient's clinical course and they should be afebrile for at least 48 hours and clinically stable before stopping antibiotics. Five days of treatment should be sufficient for patients without structural lung disease or immunosuppression, seven days if mild/moderate, or 10-14 if there is a poor clinical response, inappropriate empiric therapy, or significant immunosuppression.

Table 1: Major and Minor Criteria

Major Criteria	Minor Criteria
Septic shock + vasopressors OR Respiratory failure + mechanical ventilation	Resp. Rate $\geq$ 30 Pao2/FIo2 ratio $\leq$ 250 Multilobar infiltrates Confusion Uremia (BUN $\geq$ 20) Leukopenia (WBC $\leq$ 4000) Thrombocytopenia (PLT $\leq$ 100,000) Hypothermia ($\leq$ 36C) Hypotension requiring aggressive fluid resuscitation

Standard - Preferred

- Severe and Non-severe: Ceftriaxone 1g IV q24hr + Azithromycin 500mg PO/IV q24hr x 3 days
  - *Anaphylaxis to beta-lactams*
    - Non-severe pneumonia: Levofloxacin 750mg PO/IV q24hr
    - Severe pneumonia: Levofloxacin 750mg PO/IV q24hr +/- Vancomycin

Hospitalized within 90 days + IV ABX

- Non-severe: not recommended to empirically treat for MRSA or *Pseudomonas aeruginosa* - fullow cultures
- Severe: vancomycin 15mg/kg and cefepime 2g IV q8hr for MRSA or *Pseudomonas aeruginosa* respectively

Prior MRSA or Pseudomonas

- Preferred:
  - MRSA -- Vancomycin 15mg/kg + ceftriaxone 1g IV q24hr + azithromycin 500mg IV/PO q24hr x 3 days
  - Pseudomonas -- Cefepime 2gm IV q8hr + azithromycin 500mg PO/IV q24hr x 3 days
- *Anaphylaxis to beta-lactams*
  - MRSA -- Vancomycin 15mg/kg + Levofloxacin
  - Pseudomonas -- Levofloxain 750mg PO/IV q24hr + aztreonam 2gm IV q8hr

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No comorbid conditions or Hx of MRSA or Pseudomonas

- Preferred: amoxicillin 1gm PO TID x 5-7 days
- Alternative: doxycycline 100mg PO BID x 5-7 days

Comorbidities*

- Preferred: amoxicillin/clavulanate 875/125mg PO BID x 5-7 days + azithromycin 500mg PO daily x 3 days
- PCN allergy:
  - Non-anaphylactic reaction -- cefuroxime 500mg PO BID x 5-7 days + azithromycin 500mg PO daily x 3 days
  - Anaphylaxis -- levofloxacin 750mg PO daily x 5 days

Risk factors for MRSA or Pseudomonas**

- Treat based on previous cultures - will likely require further work up and evaluation.

*chronic heart, lung, liver, or renal disease; diabetes mellitus, alcoholism, malignancy, asplenia.
**prior isolation of said pathogen in respiratory culture OR recent hospitalization + use of IV antibiotics within 90 days

See below to download the treatment guidelines and state antibiogram.
CAP guidelines: https://www.ashnha.com/antimicrobial-stewardship/
AK 2019 Antibiogram: https://www.ashnha.com/wp-content/uploads/2021/05/AK-2019-Antibiograms-5-5-21.pdf

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Polypharmacy and Deprescribing

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Polypharmacy is defined as the regular use of five or more medications. There are several patient-related risk factors that can lead to polypharmacy such as old age, having multiple medical conditions or a chronic health condition, being treated by multiple providers, and residing in a long-term care facility. In addition, a poorly updated medical record, automated refill services, poor transition of care, and inappropriately prescribed medications can contribute to polypharmacy.[1,2] Since many of these risk factors can be identify through working at the pharmacy, pharmacy personnel can play a key role in identifying polypharmacy and evaluating potential medications to deprescribe.

Deprescribing is the "process of identifying and discontinuing drugs in which existing or potential harm outweighs existing or potential benefits within the context of an individual patient's care goals, current level of functioning, life expectancy, values, and preferences."[1] Identifying patients with potential medications to deprescribe can increase the patient's quality of life, improve global health improvements and other outcomes, decrease the risk of adverse events and mortality, and decrease the overall cost of healthcare. Deprescribing to reduce polypharmacy has also been shown to be safe and effective in several studies. In the DART-AD trial, discontinuing antipsychotics in patients with dementia showed to be successful by improving overall survival without showing changes in behavior.[3] In the RedUSe Project, deprescribing benzodiazepines and psychotropics in a residential care facility was successful and resulted in lower overall prescribing rates.[4]

Deprescribing should be initiated when possible, in certain patient populations. Patients with revised goals of care due to limited life expectancy, very old age, or cognitive impairment should be assessed for potential medications to deprescribe. In addition, complex patients with multiple morbidities, eight or more medications, or multiple prescribers should be assessed. Lastly, patients at higher risk for medication adverse reactions or with a history of nonadherence should be examined.[1,5,6]

After identifying potential candidates, healthcare providers should assess the patient's medication list and evaluate possible medications to deprescribe. There are several resources healthcare providers can use to do so:[1,2]

Resource	Description
Anticholinergic Risk Scale/ Anticholinergic Drug Scale	Used to assess the burden and risk of adverse events associated with use of anticholinergic drugs
Beer's Criteria	List of medications to avoid in older adults and alternatives to use instead
Bruyere Research Institute and the Canadian Deprescribing Network (deprescribing.org)	Guidelines and algorithms for discontinuing proton pump inhibitors, antihyperglycemics, antipsychotics, benzodiazepines, cholinesterase inhibitors, and memantine.

MedStopper (medstopper.com)	Recommendations on which medications to discontinue or switch
START/ STOPP Criteria	List of drug therapies that are potentially inappropriate for older people and should be discontinued

In addition, there are several methods of deprescribing. First, healthcare providers can initiate direct intervention. In this approach, the provider stops ordering that specific medication for the patient without any patient input. Another approach, provider education, can also be used to monitor, report, alert, educate, and suggest the patient to stop taking certain drugs. The last and most effective method is using patient engagement. In this approach, the healthcare provider uses shared decision making to ensure the patient is self-motivated to make the change.[7] Regardless of which method is used, the deprescribing protocol, or CEASE algorithm, should be followed in order to properly Confirm, Estimate, Assess, Sort, and Eliminate medications.[8] In addition, once a deprescribing plan is implemented, the healthcare provider should follow-up and review the patient at each visit.

Confirm	Verify the patient's medication history, adherence, and indication for each drug
Estimate	Consider the overall drug risk and determine the required intensity of the intervention

Assess	Assess each drug for its eligibility to be discontinued
	• Consider patient goals
	• Consider costs
	• Consider feasibility
	  ○ Patient's understanding, functional limitation, and ability to follow plan
	  ○ Rebound symptoms
	  ○ Withdrawal symptoms
	  ○ Patient's attachment/motivation to deprescribe
	  ○ Patient-provider trust

Sort	Prioritize drugs for discontinuation • Consider starting with medications that have the highest risks but lowest benefits • Consider stopping medications with the lowest likelihood of withdrawal or rebound symptoms • Consider if a taper is needed
Implement	Discontinue the drug and monitor the patient's status • Provide discontinuation instructions • Develop a monitoring plan • Develop a contingency plan

Resources:

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