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Pharmacy-Based Test and Treat Certificate Training Program

Live Seminar

Accreditation

The American Pharmacists Association (APhA) and the University of Florida College of Pharmacy are accredited by the Accreditation Council for Pharmacy Education (ACPE) as providers of continuing pharmacy education.

Test and Treat Certificate Course Contact Hours: 20.0 hours total (self-study: 12 hours; live: 8 hours)
Intended Audience: Pharmacists in all practice settings who would like to test and treat for minor, nonchronic health conditions
Dates: 02/01/2021-02/28/2023
Activity Type: Practice-Based

This live training seminar is approved for 8 hours of ACPE continuing pharmacy education credit **(UAN: 0012-0000-21-007-B04-P)** Credit for the live seminar portion of the program will be earned upon full attendance of live seminar, performing skills assessment, and completion of a final assessment with a score of at least 70%. Upon successful completion of the program, participants will earn a Certificate of Achievement available online on the participant's My Training page in the APhA learning management system: www.pharmacist.com/Education/Certificate-Training-Programs.

APhA's Pharmacy-based Test and Treat certificate training program is a joint program between APhA and the University of Florida College of Pharmacy. **The program was developed by the University of Florida. Copyright © 2021 by the University of Florida College of Pharmacy.** All rights reserved.

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Acknowledgements: Advisory Board

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Disclosure Statements

All presenters and contributors have disclosed that they have no relevant financial disclosures. No one else in a position to control content has any financial relationships to disclose.

Disclaimer: Content provided in this presentation is deemed accurate and current at the time of publication. Recommendations change often, therefore, learners are encouraged to verify all information before treating patients or employing the practices described in this activity.

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Learning Objectives

Upon the completion of this program, the learner will be able to:

- Identify opportunities for expanding patient-centered services in the pharmacy setting, using point-of care testing
- Discuss the value of collecting patient reported symptoms, medical history, and medication allergies using the Pharmacist Patient Care Process (PPCP)
- Describe and perform physical assessments, when appropriate to patient care, which may include but are not limited to: blood pressure, pulse, respiratory rate, oxygenation, cervical lymph node inspection, body temperature, throat exam, and skin assessment
- Describe and perform the following specimen collections used in point-of-care testing: throat swab, nasal swab, and finger stick blood collection

Learning Objectives (cont)

Upon the completion of this program, the learner will be able to

- Identify patients who should receive treatment for minor, nonchronic conditions and uncomplicated infections, including identification of “red flags” indicating more severe illness and appropriate actions
- Apply this information to patient-specific cases focusing on influenza, streptococcus, and other minor infections
- Discuss strategies and techniques for writing and entering into a successful point-of-care protocol agreement
- Develop policies and procedures for a CLIA-waived laboratory model

Live Seminar Agenda

- Current Landscape of Pharmacy Practice
- Test and Treat for Emerging Infectious Diseases
- Patient Case Discussion
- Developing and Implementing a Protocol Agreement
- Establishing a Point-of-Care Testing Site
- Patient Assessment and Specimen Collection Techniques
- Wrap-up and Skills Assessment

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Housekeeping

- Learners are expected to actively participate in today's live seminar
  - Will work on activities with a partner
- Live Seminar Participant Handout contains instructions for each activity to follow along
  - Will NOT be required to submit handout
- Supplies for skills assessment are provided
  - Limited supply so please only use the materials when instructed

Presenting Faculty & Assessors

- Joshua Pullo, PharmD, CPh
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CURRENT LANDSCAPE

Evolution of Pharmacy Practice

Industrial Revolution (1800s)

Mass manufacture of medicinal products

Soda Fountain Era (1920-1949)

Emphasis on increasing front-end commercial interest via soda fountains and other goods for purchase

Lick, Stick, Pour, & More Era (1950-1979)

Provision of patient care services replaced dispensing as the highest professional activity

Ninth Floor Project revolutionized clinically-focused pharmacy roles in the hospital setting

Pharmaceutical Care Era (1980-2009)

Provision of Medication Therapy Management (MTM) services and immunization authority

Development of the first community pharmacy residencies

Post-Pharmaceutical Care Era (2010-present)

Expansion of immunization-related scope of practice

Interprofessional care with collaborative practice agreements and point-of-care testing

Percent of students pursuing residencies doubled

COVID altered landscape of healthcare

PRODUCT *shift in focus* **PATIENT**

(Urick and Meggs, 2019)

Pharmacists' Unique Position to Improve Access to Care

- In 2017, average time between patient calling a doctor's office and seeing any physician for a new patient visit was 24 days
- 9 out of 10 Americans live within five miles of a pharmacy
- Patients visit their community pharmacist 12 times more frequently than their primary care provider

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(Sacdev, et.al, 2020)
(Strand, 2020)
(CDC, 2018)

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Point-of-care testing isn't just the *convenient* option; for some, it's the only option

Findings from a multicenter study analyzing 55 community pharmacies offering POCT for streptococcal pharyngitis from October 2013 to August 2014

Only a little over 50% of the patients had a primary care provider

More than 40% accessed the POCT service during evening hours, weekends, and holidays

(Collins, 2021)
(Klepser 2003)

What's the ‘Point' of Point-of-Care Testing?

- Point-of-care testing provides unique opportunity for pharmacists to work with other healthcare providers to test for and treat minor, nonchronic health conditions
  - Accessibility of pharmacies
  - Many patients go to pharmacies early in the course of infectious diseases to gain symptom relief before going to other healthcare facilities
  - Pharmacist training to collect data important to the provision of care
- Not all point-of-care tests are 'Test and Treat' eligible
  - Think about disease states that can be safely treated in the outpatient setting
  - Applies mostly to nonchronic conditions

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(Herbin, 2020)

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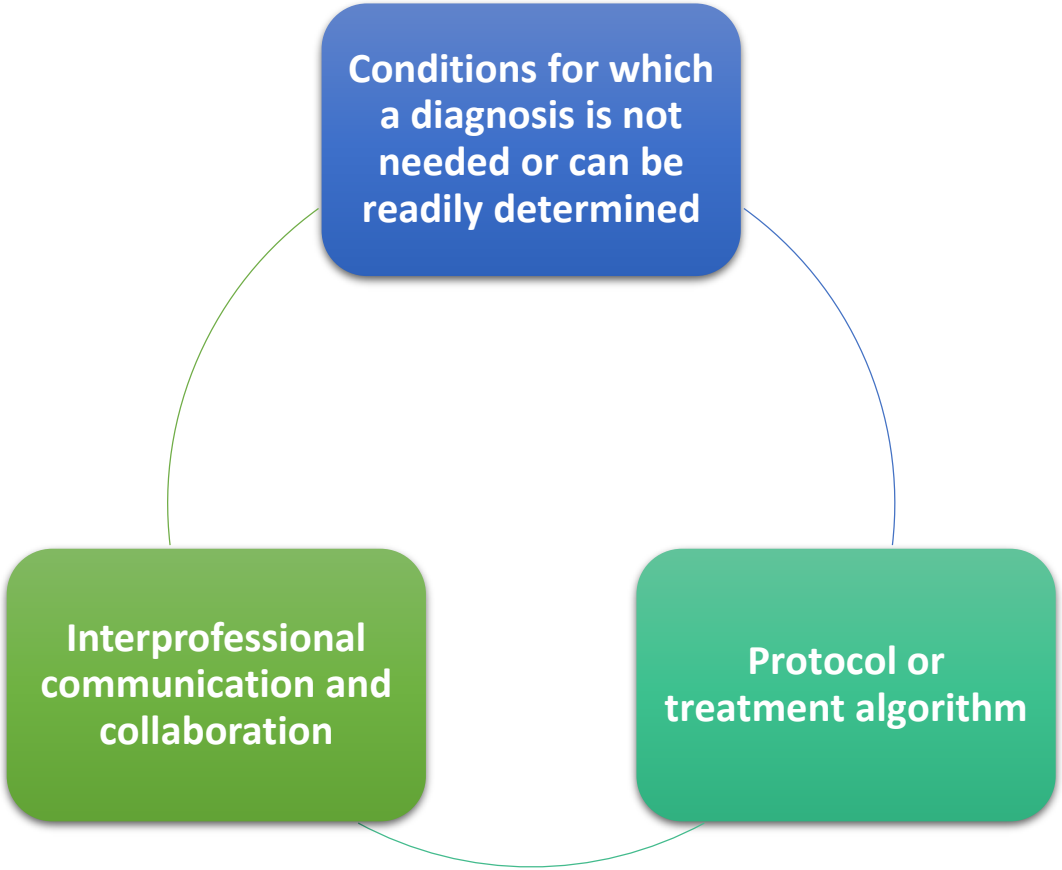
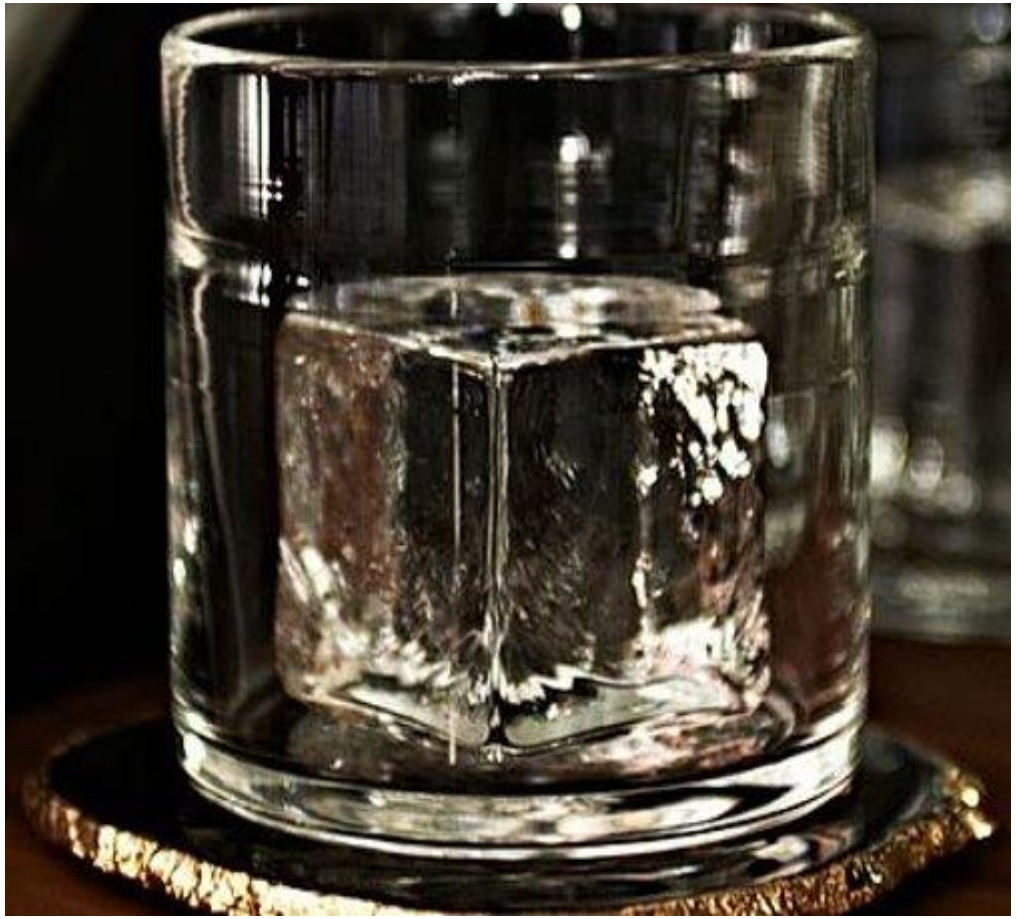
Crucial Features for Pharmacist Prescriptive Authority



(Sachdev, 2020)

Ice Breaker



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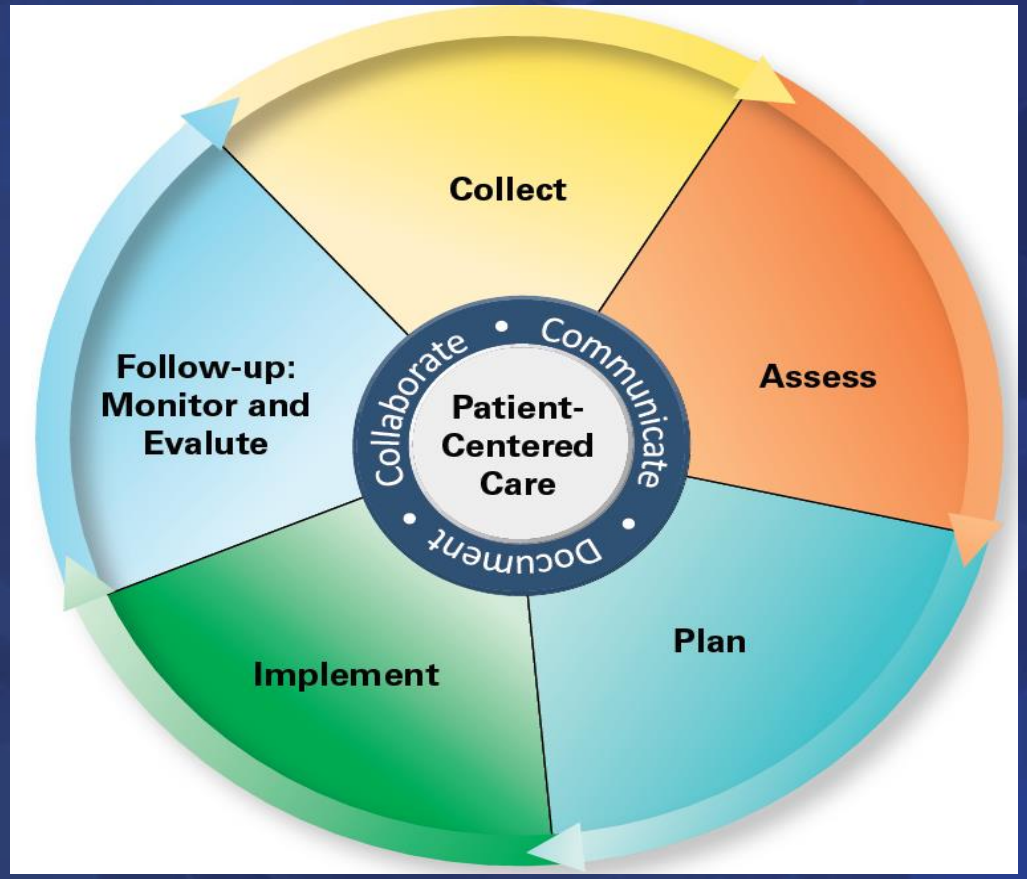


The Pharmacist Patient Care Process

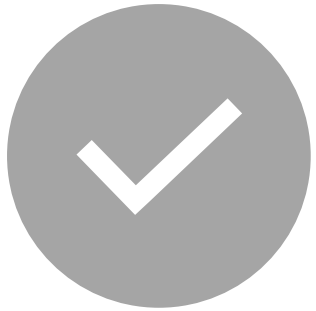
Collect

Gathering of necessary subjective and objective information about the patient:

- A current medication list and medication use history for prescription and nonprescription medications, herbal products, and other dietary supplements
- Relevant health data that may include medical history, health and wellness information, biometric test results, and physical assessment findings
- Patient lifestyle habits, preferences and beliefs, health and functional goals, and socioeconomic factors that impact access to medications and other aspects of care

Objective Patient Data

PHYSICAL EXAM



DIAGNOSTIC REPORTS

BIOMETRIC TESTS

MEDICAL RECORD DATA

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Subjective Patient Data

Patient Factors

- Preferences
- Beliefs
- Feelings
- Perceptions
- Values
- Ideas
- Demographics
- Goals
- Lifestyle
- Habits

Disease-Focused

- Reason for seeking care
- Symptoms
- History of present illness
- Past illnesses
- Family history
- Pain assessment, if applicable

(Joint Commission of Pharmacy Practitioners, 2014)

Medication-Related

- Medication history
- Medication experience

History of Present Illness (HPI) Methods

- A description of the development of the patient's present illness
- A chronological description of the progression of the patient’s current illness from the first sign and symptom to the present
  - **SCHOLAR-MAC**

SCHOLAR-MAC

Category	Information to Gather
Symptoms	What are the main and associated symptoms?
Characteristics	Describe the symptoms (how often, how severe, how long have you had them?)
History	What has been done so far? Has this happened in the past?
Onset	When did it start?
Location	Where is the location of the problem/where do you feel symptoms?
Aggravating Factors	What makes it worse?
Remitting Factors	What makes it better?
Medications	What medications do you currently take? Prescription, over-the-counter, herbals
Allergies	What medication allergies do you have?
Conditions	What medical conditions do you have?

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(APhA, 2019)

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MVP of Point-of-Care Tests = SCHOLAR-MAC

- Several nonchronic minor conditions are identified with thorough patient workup and assessment rather than a point-of-care test
- SCHOLAR-MAC applies to all patients presenting with a chief complaint looking for a treatment recommendation
  - Also applies to non-POCT patients
  - SCHOLAR-MAC essential for over-the-counter recommendations for our POCT patients who test negative

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(APhA, 2019)

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Minor, Nonchronic Conditions

SCHOLAR-MAC RELEVANT FOR ALL	
Influenza	Mild Acne
Group A streptococcal pharyngitis	Burns
Vaginal candidiasis	Tinea infections
Urinary Tract Infection	Head lice
	Allergic Rhinitis
	Cough
	Cold Sores
	Herpes Zoster

Assess

- Review all information collected to determine clinical effectiveness of patient's therapy in achieving overall health goals and to identify any potential problems.

- Based on the collected information, what does the patient likely have going on currently?
  - Is a referral warranted now or should we proceed with Test and Treat protocol?
  - Based on test results, should we treat or refer?

Plan

- Development of a patient-centered care plan which:
  - Treats condition according to established protocol
  - Addresses medication-related problems and optimizes medication therapy
  - Takes allergies and potential drug interactions into account when deciding possible treatments
  - Sets goals of therapy for achieving clinical outcomes in the context of the patient's overall health care goals and access to care
  - Engages the patient through education, empowerment, and self-management
  - Supports care continuity including follow-up and transitions of care as appropriate

(Joint Commission of Pharmacy Practitioners, 2014)

Implement

- Put the patient-centered care plan into action:
  - Initiate medication therapy as authorized per protocol
  - Address medication- and health-related problems, and engage in preventive care strategies, including vaccine administration
  - Provide education and self-management training to the patient or caregiver
  - Contribute to coordination of care, including the referral or transition of the patient to another health care professional

(Joint Commission of Pharmacy Practitioners, 2014)

Follow-up: Monitor and Evaluate

- Determine if the care plan is working or needs adjustment:
  - Follow-up with patient within established timeline
  - Have any new medication or health-related problem arisen?
  - Evaluate medication regimen again especially for adherence
  - Monitor clinical goals and outcomes
    - Is the patient making progress toward therapy
  - Does care plan need adjustment?
- Schedule additional follow-ups as needed

(Joint Commission of Pharmacy Practitioners, 2014)

Test and Treat for Emerging Infectious Diseases

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Group A Streptococcal (GAS) Pharyngitis

Patient Case

LL is a 10 year-old male presenting to your pharmacy with his mom in late December and complaining of sore throat and cough. Mom states LL has had some hoarseness in his voice over the past few days and some sweats but no runny nose, and not really running a fever at home. Several of his classmates have had similar symptoms recently.

https://thumbs.dreamstime.com/b/little-sick-boy-pharmacy-coughing-drugstore-copy-space-ill-young-suffering-seasonal-flu-152211837.jpg

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Brief Review of Group A *Streptococcus*

- Gram positive, beta-hemolytic cocci in chains
- Primary reservoirs:
  - Nose, throat, skin
- Transmission:
  - Air via respiratory droplets
  - Person to person via close contact
  - Rarely via food
- Common infections:
  - Pharyngitis
  - Skin and soft tissue infections
  - Scarlett Fever
  - Acute Rheumatic Fever

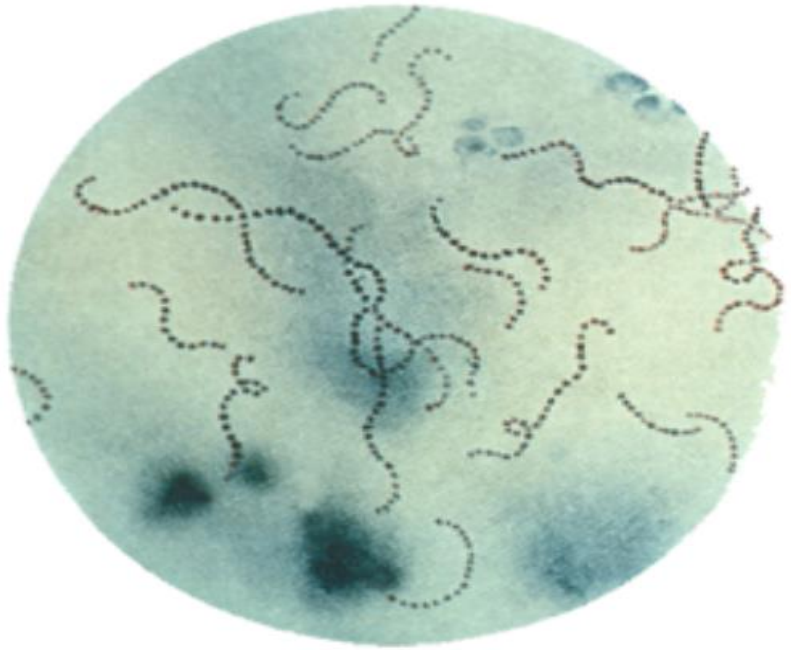
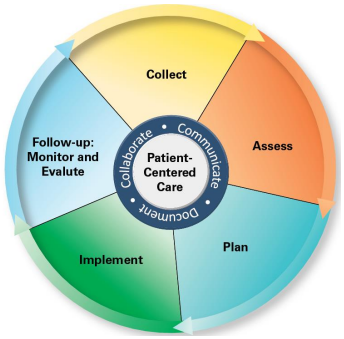


Photo from: https://www.cdc.gov/groupastrep/diseases-hcp/strep-throat.html

(CDC, 2016)

Collect: Summary



Evaluate Symptoms + Throat Exam + Throat Swab = GAS pharyngitis diagnosis

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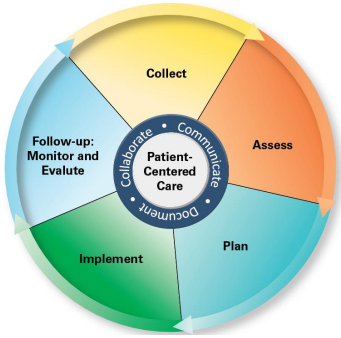
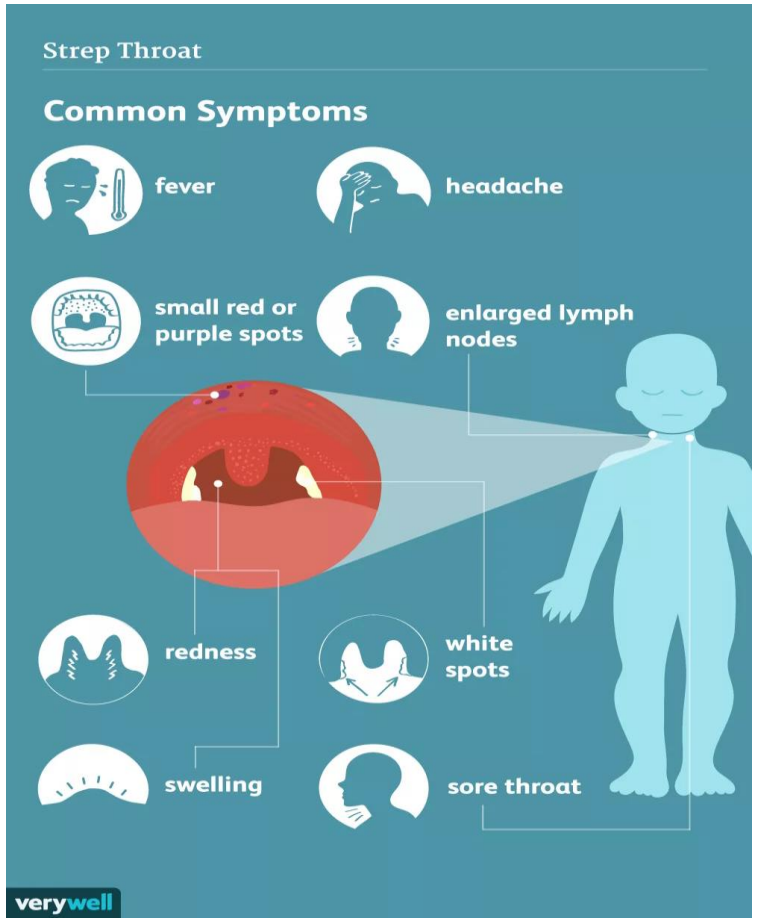
(Shulman. *Clinical infectious diseases.*2012;55(10):e86-e102)

Collect: Typical Presentation of Strep





Common signs and symptoms:

- Tonsillopharyngeal erythema and exudates
- Swollen, red uvula
- Soft palate petechiae
- Odynophagia (painful swallowing)
- Fever
- Lymphadenitis (swollen lymph nodes)
- Headache
- Abdominal pain
- Winter/early spring presentation

Incubation period of Group A streptococcal pharyngitis = 2 to 5 days

Photo from: https://www.verywellhealth.com/strep-throat-symptoms-1192160

(Shulman. *Clinical infectious diseases.*2012;55(10):e86-e102)

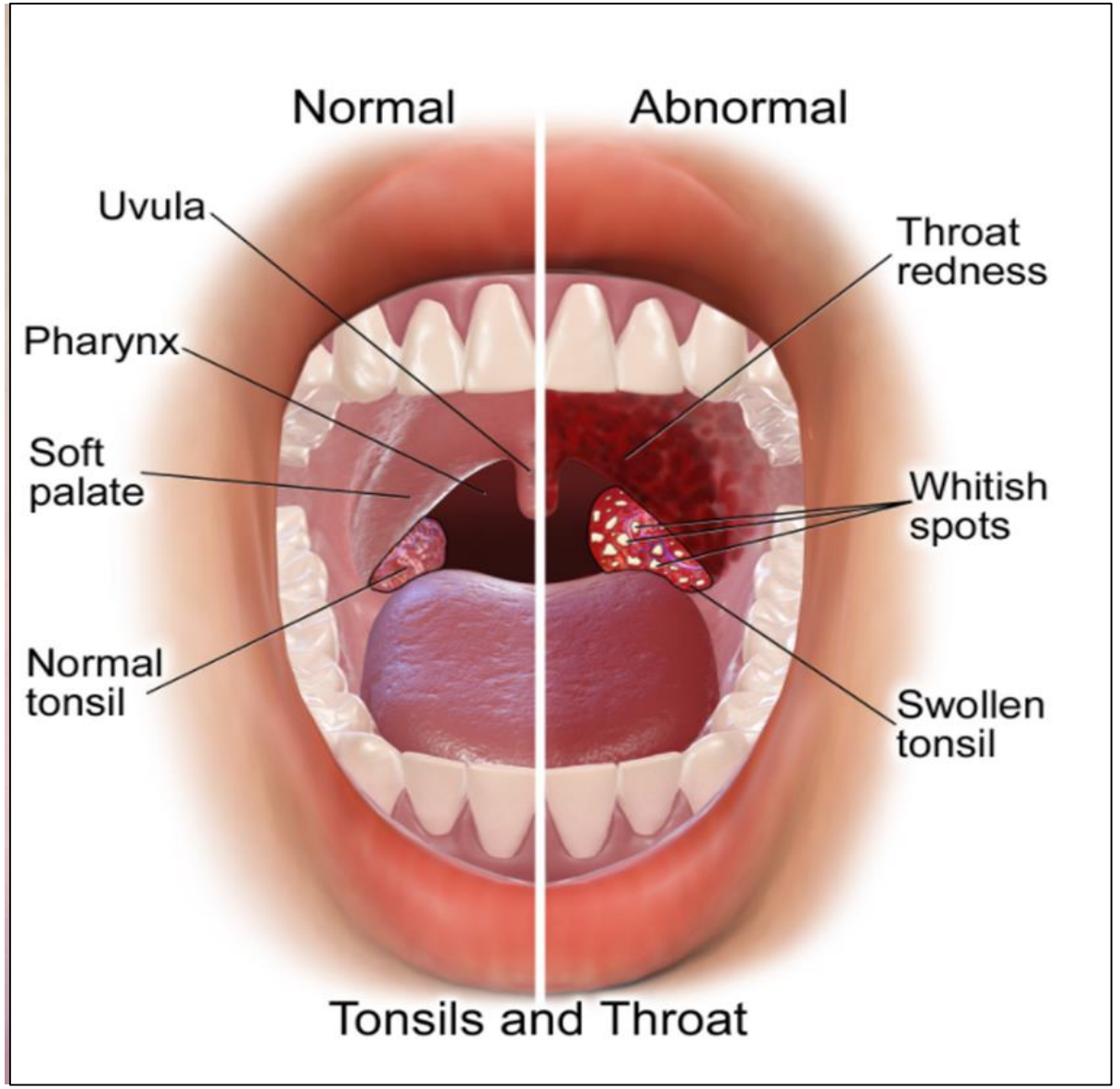
Collect: Physical Assessment

- Complete history of present illness
  - 70-95% of sore throat cases are caused by **viruses**
    - Symptoms associated with viral infection: rhinorrhea, cough, oral ulcers, hoarseness
- General appearance of patient
- Check all vitals
- Consider lymph node palpation
- Visually examine mouth and throat

(Shulman. *Clinical infectious diseases.*2012;55(10):e86-e102)

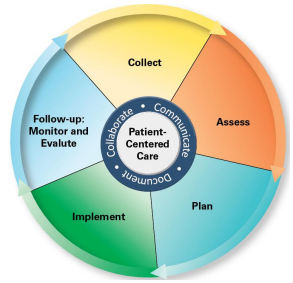
Visual Throat Exam

- Inspection by examining mouth systemically (use a bright torch and tongue depressor):
  - Tongue
  - Hard and soft palate
  - Tonsillar fossa
  - Gingivolabial/gingivobuccal sulci
  - Floor of mouth/undersurface of tongue



https://cdn.theydiffer.com/wp-content/uploads/2017/05/cws_5928e68f47be3.png; https://phil.cdc.gov/details.aspx?pid=3185

Assess: Green/Yellow/Red Flags



PROCEED WITH T&T: Patients > 3 years old presenting with symptoms consistent with GAS pharyngitis with a positive test result

CAUTION: Strong suspicion of viral etiology

RED FLAGS → REFER

- Children < 3 years old
- Systemic signs of infection
  - Hypotensive, tachycardia, shortness of breath
- Co-infection with influenza, COVID, mononucleosis
- Treated with antibiotics previously for same illness
- Symptoms consistent with Scarlet Fever
  - Red rash on trunk, strawberry tongue, paleness around mouth
  - Symptoms consistent with poststreptococcal glomerulonephritis
  - Hematuria
- Recurrent episodes of pharyngitis

May require more emergent evaluation

(Shulman. *Clinical infectious diseases.*2012;55(10):e86-e102)

Point-of-Care Testing for Strep: Throat Swab

- GAS only responsible for 5-15% of pharyngitis episodes in adults and 20-30% in children

- **Test types:**
  - **Polymerase Chain Reaction (PCR) test**
    - PCR has 95.5% sensitivity and 99.3% specificity
    - PCR results in 8-18 minutes
  - **Rapid Diagnostic Test (RDT)**
    - RDT has 85.5% sensitivity and 93.7% specificity
    - RDT results in 5 minutes

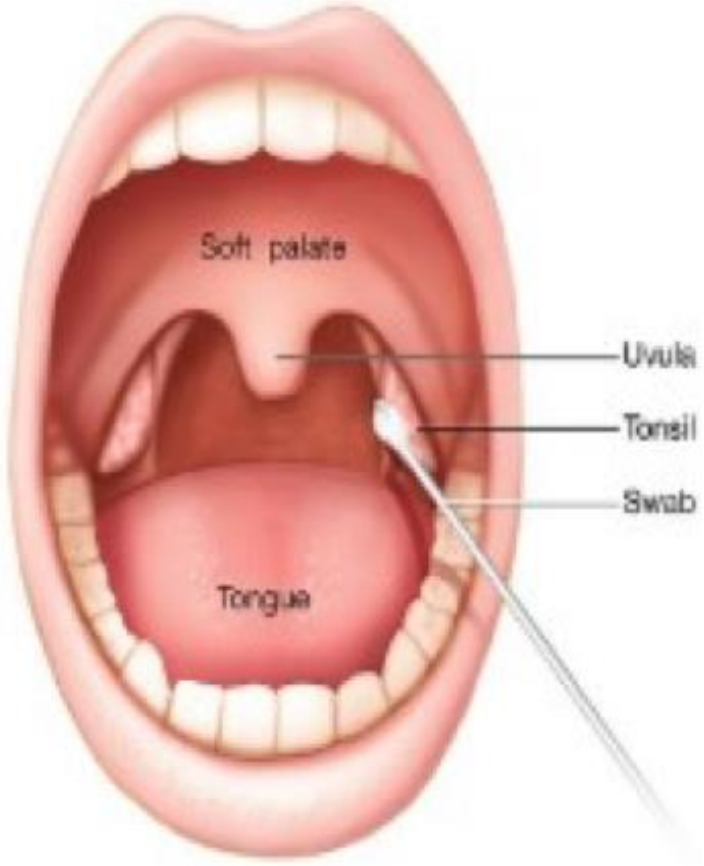


Photo from: https://infectioncontrol.ucsfmedicalcenter.org/sites/g/files/tkssra4681/f/PracticeUpdate-COVID19RNATest_multiplekits.pdf

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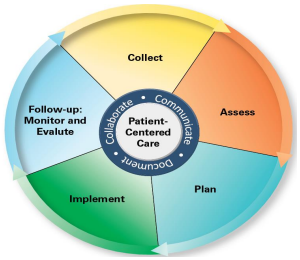
(Rao, et al. *BMC pediatrics* 19.1 (2019): 1-8)

Plan: Treatment Considerations



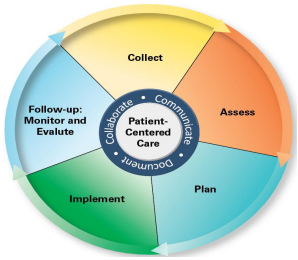
Goals of therapy: reduce duration of symptoms, decrease transmission, and prevent complications while avoiding inappropriate use of antibiotics

Start therapy as soon as possible

Most antibiotics must be given for 10 days to achieve maximal rates of pharyngeal eradication of GAS

(CDC, 2021)

Plan: Treatment Options



FIRST-LINE TREATMENT = AMOXICILLIN (OR PENICILLIN)*	
<u>Children</u>: Amoxicillin 25mg/kg by mouth every 12 hours for 10 days; max 500mg per dose	<u>Adults:</u> Amoxicillin 500mg by mouth every 12 hours for 10 days
Narrow spectrum of activity; fewer side effects; low cost	

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(Shulman. *Clinical infectious diseases.*2012;55(10):e86-e102)

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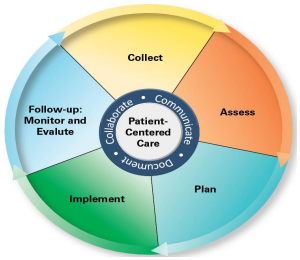
Plan: Treatment Options



Amoxicillin/Penicillin Allergy:	*Alternate Therapy*
First-generation cephalosporin • Cephalexin for 10 days* • Cefadroxil for 10 days*	• Clindamycin for 10 days • Azithromycin for 5 days# • Clarithromycin for 10 days#
**Avoid in those with anaphylactic-like hypersensitivity to penicillin*	*#High prevalence of resistance rates among pharyngeal isolates*

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(Shulman. *Clinical infectious diseases.*2012;55(10):e86-e102)

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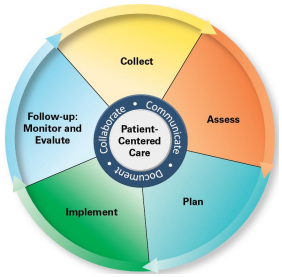
Plan: Treatment With Adjunct Therapy



- Adjunctive therapies for symptom management and/or for viral pharyngitis (those who test negative for GAS pharyngitis)

Analgesic/antipyretic agents	Adults	Non-pharmacological therapies
• Acetaminophen • NSAIDs (avoid aspirin in children) • Topical anesthetic sprays, rinses, and lozenges	• Decongestants • Antihistamines	• Cold foods • Warm liquids

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(Shulman. *Clinical infectious diseases.*2012;55(10):e86-e102)

Exclusions to Treatment

- Symptoms of severe infection
  - Scarlet Fever: Red rash on trunk, strawberry tongue, paleness around mouth
  - Poststreptococcal glomerulonephritis: Hematuria
- Symptoms of suppurative complications
  - Peritonsillar abscess, cervical lymphadenitis, mastoiditis
- Previous antibiotic use for the same illness
  - Concerns for resistance
- Contraindications to recommended therapies
  - Consider patient allergies
  - Collateral damage with broad-spectrum antibiotics

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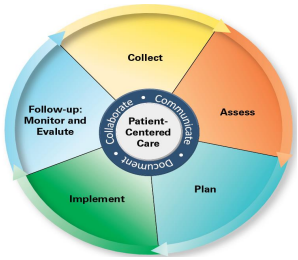
(Shulman. *Clinical infectious diseases.*2012;55(10):e86-e102)

Follow-up: Monitor and Evaluate



Follow-up

- With the patient within 24 to 72 hours after starting antibiotic
  - If the patient deteriorates or fails to improve after 3 – 5 days, consider referral
- Consider follow-up with patients who test negative for GAS within 7 days to evaluate for symptom improvement

Consider

- Referral for throat culture for those who test negative with rapid testing

Recommend

- Counsel patient to complete full course of antibiotics!

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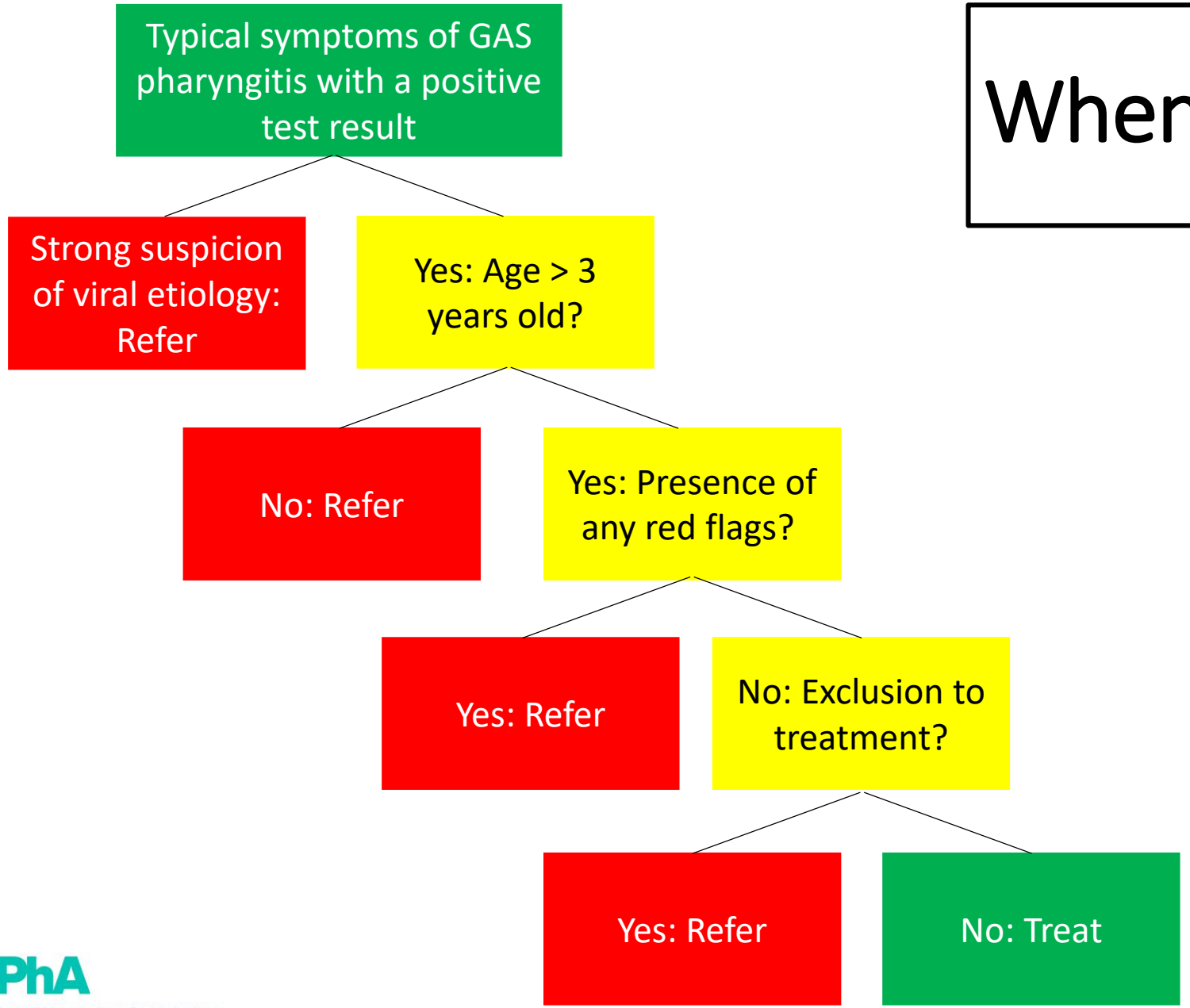
((Shulman. *Clinical infectious diseases.*2012;55(10):e86-e102))

When to Refer?



(Shulman. *Clinical infectious diseases.*2012;55(10):e86-e102)

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Influenza A & B

Patient Case

- WK is a 53 year-old woman who presents to your pharmacy in late Fall c/o a sore throat and runny nose for about 3 days now. She also has some sneezing, coughing, and body aches. She has been taking Tylenol but it doesn't seem to help the body aches. She was recently around her granddaughter who also was not feeling well.

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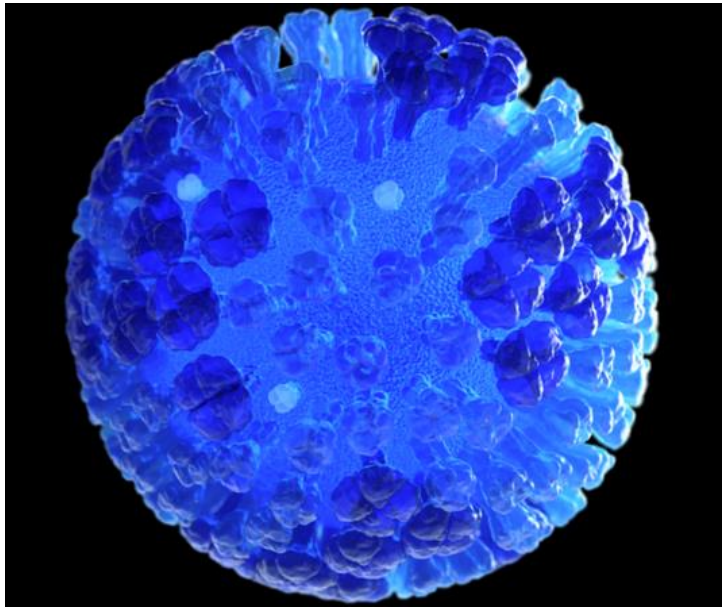
Brief Review of Influenza

- Contagious respiratory illness caused by influenza viruses
  - Two main types: A and B
- Primary reservoirs:
  - Nose, throat, lungs
- Transmission:
  - Air via respiratory droplets (cough, sneeze, talking)
  - Less often from touching surfaces or objects then touching mouth, nose, eyes
- Contagiousness:
  - 1 day before symptoms develop and up to 5-7 days after becoming sick
- Complications:
  - Pneumonia; myocarditis; encephalitis; multi-organ failure



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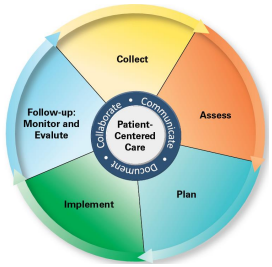
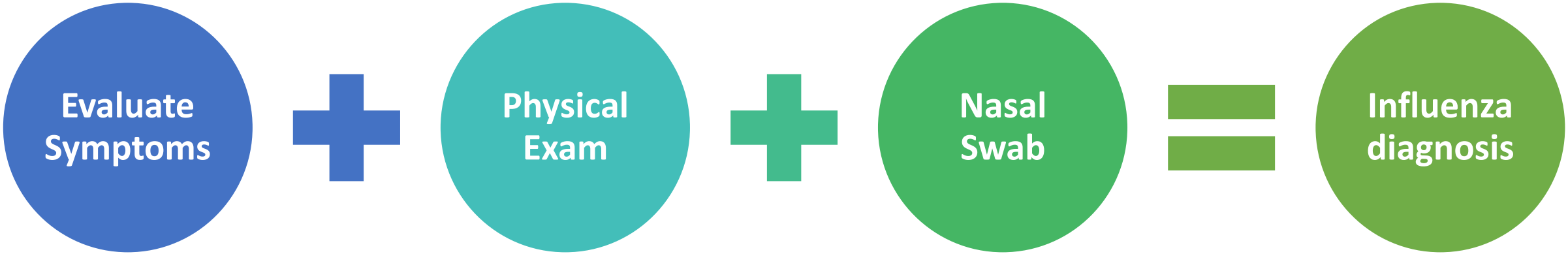
(CDC, 2016; https://www.cdc.gov/flu/about/viruses/index.htm)

Collect: Summary





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(Shulman. *Clinical infectious diseases.*2012;55(10):e86-e102)

Collect: Typical Presentation of Flu

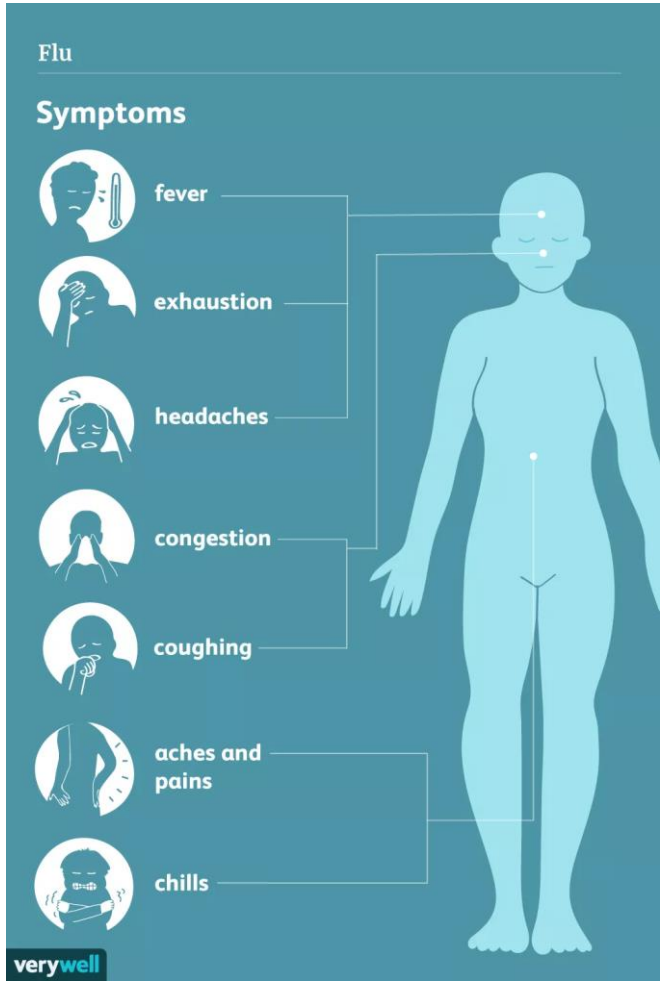


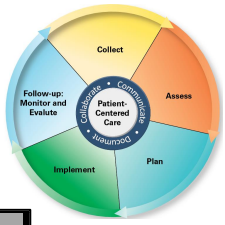
Photo from: https://www.verywellhealth.com/flu-symptoms-770514

	Subjective	Objective
General	• Chills • Malaise • Fatigue	• **Fever**
Ears, nose, throat	• Headache • Sore throat	• Nasal congestion • **Rhinorrhea**
Neuromuscular	• **Myalgia/arthralgia** • Weakness	
Gastrointestinal	• Abdominal pain	• Vomiting • Diarrhea
Pulmonary	• Chest pain	• **Nonproductive cough**

Incubation period of influenza = 1 - 4 days

(Uyeki, et al. *Clinical infectious diseases* 68.6 (2019): e1-e47)

Collect: Which Condition Is it??



Sign or Symptom	COVID-19	Flu	Cold	Allergies
Cough				
Diarrhea		More common in children		
Fatigue				
Fever		Not always		
Itchy nose, eyes, mouth or inner ear				
Muscle aches				
Nausea or vomiting		More common in children		
New loss of taste or smell	Early; often without a runny or stuffy nose		Especially with a stuffy nose	
Pink eye (conjunctivitis)				
Runny or stuffy nose				
Shortness of breath				
Sneezing				
Sore throat				
	Usually	Sometimes	Rarely	Never

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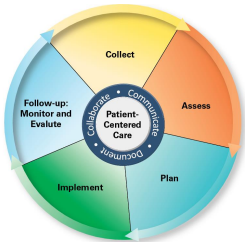
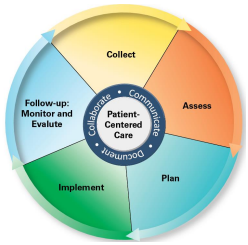
(Adapted from: https://www.pharmacytoday.org/article/S1042-0991(22)00273-0/fulltext)

Collect: Physical Assessment



- Complete history of present illness
- General appearance of patient
- Check all vitals
  - Especially assess for fever and dehydration (skin pinch test)
- Consider visual throat exam (especially if complaining of sore throat)
- Evaluate color of nasal discharge/congestion if possible or pertinent

Collect: Who Should Be Tested For Flu?



<u>During influenza season</u> (circulation of influenza A or B in the local community):

<u>Test patients who present with</u>:

- High risk for influenza complications, including immunocompromised persons with influenza-like illness, pneumonia, or nonspecific respiratory illness
- Acute onset of respiratory symptoms with or without fever and either exacerbation of chronic disease or known complications of influenza (ex. pneumonia)

<u>Consider testing patients</u>:

- Not at high risk for influenza complications who present with influenza-like illness, pneumonia, or non-specific respiratory illness

Consider testing only if results will influence clinical management

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(Uyeki, et al. *Clinical infectious diseases* 68.6 (2019): e1-e47)

Collect: Who Should Be Tested For Flu?

During low influenza activity (low or lack of circulating influenza A and B virus):

Consider testing patients with:

- Acute onset of respiratory symptoms with or without fever, especially immunocompromised and high-risk patients if results will influence clinical management

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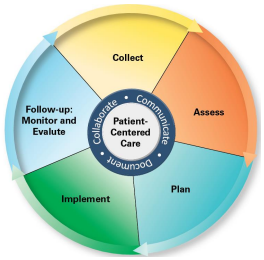
(Uyeki, et al. *Clinical infectious diseases* 68.6 (2019): e1-e47)

Assess: Green/Yellow Flags



PROCEED WITH T&T: Non-pregnant patients > 6 years old with symptoms consistent with flu with an onset of symptoms less than 48 hours

CAUTION:

- New or unexplained symptoms of COVID-19
- Evidence of bacterial coinfection
- Age ≥ 65 years or < 18 years (consider atypical presentation of influenza)
- Extreme obesity (BMI ≥40 kg/m2)
- Residents of chronic care facilities
- Recent seasonal influenza vaccination

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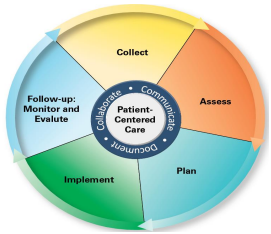
(NH Health, 2020)

Assess: Red Flags



RED FLAGS → REFER

- Age < 6 years old
- Greater than 48 hours since onset of influenza-like illness
- Pregnancy or breastfeeding
- Presence of immunocompromise
- Worsening on current influenza antiviral therapy
- History of renal dysfunction
- History of allergic reaction to neuraminidase therapy or baloxavir marboxil
- History of psychologic side effects from neuraminidase therapy
- Use of antiviral therapy in the past 4 weeks

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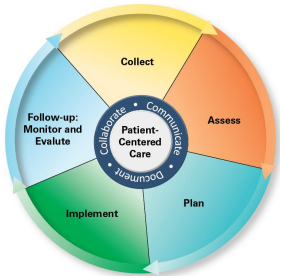
Klepser ME, Adams AJ. Int J Pharm Pract 2018 Dec;26(6):573-578.

Assess: Red Flags



RED FLAGS → REFER

- Evidence of clinical instability
  - Systolic hypotension < 100 mmHg
  - Tachypnea > 25 breaths/min (> 20 breaths/min for patients aged < 18 years)
  - Tachycardia > 100 beats/min (> 119 beats/min for patients aged < 18 years)
  - Oxygenation < 90% via pulse oximetry
  - Body temperature > 103°F (>103°F for patients aged < 18 years)

May require more emergent evaluation

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Klepser ME, Adams AJ. Int J Pharm Pract 2018 Dec;26(6):573-578.

Point-of-Care Testing for Flu: Nasal Swab

- Most accurate when nasal swab is collected close to the onset of symptoms **(< 4 days)**
- **Test Types**
  - **Rapid Influenza Diagnostic Test (RIDT)**
    - Most commonly used in outpatient setting
    - 50-70% sensitivity and 90-95% specificity
    - Results in 10-15 minutes
    - Inexpensive
  - **Rapid Molecular Assay**
    - Preferred outpatient test per the Infectious Diseases Society of America (IDSA)
    - 93-100% sensitivity and 92-97% specificity
    - Results in 15-30 minutes
    - Can be expensive

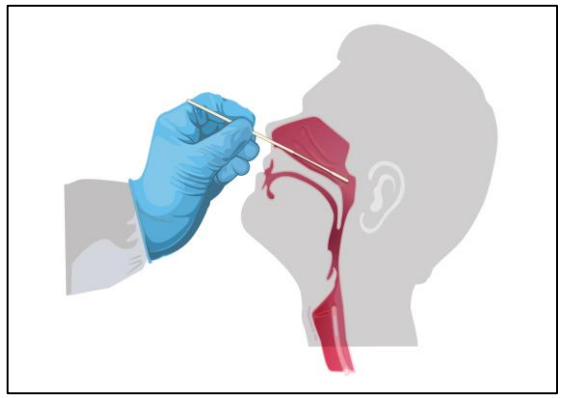

Photo from: https://www.cdc.gov/coronavirus/2019-ncov/lab/guidelines-clinical-specimens.html

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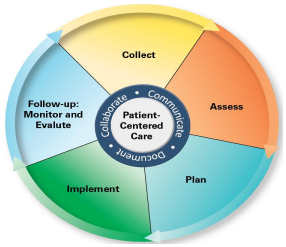
IAzar MM et al. J Clin Micro. 2018;56:e00367-18.

Plan: Treatment Considerations



Goals of therapy: reduce duration of symptoms, decrease transmission, and prevent complications while avoiding inappropriate use of antibiotics

Start therapy as soon as possible

Do not treat

- Seasonal influenza with adamantanes
  - Resistance is the issue
- If symptoms began more than 48 hours prior
  - Consider supportive therapy instead

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(CDC, 2021)

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Plan: Treatment Options

Agents	Directions for treatment	Adverse reactions	Treatment effectiveness
Neuraminidase inhibitors (NAIs): Oseltamivir (Tamiflu)	<u>Age 1 – 18 years:</u> 15 kg or less: 30 mg PO twice daily > 15 – 23 kg: 45 mg PO twice daily > 23 – 40 kg: 60 mg PO twice daily > 40 kg: 75 mg PO twice daily <u>Age > 18 years:</u> 75 mg PO twice daily	GI upset, pain, headache, sudden confusion, hallucinations	Reduced duration of symptoms by about 42 hours and reduced severity by 50%.
Neuraminidase inhibitors (NAIs): Zanamivir (Relenza)	<u>Age 7 years or older</u> 10mg (two 5-mg inhalations) twice daily	GI upset, headache, ENT infections, bronchospasm	Reduced duration of symptoms by about 1.5 days.
Polymerase acidic protein (PA) endonuclease inhibitors: Baloxavir marboxil (Xofluza)	<u>Age 12 years or older</u> < 80 kg: 40 mg PO once ≥80 kg: 80 mg PO once	GI upset, sinusitis, headache	Reduced duration of symptoms by about 27 hours.

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(CDC, 2021)
(Hayden, et al., JAMA 1999 282(13):1240-6)
(Norman, J., et al. *Am Fam Physician.* 2000 Dec 1;62(11):2467-2476)
(Kurtizkes, 2019)

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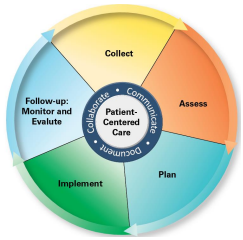
Plan: Treatment with Adjunct Therapy



- Adjunctive therapies for symptom management

Analgesic/antipyretic agents	Adults	Non-pharmacological therapies
• Acetaminophen • NSAIDs (avoid aspirin in children) • Topical anesthetic sprays, rinses, and lozenges if throat sore	• Decongestants • Antihistamines	• Cold foods • Warm liquids

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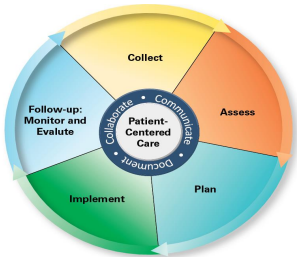
(Shulman. *Clinical infectious diseases.*2012;55(10):e86-e102)

Exclusions to Treatment

- Presence of red flags identified during assessment
- Contraindications to listed treatment options:
  - Oseltamivir (Tamiflu) is contraindicated in patients with hereditary fructose intolerance
    - Also not recommended if CrCl less than 10 mL/min if not undergoing hemodialysis
  - Zanamivir (Relenza) is contraindicated in patients with underlying respiratory disease
    - Also not recommended for patients younger than 7 years old
  - Baloxavir (Xoflluza) is not indicated in patients less than 40 kg or younger than 12 years old

(CDC, 2021)

Follow-up: Monitor and Evaluate



Follow-up

- Follow up with the patient within 24 to 48 hours
  - If the patient deteriorates or fails to improve after 3 – 5 days on antivirals, consider referral

Consider

- Consider influenza testing and chemoprophylaxis for household members and close contacts

Recommend

- Recommend/administer influenza vaccine as appropriate

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(Uyeki, et al." *Clinical infectious diseases* 68.6 (2019): e1-e47)
(Blanchon, T et al. *Clinical microbiology and infection : the official publication of the European Society of Clinical Microbiology and Infectious Diseases* vol. 19,2 (2013): 196-203. doi:10.1111/j.1469-0691.2011.03751.x)

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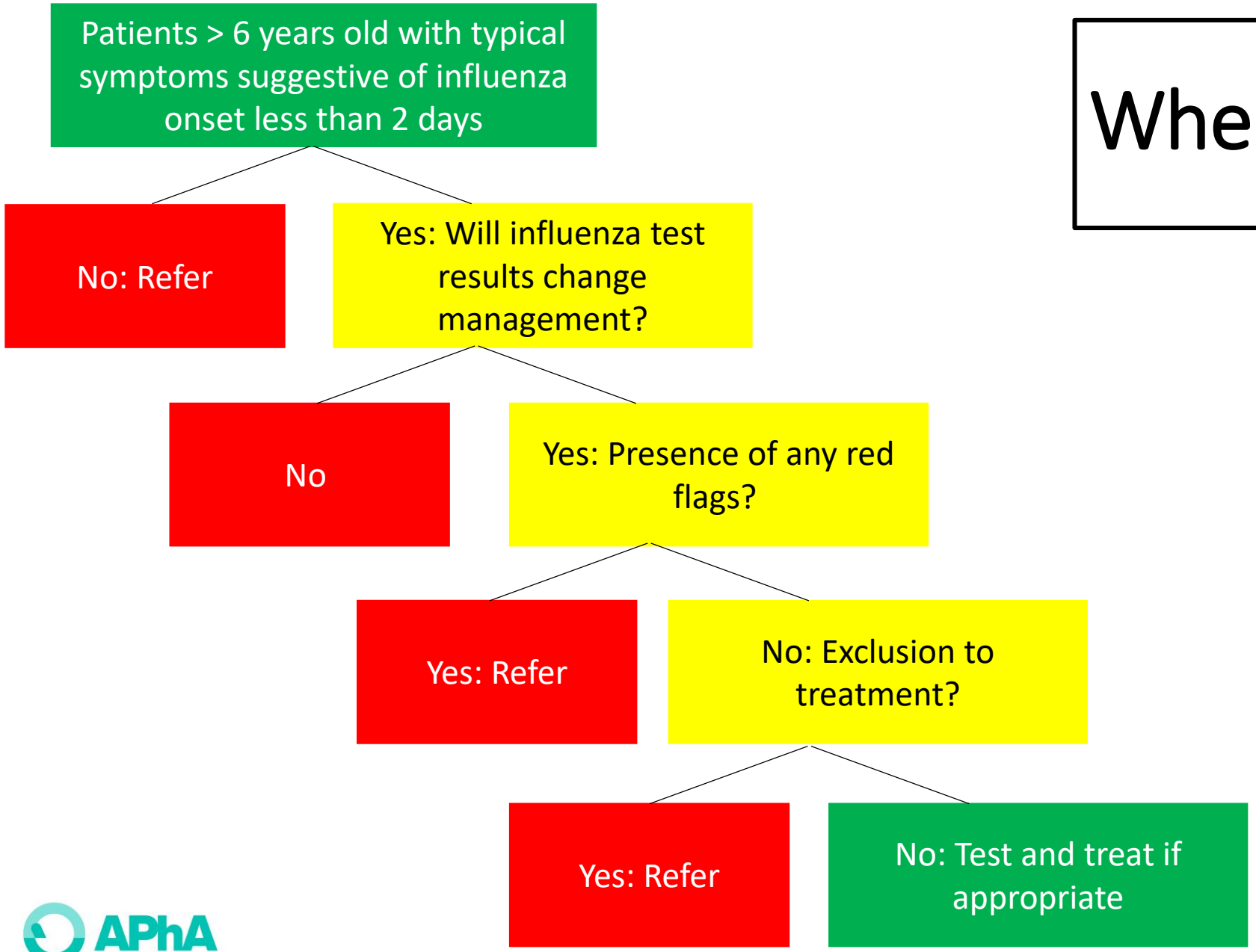
When to Refer?



(Uyeki, et al. *Clinical infectious diseases* 68.6 (2019): e1-e47)

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Urinary Tract Infections

Patient Case

RB, a 28-year-old female, comes into your pharmacy on a Friday night telling you it burns when she urinates, and she feels like she has to go to the bathroom all of the time. She is worried because it is the weekend. She says that she is not having any other symptoms and has never had this problem before.

https://www.scripps.org/news_items/6547

Brief Review of Urinary Tract infections (UTI)

- Most common outpatient infection in the United States accounting for 8.5 million healthcare visits annually
  - Prevalence greater in females
- Most common pathogens include:
  - UroPathogenic Escherichia Coli (UPEC) **86%**
  - Staphylococcus saprophyticus **4%**
  - Klebsiella species **3%**

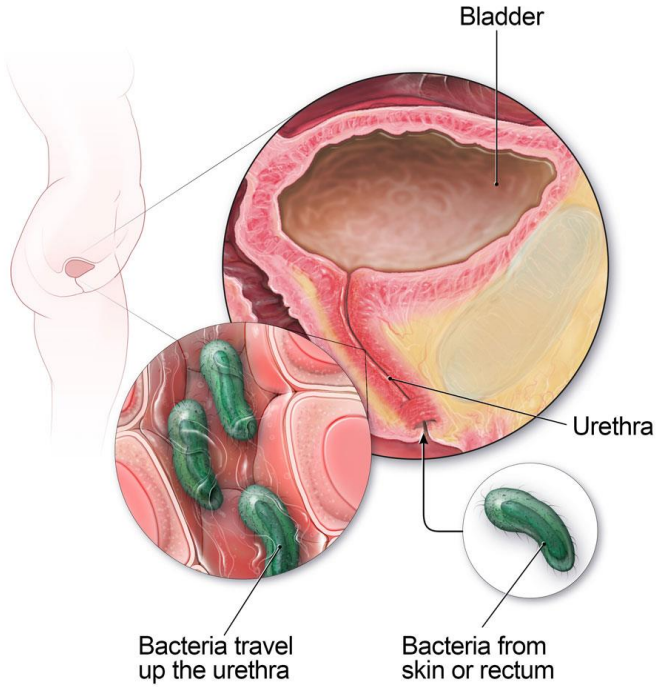
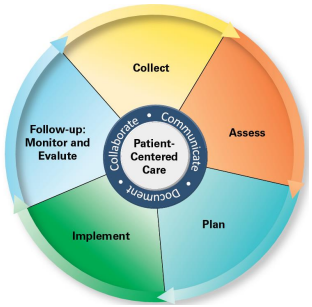


Photo from: https://www.cdc.gov/antibiotic-use/uti.html

(American Pharmacists Association; 2021)

Collect: Summary



Evaluate Symptoms + Suprapubic pain on physical exam present in 10-20% of patients + Urine Culture = UTI diagnosis

New onset of frequency and dysuria with the absence of vaginal discharge or irritation has a 90% positive predictive value for UTI

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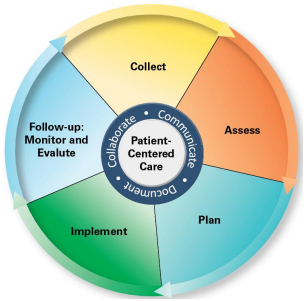
(Colgan, R., & Williams, M.. American family physician, 84(7), 771-776)

Collect: Typical Presentation of UTI



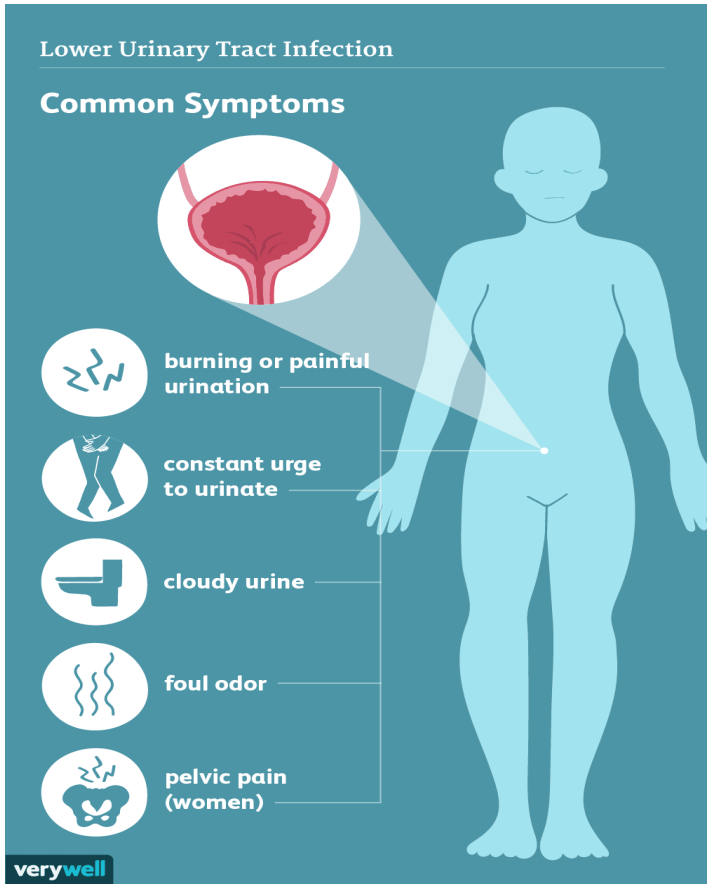


Photo from: https://www.verywellhealth.com/urinary-tract-infections-symptoms-2328460

Classic Lower Urinary Tract Symptoms:

- Burning or painful urination
- Frequent voiding with small volume
- Urinary urgency

Risk Factors:

- History of UTI
- Diabetes mellitus
- Pregnancy
- Urinary stones or obstruction

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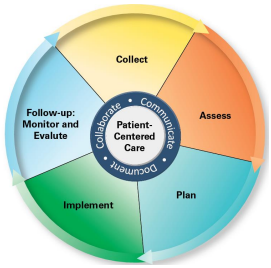
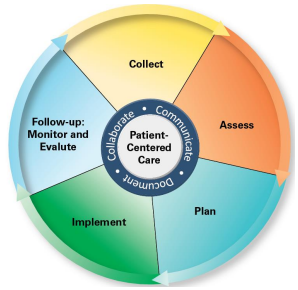
(American Pharmacists Association; 2021)

Physical Assessment



- Complete history of present illness
- General appearance of patient
- Check all relevant vitals
- Determine pregnancy status in females

Assess: Green/Yellow Flags



PROCEED WITH T&T : Non-pregnant, premenopausal women with acute uncomplicated cystitis and no comorbidities or urological abnormalities

CAUTION:

Multi-drug resistant (MDR) infection suspected if any of the following occurred in the last three months:

- A multi-drug resistant (MDR) gram-negative urinary isolate
- Inpatient stay in a healthcare facility
- Use of broad-spectrum antibiotic such as fluoroquinolone or Bactrim
- Travel to countries with high rates of resistance

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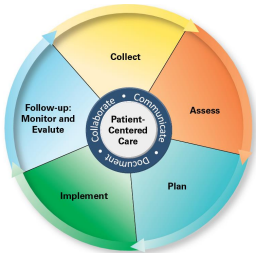
(Colgan, R., & Williams, M.. *American family physician*, *84*(7), 771-776)

Assess: Red Flags



RED FLAGS → REFER

- Symptoms suggesting infection extends past the bladder
  - Fever, flank pain, costovertebral angle tenderness
- Systemic signs of infection
  - Hypotensive, tachycardia, shortness of breath
- Underlying urologic etiologies
  - Renal transplant, nephrolithiasis, stents
- Immunocompromised
- Poorly controlled diabetes
- Pregnancy
- Males

May require more emergent evaluation

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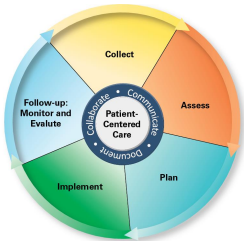
(Colgan, R., & Williams, M.. *American family physician*, *84*(7), 771-776)

Collect: Point-of-Care Test with Urinalysis



- Detects presence of nitrites and leukocyte esterase on urinalysis to help diagnose uncomplicated UTI
  - **Nitrites** are not typically present in the urine unless bacteria reduce urinary nitrates to nitrites
    - High specificity (92-100%), but not as highly sensitive (19-48%)
    - Negative nitrite dipstick does NOT rule out UTI
  - **Leukocyte esterase** is produced by neutrophils and is a sign of pyuria
    - Less sensitive (41-86%), but more sensitive (72-97%)
- Urinalysis dipstick testing commonly used due to convenience and cost
  - Results in as little as two minutes

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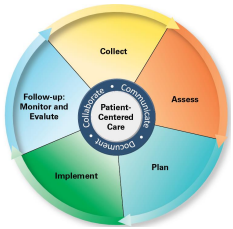
(Bent, et al., JAMA. 2002 May 22-29;287(20):2701-10. doi: 10.1001/jama.287.20.2701. PMID: 12020306)
(Simerville, 2005)



Plan: Treatment Considerations

Goals of therapy: provide symptom relief, treat infection, and prevent collateral damage such as inappropriate antibiotic use

Start therapy as soon as possible

Avoid certain antibiotics due to resistance rates/ineffectiveness

- Amoxicillin; ampicillin

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In-Text Citation

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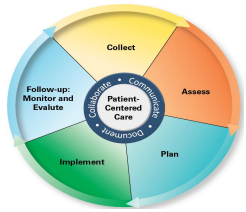
Plan: Treatment Options



FIRST-LINE TREATMENT = ANTIBIOTICS		
Nitrofurantoin 100 mg by mouth twice daily for 5 days	Bactrim DS by mouth twice daily for 3 days	Fosfomycin 3gm by mouth as a single dose

Note: choice between these three agents should be individualized based on patient allergy and compliance history, local practice patterns, local resistance patterns, cost, and availability

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(Gupta, K., CID 2011; 52: e103-120)

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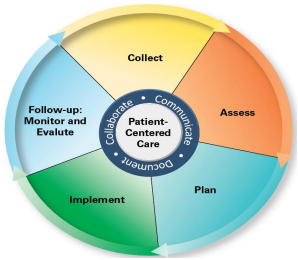
Plan: Treatment Options



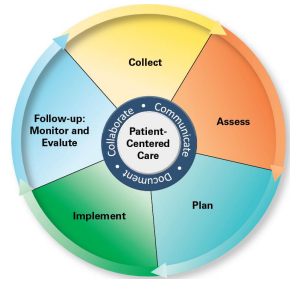
Alternate Therapy

- Fluoroquinolones
  - Resistance high in some areas; greater chance for collateral damage
- Beta-lactams (Augmentin, cefdinir)
  - Lower efficacy and more side effects

Note: Options should be individualized based on patient allergy and compliance history, local practice patterns, local resistance patterns, cost, and availability

(Gupta, K., CID 2011; 52: e103-120)

Plan: Treatment With Adjunct Therapy



Phenazopyridine (Azo)

- Treats symptoms such as burning but does not treat infection
- Not recommended for long-term use (2 days)
- Can cause urine discoloration

Methenamine/Sodium salicylate (Cystex)

- Not shown to be safe for UTI
- Dosed four times daily

Cranberry supplements

- No evidence to support the use of the tablets or juice to prevent or treat UTIs

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(Pray WS. US Pharmacist 2012; 37(6): 12-15)

Exclusions to Treatment

- Special populations
  - Males, immunosuppression, pregnancy
- Signs of pyelonephritis
  - Fever, flank pain, costovertebral angle tenderness
- Patients with underlying genitourinary disorders
  - Renal transplant, nephrolithiasis, stents, catheters
- Contraindications to recommended therapies
  - Consider patient allergies
  - Nitrofurantoin and SMX-TMP: be mindful of renal dysfunction

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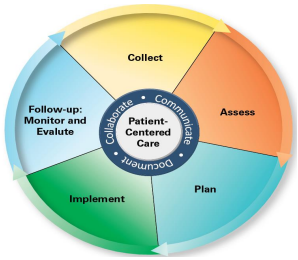
(Colgan, R., & Williams, M.. *American family physician*, *84*(7), 771-776)

Follow-up: Monitor and Evaluate



Follow-up

- With the patient within 24 to 48 hours after starting antibiotic
  - If the patient fails to improve or symptoms worsen, consider referral

Recommend

- Counsel patient to complete full course of antibiotics!
- Educate patient on preventative strategies
  - Urinate after sex, stay hydrated, showers instead of baths, proper wiping

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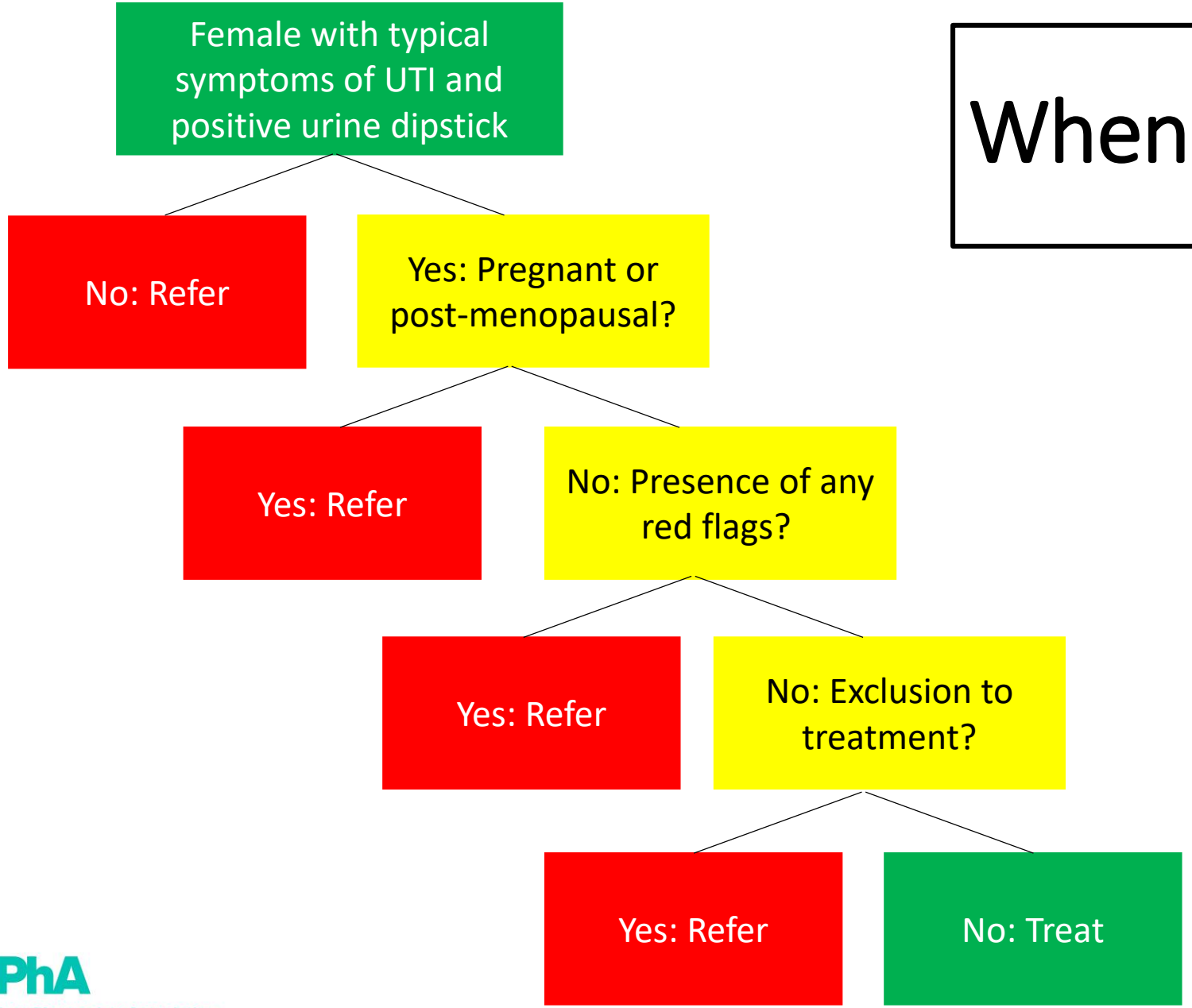
(Colgan, R., & Williams, M.. *American family physician*, *84*(7), 771-776)

When to Refer?



(Colgan, R., & Williams, M.. *American family physician*, *84*(7), 771-776)

BREAK

PATIENT CASES

Active Learning Session: Patient Cases

- Find a partner (or two) near you
- Work through each of the patient cases with your partner completing all associated questions
  - Cases can be found in your handout
- You will have 30 minutes to complete all four cases
- We will then reconvene as a group to discuss
  - You may be randomly called upon to share how you assessed the case and answered the questions

https://www.pexels.com/photo/colleagues-having-a-business-meeting-6340656/

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Case 1 Discussion

Patient Case 1

- **CC**: “I have a sore throat and runny nose that has driving me crazy for about 3 days now.”
- **HPI**: WK is a 53 year-old woman who presents to your pharmacy in late Fall. She tells you that she has a sore throat and runny nose which has been going on for about 3 days now. She also has some sneezing, coughing, and body aches. She has been taking Tylenol but it doesn’t seem to help the body aches. She was recently around her granddaughter who also was not feeling well. WK saw that your pharmacy offers testing services and she is hoping you can help her figure out if this is treatable or if she needs to go to the urgent care.

During the Patient/Physical Assessment You Find Out:

- PMH: Hypothyroidism
- Social history/lifestyle:
  - Married with 2 adult children
  - Tobacco: denies use
  - Alcohol: drinks socially
  - Illicit drugs: denies use
- Allergies: None
- Vaccines: Up to date except annual influenza vaccine

- Meds: Levothyroxine 25mcg by mouth every morning
- Vitals today
  - Weight: 152 lbs
  - Height: 5’7”
  - BP: 125/82
  - Pulse: 85
  - RR: 15
  - Temp: 100° F (orally)

Case 2 Discussion

Patient Case 2

- **CC**: “My throat hurts and I keep coughing.”
- **HPI**: LL is a 10 year-old male presenting to your pharmacy with his mom in late December and complaining of sore throat and cough. Moms states LL has had some hoarseness in his voice over the past few days and some sweats but no runny nose, and not really running a fever at home. She says LL has a history of seasonal allergies that usually flares up only in the Fall for which he takes Claritin 10mg one a day as needed. Mom says LL has been in close contact with classmates that have had similar symptoms.

https://thumbs.dreamstime.com/b/little-sick-boy-pharmacy-coughing-drugstore-copy-space-ill-young-suffering-seasonal-flu-152211837.jpg

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During the Patient/Physical Assessment You Find Out:

- PMH: Seasonal allergies (only in the Fall)
- Social history/lifestyle: N/A
- Allergies: None
- Vaccines: up to date on all vaccines including annual influenza

- Meds: Loratadine 10mg once daily when allergies flare up
- Vitals today
  - Weight: 99lbs
  - Height: 4’10”
  - BP: 112/71
  - Pulse: 85
  - RR: 18
  - Temp: 101° F (orally)

Case 3 Discussion

Patient Case 3

- **CC**: “I feel like I’ve been run over by a car. Every muscle hurts and I’m freezing cold.”
- **HPI**: JJ is a 55 year-old male who comes to your pharmacy in mid-December with complaints of 2 days of fever (doesn’t have a thermometer at home so unsure of the numbers), chills, muscle aches, and feeling very tired. He reports not really having an appetite for the last day and missed his morning doses of his medications. Before this, he had been in his usual state of health. He does mention some of his coworkers have been sick recently. He heard that your pharmacy does Test and Treat services and wants to be tested. He wants to get better as soon as possible because he has a big family gathering soon.

https://www.cdc.gov/coronavirus/2019-ncov/if-you-are-sick/care-for-someone.html

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During the Patient/Physical Assessment You Find Out:

- PMH:
  - Diabetes
  - Hyperlipidemia
  - Hypertension
  - RA
- Social history/lifestyle:
  - Divorced; lives alone; has 2 adult children; works as bank executive
  - Tobacco: denies use
  - Alcohol: drinks socially (liquor)
  - Illicit drugs: denies use
- Allergies: None
- Vaccines: Up to date on everything

- Meds:
  - Aspirin 81mg daily
  - Hydrochlorothiazide 25mg daily
  - Glyburide 5mg daily
  - Metformin 1gm twice daily
  - Atorvastatin 10mg daily
  - Folic Acid 1mg daily
  - Methotrexate 10mg weekly
- Vitals today
  - Weight: 209 lbs
  - Height: 5’11”
  - BP: 152/92
  - Pulse: 94
  - RR: 18
  - Temp: 102.2° F (orally)

Case 4 Discussion

Patient Case 4

- **CC**: “It burns when I pee and I feel like I have to go all of the time”
- **HPI**: RB, a 28-year-old female, comes into your pharmacy on a Friday night. She thinks she might have a urinary tract infection (UTI). She is worried because she can’t see her doctor until next week since it is the weekend. She says that she is not having any other symptoms and has never had this problem before.

https://www.scripps.org/news_items/6547

During the Patient/Physical Assessment You Find Out:

- PMH: None
- Social history/lifestyle:
  - Married; no children
  - Tobacco: denies use
  - Alcohol: drinks socially
  - Illicit drugs: denies use
- Allergies: Sulfa drugs
- Vaccines: up to date

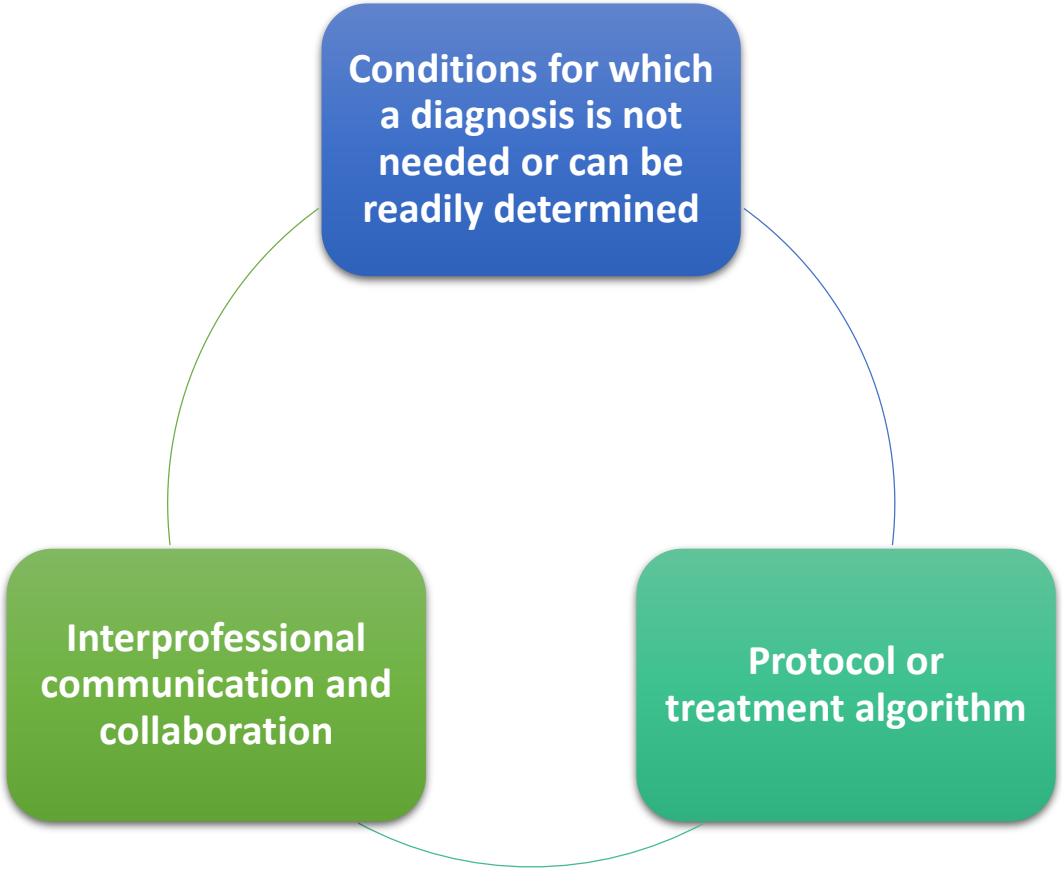
- Meds:
  - Ortho Novum 777
    - Adherent and no concerns about pregnancy
- Vitals today
  - Weight: 125 lbs
  - Height: 5’3”
  - BP: 114/80
  - Pulse: 82
  - RR: 17
  - Temp: 98.8° F (orally)

LUNCH BREAK

DEVELOPING AND IMPLEMENTING A PROTOCOL AGREEMENT

Elements of a Protocol

Crucial Features for Pharmacist Prescriptive Authority



(Sachdev, 2020)

Pharmacist Prescriptive Authority

- **Collaborative Practice Agreement (CPA):** an agreement between prescriber(s) and pharmacist(s) who work within a defined **protocol**
  - Allows pharmacist to perform services that would typically be considered *beyond their scope of practice* such as initiating, continuing, or adjusting medication regimens
  - Patient-specific and population-specific CPAs
- **Autonomous Prescribing:** allows pharmacists to prescribe certain categories of medications *without* the supervision of a collaborating physician
  - Statewide protocols and unrestricted category-specific authority

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(Adams, A. J., & Weaver, K. K. . *Annals of Pharmacotherapy*, *50*(9), 778-784)

Continuum of Pharmacist Prescriptive Authority

Patient-specific CPA

- **MOST RESTRICTIVE**
- Typically used for chronic disease management for specific patients

Population-specific CPA

- Pharmacist can provide services to patients regardless of if they were previously under the care of the collaborating physician
- Typically used for acute care management

Statewide Protocol

- Published by a state body that may be followed by any pharmacist who meets the specified criteria
- Typically used for preventative care or acute/self-limiting conditions

Unrestricted Category-Specific Authority

- **LEAST RESTRICTIVE**
- Provides authority to prescribe a medication within the pharmacist's usual course of practice

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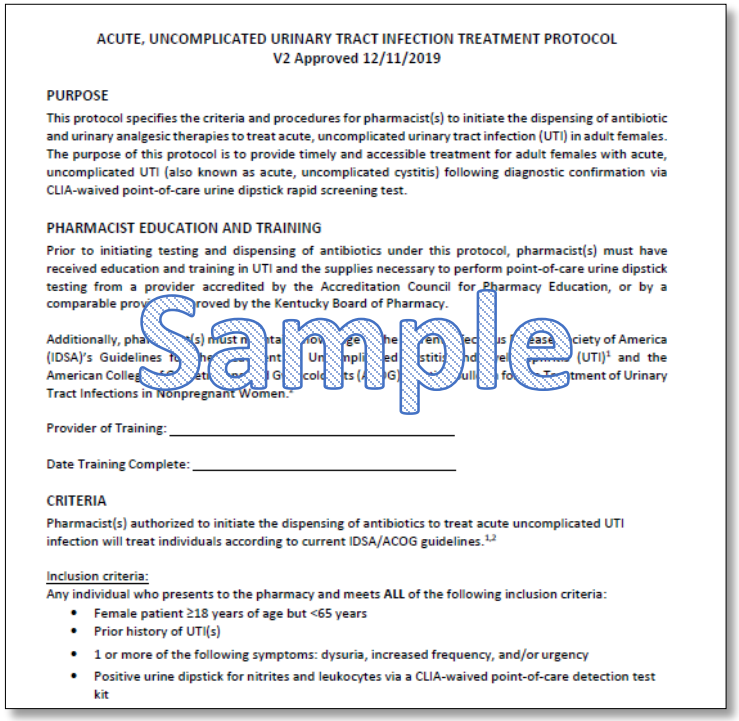
(Adams, A. J., & Weaver, K. K. . *Annals of Pharmacotherapy*, *50*(9), 778-784)

Elements of a Point-of-Care Testing Protocol

- Categories of patients who may be eligible for POCT services
- Pharmacist-physician care plan algorithm
- Documentation and communication expectations
- Quality assurance procedures



ACUTE, UNCOMPLICATED URINARY TRACT INFECTION TREATMENT PROTOCOL
V2 Approved 12/11/2019

PURPOSE

This protocol specifies the criteria and procedures for pharmacist(s) to initiate the dispensing of antibiotic and urinary analgesic therapies to treat acute, uncomplicated urinary tract infection (UTI) in adult females. The purpose of this protocol is to provide timely and accessible treatment for adult females with acute, uncomplicated UTI (also known as acute, uncomplicated cystitis) following diagnostic confirmation via CLIA-waived point-of-care urine dipstick rapid screening test.

PHARMACIST EDUCATION AND TRAINING

Prior to initiating testing and dispensing of antibiotics under this protocol, pharmacist(s) must have received education and training in UTI and the supplies necessary to perform point-of-care urine dipstick testing from a provider accredited by the Accreditation Council for Pharmacy Education, or by a comparable prov roved by the Kentucky Board of Pharmacy.

Additionally, pha (s) must n ta ov ge he rem ec as ease ciety of America (IDSA)'s Guidelines f he nt Un npli ed stiti nd e (UTI)[1] and the American Colleg et G col ts (G) ull fo tment of Urinary Tract Infections in Nonpregnant Women.[2]

Sample

Provider of Training: _____

Date Training Complete: _____

CRITERIA

Pharmacist(s) authorized to initiate the dispensing of antibiotics to treat acute uncomplicated UTI infection will treat individuals according to current IDSA/ACOG guidelines.[1,2]

Inclusion criteria:

Any individual who presents to the pharmacy and meets **ALL** of the following inclusion criteria:

- Female patient ≥18 years of age but <65 years
- Prior history of UTI(s)
- 1 or more of the following symptoms: dysuria, increased frequency, and/or urgency
- Positive urine dipstick for nitrites and leukocytes via a CLIA-waived point-of-care detection test kit

Important: This is not state specific. Please confirm with you state regulations regarding specific protocol requirements

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(Adams, A. J., & Weaver, K. K. . *Annals of Pharmacotherapy*, *50*(9), 778-784)

Categories of Patients

- Specifically identify which groups of patients may be eligible for the pharmacist's services
- Similar to inclusion criteria for a clinical trial
  - Criteria will greatly depend on the disease states covered in protocol
- Examples of criteria to consider
  - Age: *"Patients over the age of 12"*
  - Comorbidities: *"Patients who are not immunocompromised"*
  - Gender: *"Female patients"*
  - Pregnancy status: *"Non-pregnant patients"*

(Adams, A. J., & Weaver, K. K. . *Annals of Pharmacotherapy*, *50*(9), 778-784)

Instructions for Identifying Excluded Patients

- Indicate circumstances when pharmacist cannot perform designated services
  - Similar to exclusion criteria for a clinical trial
- Will likely include criteria that would need to be collected during patient assessment
  - Blood pressure
  - Body temperature
  - Heart rate
  - Respiratory rate

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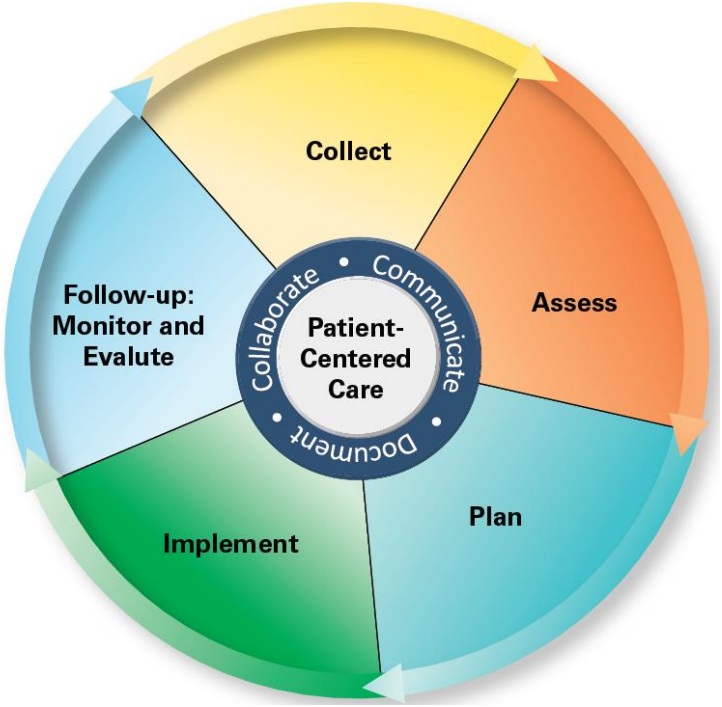
(Adams, A. J., & Weaver, K. K. . *Annals of Pharmacotherapy*, *50*(9), 778-784)

Pharmacist-Physician Care Plan Protocol

- Forms the bulk of the protocol
- Pharmacist and physician instructions for how to perform patient assessment
  - Collect and Assess
- Pharmacist and physician instructions for treatment
  - Plan, Implement, Follow-up
  - Include instructions for negative test results
- Likely include a treatment algorithm



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(U.S. Department of Health and Human Services; 2017)

Documentation and Communication

- Documentation requirements will vary by state; however, thorough documentation of clinical activities is considered *standard practice*
  - Electronic vs paper records
- Some states have specific requirements for how patient records should be maintained and for length of time
- What informational document(s) will be provided to your patients?
- Collaboration requires communication
  - Determine most appropriate method(s) of communication
  - Establish frequency and timing of communication

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(U.S. Department of Health and Human Services; 2017)

Quality Assurance Procedures

Process for physician to review the pharmacist's actions within the mutually agreed upon protocol

- How often will this occur?
- Will this occur in-person, over the phone, etc.?
- What clinical measures will you collect?
- How will you capture patient feedback?

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(U.S. Department of Health and Human Services; 2017)

Protocol Summary

Protocol requirements will vary by state but may include:

Scope of Agreement

- Parties of the agreement
- Eligible patients, disease states, and point-of-care tests
- Patient care functions

Legal Components

- Liability insurance
- Informed consent
- Protocol expiration dates
- Rescindment procedures
- Signatures of parties of the agreement

Administrative Components

- Training and education requirements
- Documentation and communication
- Quality assurance
- Maintenance of patient records

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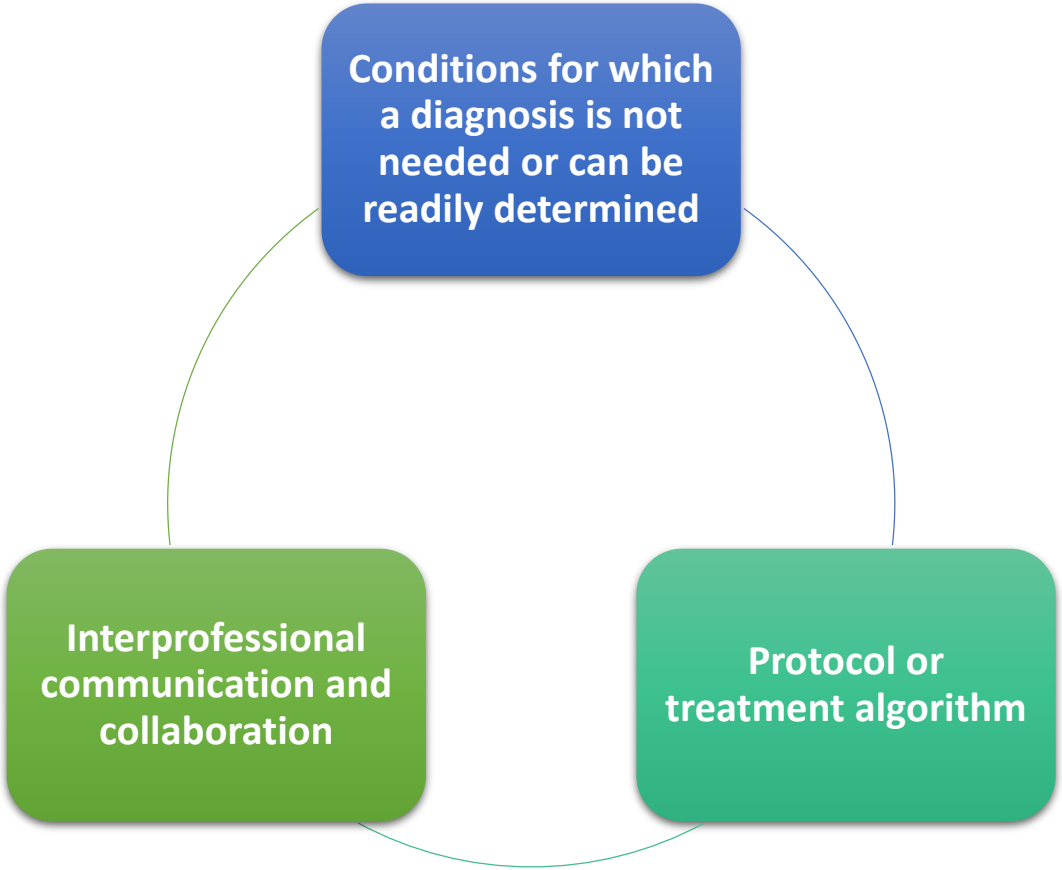
(U.S. Department of Health and Human Services; 2017)

Interprofessional Communication

Crucial Features for Pharmacist Prescriptive Authority



(Sachdev, 2020)

The *Impact* of the Pharmacist in Interprofessional Care

HEALTH IMPACT

- Improve patient outcomes
- Improve compliance with clinical guidelines
- Decrease inappropriate antimicrobial use

HEALTH DISPARITY IMPACT

- Increase access to care
- Decrease number of health care office visits
- Most accessible health care provider

ECONOMIC IMPACT

- Decrease avoidable hospitalizations
- Reduce emergency room visits
- Lowers indirect costs for patients

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(CDC, 2019)

Barriers to Interprofessional Collaboration

- Attitudes of some healthcare providers
- Lack of clear definitions of roles among stakeholders
- Lack of patient understanding of collaborative practice benefits
- Lack of communication between healthcare providers
- Practice setting
- **The degree of trust between stakeholders**

Note: This is why choosing who you will collaborate with will be the single most important decision you make regarding your Test and Treat program

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(Beardsley, Robert, 2012)
(U.S. Department of Health and Human Services; 2017)

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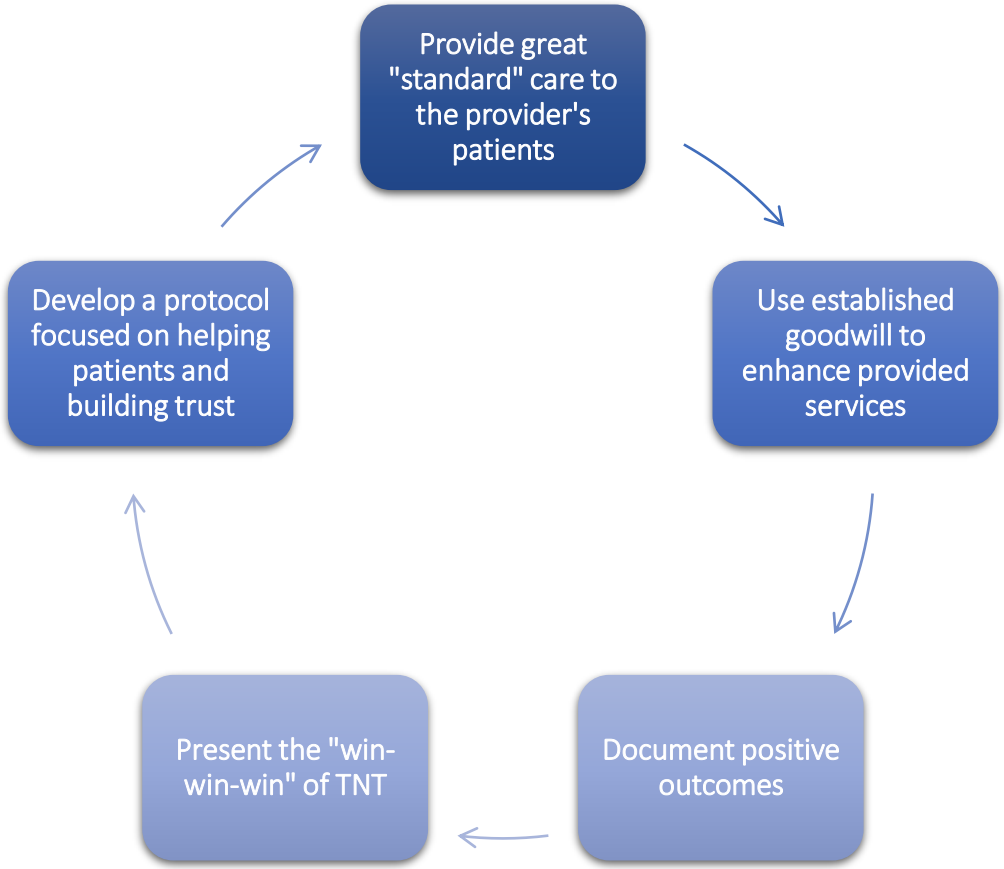
Developing the Relationship & Building Trust

- **Trustworthiness**
  - Develops over time
  - Demonstrate competencies
- **Role Specification**
  - Helps set expectations
- **Professional Interactions**
  - Effective communication
  - Practice setting



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(U.S. Department of Health and Human Services; 2017)

Strategies to Foster Interprofessional Communication

- Interpersonal communication model
  - Establishing a respectful feedback loop
- Mutual understanding of perception and knowledge
  - Involves active listening and identifying shared goals
- Direct and succinct communication
  - Avoid misunderstandings and improve patient safety
- Congruence between verbal and nonverbal communication
  - Helps build trust

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(Beardsley, 2012)

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Effective Communication

Complete	Clear	Concise	Timely
• Share all relevant information	• Use common terminology	• Be succinct	• Avoid delays in relaying information

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(AHRQ, 2019)

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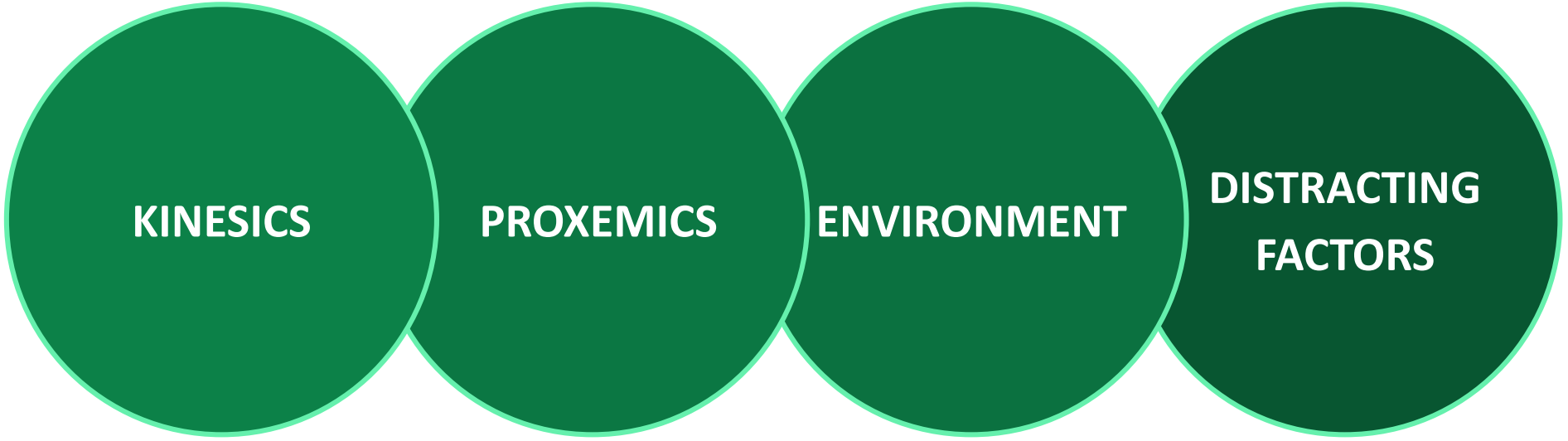
Nonverbal Communication

55-95% of the meaning of a message is transmitted nonverbally

- Thought to mirror innermost thoughts and feelings
- Difficult to fake
- If not in line with verbal message, receiver may become suspicious



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(Beardsley, Robert, 2012)

Initiating the Conversation with a Prospective Collaborator

- Schedule an in-person meeting if possible
  - Include relevant stakeholders
- Communicate goals and benefits of collaboration
  - Identify unmet needs
- Anticipate concerns/questions the perspective collaborator may have and formulate a response prior to meeting
  - Liability
  - Cost
  - Improving patient care

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(CDC, 2017; https://pixabay.com/photos/interview-deal-business-handshake-4835116/)

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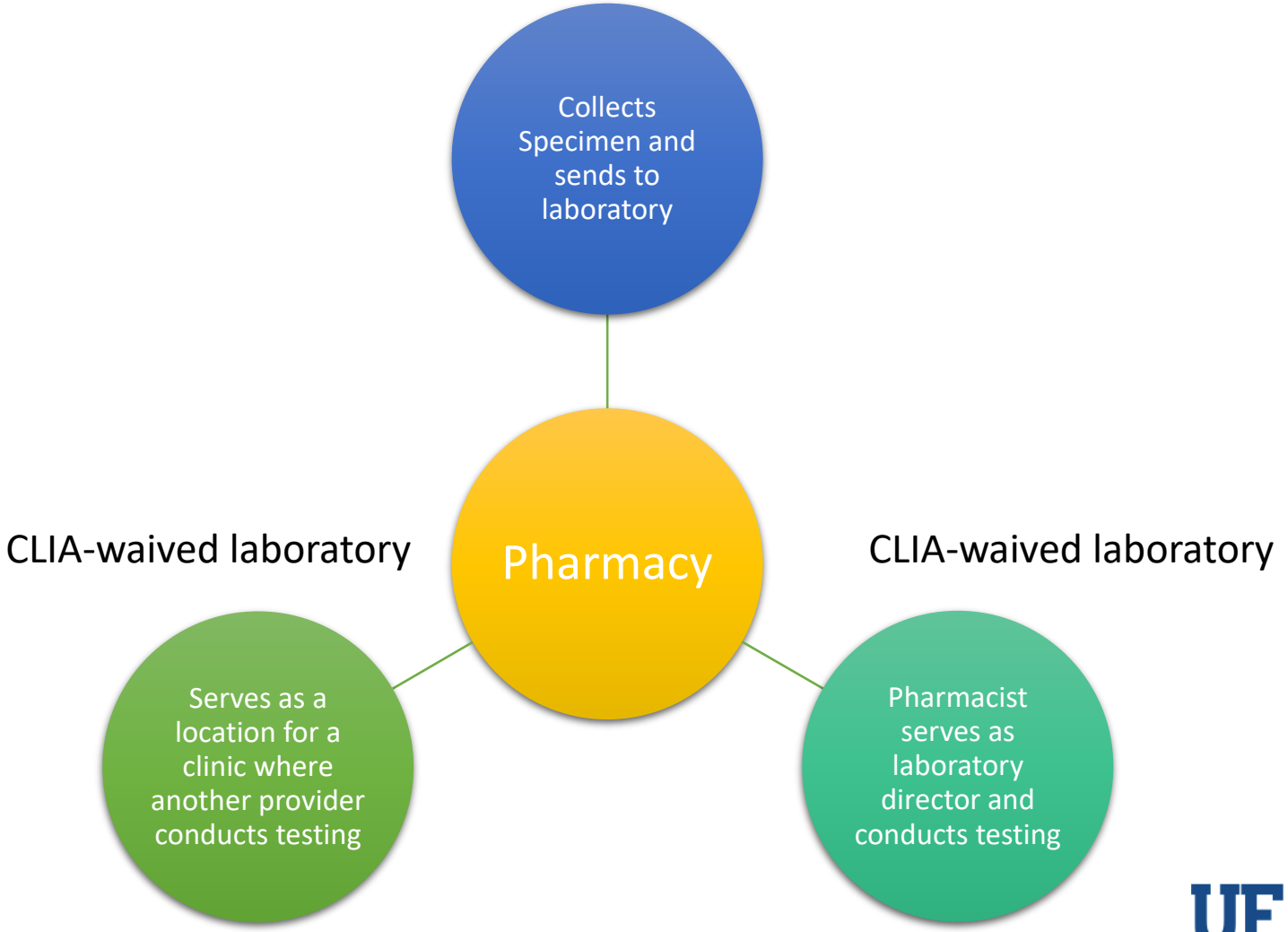
ESTABLISHING A POINT-OF-CARE TESTING SITE

Models of Point-of-Care Testing



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(Klepser et al. 18:1, 5-6, DOI:10.1080/14737159.2018.1392240, 2018)

Use a Stepwise Approach

- Step 1: Prepare
- Step 2: Regulatory Considerations
- Step 3: Testing Oversight
- Step 4: Environment
- Step 5: Select Testing Devices
- Step 6: Develop Policies and Procedures
- Step 7: Testing Personnel and Training
- Step 8: Implement – First Test!

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https://www.cdc.gov/labquality/waived-tests.html

Step 1: Prepare

Determine Type of Testing and Frequency

- Infrequent testing maybe more costly

Evaluate Associated Costs

- License and fees
- Equipment and Supplies
- Personnel – labor and training
- Safety and biohazard supplies— including sharps containers and personal protective equipment,
- Cost for record keeping
- Resources needed for additional activities— including referrals and follow-up

Regulatory Considerations

Step 2: Regulatory Considerations

- Every site will need to follow applicable federal, state, and/or local requirements for testing, safety, confidentiality, and privacy
  - State Practice Act
    - Type of point-of-care testing
    - Personnel
  - CLIA
    - Obtain CLIA Certificate of Waiver
  - OSHA
    - Regulation that prescribes safeguards to protect workers against health hazards related to bloodborne pathogens

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https://www.cdc.gov/labquality/docs/waived-tests/15_255581-test-or-not-test-booklet.pdf

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Clinical Laboratory Improvement Amendments (CLIA)

Step 2: Regulatory Considerations

- CLIA regulations of 1988 statute is an amendment to the Public Health Services Act
  - Congress revised the program for certification and oversight of clinical laboratory testing
  - Includes federal standards for all US facilities or sites that test human specimens
    - Blood, body fluid, tissue
  - Laboratories must be certified by their state and CMS according to CLIA
    - Laboratories are any facility performing testing on materials from the human body for purpose of diagnosis, prevention, treatment, or assessment of the health of human beings
- Role of FDA
  - List of waived analytes used in lab testing: https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfClia/analyteswaived.cfm

(Center for Disease Control and Prevention, 2018)
(CMS, 2020)

Step 2: Regulatory Considerations

CLIA Certificates

Vary depending on type of testing being performed

More than one type of CLIA certificate may be needed

Certificate of Waiver is obtained for laboratories performing waived tests

Waiver needed at every laboratory site

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https://www.cdc.gov/labquality/docs/waived-tests/15_255581-test-or-not-test-booklet.pdf

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Active Learning Session: CLIA Waiver Discussion

https://www.pexels.com/photo/colleagues-having-a-business-meeting-6340656/

Requirements to Perform CLIA-Waived Testing

Step 2: Regulatory Considerations

- Enroll in the CLIA program and obtain a certificate
- Pay certificate fee every two years
- Follow full manufacturer's instructions for tests being performed
- Notify State Agency of any changes in ownership, name, address, or Laboratory Director within 30 days. If you wish to add tests that are more complex, notify State Agency

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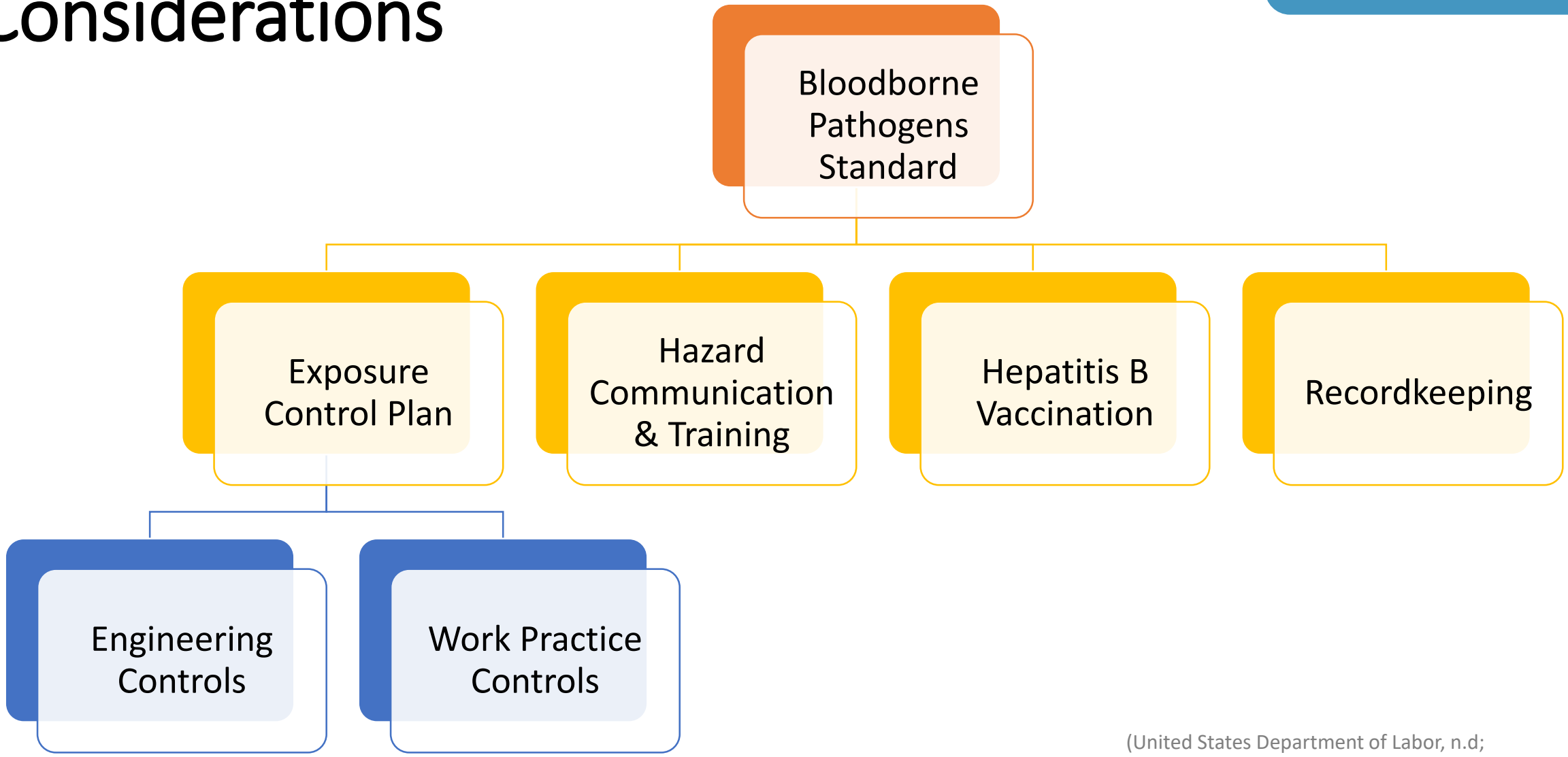
(CMS, 2020)

Regulatory Considerations

Step 2: Regulatory Considerations



(United States Department of Labor, n.d; https://www.osha.gov/bloodborne-pathogens/quick-reference)

Step 3: Testing Oversight

Testing Oversight

- **At least one person responsible for overseeing testing and decision-making for each testing site**
  - Appropriate background and knowledge for making decisions and solving problems with testing
  - Demonstrate a commitment to the quality of testing
  - Understand how to comply with applicable regulatory requirements
  - Promote good laboratory practices

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https://www.cdc.gov/labquality/docs/waived-tests/15_255581-test-or-not-test-booklet.pdf

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Testing Environment

Step 4: Environment

- Workspace
  - Clean and adequate for testing; patient privacy
- Lighting
  - Sufficient for sample collection and reading results
- Ergonomics
  - Allow for tasks to be performed efficiently
- Safety Labels
  - Area and supplies clearly labeled for hazards
- Utilities
  - Necessary for some testing and equipment; water for clean-up

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https://www.cdc.gov/labquality/docs/waived-tests/15_255581-test-or-not-test-booklet.pdf

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Testing Environment

Step 4: Environment

- Temperature
  - Should be controlled; test kits may be sensitive
- Humidity Levels
  - Can affect test kits and rate of chemical reactions
- Housekeeping
  - Clean, organized, free of clutter; proper staff training
- Waste Disposal
  - Know requirements around proper disposal; OSHA regulations

https://www.cdc.gov/labquality/docs/waived-tests/15_255581-test-or-not-test-booklet.pdf

Select Testing Devices

Step 5: Select Testing Devices

CLIA classification (waived tests only)

Accuracy and precision

Manufacturer support

Cost

- Device
- Consumables: including test kits, supplies, reagents, disposables, controls and calibration materials
- Equipment and related costs: repairs or maintenance contracts, training requirements and continuing education, etc.

https://www.cdc.gov/labquality/docs/waived-tests/15_255581-test-or-not-test-booklet.pdf

Select Testing Devices

Step 5: Select Testing Devices

Storage Requirements

Temperature Sensitivity

Samples
- Collection device included
- Amount of sample required
- Length of time sample is stable
- Disposal of sample

Handling of Components

Timing of Results

Range

QC Policy and Procedure

Limitations

https://www.cdc.gov/labquality/docs/waived-tests/15_255581-test-or-not-test-booklet.pdf

Active Learning Session: Test Kit Discussion

https://www.pexels.com/photo/colleagues-having-a-business-meeting-6340656/

Develop Policies and Procedures

Step 6: Develop Policies and Procedures

- Standard operating procedures are necessary to guide your testing practices
  - Create them and follow them!!
    - Testing activities
    - Specimen collection (rapid results versus lab results)
    - Disposal of supplies and hazardous material
    - Documentation requirements
    - Quality control and improvement
- Always follow **all** manufacturer's instructions for test kits
  - Ensure you are using newest instructions
    - Provided with each testing kit

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https://www.cdc.gov/labquality/docs/waived-tests/15_255581-test-or-not-test-booklet.pdf

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Develop Policies and Procedures

Step 6: Develop Policies and Procedures

Quality Control (QC)

- Performing and documenting QC procedures and results
  - Frequency of performing quality control
- Reviewing QC records and test results
- Reviewing room and refrigerator temperature log sheets for complete documentation
- Documenting and reviewing problems and establishing a plan to improve processes
- Documenting and reviewing injury/incident reports

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https://www.cdc.gov/labquality/docs/waived-tests/15_255581-test-or-not-test-booklet.pdf

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Develop Policies and Procedures

Step 6: Develop Policies and Procedures

- Documentation
  - Quality control
    - Equipment
      - Maintenance
      - Service records
      - Calibrations
      - Daily record of monitored conditions and corrective actions
  - Patient results
    - Follow-up and referral
    - Result interpretation
      - Critical values - test results that require immediate treatment or evaluation
  - Personnel training

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https://www.cdc.gov/labquality/docs/waived-tests/15_255581-test-or-not-test-booklet.pdf

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Testing Personnel and Training

Step 7: Testing Personnel and Training

Pharmacist Training

- OSHA
- Device technique and maintenance
- Quality assurance
- Troubleshooting
- Result interpretation
- Billing procedures

Routinely assessed for competency

Designated and credentialed to perform specific tasks

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https://www.cdc.gov/labquality/docs/waived-tests/15_255581-test-or-not-test-booklet.pdf

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Testing Personnel and Training

Step 7: Testing Personnel and Training

Support Staff Training

- OSHA
- Patient process procedures
- Billing

Document Activities

- Orientation
- Training
- Continuing education
- Performance evaluations
- Communication

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https://www.cdc.gov/labquality/docs/waived-tests/15_255581-test-or-not-test-booklet.pdf

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Step 8: Implement Your Program

Step 8: Implement – First Test!

- Conduct first point of care test!

(Kendrick, 2019)

Step 8: Implement – First Test!

Prepare for Testing: Tips

- Check inventory regularly to ensure you will have enough reagents and supplies on hand for testing
- Check and record expiration dates of reagents/kits, and discard any reagents or tests that have expired
- Check that all kit reagents came from the same kit lot. Do not mix reagents
- Allow time for refrigerated reagents/samples to come to room temperature prior to testing
- Perform equipment calibration checks, as needed, following the manufacturer's instructions

https://www.nih.gov/sites/default/files/styles/featured_media_breakpoint-medium/public/news-events/news-releases/2021/20211014-RADx.jpg?itok=xc5DaECd&timestamp=1634229590

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BREAK

PATIENT ASSESSMENT AND SPECIMEN COLLECTION TECHNIQUES

Vital Signs and Physical Assessment Process

Vital Signs and Statistics

- Assess vital signs and statistics at the beginning of the exam (as applicable) after patient assessment:
  - Weight
  - Height
  - Temperature
  - Pulse
  - Respiratory rate
  - Blood pressure
  - Pulse oximetry
- Document whether normal or abnormal

Clinical Pearls: Vital Sign--Temperature

- "Normal" body temperature
  - 97-99° F; 36.1-37.2° C
- Body temperature can be affected by:
  - Site measured: rectally-higher; axillary-lower
  - Age: children-higher; elderly-lower
  - Time of day: fluctuates during the day: morning-lower; afternoon-higher
  - Physical exertion: higher temps
  - Emotions: higher temps when stressed
  - Meals: higher 20-30 minutes after eating
  - Drugs/smoking: higher temps

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(Bello-Quintero, 2014)
([Untitled Illustration of Digital Thermometer], Jainsons Lights Online)
([Untitled Illustration of Non-Contact Forehead Thermometer], CDN11 Big Commerce)

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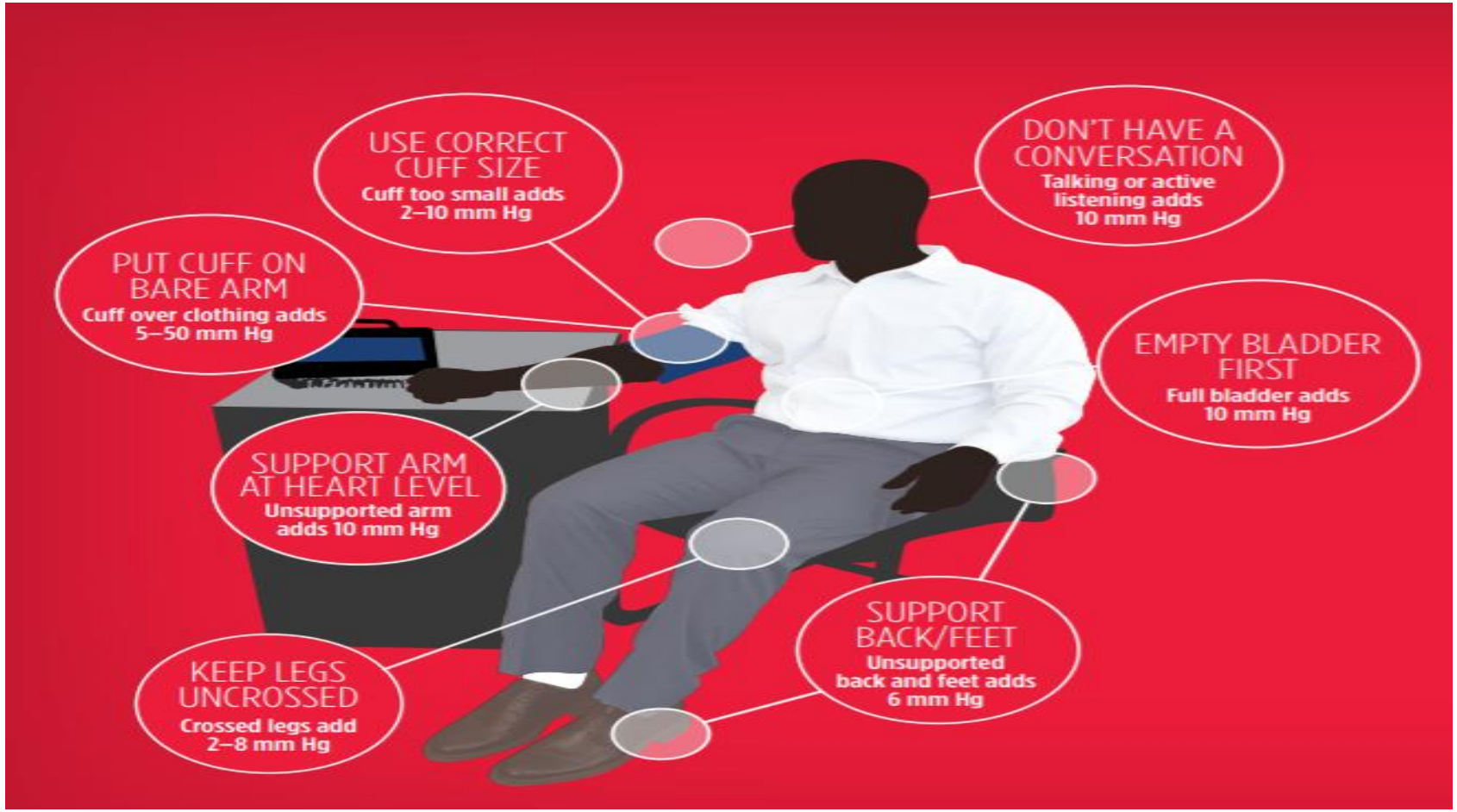
Clinical Pearl: Blood Pressure--Proper Positioning Matters



(Target:BP, n.d.)
(AMA, 2017)

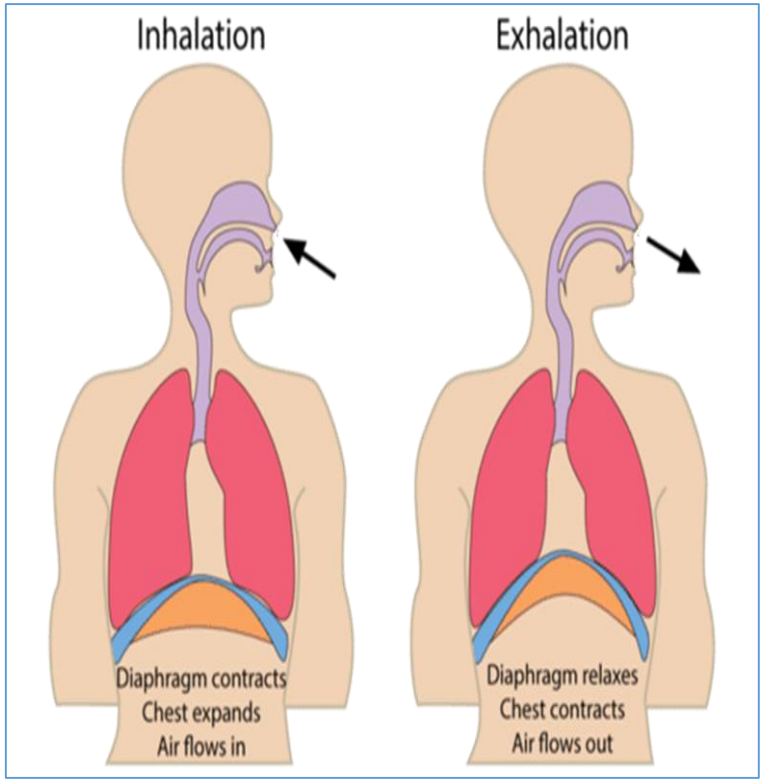
Clinical Pearls: Vital Sign--Pulse

- A normal resting heart rate should be 60–100 beats per minute
  - Can vary from minute to minute and by patient
- Don’t push too hard when trying to measure a patient’s pulse
  - May cause you to feel your own pulse
- Avoid using your thumb for checking pulse
- Pulse can be affected by:
  - Air temperature: higher pulse when hot/humid
  - Body position: higher when standing
  - Emotions: higher when stressed or anxious
  - Body size: higher resting pulse when obese
  - Medications: some lower while some increase pulse

(Bello-Quintero, 2014)

Clinical Pearls: Vital Sign--Respiratory Rate (RR)

- Normal rate for adult person at rest is 12-16 breaths per minute
- Measure when patient is relaxed and unaware you are measuring
- Rate can be affected by:
  - Alcohol: decreases rate
  - Health conditions:
    - Rate decreases in hypothyroidism, stroke, narcotic use
    - Rate increases in fever, dehydration, asthma/COPD, heart conditions, infections, anxiety, pain, etc



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(Bello- Quintero, 2014)
([Untitled Illustration of Inhalation and Exhalation], CloudFront)

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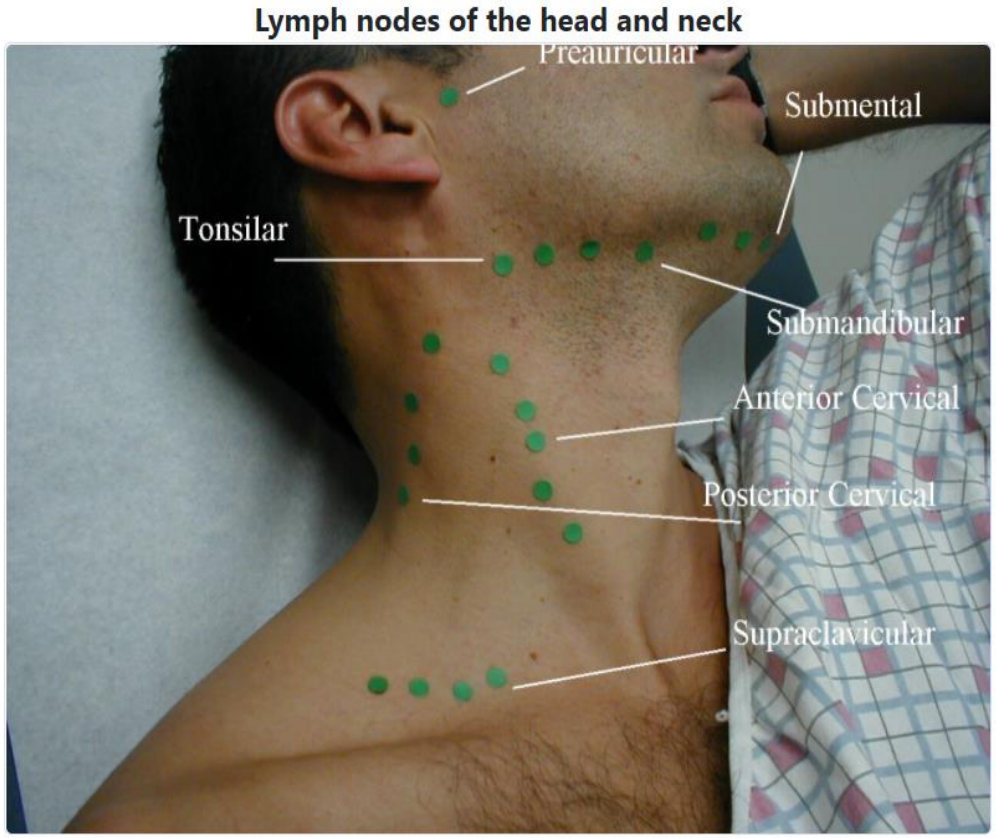
Clinical Pearls: Vital Sign--Pulse Oximetry

- Normal range: 95-100%
- Pulse oximetry can be affected by:
  - Bright light shining on finger/device
  - Poor circulation
  - Weak pulse
  - Skin pigment
  - Skin thickness
  - Skin temperature
  - Fingernail polish
  - Current tobacco use

(American Lung Association, n.d)

Clinical Pearls: Lymph Node Palpation

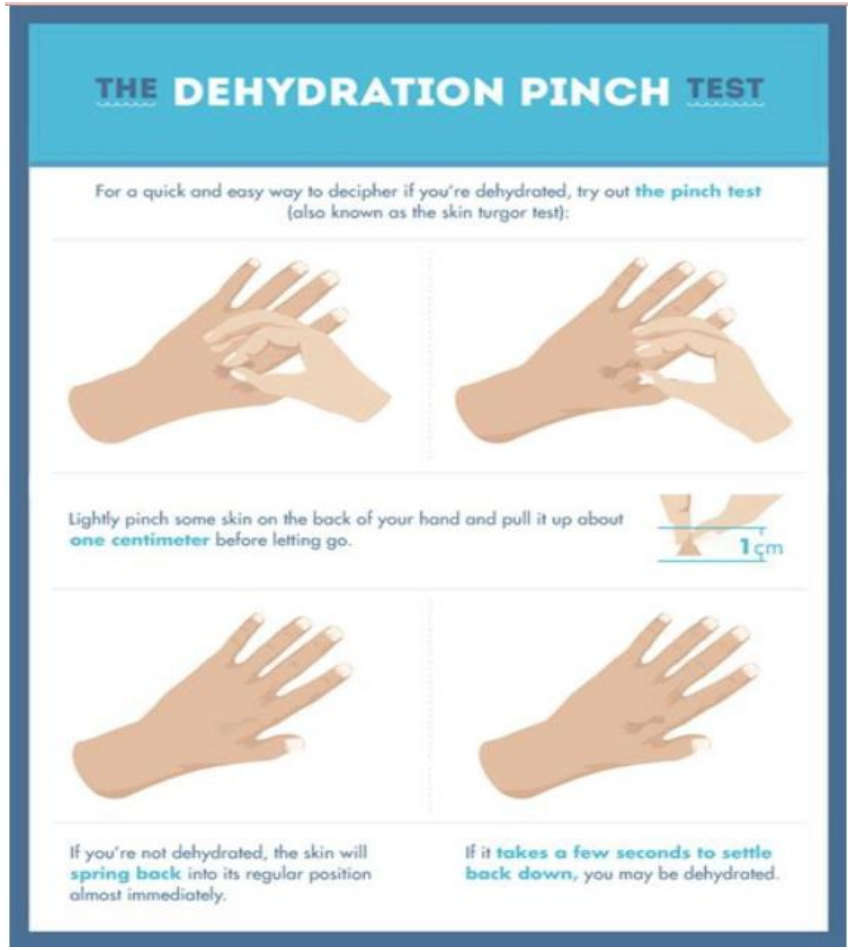
- Enlarged lymph nodes can be a sign of infection
  - Viral (cold) or bacterial (strep)
  - Can also signal <u>many</u> other conditions
- Tell patient what to expect before you start touching their lymph nodes
  - You should be comfortable and confident in your ability to palpate



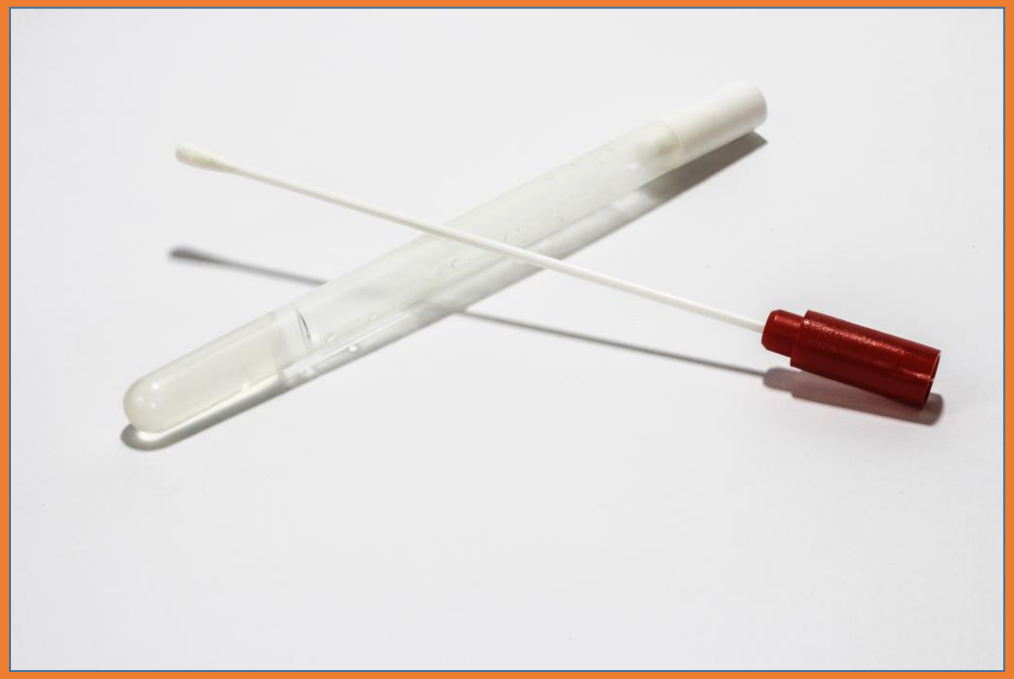
(AMBOSS: Medical Knowledge Distilled, 2016)

Clinical Pearls: Skin Assessment

- There are five key parameters to take note of during a skin assessment:
  1. Temperature
  2. Color
  3. Moisture level
  4. Turgor
  5. Skin integrity (skin intact?)
- Tell patient what to expect before you start touching their hands
  - You should be comfortable touching their hands and completing the pinch test



(Bello-Quintero, 2014)
([Untitled Illustration of the Dehydration Pinch Test], Fix



Preparing for Specimen Collection

Get Ready: Equipment and Supplies

Gather appropriate supplies

Only use devices and collection equipment approved by the manufacturer

Set the supplies in the area where testing will occur

Ensure biohazard waste is nearby

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(CDC, 2019)

Personal Protective Equipment (PPE)

Order for *Putting On* Your PPE

Order for *Taking Off* Your PPE

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https://www.cdc.gov/coronavirus/2019-ncov/downloads/lab/NP-Specimen-Collection-Infographic.pdf

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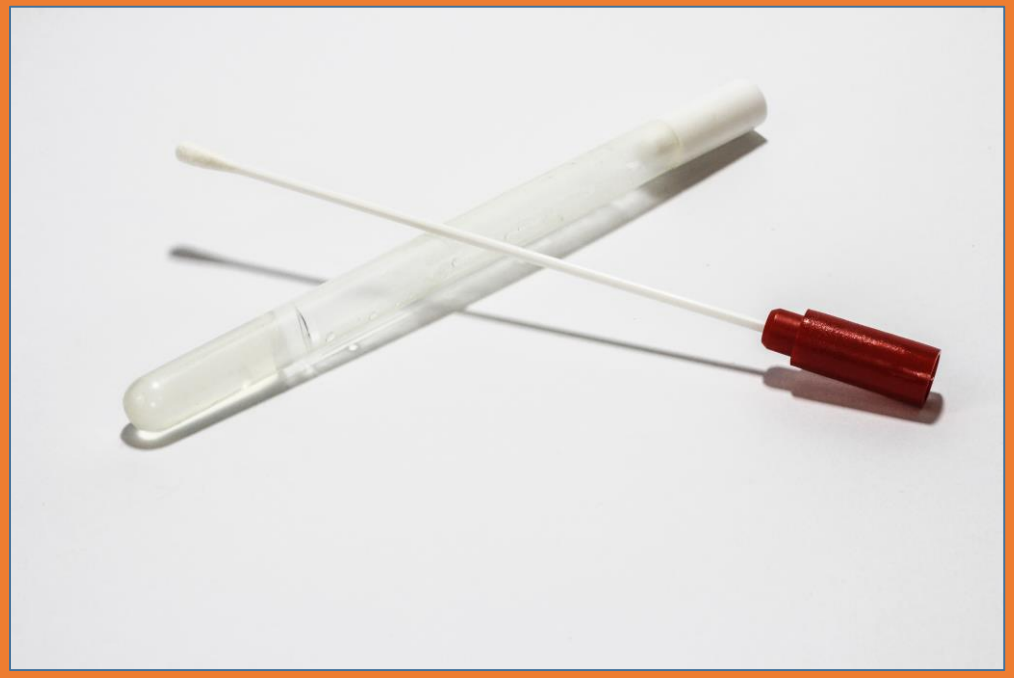
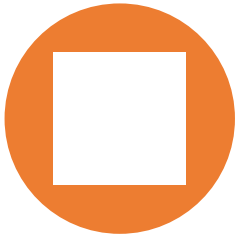
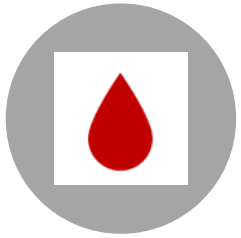


Specimen Collection Process

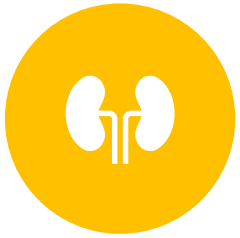
Types of POCT Specimens



MUCUS



BLOOD



URINE

ORAL FLUID

STOOL

(CDC, 2019)

Blood-Based Point-of-Care Testing: Finger Stick

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Blood-Based Point-of-Care Tests

- Diabetes
  - Blood glucose levels
  - Hemoglobin A1c
- H. pylori
- Human immunodeficiency virus
- Lipid panel
- Malaria
- Mononucleosis
- Prothrombin time/international normalized ratio (PT/INR)
  - Blood clotting times
  - Often done in primary care settings

(Indiana Department of Health, 2018)

Video: How to Perform a Finger Stick

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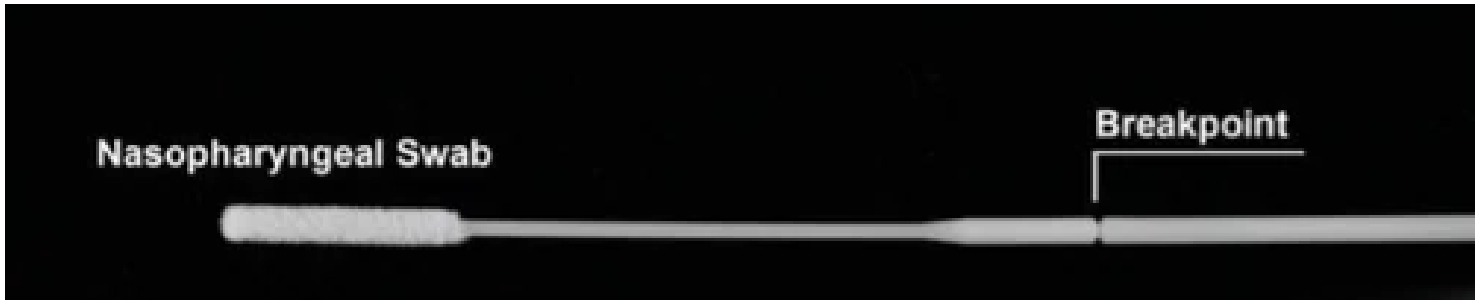
Steps for Taking Finger Stick Sample

- Gather supplies (chux pad, alcohol swab, lancet, strip/capillary tube, sterile bandage, sharps container)
- Put on gloves
- Turn patient's hand upward; massage finger to increase blood flow
- Clean area with alcohol swab; let dry
- Hold finger in upward position pressing firmly on the finger as you puncture skin with lancet
- Blot first drop of blood with gauze pad continuing to massage finger to increase blood flow
- Hold strip (or capillary tube) near blood drop without touching the skin gathering enough blood for sample
- Apply sterile adhesive bandage over puncture site (based on patient's desire)
- Follow test kit instructions for testing sample
- Discard all used materials appropriately

Practice Pearls: Finger Stick

- Ask patient which finger they prefer
- Select single-use lancets that permanently retract upon puncture
  - This adds an extra layer of safety for the patient and the provider
- Never reuse lancets (on the same patient or a different patient)
- Discard all blood collection materials and “sharps” in properly labeled biohazard containers approved for their disposal
- Unused supplies and medications should be maintained in clean areas separate from used supplies and equipment
  - Do not carry supplies and medications in pockets

Fluid Point-of-Care Testing: Nasopharyngeal (Nasal) Swab



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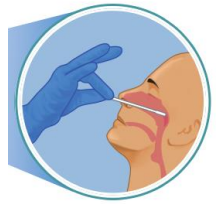
Video: How to Perform a Nasopharyngeal Swab



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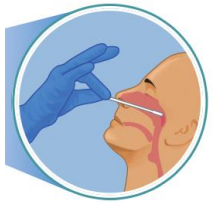
Steps for Taking a Nasal Swab



- Gather supplies (nasopharyngeal swab, collection tube or test kit, tissue)
- Put on gloves (and any other PPE)
- Have the patient blow their nose before you begin to clear secretions
- Tilt patient's head back 70 degrees
- Gently and slowly insert the swab through the nostril parallel to the palate until you feel resistance (distance is equal to that from nostril to the ear)
  - Tests vary as to how far into the nostril you should go for sample so follow kit instructions carefully
- Gently rub and roll the swab leaving in place for several seconds
- Slowly remove swab while rotating it
- Follow test kit instructions for testing sample (or place swab in tube for transport)
- Discard all used materials appropriately

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https://www.cdc.gov/coronavirus/2019-ncov/downloads/lab/NP-Specimen-Collection-Infographic.pdf

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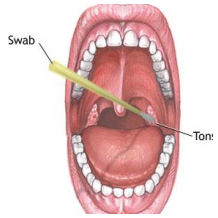
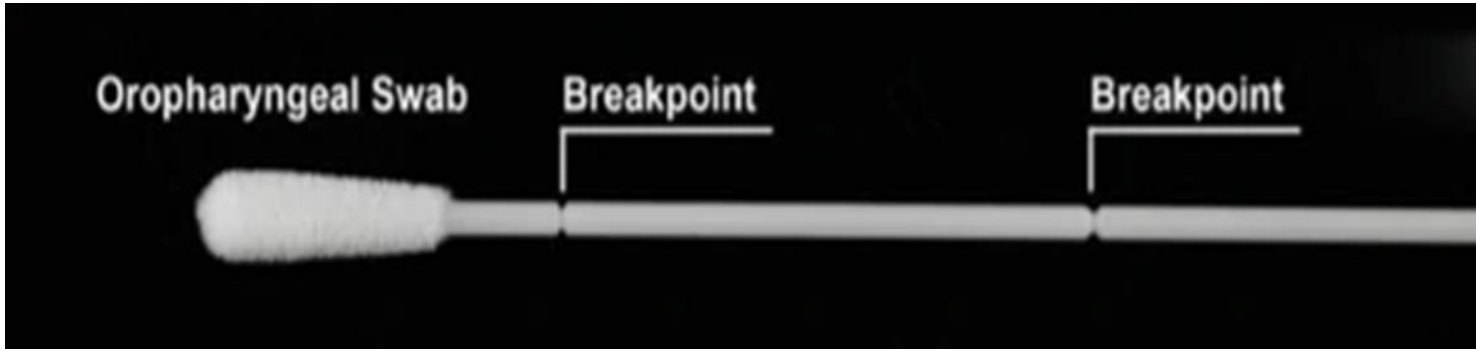
Practice Pearls: Nasopharyngeal (Nasal) Swab

- Tell the patient what to expect and ask if it is ok to touch their head
- Support the patient's head at the nape of their neck
- Swab can be uncomfortable and may cause coughing or gagging
- Discard all collection materials properly
- Unused supplies and medications should be maintained in clean areas separate from used supplies and equipment. Do not carry supplies and medications in pockets.



Fluid Point-of-Care Testing: Oropharyngeal (Throat) Swab



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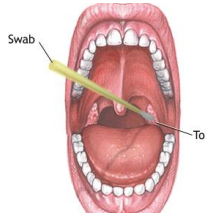
Video: How to Perform an Oropharyngeal (Throat) Swab



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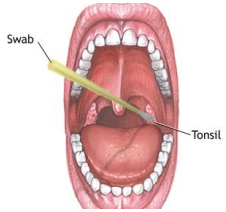
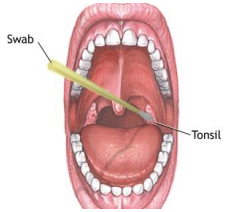
Steps for Taking a Throat Swab



- Gather supplies (oropharyngeal swab, collection tube or test kit, tongue depressor)
- Put on gloves (and any other PPE)
- Tilt patient's head back 70 degrees
- Use tongue depressor to hold down tongue; have patient say "aaahhh"
- Gently and slowly insert the swab into the posterior pharynx and tonsillar areas
- Rub swab over both tonsillar pillars and posterior pharynx without touching tongue, teeth, or gums
- Slowly remove swab and tongue depressor
- Follow test kit instructions for testing sample (or place swab in tube for transport)
- Discard all used materials appropriately

Practice Pearls: Oropharyngeal (Throat) Swab



- Tell the patient what to expect and ask if it is ok to touch them
- Swab can be uncomfortable and may cause gagging
- Discard all collection materials properly
- Unused supplies and medications should be maintained in clean areas separate from used supplies and equipment
  - Do not carry supplies and medications in pockets

QUESTIONS

CLOSING AND SKILLS ASSESSMENT

Next Steps

<u>On your own within 30 days</u>

- ❑You should have a supply kit (next slide)
- ❑Perform Point-of-Care Testing Specimen Collection for Skills Assessment and complete assessment form completely
  - ❑Throat swab
  - ❑Nasal swab
  - ❑Finger stick testing
- ❑<u>Must be uploaded into APhA LMS</u>
- ❑Claim CE credit and receive Certificate of Achievement

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Your Supply Kit Includes:

- 2 alcohol swabs
- 4 gloves
- 2 lancets
- 2 sterile gauze pads
- 2 adhesive bandages

- 2 sterile nasal swabs
- 2 sterile throat swabs
- 2 sterile tongue depressors
- 3-4 facial tissues
- 2 test strips

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