



Test-and-Treat: Utilizing POCT and Pharmacist Prescribing to Enhance Care

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Disclosures

Our speaker Michael Klepser declares that he has a current affiliation or financial arrangement with ineligible companies as a consultant with BD Diagnostics and Qorvo Biotechnologies and as a grant recipient from Genentech. He also declares that he has a past affiliation or financial arrangement with ineligible companies as a consultant with PrimaryHealth and Lam Simply and as a grant recipient from Roche Diagnostics within the past 24 months.

Additionally, the individuals involved in the planning of this activity have not had an affiliation or financial arrangement with any ineligible companies that may have a direct interest in the subject matter of this CPE program within the past 24 months.

All relevant financial relationships have been mitigated.



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Objectives

After completing this activity, participants should be able to:

1. Summarize the outcomes data surrounding pharmacy-based test-and-treat programs.
2. List features of a test-and-treat program that would be considered best practice.
3. Identify similarities and differences in states with respect to permissibility of pharmacy-based test-and-treat programs.



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Audience Response



Log in to Poll Everywhere

To present live activities, please log in to your Poll Everywhere account in a separate window.

[Launch log-in window](#)

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Evolution of Community Pharmacy

- Community-based pharmacy is evolving from a place of product distribution into a healthcare destination
 - Pharmacists collaborate with primary care practices as part of an integrated healthcare team on one shared medical record.
 - Start, stop, and modify drug therapy
 - Order labs
 - Patients go to their pharmacists for point-of-care testing, immunizations and travel consultations, or prescriptions for contraception, smoking cessation, minor ailments, and HIV prevention.



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Growth of The CLIA-waived and Home Testing Markets

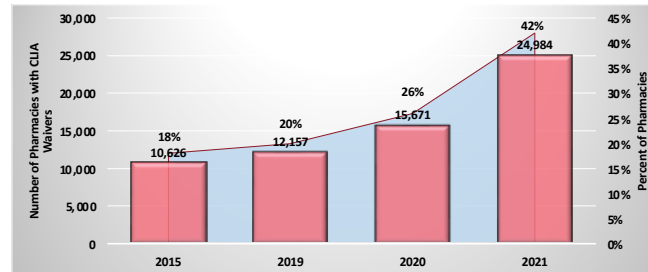
- Testing is not an endpoint, rather it is a means to expand access to care.
 - Patients do not want to get tested, they want to get better and feel heard.
 - Patients want to make decisions that:
 - Improve efficiency of their care
 - Increase convenience of their care
 - Reduce the cost of their care



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Growth of CLIA-Waived Services

- Ten years ago CLIA-waived testing in pharmacies was uncommon.
- Pharmacies exhibited the largest growth of CLIA-waived facilities between 2015 and 2021 (230% increase and 14,358 new locations)



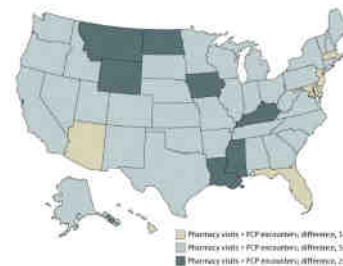
N3 Kleper, et al. Impact of COVID-19 on prevalence of community pharmacies as CLIA-Waived facilities. Res Social Adm Pharm. 2021 Sep;17(9):1574-1578.



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Justification for Pharmacy-Based Services

- Need.
 - At least 30% of adults do not identify a primary care provider.
- Accessibility.
 - Patients visit pharmacies more than 13 billion times each year versus 447 million visits to physician offices.
- Demand.
 - 61% of Americans envision most primary care services being provided at pharmacies, retail clinics and/or pharmacy clinics.

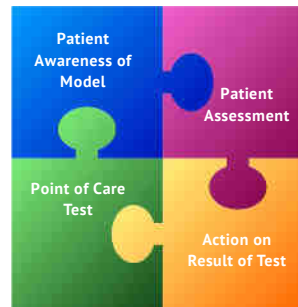


Berenbrok LA, et al. JAMA Network Open. 2020;3(7):e209132. doi:10.1001/jamanetworkopen.2020.9132.
<https://www.cdc.gov/nchs/fastats/physician-visits.htm>
<https://www.wolterskluwer.com/en/news/us-survey-signals-big-shifts-in-primary-care-to-pharmacy-and-clinic-settings>



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Model of Care for Acute Conditions

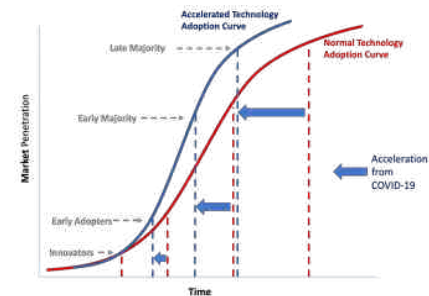


Adams AJ. Toward permissionless innovation in health care. J Am Pharm Assoc 2015;55:359-362

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Patient Awareness

- The pandemic has been an accelerating event with respect to many technologies including point-of-care tests.
 - Pre-pandemic, most Americans did not consider going to a pharmacy for management of an acute illness.
 - Post-pandemic, 61% of Americans envision most primary care services being provided at pharmacies.
 - Up to 70% for younger cohorts



<https://www.wolterskluwer.com/en/news/us-survey-signals-big-shifts-in-primary-care-to-pharmacy-and-clinic-settings>

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Patient Assessment

- Assessment is critical to develop a care plan.
 - Symptoms
 - Vital signs
 - Medical history
 - Medication history
 - Immunization history
 - Social and travel histories



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Point-of-Care Testing

- Tool to help with decision making.
 - Testing is not always the answer.



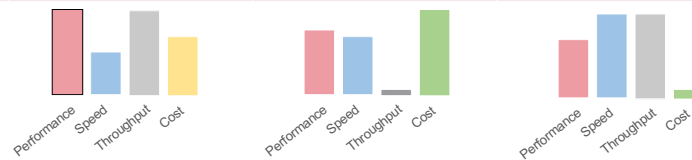
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No Test is Perfect

	High Complexity PCR	Moderate-Waived PCR	Waived/Home Antigen
Benefits	<ul style="list-style-type: none"> Excellent performance characteristics 	<ul style="list-style-type: none"> Good performance characteristics Quick turn-around time 	<ul style="list-style-type: none"> Quick turn-around time Inexpensive Easy to use
Limitations	<ul style="list-style-type: none"> Expensive Long turn around High complexity 	<ul style="list-style-type: none"> Require expensive analyzers Low throughput 	<ul style="list-style-type: none"> May experience high false positive and/or false negative results

Which is the best test?



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Situational Relevance

- Situationally relevant information is explained in terms of changes of view in relation to questions of concern.
 - A solution is only as good as the situation.
 - Optimize pre-test probability

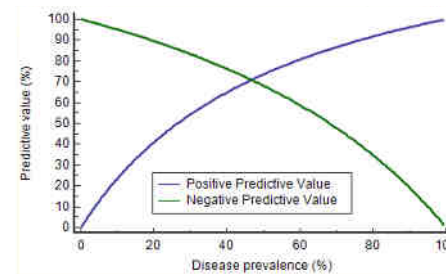


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Diagnostic Accuracy

- PPV and NPV
 - Influenced by the prevalence of disease in the population that is being tested.
 - If the prevalence of disease is high, positive tests typically are true. False negative may be likely.
 - If the prevalence of disease is low, negative tests are typically true. False positives may be likely.



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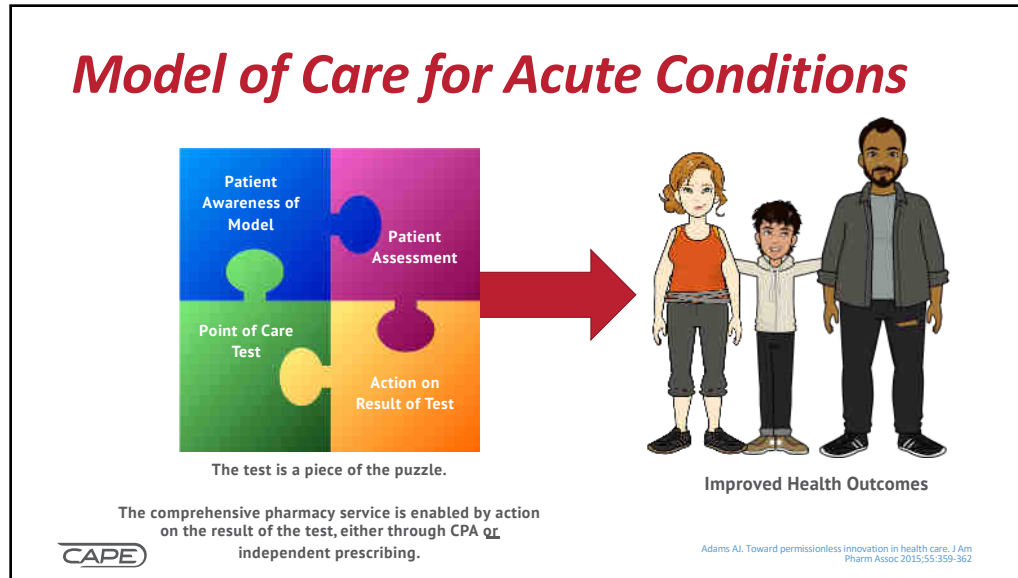
Action on Test Results

- Disease management programs not disease testing programs.
 - Test-and-treat
 - Acute illness
 - Test-and-refer
 - HIV, lead screening
 - Test-and-monitor
 - Stable chronic conditions
 - Test-and-modify
 - Dynamic chronic conditions



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Audience Question Poll

When poll is active respond at PollEv.com/michaelklepser450

Can pharmacists in your state offer test-and-treat services?
Loading...

Yes	0%
No	0%
Unsure	0%

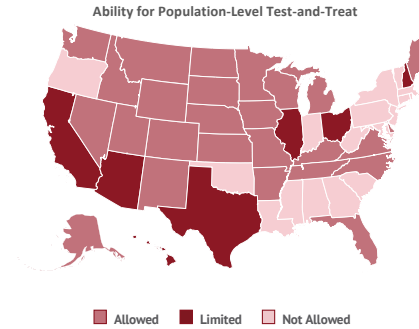
[Instructions](#)
[Responses](#)
[Clear responses](#)

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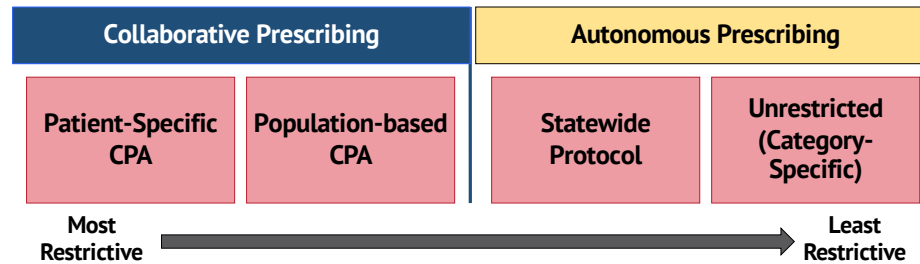
POCT-Centered Patient Care Models

- 26 states currently allow for some population-level test-and-treat programs in pharmacies
 - Numerous states with pending legislation
- CLIA-waived rapid diagnostic tests should be used by clinicians with an understanding of when to test and how interpret results
 - >11,000 pharmacists have been trained through the NASPA certificate program



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Continuum of Pharmacist Prescriptive Authority



Adams AJ, Weaver KK. The Continuum of Pharmacist Prescriptive Authority. *Annals of Pharmacotherapy*. In Press.

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Protocols and Collaborative Practice Agreements

- Collaborative Practice Agreement (CPA)
 - A formal practice relationship between pharmacists and prescriber(s).
 - Allow for the delegation of various prescriber functions to the pharmacist.
 - State may allow for patient-specific CPA's or population CPA's
 - Patient-specific CPA's require an existing relationship between the patient and the prescriber that signs the CPA.
 - Population-level CPA's allow a prescriber to sign a CPA that authorizes the pharmacist to provide care to individuals that do not have an existing relationship with the prescriber.



<https://www.cdc.gov/dhisp/pubs/guides/best-practices/pharmacist-cdtm.htm>

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Protocols and Collaborative Practice Agreements

- Protocols
 - A framework that specifies the conditions under which pharmacists are authorized to prescribe a medication or order a tests when providing a clinical service.
 - Issued by an authorized state body pursuant to relevant state laws and regulations. Each protocol specifies the qualifications required for pharmacists to implement the protocol and the procedure(s) that must be followed.




<https://nasp.us/resource/swp/#unique-identifier-continuum>

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Audience Participation


When poll is active respond at [PollEv.com/michaelkepser450](https://poll.evo.com/michaelkepser450)



How are pharmacists authorized to provide test-and-treat services if your state?
Loading...

Physician-level CPA
Pharmacist-level CPA
They are not all
with prescriptive authority


Instructions Responses Clear responses



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Pharmacies as CLIA-waived Laboratories

- Considerations before introducing waived testing or offering a new waived test
 - Management responsibility for testing
 - Who will be responsible and accountable for testing oversight at the site, and does this person have the appropriate training for making decisions on testing?
 - Regulatory requirements
 - What federal, state, and local regulations apply to testing, and is the site adequately prepared to comply with all regulations?
 - Safety
 - What are the safety considerations for persons conducting testing and those being tested?
 - Testing space and facilities
 - What are the physical and environmental requirements for testing?

 <https://www.cdc.gov/mmwr/preview/mmwrhtml/rr5413a1.htm>

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Components of a Successful Disease Management Program

- Means to provide follow-up care
- Identify suitable CLIA-waived POC tests
- Trained personnel
 - NASPA POC certificate program for pharmacists
 - Tests are only a component of a disease management program
- Plan for patient follow-up
- Data sharing plan
- Good business plan



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Supporting Transformation

- New practice models cannot be sustained without change to existing workspace and workflow.
- Pharmacists will need to embrace new roles for themselves and technicians.
 - Understand division of labor strategies to optimize roles for all members of the pharmacy team.
- Need a better understanding of billing and coding procedures.



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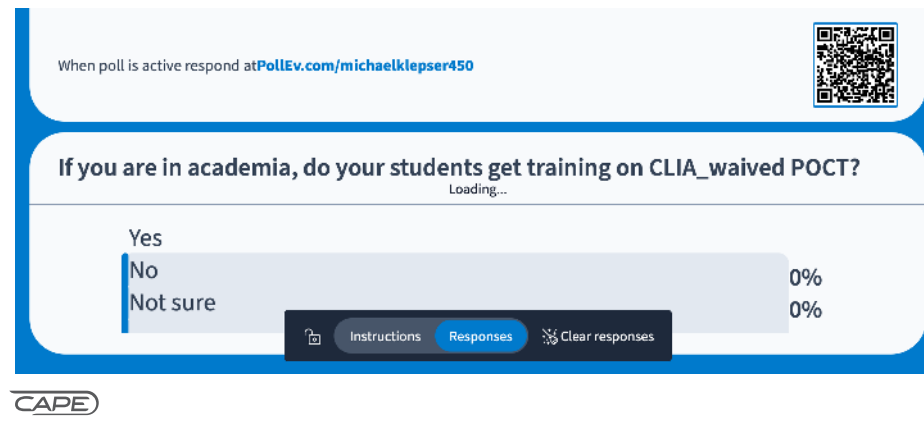
Supporting Transformation

- Practice and education need to align
 - In its 2018 report, “The Next Transition in Community-Based Pharmacy Practice,” the American Pharmacists Association found that pharmacists are trained to perform a variety of tasks but often experience work settings that are not conducive to such practice.



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Audience Response



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Audience Response


When poll is active respond at [PollEv.com/michaelklepser450](https://poll.ev.com/michaelklepser450)



What type of traing do your students' get on CLIA-waived POCT (eg., didactic, specimen collection, running tests) Loading...

Nobody has responded yet.
Hang tight! Responses are coming in.

Instructions Responses Clear responses



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Pharmacy-Based Disease Management Models

- Offer convenient, evidence-based care with a patient-centered approach.
 - Up to 50% of patients seek care outside of established physicians' office hours.
 - Rates of provision of antimicrobials inline with pathogen incidence.
 - Patient satisfaction is high
 - Patients do not want to get tested, they want to get better and feel heard.





ME Klepser, et al J Am Pharm Assoc. 2016; 56:14-21.
DG Klepser, et al. J Am Pharm Assoc. 2016;56:323-9.

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Journal of the American Pharmacists Association 56 (2016) 14–21

Contents lists available at ScienceDirect



Journal of the American Pharmacists Association

Journal homepage: www.japha.org



SCIENCE AND PRACTICE

RESEARCH

Effectiveness of a pharmacist-physician collaborative program to manage influenza-like illness

Michael E. Klepser, Donald G. Klepser^a, Allison M. Dering-Anderson, Jacqueline A. Morse, Jaclyn K. Smith, Stephanie A. Klepser

Journal of Clinical Pharmacy and Therapeutics
doi:10.1093/joc/dkw264

EXPERIENCE


A feasibility study of a community pharmacist-physician collaborative streptococcal pharyngitis management program

Donald G. Klepser^a, Michael E. Klepser, Allison M. Dering-Anderson, Jacqueline A. Morse, Jaclyn K. Smith, Stephanie A. Klepser, F. Thornley^{b,c}, G. Marshall^b, R. Howard^d and A. P. R. Wilson^{a*}

^aBoots UK, Nottingham NG90 1BS, UK; ^bSchool of Pharmacy, University of Nottingham, University Park, Nottingham NG7 2RD, UK; ^cMedicines Management & Pharmacy, Leeds Teaching Hospitals NHS Trust, Leeds LS2 3BE, UK; ^dDepartment of Microbiology & Virology, University College London Hospitals, London W11 4EJ, UK

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Received 13 November 2015; returned 22 April 2016; revised 24 May 2016; accepted 30 May 2016



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Collaborative Influenza Disease State Management Program

	n/N (%)
Total Number of Patients Screened	121
• Excluded from participation	45/121 (37.2%)
• Eligible for participation	76/121 (62.8%)
Patients Tested for Influenza	
• Did not have a primary care provider	26/75 (34.6%)
• Seen outside of regular clinic office hours	29/75 (38.7%)
POC Test Result	
• Positive	8/75 (10.7%)
• Negative	67/75 (89.3%)
Patient Receipt of Oseltamivir	
• Positive test	
○ CPA Site	5/5 (100%)
○ Physician Call	1/3 (33.3%)
• Negative test	0/67 (0%)



ME Klepser, et al J Am Pharm Assoc. 2016; 56:14-21.

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Collaborative Influenza Disease State Management Program

- Key findings:
 - Using a collaborative practice agreement and judicious use of an influenza POC test, pharmacists were appropriately able to identify and management patients with influenza.
 - Approximately **11%** of patients evaluated tested positive for influenza and received an antiviral.
 - Inline with national data for 2013-14.
 - Most patients received recommendations for management of symptoms.
 - No adverse clinical outcomes were noted.
 - **Patient satisfaction was >92%.**
 - Time and motion studies demonstrated that this model fit nicely into pharmacy workflow.



ME Klepser, et al J Am Pharm Assoc. 2016; 56:14-21.

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Collaborative GAS Pharyngitis Disease State Management Program

- Key Findings:
 - 316 patients were screened and 273 (86.3%) were eligible for participation.
 - 48 (**17.5%**) had a positive POCT result and were dispensed an antibiotic.
 - 37.3% did not identify a primary care provider.
 - 43.9% visited the pharmacy outside of established physician's office hours.



DG Klepser, et al. J Am Pharm Assoc. 2016;56:323-9.

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GAS Pharyngitis Disease State Management Program (UK)

- GAS pharyngitis management program
 - Developed with multidisciplinary input.
 - Trained pharmacists determined a Centor score and performed a POCT, if appropriate.
 - Patients with a severe presentation were referred.
 - Antibiotics were administered if the POCT was positive.
 - Patients paid £7.50 (\$10.00) for the test.
- Key Findings:
 - 367 patients were screened and 149 were eligible for POCT.
 - 24.2% (36/149) tested positive and received antibiotics.
 - 9.8% of the screened population.

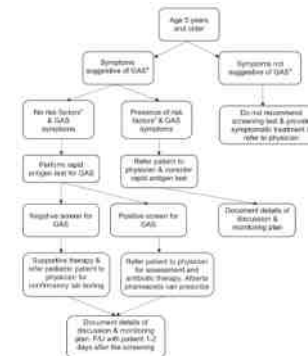


Thornley T, et al. J Antimicrob Chemother. 2016;71:3293-9.

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GAS Pharyngitis Disease State Management Program (Canada)

- Screened 7,050 patients >5 years of age from 204 pharmacies across Canada from 2015-16.
 - Screening cost was \$20.
 - Patients with negative results were managed with OTC medications.
 - 25% of patients were positive for GAS.
 - 68.7% and 5.6% of patients with positive and negative results, respectively, got an antibiotic the same day.



Papastergiou, et al. IAPHA. 2018;S8:450-6.

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GAS Pharyngitis Disease State Management Program (Canada)

- Patient satisfaction was >80%.
- 75% of patients reported going to the pharmacy first when they had a sore throat.
- 54% of patients stated that their doctor was unavailable to see them.



Papastergiou, et al. JAPhA. 2018;58:450-6.

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Data, Data, Data

Received: 29 November 2022 | Revised: 12 April 2023 | Accepted: 13 April 2023
DOI: 10.1002/jcp.51739

CLINICAL PHARMACY FORUM



Community pharmacist-provided test and treat programs for acute infectious conditions

Renee R. Koski Pharm.D.¹ | Nick Klepser MPH² | Madelyn Koski³ |
Michael Klepser Pharm.D., FCCP⁴ | Donald Klepser Ph.D., MBA⁵

- Thirteen studies were found that evaluated U.S.-based community pharmacy CLIA-waived POCT programs .
 - Three for influenza
 - Two for group A streptococcal pharyngitis
 - Three for influenza and/or group A streptococcal pharyngitis
 - Five for COVID-19 testing.



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Opportunities for ID-related, POCT-supported, Disease Management Programs in Pharmacies

- Conjunctivitis
- Sexually transmitted infections
- Lyme Disease
- **Respiratory infections**
 - SARS-CoV-2, Influenza, RSV
- **Acute pharyngitis**
- Urinary tract infections
- Infectious mononucleosis
- HIV
- HCV



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Opportunities for ID-related, POCT-supported, Disease Management Programs in Pharmacies

- Chronic disease management
 - More than diabetes and cholesterol.




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Audience Response

Join by [WebPollEv.com/michaelklepser450](https://webpoll.ev.com/michaelklepser450)



Students at my college are traing to to collect blood via venipuncture.

Loading...

True	False	Undure
0%	0%	0%

Instructions Responses Clear responses

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Blood Collection Regulations

- Requirements/training
 - There are no Federal statutes that address qualifications for individuals performing blood collection.
 - Left for individual states to regulate.



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Blood Collection Regulations

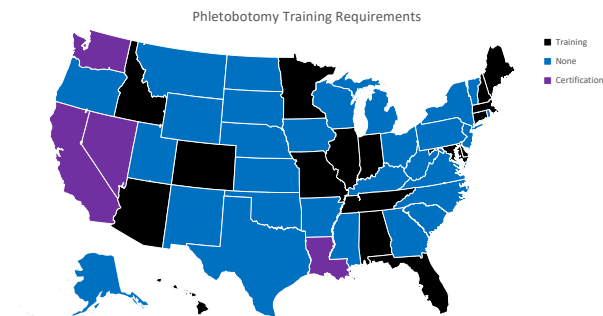
- Training and certification
 - Only four states (California, Louisiana, Nevada, and Washington) require certification or licensure to draw blood.
 - Other states may have training requirements or allow employers to set qualification requirements for individuals who draw blood.



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State Requirements

- Vary from requiring certification (n=4) completion of an accredited training course (n=17) to no specified training (n=29).



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Venipuncture Training



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Summary

- Pharmacy-based models of care provide convenient, evidence-based care with a patient-centered approach.
- The dominos are falling.
 - More states allow for autonomous pharmacy-delivered care.

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**Collaboration to Advance
Pharmacy Enterprises (CAPE)**

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Assessment Questions

The most desirable approach for authorizing pharmacists to offer test-and-treat programs in a state is:

1. Physician-level CPA
2. Population-level CPA
3. State-wide protocol
4. Autonomous prescriptive authority



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Assessment Question

Which of the following is essential for offering a pharmacy-based, CLIA-waived POCT-supported disease management service?

1. A physician collaborator
2. A test with high sensitivity and specificity
3. A plan for patient follow-up
4. A laboratory manager



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Assessment Question

Which disease states currently have the most data to support their implementation

1. Acute pharyngitis
2. Conjunctivitis
3. Influenza
4. 1 and 2
5. 1 and 3



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