COVER STORY

In the United States, there are roughly 7 million individuals with undiagnosed diabetes and 25 million individuals with unrecognized dyslipidemia. Furthermore, it has been estimated that 240,000 persons are living unknowingly with HIV and another 1 million with hepatitis C (HCV). From 1997-2010, there were approximately 92 million visits by adults to emergency departments and physicians’ offices for pharyngitis. Antibiotics were prescribed to these patients for treatment of group A streptococcus roughly 60 percent of the time. This is an interesting statistic, especially when one considers that group A Streptococcus accounts for only 5-15 percent of cases of pharyngitis in adult patients. Lastly, in the United States (U.S.) alone it is estimated that 3,000-50,000 individuals die each year from influenza. It should be noted that many patients with influenza never receive antiviral therapy because they fail to seek care from a health care professional within the 48-hour treatment window.

Opportunities for Pharmacists to Improve Access to Primary Care Through Use of CLIA-waived Tests

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It is relatively easy to conclude from these statistics that there is a problem with the provision of health in the U.S. and hope that someday access to care and antimicrobial use improves. From the perspective of some pharmacists, it may seem that there is little that we can do to help solve these problems. However, we should take a step back from our day-to-day practice and consider the following:

- It is estimated that there are between 59,000-67,000 community pharmacies in the U.S.
- In 2010, there were approximately 225,000 pharmacists in the U.S. By comparison, there were 208,000 primary care physicians, 30,000 physician assistants and 56,000 nurse practitioners.
- Roughly 250 million people visit a pharmacy weekly, or 13 billion visits each year. This would be an average of 3,700-4,000 weekly visits per pharmacy. In the U.S., there are only 470 million physician office visits annually.
- Estimates place the number of newly-insured individuals through the Affordable Care Act somewhere between 1-3 million.

From these data, it is clear that pharmacists have unsurpassed access to patients. Additionally, with the number of newly-insured individuals increasing by several million, there is going to be additional stress on already strained primary care health providers. This places pharmacists in an ideal position to improve patient access to primary care through the expansion of clinical services. Some pharmacies already offer health screenings and testing for disease makers such as hemoglobin A1C and cholesterol; however, what is done with this information and are pharmacists using the data to improve patient care? Additionally, are pharmacists leveraging all of the tools at their disposal to practice at the highest level afforded them by the law?

In 1988, the Clinical Laboratory Improvement Amendments (CLIA) were passed in an effort to ensure the accuracy, reliability and timeliness of laboratory test results regardless of where the test was performed. Under these regulations, laboratories had to undergo a rigorous certification process in order to be able to perform tests on clinical specimens. However, an exception was created if a laboratory test could be performed with a minimal level of complexity and had a low risk of erroneous results. If these criteria were met, the manufactures of the test were allowed to apply for a CLIA-waiver. Approval of the CLIA-waiver application indicated that the test could be performed in a non-traditional laboratory setting if that site followed good laboratory practices and possessed a valid CLIA waiver. This includes pharmacies. Surprisingly, this one piece of legislation passed nearly 30 years ago to regulate clinical laboratories created one of the most significant opportunities for pharmacists to play a significant role in advancing public health. Unfortunately, pharmacists have not yet taken full advantage of this legislation.

Currently, there are more than 120 different CLIA-waived laboratory tests available in the U.S. (Table 1). Many of these tests can be performed without specialized equipment and provide results within 5-20 minutes. Imagine if a community pharmacist engaged in medication management. What if the pharmacist could then dispense antibiotics to clinically stable patients and refer unstable or high-risk patients? Imagine if a community pharmacist engaged in medication therapy management (MTM) had current serum chemistry data available to them upon which they could base their recommendations. Using the available CLIA-waived tests, pharmacists could offer these clinical services now. So why are pharmacists not using more CLIA-waived rapid diagnostic tests (RDTs) and point-of-care (POC) tests in their practice?

We have identified several barriers to the use of CLIA-waived RDTs and POC tests in pharmacy practice.

- **Test familiarity.** In a recent survey of pharmacists and student pharmacists regarding their familiarity with CLIA-waived infectious diseases RDTs, greater than 85 percent of respondents stated that they had never learned about these tests and would not be comfortable discussing tests or test results with their patients or prescribers. A separate survey conducted by the Society of Infectious Diseases Pharmacists determined that most (greater than 66 percent) of colleges of pharmacy did not include these RDTs in their curricula.

- **Physical assessment skills.** In order for the positive predictive value of a given RDT or POC test to be optimized, a relevant patient population must be identified through performance of a systematic physical assessment. Additionally, pharmacists need to be able to interpret data to determine the clinical stability of patients and then select the appropriate venue (i.e.,

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**Table 1. Selected CLIA-waived Tests**

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<thead>
<tr>
<th>Test</th>
<th>Group A Streptococcus</th>
<th>Thyroid stimulating hormone (TSH)</th>
<th>Opioids</th>
<th>Respiratory syncytial virus (RSV)</th>
<th>Hemoglobin A1C</th>
<th>INR</th>
<th>Serum chemistries (e.g., sodium, potassium, chloride)</th>
<th>B-Type natriuretic peptide (BNP)</th>
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Pharmacy, physician’s office or emergency department) for provision of care. Unfortunately, many pharmacists either never received training on or have forgotten how to conduct a systematic physical assessment.

- **Specimen collection techniques.** Although most pharmacists are comfortable collecting a fingerstick blood specimen, the majority of pharmacists have never been trained on how to collect a nasal, throat or oral swab or blood by venipuncture. If POC tests are to be used, it is absolutely essential that specimens are collected and handled correctly. Furthermore, in order for patients to have confidence in the pharmacist and the test results, the pharmacist must be comfortable collecting various types of specimens.

- **Reimbursement.** Apart from MTM, pharmacists rarely get reimbursed from third-party payers for services other than dispensing. POC testing will only become sustainable if the pharmacy is able to recoup the costs associated with the test device and pharmacist time. Under current billing models, the pharmacy may be able to bill for the cost of the test but not pharmacist time, thus potentially making testing not economically sustainable if alternate billing strategies are not explored.

- **Patient awareness.** Patients typically do not associate the pharmacy with POC testing. In order for a POC testing program to succeed, an aggressive program to raise patient awareness needs to be developed.

- **Data sharing and follow-up.** Once a test is performed, the pharmacist must have a plan in place for how the information will be archived and acted upon. Decisions need to be made on whether patients will be referred to a clinician or if the pharmacist will be able to dispense or alter medications based on the test results. Also, regardless of recommending treatment or watchfully waiting, the pharmacy should have a plan in place to contact the patient to assess the outcome and the need for additional medical attention. This may require the pharmacy identifying a physician(s) to collaborate with to develop practice agreements. Furthermore, a plan to share data with the patient and their physician must be developed. Lastly, it should be kept in mind that the pharmacy may be required to report certain test results to the local health departments.

- **Physician acceptance.** As with the implementation of any new service, there are likely to be questions raised from other health professions. Since POC testing and pharmacist patient management is quite novel, providers such as physicians might have questions and concerns regarding pharmacists offering these tests and follow-up care. It is important to seize these opportunities and discuss the benefits that can be realized by developing collaborative working relationships. By working closely together, pharmacists and physicians can create collaborative practice models that allow for efficient provision of patient care and establish parameters for sharing data between collaborators.

In an effort to help pharmacists identify and overcome barriers such as those listed above, a certificate program on RDTs was jointly developed by clinicians, faculty from Ferris State University College of Pharmacy and the University of Nebraska Medical College of Pharmacy, and the Michigan Pharmacists Association. This program was created to fill knowledge and skills gaps that would hinder pharmacists from safely and effectively developing disease state management programs based on physical assessment of POC testing. The intent of the certificate program is to educate practicing pharmacists and student pharmacists until colleges of pharmacy nationwide are able to incorporate sufficient content in their curricula. Unfortunately, it could take a considerable amount of time before this goal is achieved. Therefore, although RDT certification was not intended to be a

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practice credential, it should at least ensure employers and collaborating phys-
icians that certified pharmacists have successfully met minimal competency
standards in physical assessment and use of RDTs. However, it should be
noted that physical assessment and specimen collection are skills. A one-time
verification of competency does not guarantee lifelong competency. These
skills must be continually practiced and refined.

Leaders in pharmacy have been paying attention to the changing role of
the pharmacy professionals in improving public health and wellness. Many factors
such as mail-order programs, centralized fill operations and automation are
freeing up the pharmacists’ time and providing opportunities to practice at the
top of their license. So what do these factors mean for the future of pharmacy?
First, with the aging population, emphasis on preventative care and shortage of
primary health care providers, community pharmacy has tremendous growth
potential. Secondly, since dispensing tasks/responsibilities are being shifted
away from local pharmacies, many community pharmacists will need to expand
their clinical services. Again, owing to the pressures placed on primary health
that is eager to enter in to collaborative disease management programs with
pharmacists, the pharmacist is uniquely positioned to help relieve some of
these pressures by offering disease state management and medication manage-
ment programs. These types of programs have the potential to improve patient
outcomes and improve access to care.

These could be the best of times or the worst of times for the profession of
pharmacy. It is a matter of being prepared to meet the opportunities presented to
us. A pharmacy workforce skilled in physical assessment and use of POC tests
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physicians is just what the profession needs.

References:
• U. S. Public Health Service Pharmacy Prevention Strategy, 2011.
• The Number of Practicing Primary Care Physicians in the United States, www.ahrq.gov/research/findings/factsheets/primary/pcwork1/index.html
• The Number of Nurse Practitioners and Physician Assistants Practicing Primary Care in the United States, www.ahrq.gov/research/findings/factsheets/primary/pc-work2/index.html
• How many people have signed up for Obamacare: http://money.cnn.com/interactive/economy/ obamacare-enrollment
• CLIA - Clinical Laboratory Improvement Amendments - Currently Waived Analytes, www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfClia/analyteswaived.cfm

Train-the-Trainer Program Description
• Who: For individuals interested in becoming faculty members to deliver the Community Pharmacy-Based Rapid Diagnostic Testing Certificate Course and for those who want to deliver the certificate course within their own organization.
• Why: When preparing faculty members in the delivery of rapid diagnostic testing, your teaching will directly impact the pharmacists you train and the quality in which they provide patient care in the field of RDTs, thereby, making the delivery of RDTs within community pharmacies a standard of practice.
• How: This day-long training program will provide a more in-depth review of the Community Pharmacy-Based Rapid Diagnostic Testing Certificate Course’s educational content as well as provide tips and techniques to prepare faculty members to deliver a quality presentation.
• Requirements: Complete the Certificate Course and receive a Certificate of Achievement. In addition, complete the assessment and activity evaluation provided during the train-the-trainer program.