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Time and Motion Study of Influenza Diagnostic Testing in a Community Pharmacy

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Abstract

Background: It has been shown that use of rapid diagnostic tests (RDTs) is able to reduce costs and improve the prescribing practice of antivirals (i.e. oseltamivir) among patients with influenza-like illnesses (ILIs). Using existing Clinical Laboratory Improvement Amendment (CLIA)-waived RDTs and collaborative practice agreements, similar to those used to allow pharmacists to administer vaccines, it is possible for patients to seek point-of-care treatment for influenza or flu-like symptoms at a local pharmacy. Following a review of the patient's symptoms by a trained pharmacist, the qualified patient is offered an RDT to determine if the influenza virus is the cause of the symptoms. Based on the results of the RDT, the patient is provided with the appropriate treatment as defined by an approved practice agreement. **Objective:** The aim of this study was to evaluate the feasibility of incorporating an RDT for influenza into community pharmacy practice. **Methods:** This time and motion study was conducted at three community pharmacy locations, and a total of eight simulated patient visits were completed utilizing a standardized patient. In addition to determining a total time of the encounter, each simulation was divided into nine timed sub-categories. For data analysis, the time spent in each of the nine sub-categories was assigned to the pharmacist, pharmacy technician, or patient. Time and motion methodologies were used to estimate the total time required to provide the RDT service, to determine the amount of active time required of the pharmacist and pharmacy technician, and to evaluate the ability of the staff to provide the service within its existing workflow. **Results:** The average total time to complete the entire patient encounter for an influenza assessment utilizing an RDT was 35.5 minutes (± 3.1 minutes). On average, the pharmacist spent 9.4 minutes (± 3 minutes) per encounter or about 26.5% of the entire encounter. When the pharmacy technician collected the vital signs, the pharmacist-required time was reduced to 4.95 minutes (± 2.7 minutes), which was about a 48% reduction. **Conclusions:** The results indicate that an RDT program for influenza assessment required no more than a modest amount of pharmacist time and could be successfully incorporated into regular workflow with little to no disruption of other activities. As such, this approach to influenza management may be a feasible service for community pharmacies to offer patients. This was especially true if the pharmacy had well-trained technicians on staff that could support the service with collection of patient histories and vital signs.

Introduction

With ongoing implementation of the Affordable Care Act, the traditional delivery models of health care are bound to change. As highly accessible health care professionals, community pharmacists could be looked to as an alternative avenue in which patients can receive efficient and quality care for acute illnesses. One such illness for which pharmacists could make a significant impact is influenza. Each year 6 to 20% of United States residents are infected with influenza. While influenza is a self-limiting illness requiring little or no treatment for many patients, more than 200,000

people are hospitalized due to influenza and influenza-related complications each year.¹ It is important to treat individuals diagnosed with influenza with the proper antiviral therapy. If started within 48 hours of the onset of symptoms, the antivirals may decrease the severity of symptoms, shorten the duration of a patient's sickness by 1 to 2 days, decrease the risk of viral transmission, and prevent serious flu-related complications.² This study aims to evaluate the feasibility of incorporating a rapid diagnostic test (RDT) for influenza into community pharmacy practice.

It has been shown that RDTs are able to reduce costs and improve the prescribing practice of antivirals (i.e. oseltamivir) in patients with influenza-like illnesses (ILIs).³ Using existing Clinical Laboratory Improvement Amendments (CLIA) waived rapid diagnostic tests and collaborative practice agreements similar to those used by pharmacists determining the need

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for and administering vaccines, it is possible to provide patients with point-of-care treatment for influenza or flu-like symptoms at a local pharmacy. Upon arrival at the pharmacy and following a review of history and symptoms with the pharmacist, the patient undergoes a brief physical assessment and is offered the RDT to determine if the patient is infected with the influenza virus. Based on the results of the RDT and physical assessment findings, the patient is managed according to an approved protocol. Patients who are deemed to be at high risk for complications and/or exhibit signs of clinical instability (i.e. patients with hypotension, hyperventilation, low oxygenations, etc.) are referred to a physician for management.

In order for the use of RDTs for influenza to be a feasible service within a community pharmacy three criteria must be met. First, it needs to contribute to provision of high quality patient-centered care. Secondly, it must be offered at a competitive cost. Lastly, it must not be unduly disruptive to the existing pharmacy workflow or consume an excessive amount of pharmacist time. As part of a larger community pharmacy-based RDT study, we conducted a time and motion analysis to determine whether or not an RDT program could be practically offered in a community pharmacy. The purpose of this study was to estimate the time costs associated with provision of an influenza disease management program in a community pharmacy. Specifically, we sought to determine the amount of active time required of the pharmacist and pharmacy technician(s), and to evaluate the ability of the pharmacy staff to provide the service within its existing workflow.

Key Findings

- The average total time it took to complete the entire patient encounter for a rapid diagnostic influenza test was 35.5 minutes (± 3.1 minutes).
- The average pharmacist participation time per encounter was 9.4 minutes (± 3 minutes).
- When a pharmacy technician collects patient vital signs, the pharmacist participation time per encounter was 4.95 minutes (± 2.7 minutes).
- The results of this study indicate that the incorporation of a RDT for the influenza virus into an influenza disease management program could be a feasible service offered in a community pharmacy.

Study Methods

This time and motion study was conducted at three community pharmacy locations participating in a larger rapid diagnostic testing study. A single standardized patient was

used to portray a patient with ILI presenting to the participating sites. Patient visits were observed by a researcher trained in time and motion study methodologies. This study did employ the direct observation and timing techniques used in a traditional time and motion study, but the nature of the observed service, with the lack of clearly defined steps, makes it something of a hybrid between a time and motion and work sampling study. The study was approved by the Institutional Review Board of the University of Nebraska Medical Center.

The methodologies for conducting this study were as follows: Each simulated encounter was divided into nine timed categories. The time of the entire encounter was also documented. Timed categories included:

1. Patient arrival at the counter until presence noted by pharmacy staff
2. Initial patient contact with pharmacy staff and screening
3. Patient completion of paperwork/review of symptoms
4. Pharmacist consultation
5. Waiting for RDT/physical assessment
6. Collection of vital signs
7. Performance of RDT
8. Waiting for test results
9. Patient counseled on treatment plan

The first category encompassed the time from the patient's arrival at the community pharmacy counter until a member of the pharmacy staff acknowledged the patient's presence. Once the patient's presence was noted the second category began. This category included the discussion between the technician and patient about what brought the patient into the pharmacy that day. When the patient described symptoms matching the symptoms listed in the influenza management protocol, the technician provided the patient with the paperwork necessary for the initial assessment. As the patient filled out the paperwork, the third category began and included the time it took for the technician to confirm the answers provided with the patient. In addition, the third category included the time it took for the pharmacist to assess the paperwork.

The fourth category, the first with active participation by the pharmacist, began when the pharmacist approached the counter to review the symptoms with the patient and to advise the patient to receive an RDT. This fourth category ended by the beginning of the patient's wait for the RDT/physical assessment to be performed (category 5). The wait period was time the patient spends in the waiting area of the pharmacy or the time the patient spent in the

consultation room waiting for the pharmacy staff to set up the supplies necessary to take vital signs and perform the RDT. It may have also been the time when the payment for the rapid diagnostic test is transacted.

The sixth category started when the pharmacy staff began collection of the patient's vital signs. The order in which vital signs were collected and the individual times associated with each were not recorded. Rather, the total time it took to record the patient's temperature, blood pressure, pulse, respiratory rate, and oxygen saturation was recorded as a single number for the sixth category.

Select pharmacy technicians were trained to use automated blood pressure devices, pulse oximeters, and temporal scan thermometers. This left each study site with the freedom to decide whether the vital signs were to be assessed by the pharmacist or a technician trained in an accredited program.

The start of the seventh category was signaled by the collection of specimen for processing. This category included the process of performing the nasal swab and processing the sample according to manufacturer's instructions. In this study, the Sofia Influenza A+B Fluorescent Immunoassay (FIA) (Quidel Corporation, San Diego, CA) was the RDT used. All tests were performed in accordance with the package insert for the Sofia system being used in the "walk away mode".⁴ Specific steps included the preparation of the reagent, nasal swab specimen collection, insertion of the swab into the reagent tube, and filling of the sample cassette.

The eighth category was defined as the time that the patient spent waiting for the RDT results. The Sofia system used in this study takes approximately 15 minutes to provide results.

During this time the pharmacist was able to resume other pharmacy tasks. At the end of the 15 minutes, the pharmacist returned to the consultation room to discuss the results of the test with patient. Based on the results the pharmacist counseled the patient on the management plan (category 9).

While the categories above are described to follow a step-by-step timeline, modifications to this timeline can be made. For instance, category 6 (collection of vital signs) can be conducted during category 8 (patient waiting for the test results). By doing this, not only will the pharmacist or technician be able to take more accurate measurements of the patient's vital signs because they will have been seated for a longer time, but the total time spent by the patient in the pharmacy will potentially be reduced.

This study did not include the time necessary to dispense a prescription (if appropriate) or purchase an over the counter product, since that would be part of the existing pharmacy workflow. It would be no different than the pharmacy filling a prescription brought in by a patient who had been diagnosed by their physician.

For data analysis, the time spent in each of the nine categories was assigned to the pharmacist, technician, or the patient (labeled as "waiting time"). Depending on whether or not the pharmacist collected the vital signs, this sub-category was assigned to the respective member of the pharmacy team. The different groupings used to allocate time measurements to the pharmacist, technician, and patient can be seen in Table 1.

Table 1: Groupings of Pharmacist, Technician, and Patient Time

Point of Care Sequence 1: Technician does not perform vitals		Point of Care Sequence 2: Technician performs vitals		Patient time in either sequence
Pharmacist Time	Tech Time	Pharmacist Time	Tech time	Total "waiting time" for patient
(4) Pharmacist consult	(2) Initial patient contact with pharmacy staff	(4) Pharmacist consult	(2) Initial patient contact with pharmacy staff	(1) Patient arrival at the counter until presence noted by pharmacy staff
(6) Collection of Vital Signs	(3) Pt. Completion of paperwork/ review of symptoms	(7) Rapid Diagnostic Test	(3) Pt. Completion of paperwork/ review of symptoms	(5) Waiting for rapid diagnostic test/ physical assessment
(7) Rapid Diagnostic Test		(9) Patient counseled on treatment	(6) Collection of Vital signs	(8) Waiting for test results
(9) Patient counseled on treatment				

Results

A total of eight simulated patient visits were completed by the standardized patient at the three locations. Visits took place over two days in June 2013, were made between 9 AM

and 5 PM, and were made without knowledge of or regard for staffing or workload levels. The timed results from the three pharmacies in the time and motion study can be seen in Table 2a-c (time measured in seconds).

Table 2a: Three Timed Encounters at Pharmacy 1

<u>Pharmacy 1</u>	Encounter 1 ¹	Encounter 2 ^{1,2}	Encounter 3 ^{1,2}
Patient Arrives at Counter	31	19	27
Patients' Presence Noted	86	259	248
Patient completion of paperwork/ review of symptoms	200	233	358
Pharmacist Consult/	140	58	34
Waiting for rapid diagnostic test/ physical assessment	371	414	444
Rapid Diagnostic Test	155	136	149
Vital Signs	0	390	385
Waiting for Test Results	1024	606	615
Patient Counseled on Treatment	54	32	32
Total Time	2061	2147	2292

¹All times were recorded in seconds

²For encounters 2 and 3, the vital signs were collected while the patient waited for the results of the RDT.

Table 2b: Two Timed Encounters at Pharmacy 2

<u>Pharmacy 2</u>	Encounter 1 ¹	Encounter 2 ¹
Patient Arrives at Counter	10	19
Patients' Presence Noted	20	135
Patient completion of paperwork/ review of symptoms	125	65
Pharmacist Consult	30	31
Waiting for rapid diagnostic test/ physical assessment	192	276
Rapid Diagnostic Test	92	189
Vital Signs	449	176
Waiting for Test Results	1005	954
Patient Counseled on Treatment	5	5
Total Time	1928	1850

¹All times were recorded in seconds

Table 2c: Three Timed Encounters at Pharmacy 3

<u>Pharmacy 3</u>	Encounter 1 ^{1,2}	Encounter 2 ^{1,2}	Encounter 3 ^{1,2}
Patient Arrives at Counter	27	56	19.2
Patients' Presence Noted	181	54	100
Patient completion of paperwork/ review of symptoms	354	217	100
Pharmacist Consult	20	83	24
Waiting for rapid diagnostic test/physical assessment	397	530	600
Rapid Diagnostic Test	137	417	462
Vital Signs	266	367	180
Waiting for Test Results	667	538	921
Patient Counseled on Treatment	10	50	30
Total Time	2059	2312	2436.2

¹All times were recorded in seconds

²For all encounters, the vital signs were collected while the patient waited for the results of the RDT.

As the results of the eight visits indicate, the average total time it took to complete the entire patient encounter was 35.5 minutes (± 3.1 minutes). Of that time, the average time it took for the pharmacist to complete the initial consultation/review of symptoms, RDT, the collection of vital signs, and the counseling of the patient on an appropriate treatment plan was 9.4 minutes (± 3 minutes). Encounters in which the pharmacist collected vital signs will be referred to as option 1. In this option, pharmacists were involved in 26.5% of the entire encounter. The two most time-consuming steps for the pharmacist were the performing the RDT and the collection of vital signs. If a pharmacy technician collected the vital signs (option 2), the average time the pharmacist spends per encounter was reduced to 4.95 minutes (± 2.7 minutes). This resulted in about a 48%

reduction in the pharmacist time requirement. For the patient, the average total wait time spent at the pharmacy was 20.6 minutes. The majority of the patient's time was spent waiting for the RDT results. As mentioned, the testing time for the Sofia analyzer system is minimally 15 minutes.

In most cases, a patient's encounter time could be reduced if the vital signs (whether collected by the pharmacist or the technician) were collected during the time the RDT is processing. This was evident in the second and third encounters at Pharmacy 1, as well as the three encounters at Pharmacy 3. In all five of these encounters, the wait time for the results was shorter than the wait time the patient spent at Pharmacy 2 (where the vital signs are done before the RDT).

Table 3. Time required based on staff member assessing vital signs

	Min	Max	Average
Total Encounter Time	30.8	40.6	35.5
Point of Care Option 1. Pharmacist Time w/ Vitals	5.82	15.28	9.4
Point of Care Option 1. Tech Time w/o Vitals	2.25	10.1	5.56
Point of Care Option 2. Pharmacist Time w/o Vitals	2.12	9.17	4.95
Point of Care Option 2. Tech Time w/ Vitals	4.77	16.52	10.05
Total Patient "Waiting Time"	17.3	25.7	20.6

*Time recorded in minutes

The numerical values in Table 3 are presented again in a graphical manner below:

Figure 1: Average time required to conduct service

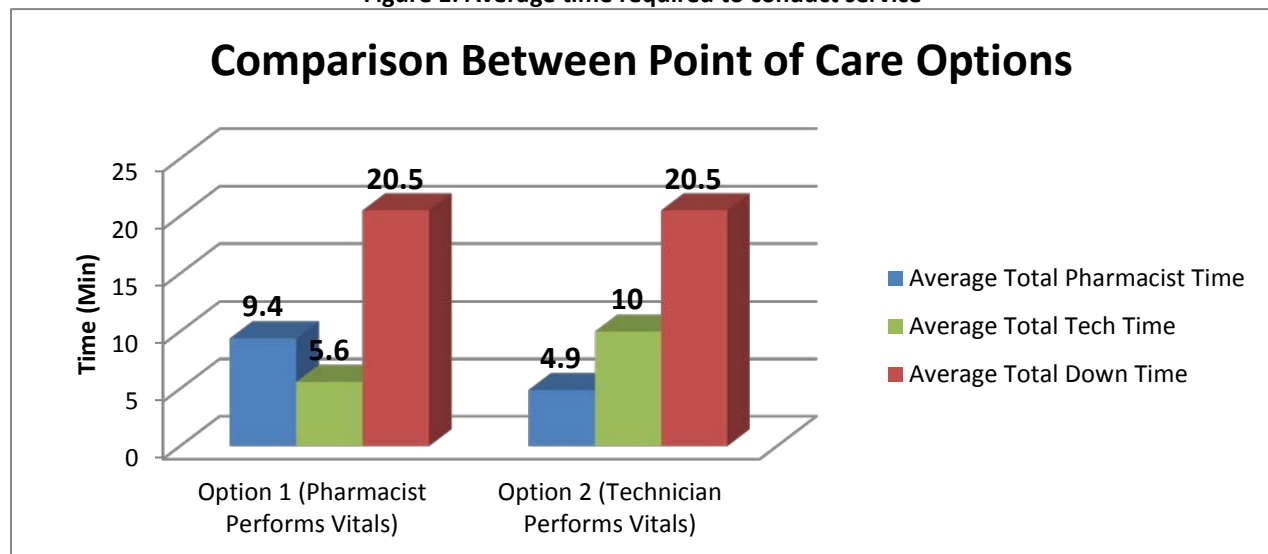


Figure 2a: Summary of Average Time Requirements in Point of Care Option 1

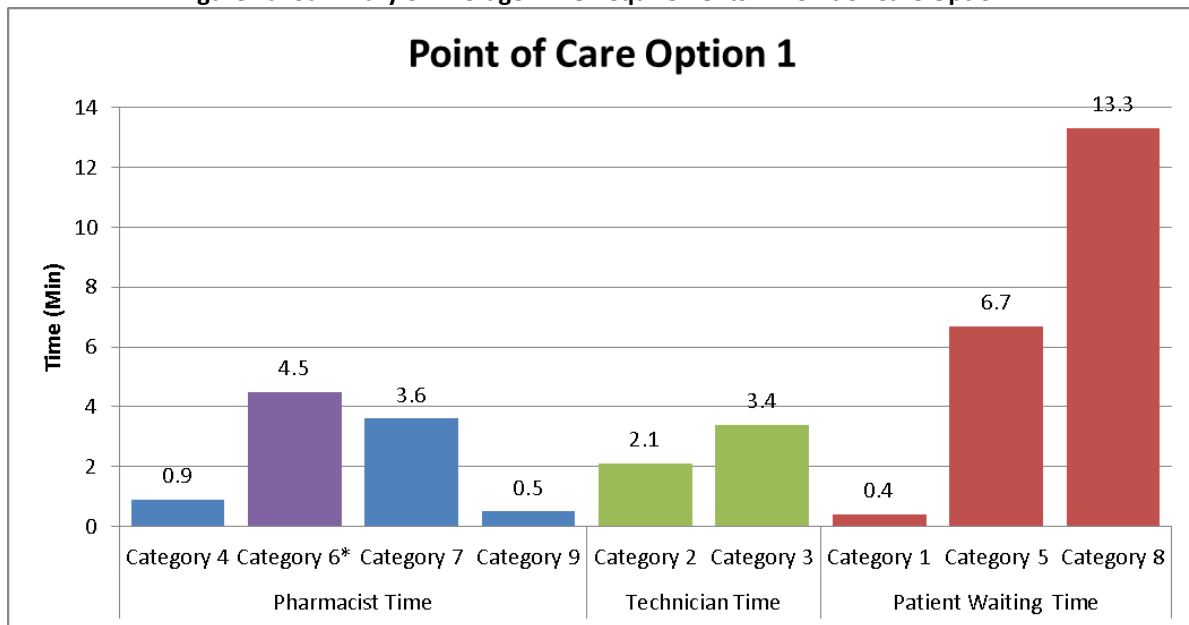
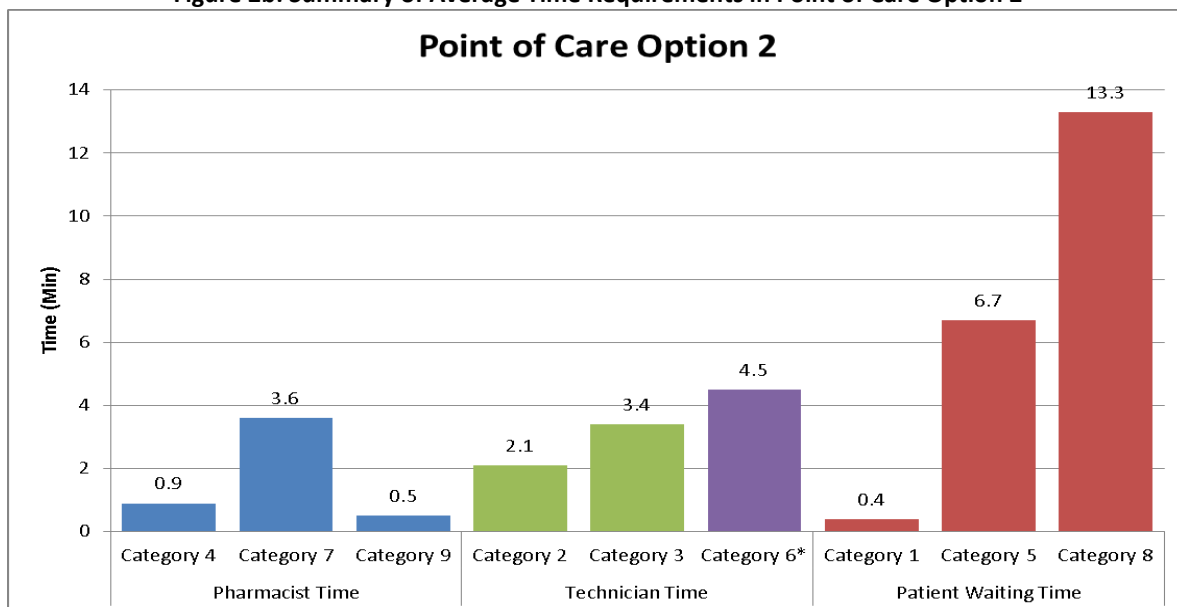


Figure 2b: Summary of Average Time Requirements in Point of Care Option 2



*Category 6 is the collection of vital signs. In option 1, vital sign collection was done by the pharmacist. In option 2, vital sign collection was done by the pharmacy technician

** Categories 1-9 correlate to the nine categories utilized in this time and motion study. [(1) Patient arrival at the counter until presence noted by pharmacy staff, (2) Initial patient contact with pharmacy staff and screening, (3) Patient completion of paperwork/review of symptoms, (4) Pharmacist consultation, (5) Waiting for RDT/physical assessment, (6) Collection of vital signs, (7) Performance of RDT, (8) Waiting for test results, (9) Patient counseled on treatment plan]

Discussion

When analyzing the data collected, it is important to recognize the limitations of this study. A primary limitation of was the presence of the observer. While the observer did not interact directly with the pharmacy staff, they were aware of his presence. This awareness may have increased the anxiety of the staff and thus affected the speed at which they performed activities.

The second limitation relates to the timing associated with the third category (patient completion of paperwork/review of symptoms). From the description above, it is evident this category required some pharmacist time for paperwork evaluation, but it was minimal compared to the time the patient spent talking with the technician and filling out paperwork. Even though the third category included numerous steps within the pharmacy's RDT workflow, the entire time spent in this category was grouped under technician time in the results portion of this study. This was due to the fact that, in this real-life pharmacy setting, the observer was unable to see all the individual steps occurring behind the counter. Since this category did not always have clearly-defined times assigned to the pharmacist, technician, and patient, it is recognized as a limitation of the study.

The third limitation deals with when the pharmacy staff was trained and when the study was actually conducted. The pharmacy staff was originally trained on the skills required to conduct an RDT and vital signs in December 2012. While the staff had the opportunity to conduct the service during the 2012-2103 influenza season, roughly three months had passed between the last actual patient presenting and the first standardized patient simulation in June 2013. Moreover, due to late implementation of the RDT program, some staff members had not tested a patient during the influenza season, so the simulated patient was their first "real" experience in providing the service. As such, the pharmacies were probably not at peak efficiency for the time and motion study. With each simulation, however, the staff's confidence and efficiency in conducting the vital signs and RDT improved. While the relatively small number of observations is a limitation of this study, there was enough variation between sites and visits to suggest that we had achieved a fairly representative sample.

Even with consideration of the limitations, the results of this analysis show that an RDT for influenza could be a feasible service for community pharmacies to offer patients. In observing the pharmacies, it was noted that the pharmacy staff was able to work the rapid diagnostic testing into the regular workflow with little to no disruption of other activities. This is especially true if the pharmacy had well-trained technicians on staff. By delegating the collection of

vital signs to technicians, the pharmacist dedicated approximately 5 minutes per patient encounter, which primarily consisted of sample collection, test interpretation, and patient counseling.

Some of the pharmacies in this study also identified the potential benefit of collecting the vital signs while waiting for the test results because, by doing so, the patient's wait time could be reduced.. This may be appropriate and prove to be beneficial since the vital signs influence the treatment decision and not the testing decision. It is also possible that the measurements of the patient's vital signs will be more accurate since the patient will have been seated for a longer period of time.

When considering the possibility of incorporating rapid diagnostic testing for influenza into a community pharmacy's workflow, it may be useful to compare it to the time required to administer vaccines in the community pharmacy setting. According to one study, the average wait period and vaccination time for a patient receiving a flu shot is approximately 12 minutes.⁵ While the overall time required for the RDT is longer, the majority of that time does not require active involvement from the pharmacist or technician, making the two services comparable in terms of resources used. It is also worth noting that the per-visit revenue for a rapid diagnostic testing service may be two to three times higher than an influenza vaccination visit.

Implementation and delivery of an influenza rapid diagnostic testing service is still in its infancy. Pharmacists and technicians are still learning how to best develop and deliver these services in their practice settings. In follow-up discussions with the pharmacists and technicians, they admitted to being nervous about and somewhat uncomfortable with providing this novel service, but they also recognized how much easier and more confident they felt after providing the service one time. Moreover, they felt that, with practice, they would be able to deliver this service within their existing workflow just as they do with vaccinations.

Conclusion

Though additional studies examining patient demand and willingness to pay for this type of service are needed before feasibility can be fully assessed, this study indicates that an influenza rapid diagnostic testing service could be incorporated into an existing community pharmacy with limited disruption to the workflow and staffing levels.

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