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Direct to Consumer Laboratory Testing: A Review

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Historical Background

“Direct to consumer laboratory testing also known as direct access testing (DAT), permits consumers to order laboratory tests directly from a laboratory without necessarily having to work with their healthcare provide [1]”. As early as the 1950s the public was introduced to the concept of being directly involved in their healthcare, and this was accomplished with the availability of over the counter (OTC) urine glucose and ketone tests. Healthcare has shifted from being physician-focused to being consumer-focused, DAT is one manifestation of this shift and it has been steadily growing since its establishment in the 1950s. “The market for direct-to consumer (DTC) health services continues to grow rapidly with former patients converting to customers for the opportunity to purchase varied diagnostic tests without the involvement of their clinician [2].” The American Society for Clinical Laboratory Science (ASCLS) has also developed the Consumer Information Webpage (CIW), in 1999, to meet the enquiring needs of consumers, as many desired detailed explanations of their test results. The page is monitored by a team of trained volunteers who respond to the concerns and questions of patients or consumers.

Criteria for direct to consumer laboratory tests

Many of the laboratories that offer DAT have limited the tests to simple and/or general health tests such as chemistry panels, complete blood count (CBC), pregnancy test, diabetes screening and blood typing. However, the ASCLS has stipulated a few requirements for the tests that are to be offered under the banner of DAT. According to a report from the ASCLS in 2012 [3], screening tests are to be offered to facilitate the early detection of diseases. The tests are to also serve the purpose of monitoring a disease and the effects treatment, for example therapeutic drug monitoring or HIV status monitoring. These tests should also not necessitate a consultation or permission from a medical practitioner. Such tests are to possess methodologies that are user friendly and easily understood, while yielding results that are clear and easily interpreted. Additionally, the tests should come equipped with descriptions of benefits, risks and limitations that are also easily understood. The tests offered by DAT are frequently waived tests to ensure a low risk of obtaining

incorrect results. However, despite the simplicity of the test, an incorrectly done procedure will yield inaccurate results.

Legal implications of direct to consumer laboratory testing

The legal implications of direct to consumer laboratory testing are the law determined penalties surrounding the negative outcomes of these services. The primary cause of a negative outcome would be a consumer’s misinterpretation of his/her test results. The Centres for Medicare and Medicaid Services (CMS) and the Food and Drug Administration (FDA) are urged to implement requirements for the full disclosure of the services and products available from laboratories that offer DAT. Information offered by the disclosure includes – but is not limited to – listing of tests offered and their respective charges, simple or easily understood description of risks, benefits and limitations of all services offered and the obligation to provide sufficient information upon the reporting of results for assistance in making appropriate decisions. The disclosure serves as a quality control to legally protect laboratories and consumers from possible errors in misinterpretation. In an article by Dr. Michael A. Noble, he stated that cases have been seen where patients “seek redress through litigation [4]” because they were misdiagnosed as a result of misinterpretation or unnoticed errors. While the physician may be aware of reference ranges and may be able to detect errors and make the necessary adjustments in diagnosis, a consumer – on the other hand – may not have this knowledge and will make decisions solely on the information provided by the technologist. If this information is incorrect and health conditions worsen as a result, the laboratory may be sued and consequently, business would be severely affected. The technologist will undoubtedly lose his/her job and re-employment in a similar capacity may be highly unlikely.

Effect of direct to consumer laboratory testing on patient care

Patient care is the term used to refer to the services provided by members of the health profession geared towards the improvement or betterment of the patient. The concept of direct to consumer laboratory testing offers many benefits as it relates to patient care. The process of acquiring knowledge

of one's health, through a healthcare provider – such as a physician – can be time consuming. Long periods of waiting and inconvenience are usually encountered when results are to be delivered. Now there is the option of requesting and purchasing laboratory services in more convenient, though non-traditional, settings like pharmacies, wellness centres and retail centres. These settings usually offer timelier services to include efficient generation of results. Additionally, with individuals being more health conscious, direct access testing allows them to cost-effectively monitor their health. Reduced cost in acquiring healthcare is another benefit, instead of paying a physician to order tests that are already suspected to be needed, the consumer can simply pay for the tests and therefore reduce the cost associated with the process. DAT is, however, not without its downfalls and can result in unnecessary anxiety by misdiagnosis of one's self. It can also be to the detriment of patients who require follow-up visits to a physician and refrain from doing so after receiving their results because they are unable to comprehend the gravity of said results.

Implications of direct to consumer laboratory testing on healthcare facilities

A healthcare facility is any establishment that provides basic and or complex services for the diagnosis or treatment of a disease, as well as monitoring the health status of consumers. These establishments can include, but are not limited to, Hospitals, Clinics, physician's office, pharmacies and laboratories. The concept of DAT could significantly reduce the utilization of services offered physician, and by extension decreases the major services offered by pharmacies. However, it allows for the exploration of partnerships between physicians and laboratories. These partnerships can prove to be beneficial, because despite the simplistic nature of the tests, they may require further discussion into a consumer's family history and lifestyle; opening the way for incorporation of a primary care physician. The pharmacies will benefit also because many medications cannot be purchased over the counter and as such, prescriptions will always be a necessity. Ultimately, laboratories stand to be affected the most because they are now in the spotlight. Direct correspondence with consumers compel laboratories to offer service of the highest quality because there is now a higher possibility of legal penalties in the event of an error. Furthermore, it emphasizes the need for accreditation because consumers are more likely to have confidence in a laboratory that has been internationally recognized via accreditation. DAT may provide the financial boost that many laboratories need to begin the process of accreditation.

Implications of direct to consumer testing on medical technologists

Medical Technologists are members of the allied health profession, performing a variety of scientific tests on bodily fluids; from waived tests like faecal occult blood testing to the complexity involved with using high performance liquid chromatography (HPLC) to detect haemoglobin defects. Their

responsibilities include analysing generated results, maintaining the automated instruments/analysers, conducting troubleshooting procedures and performing quality control on tests to prevent the procurement of erroneous results. By virtue of the nature of their profession, medical technologists typically have no face to face interaction with patients or consumers. DAT introduces this direct interaction and consequently, additional responsibilities. These include, but are not limited to, interpretation and clear explanation of results as well as improvement of customer service and counselling skills. Not only will they be required to provide pre-testing requirements but medical technologists must now also be able to efficiently explain the results and provide some assistance on the decisions that the customer should take to move forward. They should be able to provide information pertaining to the limitations of each test and conditions that make each test a requirement. Additionally, the sensitivity of some tests requires the medical technologist to demonstrate some empathy and ideally, provide some counselling when communicating these results. Laboratory professionals are encouraged to see DAT as an opportunity to demonstrate their significance and necessity as important members of the healthcare team. However, being on the front page of the healthcare system increases and more so, emphasizes the obligation of a medical technologist to exercise consistency in the generation of accurate results. This is strengthened by frequent proficiency testing, the strict adherence or compliance to international standards and continuing education.

Effect of direct to consumer testing on the quality of training for medical technologists

According to a journal by the AACC [5], since DAT requires face to face interactions between medical technologists and consumers, it is critical for laboratory professionals to be trained so as to provide accurate and precise results. Such training should also allow for the appropriate communication of the interpretation of results, as well as information on additional tests for confirmation and the possible need for follow-up consultations with other medical professionals, like a physician. The medical technologist's inability to facilitate the consumer's absolute comprehension of his/her results is the basis of many shortcomings associated with Direct to Consumer Testing. It is no longer enough to merely possess the knowledge but the technologist must be able to impart such knowledge in an easily understood manner without lessening the significance of the information. Common misunderstandings surround the methodology of certain tests and the variety of ways in which the tests can be interpreted. For that reason medical technologists must be well equipped with requisite knowledge of how to best assist the consumer. Training for medical technologists is to be harmonized for the synchronization of information. Information received at one lab should correlate with that received at other labs, regardless of the machines and brands of reagents used. Direct to Consumer Testing requires exceptionally trained medical technologists that will provide accurate, quality service

regardless of their place of employment or accreditation status [6-12].

Summary

Direct to Consumer Laboratory Testing is a fairly recent phenomenon that has caused a drastic – and almost unwelcome – shift in the world of healthcare. It allows individuals to take charge of their health by directly corresponding with laboratories and removing physicians as the medium for this correspondence. ASCLS has generously provided certain criteria that must be met for the services offered and these include simple, easily understood and interpreted tests. While the tests are usually waived and of screening and monitory purposes, it does not exclude legal consequences in the event of a negative outcome. Disclosures supplying adequate information will provide legal protection for the laboratories and its employees while simultaneously, enabling informed decisions to be made by consumers. The possibility of misinterpretation of results and subsequent anxiety and misdiagnosis is regrettably high; the benefits are, however, not outweighed, offering privacy, convenience, cost effectiveness and timely generation of results for consumers. It may appear as though physicians are being pushed into the shadows while laboratory professionals enter the spotlight but physicians should not disregard the possible opportunities offered, like collaboration with laboratories. The subject of accreditation undoubtedly becomes a main focus for laboratories, with the consideration that consumers will inevitably place their trust in a laboratory that has been deemed to meet international standards.

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