

What is the impact of
point of care
diagnostics?



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What is the Impact of Point of Care Diagnostics?

- Nicolas Piperno

Multi-stakeholder approach to market for Point of Care Diagnostics in Canada

Point of care diagnostics, otherwise referred to as point of care testing (POCT), is a form of in vitro medical testing that is performed near the site of patient care, and does not involve the use of laboratory staff and facilities to provide the result. Point of care can mean, for example, on the wards in a hospital, at a patient's bedside, in their home, in a consulting room in a doctor's office or using tele-health technologies. This concept is not new. Urine testing or blood glucose tests, for example, have been traditionally done at the bedside. Over the past few years, however, analytical systems have been developed that enable a wide range of tests to be done quickly and simply without the need for pre-preparation or sophisticated laboratory equipment. [1] These tests are designed to sample blood, saliva, urine, or other bodily fluids in order to measure proteins, nucleic acids, metabolites, drugs, dissolved ions and gases, human cells, or microbes. [2] The tests require only elementary instruction to use and some can measure multiple bodily agents. [3] Interpretation may be as simple as viewing a stripe or spot of color on a strip of paper or polymer.

The key objective of POCT is to generate a result quickly so that appropriate treatment can be implemented. As technology plays a bigger role within healthcare, POCT and accompanying decision-making tools such as medical databases are becoming more prominent. Other major benefits are obtained when POCT is linked directly with an electronic medical record. Results can

be shared instantaneously with all members of the patient's circle of care through a software interface enhancing communication among its members. All of these benefits can eventually lead to improved clinical and economic outcomes.

With the increasing availability and use of POCT, many stakeholders stand to be impacted by its innovation, application, and market opportunities. More specifically, physicians and patients would be impacted by the clinical outcomes, and the provincial government and pharmaceutical companies would be mainly impacted by the economic outcomes. This paper seeks to evaluate how each stakeholder plays a role in the increased use of POCT, and if there are points of resistance or leverage for this idea.

Physicians

POCT have the greatest potential for facilitating faster decision making and therefore more effective patient triage in the emergency department or reduced operation time in the operating room. For example, assessment of the coagulation status via POCT during cardiopulmonary bypass surgery reduces the requirement for blood products, postoperative blood loss, and the time spent in postoperative high dependency care.[4] Little evidence, however, supports the use of point of care testing in primary care.[5] Hence, physicians would be able to start treatment earlier because they would not need to wait for laboratory test results to come in before they can perform any subsequent treatments. Any POCT, however, will only be beneficial if appropriate action is taken on the result. Thus, the rate limiting step in reducing length of hospital stay may not be delivery of a test result[6], but

acknowledgement and communication of the result, and the appropriate action that follows.[7]

Physicians, as well as nurses that would actually be the main administrators of POCT, just want to be able to do their job effectively. POCT would allow them to do that, and would therefore be a welcoming new tool for them. Challenges remain, however, in the training of staff. Even with the most sophisticated device, reliable results can be obtained only if the patient is prepared appropriately and the correct technique is used. As POCT is likely to be done by staff with limited technical background, training and quality control are critical.[8]If the POCT is linked to an online database, an opportunity arises where technicians can monitor if the POCT is being used properly and realistic results are being uploaded to the patient record. Obviously, privacy issues come into play when more than one person has access to a patient's medical record.

Medical practitioners would be strong advocates for POCT, because they are the ones that would see the on-the-field benefits of its use. The only point of resistance would be the fact that they would need to be trained every time a new POCT is put into use. A way to mitigate this would be to make the POCT device as simple as possible. This becomes less obvious when POCT devices become more sophisticated with options to measure many things at once. Additionally, medical databases will eventually become more sophisticated, and users will need to adapt to changes with the system.

Not listed as a key stakeholder, but just as important is the laboratory personnel that could potentially lose their jobs because the POCT will be

replacing what they do. This might also be a point of resistance. However, as stated above, there might be a possibility to reassign them as technicians that ensure the quality of the POCT results.

Patients

POCT will also allow patients to perform the tests themselves in the comfort of their own home. This is the case for diabetics, however POCT can also be performed for patients taking anticoagulants. A major challenge in this scenario would be compliance. Getting patients to perform POCT on their own time might result in them forgetting, especially with older patients. There are however technological tools that can correct for this such as apps that remind the patient when to perform the next test.[9]However, this requires the patient to be comfortable with technological devices.

Patients are another stakeholder that would be able to see the on-the-field benefits of POCT use. They will be able to take ownership of their disease if they do the POCT themselves, be able to receive feedback immediately, and not have to wait for laboratory results in which the waiting time can be often a very stressful scenario. POCT will give the impression of a faster access to healthcare in a country where wait times make it seem that the healthcare process is incredibly slow. This will increase patient satisfaction, and thus will be a reason that POCT will be favourable for them.

Other ways that POCT will increase patient satisfaction would be with fewer journeys to the hospital as some tests can be done in the comfort of their own home. Furthermore, POCT can be used to figure out an optimal treatment for them. Quicker optimization of treatment, without the need for

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trial and error, can lead to less adverse side effects and a more comfortable healthcare experience.

As for physicians and nurses, training becomes an issue because the average patient does not have technical knowledge. Again, the answer lies in the simplicity and ease of use of the POCT device.

Provincial government

One of the main objectives of the provincial government when it comes to healthcare is the control of its increasing costs. Healthcare has become really expensive in Canada, and it risks being not sustainable if we maintain the status quo. Innovative technologies such as POCT and the complementary medical databases can serve to reduce costs in many ways.

The economic benefit of POCT can be looked at from a short term point of view or a long term one. In the short term, POCT can gain from a more effective use of resources. For example, one study comparing laboratory and POCT suggested that certain tests might be used to rule out the need for other tests as in the case of suspected urinary tract infection.[10]Fenwick et al argued that urine leucocyte esterase and nitrite tests can effectively rule out patients with suspected urinary tract infection, which could reduce the inappropriate use of antibiotics as well as laboratory workload.[11]Providing a more rapid result, however, does not always save time and money. No savings can occur unless the result is acknowledged and action taken because of this result.

Other short term savings involve a reduction in the length of hospital stay. The rapid availability of a result reduces the time to make decisions, thereby allowing more rapid triage, treatment, or discharge. In addition, POCT can be used to know whether a patient needs admitting to hospital.[12]This saves the hospital, and subsequently, the provincial government a huge amount of money because resources are spent more efficiently.

When it comes to long term savings, societal benefits, measured through quality of life indices can be seen as a gain for the government since this would allow less sick days, and more working hours, thus, more tax revenue. There is also an option for POCT via medical databases to become an important resource for public health officials. Big data can be used to guide preventative health policy and possibly save the government millions of dollars in the avoidable healthcare costs.

The government could potentially be favourable of POCT because of all of its economic benefits, however risks arise when considering the reliability of POCT results, which can negate the cost savings, and the potential for infection outbreaks - since we exposing bodily fluids to perform such tests.

Furthermore, because POCT allows for testing to be decentralized from the traditional laboratory, data management and privacy becomes an issue. Provincial Governments will have to consider these risks and may impose certain regulations that might prevent the extent of the economic benefits of POCT.

Pharmaceutical Companies

This stakeholder comes in two types. The first type is the pharmaceutical company that is involved in diagnostics equipment. This type of stakeholder stands to gain a lot from POCT because it opens up market opportunities and additional revenue streams. The second type of pharmaceutical company is the one that is involved in drug R&D and sales. These pharmaceutical companies might lose revenue as a result of a more efficient healthcare system and less inappropriate use of drugs.

Pharmaceutical companies that do both might have to evaluate whether the loss in drug sales is less than the profit made from POCT device sales.

Furthermore, because POCT devices will still need to go through a lot of R&D, the sale price might be so high that the provincial government might not see the economic value in it. Laboratories already profit from economies of scale, and POCT would be less likely to profit from such economies since its use is decentralized.

In general, lobby groups from drug companies risk being the biggest threat to the proliferation of POCT if they see it as a risk to their bottom line. Their lobby groups tend to influence government decisions on regulation and application of certain healthcare devices. Getting them on board would be critical to the widespread of POCT.

Conclusion

In general, the biggest wins come from doing healthcare differently. Because of the huge labour and pharmaceutical costs involved in healthcare, having the practice of medicine shift towards individuals outside of hospitals might be more economically viable. Rapid delivery of results can facilitate better

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clinical decision making, improved patient adherence, and greater patient satisfaction, all of which lead to improved clinical outcomes. Most stakeholders stand to benefit from POCT albeit with some concerns, however pharmaceutical companies and laboratory testing companies would be the biggest opponents of POCT. Finding ways to appease their concerns without sacrificing the added benefits of POCT would be the best way to proceed.

Appendix 1: Key Stakeholders with Regard to POCT

	Patients	Provincial Government	Pharmaceutical Companies	Physicians
Assumptions and definitions of health	<ul style="list-style-type: none"> Healthcare is supposed to be for their benefit 	<ul style="list-style-type: none"> Health is a necessity for their constituents 	<ul style="list-style-type: none"> Drug therapies needed to preserve population health 	<ul style="list-style-type: none"> Hippocrates Oath They are the protectors of health
Values	<ul style="list-style-type: none"> Good health Quick feedback Answers to their 	<ul style="list-style-type: none"> Do anything that garners public votes Prevent 	<ul style="list-style-type: none"> ROI Reputation Partnerships with other stakeholders 	<ul style="list-style-type: none"> Healthy patients Using best tools possible

			Healthca	
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	s		(value for	• Patent
			money)	protection
			• Increase	
			public	
			health	
				• Patient
				vital signs
Indicators	• Wait			
(monitor/t	times	• Popularit		• Sales
rack)	• Their	y		• ROI
	own	• Health		• Clinical
	health	costs		Studies
				• HTAs
				• Medical
				record
Definition	• Access	• Win re-	• ROI	• Patients
of success	to	election	• Winning	leave
	healthca	• Healthca	governme	hospital
	re in a	re	nt	better
	reasona	budget	contracts	than
	ble	under	• Successfu	when
	amount	control	lly	they

				came in
				<ul style="list-style-type: none"> • They are given medical devices/diagnostic tools that help them perform their job properly.
	<ul style="list-style-type: none"> • Feeling healthier after hospital visit 	<ul style="list-style-type: none"> • Healthy economy with healthy people 	<ul style="list-style-type: none"> • bringing products to market 	
Role(s)	<ul style="list-style-type: none"> • User of the healthcare system 	<ul style="list-style-type: none"> • Decider of provincial healthcare budget 	<ul style="list-style-type: none"> • Researcher, innovator, supplier 	<ul style="list-style-type: none"> • Provider of healthcare
Legitimate source of info	<ul style="list-style-type: none"> • Media • Physicians • Nurses • Wait times Reports 	<ul style="list-style-type: none"> • Opinion Polls • Provincial Financial Reports 	<ul style="list-style-type: none"> • Market research • R&D, literature • Media 	<ul style="list-style-type: none"> • Patient reports • Literature • Media

		• Media		
Key questions	• Will POCT help me heal faster?	• Will POCT cut costs and increase public health?	• Is POCT marketabl e and can I make money of it?	• Will POCT allow me to do my job better?

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