



Infectious Disease and the Application of Point of Care Testing (PoCT) in India

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ABSTRACT

Point-of-care testing (PoCT) is a simple medical test performed close to the patient where the results are available more quickly than for samples sent to a laboratory. The recognition of PoCT has steadily increased over the last 20 years since its widespread introduction. Distinct features of PoCT like-rapid results, reduced patient discomfort, simplicity, cost-effectiveness, enablement of early diagnosing and accessibility in remote areas, is establishing it as a better option for the diagnostic industry. The developing parts of the world are striving to impart more efficient care for infectious diseases and use of PoCT may ease them strive in the future. Exploring various options and methods of PoCT can help the medical field to change the scenario of patient management in terms of effective and timely patient management with lesser burden on patients as well as on hospitals. Present review briefs about the basic details of POCT and its varied application in context to current scenario.

Keywords: PoCT, bedside testing, Molecular diagnosis, Infectious disease.

INTRODUCTION

As per, WHO report (2012) there is a major burden of morbidity and mortality due to infectious diseases such as diarrhea, worm infestations, malaria, Respiratory diseases, and tuberculosis in middle and low-income countries. It not only poses a greater threat to the poor section of the population but also push individuals into poverty (Boschi et al., 2012).

A developing country like India is also going through the period of demographic and epidemiologic transition, and as a result of industrialization, socio-economic development, urbanization, and changing lifestyles, India is also facing a growing burden of non-communicable diseases, as well (Bosch et al., 2002, Coffey et al., 2014).

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India is experiencing the double burden of the disease, as there is still a high prevalence of the infectious disease among lower socio-economic groups due to poverty, lack of primary health facility, poor sanitation, and hygiene. While on the other end among the upper class of society who are rich there is an increase in non-communicable diseases due to the adoption of lifestyle similar to developed countries (Bosch et al., 2002, Coffey et al., 2014).

As per the Census of India, 2011 basic hygiene requirements such as toilets are still a big dream and there are approximately 67% of rural households and 13% of urban households still defecating in the open spaces. Apart from the high population density, increases in air pollutants, Water poverty, and the lack of safe drinking water in many parts of India have led to the increasing incidence of infectious diseases (Bosch et al., 2002, Coffey et al., 2014).

In India, the problem of HIV/AIDS has been increasing for the past one and a half-decade, also every year there are approximately 2.2 million new cases of tuberculosis, of which approximately one million are new smear-positive cases that are highly infectious. Every year half a million deaths take place due to tuberculosis. Diarrhea diseases and acute respiratory infections combined are the main killers of children below five years of age and account for 2/3rd of childhood mortality (Baridalyne et al., 2004).

However, healthcare system is changing, partly as a result of economic pressures, and also because of the general

recognition that care needs to be less fragmented and more patient-centered (consumer oriented) (Price et al., 2012). So, the need for convenient diagnosis, monitoring, and screening tests is expanding worldwide, and that's how PoCT is becoming popular. PoCT allows faster and quick clinical decisions in hospitals, physicians' offices, ambulances, patient homes, and in the field itself which will allow detection of the disease at a point source and increase the survival chances of the patients.

The PoCT is defined as a "testing that is performed near or at the site of a patient with the result leading to a possible change in the care of the patient." as per the College of American Pathologists (CAP) (Ana et al., 2008). The popularity of PoCT is increasing day by day as it is convenient, time-efficient, and has the potential to improve patient outcomes. The facility of decision making at the patient's side has the potential of creating a significant impact on healthcare delivery and to help address several challenges of health disparities. Since the testing moved to the patient side because of the use of PoCT, it increases the chance that the patient, physician, and care team will receive the results faster, allowing for immediate clinical management decisions and faster treatment and recovery of the patient. Furthermore, the development, implementation, and connectivity of portable diagnostic and monitoring devices for PoCT will be part of a successful shift from curative medicine to predictive, personalized, and presumptive medicine at the bedside of the patient (Fig-1).



Fig. 1: Point of Care Diagnostic Methods [Source - usc.edu]

Laboratory findings are the base of medical decisions in 80% of cases and act as a base for planning any treatment strategy by the doctor for a particular patient. Thus, it can be stated that *in vitro* laboratory test reports are a vital aspect of medical decision making. However, in the context of the global market, the costs of *in vitro* laboratory diagnosis account for a negligible percentage of overall health care expenditures. Although still insignificant, this share has shown some increase in the last few years in the global market and gaining importance day by day (Julie & Shaw, 2016).

Current scientific advancements and the increase in knowledge of the whole genome sequence, transcriptome, proteome, and metabolome study of the individual on the one hand, and technological application of novel sequencing platforms, microarray devices, and other systems, on the other hand, make the basis of further improvements towards the medicine of a new future era to come soon (Trevino et al., 2007).

In the emergency conditions, the testing is often performed to facilitate rapid clinical decision making and start quick treatment of the patients, often the choice to perform PoCT or any other traditional diagnosis is made by the nurse or other clinical team members in that particular moment. An increase in awareness and knowledge among such health care professionals shift their choice from traditional methods to the current and advanced PoCT methods (Trevino et al., 2007).

The Gram's staining can be considered as a very early PoCT, if we look back in history, as it was very much portable and can be easily performed in an anteroom adjacent to the patient. The use of this differential stain has enabled prompt and appropriate treatment for many patients in due course of time. The availability of quick and rapid results makes it possible for the doctor to administer a more specific antibiotic for immediate treatment of the patient and increase the chances of survival (Dumitrescu et al., 2011).

As per the global market research report of prnewswire and markets, 2019, the worldwide diagnostics market of PoCT is forecasted to grow at a compound annual growth rate (CAGR) of 9.3% from 2013 to 2018, and to reach \$27.5 billion by 2018. As per the recently published data it is projected to reach USD 46.7 billion by 2024 from USD 28.5 billion in 2019, at a CAGR of 10.4%. In rural areas of developing countries like India, PoCT can serve as an effective means of improving efficiency and outcomes and responding to essential healthcare needs among the large populations and. It provides a cost-effective, timely medical care for ambulatory patients that is why PoCT laboratory testing has become one of the fastest areas of growth in the medical field, with the number of tests increasing at an estimated 10% to 12% every year (Murray et al., 2014).

According to the International Diabetes Federation, the global prevalence of diabetes is expected to increase from 382 million in 2013 to 592 million in 2035. Because of the high prevalence of diabetes and the need for constant monitoring of blood glucose levels, the report published by prnewswire in 2014 states that the hospital glucose testing market is the largest PoCT market segment worldwide. Moreover, increasing demand for home healthcare to address the rising incidence of diabetes is another market driver factor. As per the 2012 data, the blood glucose monitoring device market is a very lucrative business with vast future potential—valued at more than \$2 billion and is hypothesized to increase further as stated by market analysis report published by grandviewresearch in march 2020. Current report of prnewswire states that India has the highest number of Diabetic patients in the world and as per the International Federation of Diabetes, the numbers are likely to increase to 151 Million by 2025. The market is expected to register a positive CAGR of 11.9% in terms of revenue during the forecast period FY'2018-FY'2023 as per the latest market report.

As per the databrigade market research the Global point of care testing market is expected to reach USD 41.7 billion by year 2026, growing at a substantial CAGR of 8.4% in the forecast period of 2019 to 2026. The new market report contains data for historic year 2017, the base year of calculation is 2018 and the forecast period is 2019 to 2026.

The greater emphasis of healthcare is shifting more toward prevention and early detection of disease, as well as management of multiple chronic conditions. Numbers of tests are being developed in PoCT, from new

infectious disease biomarkers to polymerase chain reaction (PCR) and molecular testing which can be undertaken at the bedside of the patients. Wearable biosensors and lab tests on a chip are no longer science fiction now and are actually in the development stages to get launched in the markets. Furthermore, to new advancements of technology, research findings, new regulatory scrutiny, and economic and business obligations, all these factors all together, pushing PoCT to carve out a new niche (Fig 2 and 3) within the healthcare system (Paxton., 2014).

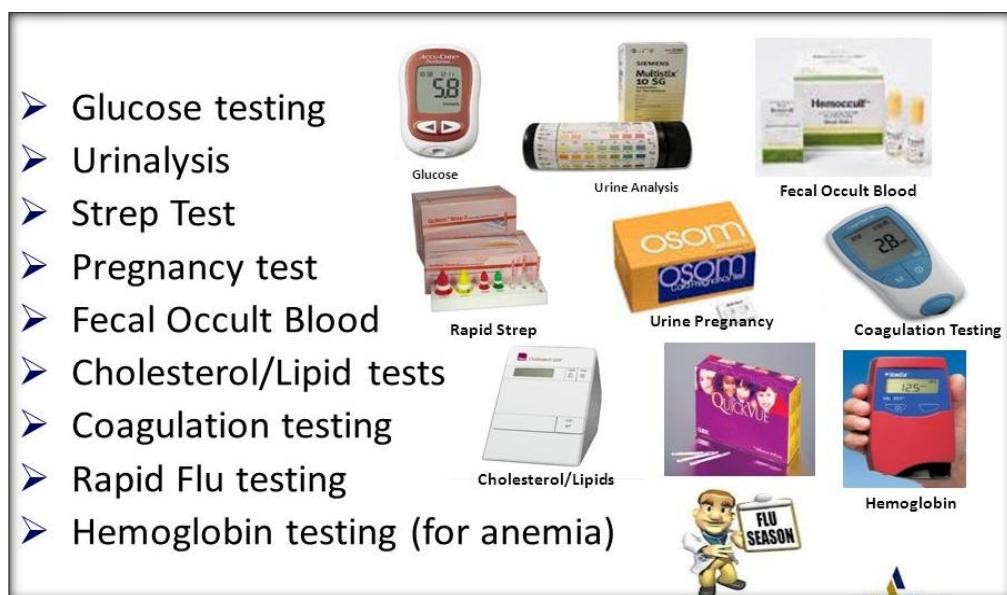


Fig. 2: Point of Care Techniques routinely used nowadays.

[Source – Virtual Medical Group]

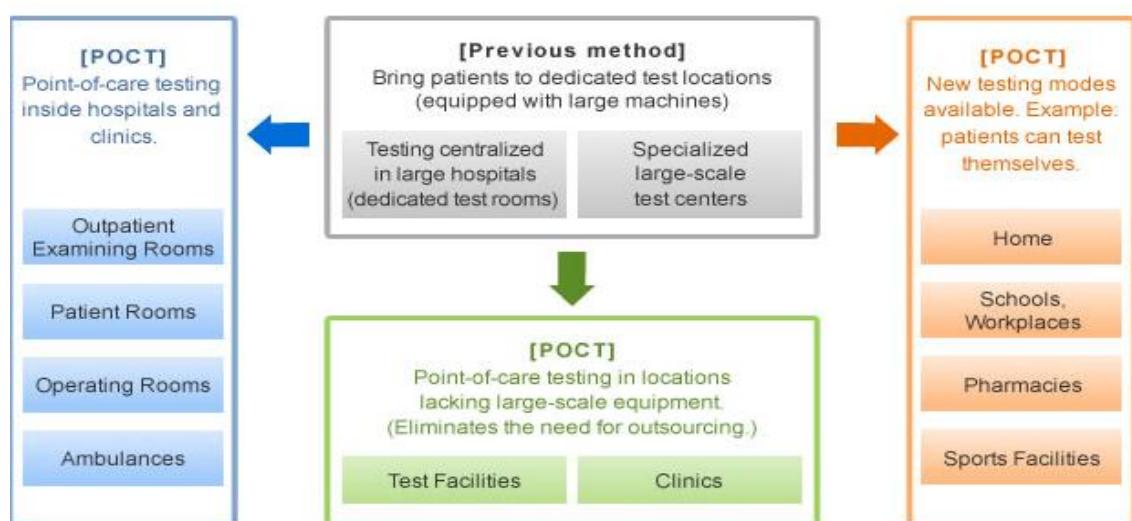


Fig. 3: Difference between Traditional Methods and PoCT

[Source - www.renesas.com]

BENEFITS ATTRIBUTED TO THE USE OF POCT METHODS FOR DIAGNOSIS

As per the PoCT toolkit of College of American Pathology published in September 2013, additional PoCT benefits are the requirement of less sample for testing as compared to traditional diagnosis. The requirement of a smaller sample volume is more convenient for patients, specifically for pediatric or neonatal patients. This low sample requirement can also cause less blood loss and anemia among patients who require frequent

testing's, such as intensive care patients. Moreover, whole blood PoCT requires less hands-on time for processing and reduces the potential for sample deterioration. Often, after the sample collection testing should be performed immediately, so it reduces the chances of the changes that occur due to continued cellular metabolism, cooling, analyte instability, exposure to the environment, etc. and increase the efficiency of the test results.

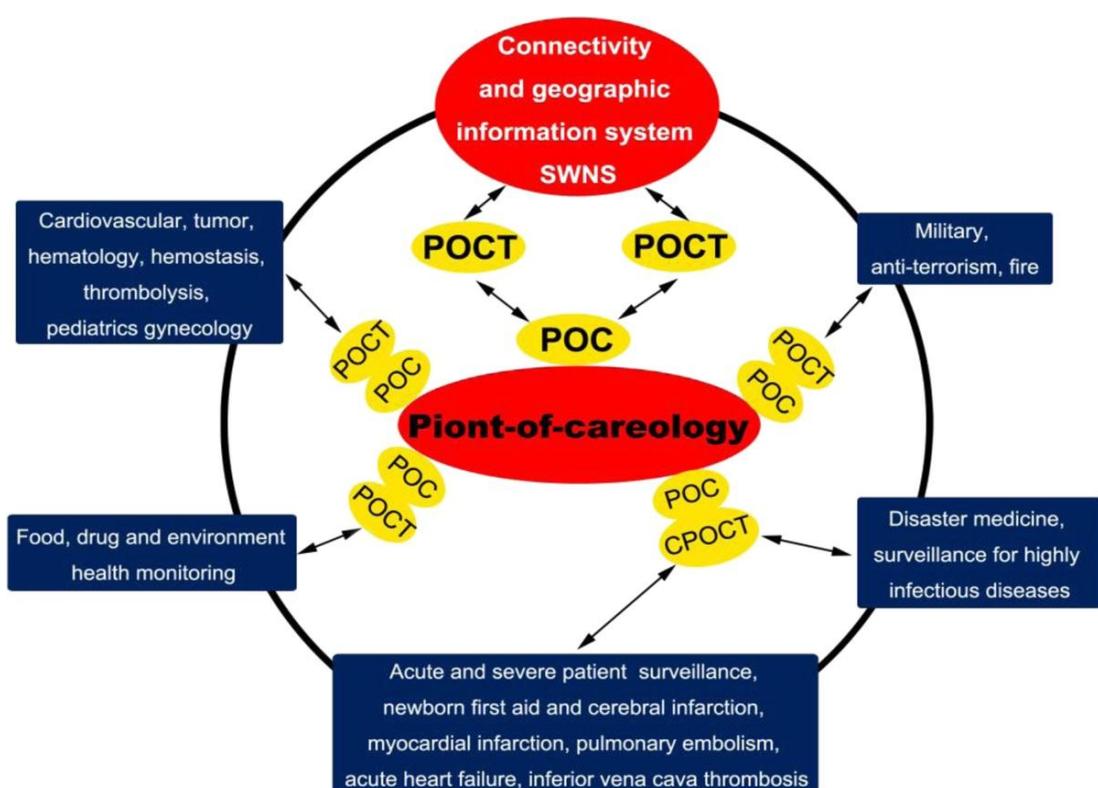


Fig. 4: Various applications of PoCT.
[Source - The Creation of Point-of-Careology]

CHALLENGES FACED BY POCT IN A WIDER APPLICATION

Although PoCT is efficient and quick enough in providing rapid results and the opportunity for faster medical decisions, the risk of errors with PoCT often raises concern over the reliability of test results. In the core lab diagnostics, most frequently the errors occur in pre- and post-analytic phases whereas in the PoCT method of testing the errors occur primarily in the analytic phase of testing. The probable reason for this may be related to a

lack of understanding or training of non-laboratory staff who are typically involved in PoCT or as a result of test limitations and misuse of PoCT in extreme environmental conditions (Sarah et al., 2014).

PoCT can vary magnificently as compared to the structured, controlled testing environment, testing conditions of the laboratory. Generally, the PoCT at the bedside is performed by clinical staff rather than laboratory trained individuals who lack the understanding of the importance of quality

control and quality assurance practices (Trevino et al., 2007).

As compared to testing performed in the central laboratory, PoCT is relatively more

expensive and requires a significant amount of support from the laboratory to ensure quality testing and meet accreditation requirements (Trevino et al., 2007).

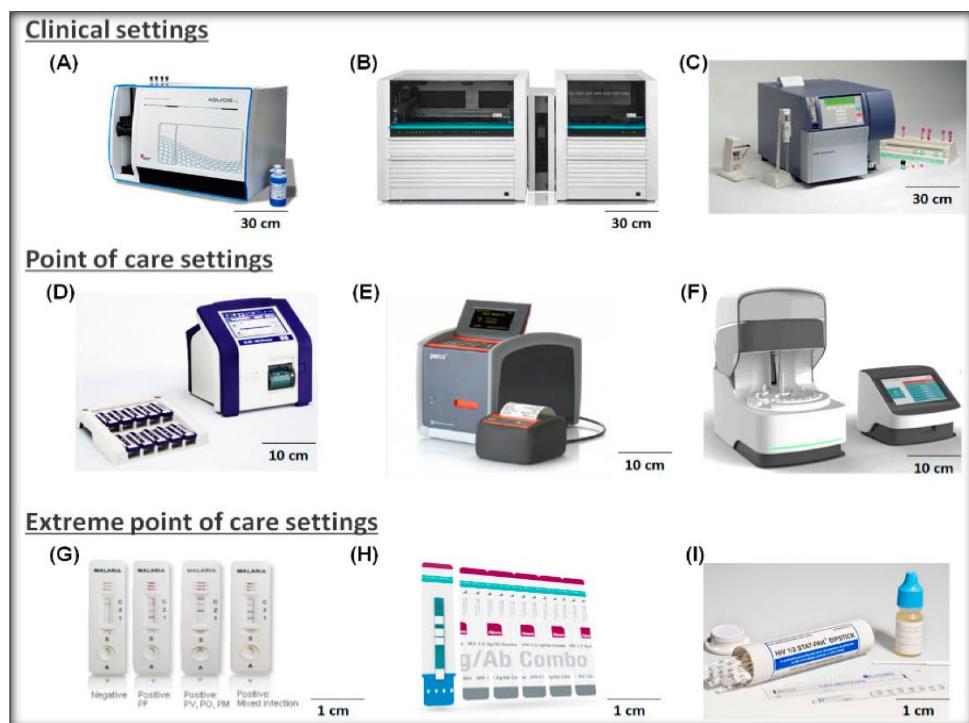


Fig. 5: Examples of different IVD technology in different treatment settings.

[Source – Issac et al., 2016]

PoCTs are also having a series of many hidden costs that are often not considered by clinical areas, including reagents for validating instruments, quality control materials, and proficiency testing costs. The medical laboratory technologists required to provide support of the quality assurance system for PoCT and information system/information technology staff that is instrumental in supporting PoCT connectivity platforms also need to be considered as a cost factor in PoCT. There is also a quite significant cost of creating the interface between PoCT software and devices to the laboratory information system and/or electronic medical record. PoCT also possesses certain quality issues, such as the assays employed are generally less analytically sensitive than assays performed in the central laboratory and are often more at risk of interferences than traditional laboratory tests.

CONCLUSION

Despite the declining mortality and morbidity pattern with the advancement in the healthcare system, India still has the priority agenda of fighting back against infectious diseases, which contributes to the heavy burden of the disease and forms a major concern of society. Together with this country has to additionally think about the emerging trend of incidence of chronic and newer diseases arising because of altered age patterns, changed lifestyles, and an increase in environmental pollution.

Among the developed nations, the emphasis is to be kept on the significant increase in the burden of infectious diseases such as respiratory and sexually transmitted infections, which also require better PoCT technology for faster disease diagnosis and better treatment planning to decrease the mortality rates.

PoCT can deliver “real-time” therapeutic decision making and can act as an important diagnostic tool to combat a group of diseases that are the most common cause of death worldwide.

In the case of influenza, onsite testing in a pandemic, nursing homes and closed environments, fever clinics, and community respiratory surveillance are get benefitted by PoCT in providing faster results. This rapid detection can assist in patient isolation, which minimizes the spread of disease. PoCT can also lead to justified use of necessary medications such as antibiotics and anti-influenza medication which proved to provide greater efficacy if started within 48 hours of the development of the disease symptoms.

There will be better patients' outcomes, with the rapid and correct diagnosis of the specific pathogen, which leads to the rapid management of the patients with the identified infectious disease, allowing prompt relevant medical therapy, which has been proven to improve the outcome of critically ill patients. There is well-documented proof of decreasing morbidity of septic shock in the relevance of speedy identification of the offending organism among the patients.

In the developing country like India where there is lack of sophisticated laboratory facilities and were electricity is still dream among the weaker section living in interior regions of the country “point of need” testing should be referred to, making pathology tests available in hospitals where they are needed and the cost-effectiveness of implementing PoCT is likely to be significant.

Treatment can be administered faster and transmission of a disease such as HIV is reduced if the doctors and patients know their results onsite rapidly. Rapid tests, even with current limitations of moderate sensitivity, effectively reduce sexually transmitted diseases in a high prevalence population especially where it is unlikely that patients will return for treatment after knowing their results.

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