POINT OF CARE TESTING (POCT) TEAM ROLES ON JOURNEY OF GLUCOMETER TESTING AT SUNWAY MEDICAL CENTRE

[1]Jamuna Jairaman, [1]Lau Shu Ying, [1]Annie V V Thomas, [2]Ho Yin Fen, [2]Suguna Thannimalai, [2]Sharon Ann, [2]Serene Lum Fuai Sian, [2]Daljit Kaur, [2]Yogeswary Rajagopal, [2]Tan Shuk Yuan, [2]Sharan Kaur, [2]Neh Heong Tin, [3]Irman Masron, [4]Vimala Gunusegran

1. Pathology Laboratory, Sunway Medical Centre Sdn Bhd
2. Division of Nursing, Sunway Medical Centre Sdn Bhd
3. Information & Communication Technologies Department, Sunway Medical Centre Sdn Bhd
4. Nursing Education, Sunway Medical Centre Sdn Bhd

Sunway Medical Centre Sdn Bhd, Malaysia,
No, 5, Jalan Lagoon Selatan, 47500 Bandar Sunway, Selangor

ABSTRACT

Keywords: POCT, Glucometer, IT 1000 Software.

Objective: Laboratory plays a lead role in procuring POCT devices, managing the equipment quality control (QC), documentation and monitoring of users competency prior to the hospital-wide implementation. The establishment of POCT team at SunMed achieved the study aims on procuring high quality glucometer device, ensuring these devices are handled by trained and credetialed users, standardization of QC practices by users and introduction of IT 1000 software to reduce financial risk as well ensured traceability of patient results.

Method: This process improvement study was carried out in various stages from 2010 to 2015 involving members of POCT team, the study started with the method evaluation process of glucometer device against laboratory method, users training, privileging and credentialing, standardization of QC practices, subsequently led to implementation of IT 1000 software and interfacing with the Hospital Information System. The traceability of testing process is monitored through IT 1000 system. Till today, the POCT team takes the lead in constant monitoring of the user privileging and credentialing, QC monitoring and financial lost tracking on monthly basis.

Results: Accuchek Performa/Inform II glucometer device which are comparable with the laboratory centralized system with R2 of 90.7%, precision of less than 5% and 92 % of the results falling within the predetermined compliance limit as per the acceptance criteria of ISO 15197.2003(E) were procured. As of December 2015, 100% of the users of glucometer are privileged and credentialed with 100% compliance rate on QC practices among users. There is100% reduction in financial risk in which the revenue leakage reduced to RM 0 in December 2015 as compared to RM 104,923 in 2011 resulting in low risk matrix score.

Conclusion: Therefore at SunMed we could conclude that the POCT team has clearly defined and well governed the POCT system in this facility.

INTRODUCTION

Continuous blood glucose monitoring is very important in patients with diabetes, as well as in patients with hyperglycaemia and hypoglycaemia, basically to deliver proper treatments, correct dosage of medications and adjustment of diet intake to these patients. In order to have an effective monitoring of blood glucose level, glucometer, a Point of Care Testing (POCT) device is required in hospitals. Glucometer plays a critical role in providing quick and accurate analytical information to facilitate rapid treatment decisions for doctors right at patient's bedside, as opposed to time-consuming conventional laboratory tests that must be run only at a central laboratory. However, pathology laboratory plays a lead crucial role in managing POCT on procurement of high quality devices for its intended use, management of equipment quality control and documentation as well monitoring of users competency into consideration prior to the hospital-wide implementation of the device. Therefore, we felt there is a need for the establishment of POCT team at SunMed in order to achieve this study aims on managing glucometer device in terms of procuring high quality and reliable results devices, to ensure glucometer devices are only handled by trained and credentialed users, to standardize internal quality control practices for all glucometer users throughout the hospital and to introduce POCT data management software to reduce financial risk in glucometer testing as well ensure traceability of patient results from all sites.

THE SIGNIFICANCE OF THE STUDY FOR THE ORGANIZATION

The use of glucometer as point-of-care-testing (POCT) devices enables SunMed clinicians to make quick medical decisions at fatal situations and at the same time favors patient care. It is the utmost important to realize that the patients in SunMed hospitals will be tested in both point of care methods and laboratory methods, thus the differences that exist between the methods is crucial to be constantly monitored and relevant to caution the clinicians about their existence. POCT team plays essential roles to ensure the results are carried out in a proper selected system by well-trained users and the team may allow reliable documentation of the results and optimization of quality assurance. Furthermore, every test that is being tested shall be charged in timely manner to avoid any revenue leakage, thus there should be proper monitoring process established. In addition to the medical significance it also contributes to organizational aspect benefits more important in outpatient clinics management and speedy patient admission process.

MATERIALS AND METHOD

POCT team involving various stakeholders from Nursing Department, Information Communication and Technology department, as well as Laboratory were established .This process improvement study was carried out in various stages from 2010 to 2015 involving the evaluation process of the five various glucometer device in terms of correlation, precision , bias and compliance limits, users training , privileging and credentialing, standardization of quality control practices, implementation of POCT data management software IT 1000 and interfacing the system with the Hospital Information System (HIS). In addition to that the POCT team ensured the service agreement was established with the vendor on the selected system and creation of standard operating procedure for users on handling the device. The POCT Coordinator are able to tract the testing process through the IT 1000 system which was installed at the point of device implementation phase at all sites in the hospital .The POCT coordinator produced monthly report to all head of departments of the users on the discrepancies of utilization and charging of strips captured in the HIS to minimize financial risk. In order to further reduce the revenue leakage the IT 1000 was interfaced with the HIS. There were various activities coordinated by the POCT team to mitigate the causes and effects for the discrepancies found in utilization and charging of strips and this was illustrated in a Fishbone diagram. Till today, the POCT team takes the lead in constant monitoring of the user training, privileging and credentialing, quality control (QC) monitoring and financial lost tracking on monthly basis.

RESULTS

	Statstrip	Performa	Contour	Xceed	Surestrep
R2	0.95073	0.90697	0.93516	0.88785	0.91374
Slope (X)	0.97	0.97	0.92	1.03	0.93
Intercept (Y)	0.29	0.54	0.60	0.36	0.60

Table 1: Linear regression analysis for glucose meters versus laboratory method. n=50.

Glucose System	Bias (mmol/L)	95% CI
Nova - Statstrip	0.050	-0.079 to 0.180
Roche - Performa	0.324	0.143 to 0.505
Bayer - Contour	0.054	-0.090 to 0.200
Abbott - Xceed	0.531	0.219 to 0.743
Lifescan - Surestrep	0.092	-0.079 to 0.263

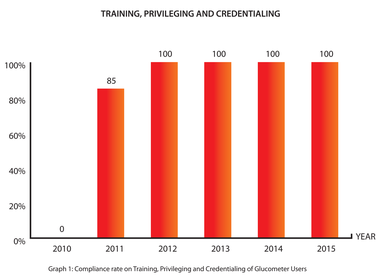
Table 2: Summary of the Bland & Altman Bias test

Glucose System	% Results within compliance limits (>95%)	% Results outside acceptable limits (<5%)
Nova - Statstrip	98%	2%
Roche - Performa	92%	8%
Bayer - Contour	96%	4%
Abbott - Xceed	90%	10%
Lifescan - Surestrep	96%	4%

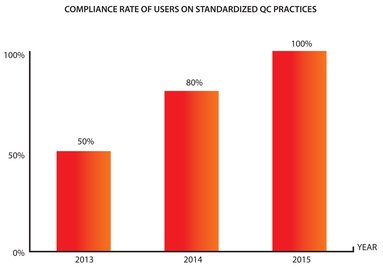
Table 3: Summarizes compliance to ISO 15197.2003(E)

Meter	QC Low Level CV %	QC High Level CV %	Subjects Within Run Precision CV %
Xceed Abbott	3.11	2.46	4.24
Nova Statstrip	3.87	2.15	3.43
Accuchek Performa	2.34	1.79	3.22
Contour TS	3.69	1.39	3.56
SurestrepLifescan	2.17	1.45	2.02
Reference Method	1.47	1.37	0.63

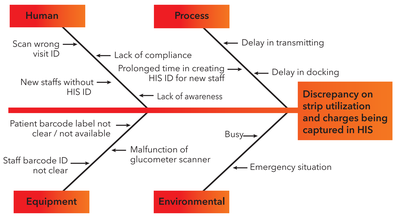
Table 4: Summarizes within – run precision for the five glucose devices when tested with the aqueous controls and patient. The CVs ranged from 1.39% - 3.87%. Generally the largest CVs resulted when testing lowest glucose levels in control solutions.

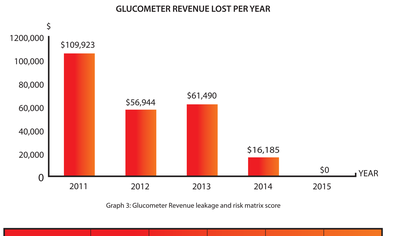


Graph 1: Compliance rate on Training, Privileging and Credentialing of Glucometer Users



Graph 2: Compliance rate of Users on standardized QC practices





Graph 3: Glucometer Revenue leakage and risk matrix score

Year	2011	2012	2013	2014	2015
Revenue Lost	$104, 923.00	$56,944.00	$61,490.00	$16,185.00	$ 0
Consequences	5	3	3	2	1
Likelihood	5	5	5	4	2
Risk Priority Number	25	15	15	8	2
Risk Rating	Extreme	High	High	Moderate	Low

Figure 1 below shows Cause and Effect analysis on Discrepancies' of strip utilization as compared to stripcharges captured in Hospital Information System

DISCUSSION / CONCLUSION

The POCT team has substantially contributed to a vast improvement in the implementation journey of glucometer at SunMed in terms of managing the procurement of the Accuchek Performa/Inform II glucometer device which are comparable with the laboratory centralized system with R2 of 90.7%, precision of less than 5% and 92 % of the results falling within the predetermined compliance limit as per the acceptance criteria of ISO 15197.2003(E).There were substantial improvement and consistency in training, privileging and credentialing as well on QC practices since the POCT team were established. As of December 2015, 100% of the users of glucometer are privileged and credentialed with 100% compliance rate on QC practices among users. There is 100% reduction in financial risk in which the revenue leakage was cut down to RM0 in 2015 as compared to RM104923 in 2011 and resulted in a risk matrix score of low as compared to extreme in 2011. All documentation and traceability of patient results as well as on the operators are available in the IT 1000 POCT data management system. Therefore at SunMed we could conclude that the POCT team has clearly defined and well governed the POCT system in this facility.

Accu-check Inform II meter

Cobas IT 1000

Hospital Information System

References

1. International Standard ISO 15197. In vitro diagnostic test systems – Requirements for blood-glucose monitoring systems for self testing in managing diabetes mellitus. ISO 15197:2003 (E).
2. Bland JM, Altman DG. Comparing methods of measurement: why plotting difference against a standard method is misleading. Lancet 1995;346:1085-7.
3. Sacks et al. Position Statement Executive summary: Guidelines and recommendations for laboratory analysis in the diagnosis and management of diabetes mellitus. Diabetes Care 2011;34:1419-23.
4. Ministry of Health Malaysia 2013, 'Registry National Diabetes Report', National Diabetes Registry, vol 1, pp. 1-48.
5. Noor, HM, Nurhanani, MN & Ramli M 2010, 'Medical complications among type 2 diabetes mellitus patients at a general hospital in East Coast Malaysia', The International Medical Journal, vol. 9, no. 1, pp. 15-19., 15-19.