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CLINICAL ENGINEERING REVIEW OF LARGE SCALE LABORATORY AUTOMATION IN TWO HEALTHCARE SETTINGS. CASE OF NHS TAYSIDE, DUNDEE, SCOTLAND & NIAGARA HEALTH, ONTARIO CANADA.

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Abstract—

This comparative study examines approaches to large scale laboratory automation in two different healthcare organizations. It considers the acquisition, implementation and the use of the technology. The two organizations studied, NHS Tayside in Dundee, Scotland and Niagara Health in Niagara, Canada have similar population density, land area and healthcare systems. Each organization implemented laboratory automation systems at around the same time. The study examined laboratory configurations, processes, key performance indicators such as turnaround time, workflow and productivity and identified that the implementation of laboratory automation, together with the use of information technology enabled both laboratories improve their efficiencies. Our research identified key similarities and differences in the organizational approaches to laboratory automation; areas of mutual interest to both organisations were identified where continuing collaboration may be of value moving forward. This is enabled by comparison of key performance indicators, sharing best practices, and enhancing mutual learning.

This research shows that both organizations managed to increase productivity and reduce turnaround time through introduction of automation. At the same time, NHS Tayside has taken advantage of technology to deliver additional benefit of increasing the effectiveness of laboratory services in patient care delivery by introducing new diagnostic pathways made possible by automation and associated information technology. Such approaches combined, with developments in the clinical applications of artificial intelligence, provide great future opportunity for Clinical Scientist and Clinical Engineers working together to transform the way modern clinical laboratory operate and impact positively on patient care and outcomes.

Keywords— **Laboratory automation, Middleware, Diagnostic techniques, Clinical Engineering.**

I. INTRODUCTION

Various studies acknowledge that up to 70% of clinical decisions that guide or inform patient admission, discharge and medication are based on laboratory results (Streitberg, et al., 2009). Currently, there is a growing pressure from healthcare executives to demonstrate that laboratory service delivery meets accreditation standards, apply lean principles, are clinically effective, address patient safety issues and enable optimal use of human and other resources. These issues if addressed successfully will enable delivery of good patient care. While services need to be affordable those involved in designing services should not lose sight of the fact that it is delivery value that should drive change. A value based approach needs to focus on clinical impact of investment in terms of desirable patient outcomes. This can be achieved by exploiting developments in information and analytical technology, adopting a whole system focus rather than a fixed focus on the laboratory components of the request to report cycle.

Health care systems within the UK share common pressures and are subject to many drivers for change that will be recognized internationally. Services need to transform to meet the challenges extant; delivering new configurations that focus on the delivery of benefit to the populations served in terms of quality of care, experience of care and cost of care (Triple Aim) is an imperative. This requires a focus on many issues including the delivery of realistic medicine. This appears as a cornerstone of NHS Scotland National Clinical Strategy highlighting the need for service providers and users to work together to prevent application of ineffective or wasteful investigations and treatments that do not add value to patients. (Scottish Government, 2016)

The most recent published Action plan 2014-2019 by Public Health Ontario (PHO), Canada stated that," Economic circumstances demand that all publicly-funded services, and the health care systems, demonstrate value for money. Health service providers need to demonstrate both improved health outcomes and economic sustainability. Demographic changes are transforming health human resources. The work-

force must continually adapt to rapid technological innovations as well as the current economic context" (p.8). (Public Health Ontario, 2014)

To meet health care needs of the population while operating within a challenging economic environment, in 2012, NHS Tayside acquired and deployed APTIO™ Automation from Siemens Healthcare Diagnostics. This followed a procurement process which challenged potential vendors to propose solutions that would enable delivery of a service vision that was focused on increasing clinical effectiveness and value (cost utility).

In March 2013, Niagara Health took advantage of building of a new hospital in St Catharine, Ontario to introduce total laboratory automation. This allowed them to redesign their model of delivery for laboratory services across the region. The ADVIA® LabCell® system from Siemens Healthcare Diagnostic was selected through a tender process as the automation system of choice for the hospital.

II. Materials and Methods

The methodology used in this research combined primary research approach, structured interviews during site visits, document analysis and data collection.

As part of primary research, a literature review was conducted to understand and document status of laboratory automation within the context of both healthcare settings. Among documents consulted for analysis were the NHS Scotland Clinical strategy, Laboratory Service Ontario, Expert panel report, WHO, Laboratory Standards and their implementation, Medical laboratory requirements for quality and competence (ISO 15189:2012), Google scholar, various papers from Journal of Clinical Microbiology, Journal of Clinical Chemistry and Journal of Laboratory Automation and several books and related book chapters.

A Strength, Weaknesses, Opportunities and Threats analysis (SWOT) was used to examine the current service provision. The revue also focused on the history of both laboratories to help gain some understanding on impacts of the adopted laboratory automation solutions. Political, Economic, Social, Technological, Legal and Environmental analysis (PESTLE) analysis was used to gain insight into prevalent factors that are driving change in laboratories.

Two site visits to Niagara Health laboratory in St. Catharine, Ontario, Canada, fourteen semi structured interviews and four structured interviews with stakeholders in NHS Tayside, Scotland and Niagara, Health were conducted. The interviews were designed to understand the history of both laboratories, address current and potential future clinical impact of technology on workforce, and on patient populations.

III. Results

A. SWOT Analysis

S: Strengths	**W: Weakness**
❖ Clear focus and reaction to local healthcare priorities ❖ Opportunities for local innovation ❖ Strong link with local teaching institutions ❖ Availability of the laboratory automation in both settings ❖ Introduction of new models of tests (diagnostic pathways)	❖ Limited funds available due to competing local priorities ❖ Variation in quality of and delivery of service ❖ High cost of maintaining quality management systems and accreditation ❖ Laboratory automation underutilized ❖ Limited local capacity to develop new tests ❖ Heterogeneity of data across systems
O: Opportunities	**T: Threats**
❖ Use of data analytics and information technology to provide new models of patient care delivery ❖ Share local innovation to enhance best practice in both settings ❖ New approaches to affordable and cost-effective financing laboratory service delivery ❖ Respond to local needs with local solutions based on local knowledge and expertise available ❖ Compare data for benchmarking and mutual learning	❖ Increasing ageing population and the need for diagnostic services ❖ Ageing infrastructure that require capital investment ❖ Rapidly evolving healthcare systems ❖ Rigorous regulatory requirements for laboratory accreditation ❖ Local IT historical approach to new technology and the delivery of clinical diagnostics

Table 1: SWOT analysis

B. PESTLE Analysis

P: Political factors	**E: Economic factors**
❖ Provincial approach to planning and delivery of diagnostic laboratory services in Ontario ❖ National approach to delivery of laboratory services in Scotland ❖ Governments set health care targets ❖ Health Canada and MHRA regulations ❖ Integration of health and social care ❖ Introduction of seven day working ❖ Withdrawal from European Union for NHS Tayside ❖ Sharing borders with the United State for Niagara Health	❖ Healthcare budgetary constraint; ❖ Merging healthcare and social care budgets; ❖ Inflation and exchange rate; ❖ High cost of new technology; ❖ New approaches to financing models.
S: Social factors	**T: Technological factors**
❖ Ageing population; ❖ Increase number of middle-income families; ❖ Presence of social depravation in some areas; ❖ Substance abuse; ❖ Life style changing and new attitudes toward health and wellbeing; ❖ Patient empowerment; ❖ Easy access to information; ❖ Population expectations	❖ Information technology, data and knowledge management; ❖ Mobile technology (mobile applications) ❖ Point of care testing (POCT); ❖ Personalized medicine; ❖ Automated solutions; ❖ Disruptive technologies; ❖ Internet of things.
L: Legal factors	**E: Environmental factors**
❖ Litigations; ❖ Provincial and national legislations; ❖ Data protection and freedom of information acts; ❖ Health and safety; ❖ Retention and storage of pathological records and specimens; ❖ Human rights; ❖ Healthcare professions regulation and licensing	❖ Carbon footprint ❖ Waste management ❖ Hazardous substances

Table 2: PESTLE analysis

C. Workflow and turnaround time

Niagara Health					
	Old system (2012)	**% resulted**	**ADVIA (2017)**	**% resulted**	**TAT %**
	Avg. TAT in min	within 60 min	Avg. TAT in min	within 60 min	Improvement
Serum Creatinine	47	80%	41	93%	13%
Sodium	44.2	85%	40	94%	9%
Troponin	52	75%	44	90%	15%

Table 3: Turnaround time (TAT) for tests observed in Niagara Health

NHS Tayside					
	Old system (2012)	**% resulted**	**APTIO (2017)**	**% resulted**	**TAT %**
	Avg. TAT in min	within 60 min	Avg. TAT in min	within 60 min	Improvement
Serum Creatinine	75	71%	56	95%	24%
Sodium	60	56%	37	94%	38%
Troponin	49	64%	33.6	95%	31%

Table 4: Turnaround time (TAT) for tests observed in NHS Tayside

D. Overall Productivity and Turnaround time

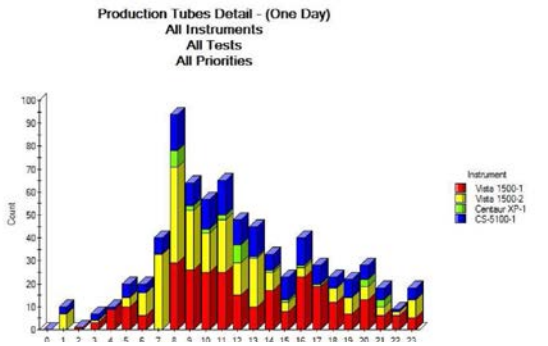

Figure1: Niagara Health overall daily productivity using ADVIA automation system

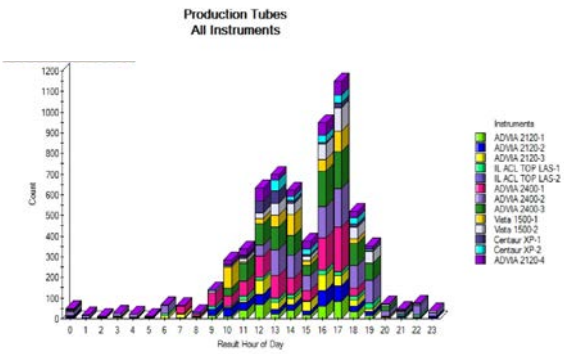

Figure 2: NHS Tayside overall daily productivity using APTIO automation system

IV. Discussion

A. SWOT Analysis

Table 1 shows that analytics and information technology are used by both laboratories to enable operational delivery of service, clinical functions and business management. Both services use complex information technology architectures to enable delivery of their information, data and knowledge management requirements.

B. PESTLE Analysis

PESTLE analysis indicates that the National and provincial approach to healthcare is driven by both the Scottish Government and the Government of Ontario respectively. A Distributed Service Model (DSM) (Bartlett, Bill, 2018) is being developed by NHS Scotland and the Local Health Integration Networks (LHINs) are being used to enhance consolidation of healthcare services in Ontario. These models are being driven by driven by a growing number of aging population that requires changes in the quantity and types of services available; advances in medical technology (i.e., diagnostics, therapies, surgical techniques, medication), that are enabling people to live longer and in better health; and the improvements in health care techniques and technologies that are changing the way that hospitals are used; advances in information/communication technology and the availability of health information, which are empowering people to assume greater responsibility for their own health.

C. Workflow

In both settings, the rack is loaded onto the track, followed by robotic triage, centrifugation and sample identification via bar codes. The track then moves samples to the appropriate analyzer for processing. Once completed the samples are automatically placed into a rack for storage. In the Tayside APTIO system, storage is on line enabling automated access to 15,400 specimens for secondary testing that can be algorithm or manually driven.

Finally, the analyzers produces the lab results; sends them to CentraLink (middleware) for auto-validation. Then, validated result is sent to the LIS. The latter generates a lab report and sends it to patient health records. A printout of lab report is then sent to the renal nursing station.

The same mapping process applied in Niagara Health was applied in Ninewells Hospital within NHS Tayside. The Renal department was also selected, with the same test requests identified as targets for study. However the time selected was between 10:00 AM and 01:00 PM for the peak time and then 02:30 PM to 04:30 PM for the quiet time.

The Health check report confirmed that overall productivity of the NHS Tayside laboratory is currently at 95%. Vali-

dation of test results is now automated for up to 88%. Therefore, laboratory personnel are required to validate only 12% of results that fall outside of outside of the set parameters.

Niagara Health Laboratory in St Catharine's, Ontario process over 3600 tubes a day using ADVIA automation tracked system. Turnaround time as well as the productivity of the laboratory were assessed for 3 target tests. (Serum creatinine, Sodium and Troponin). Tables 3 & 4 above show that turnaround time for all 3 tests have improved since ADVIA automation system was introduced. Productivity improved in terms of percentage of tests results being available in less than 60 minutes; this increased from an average of 80% to 93%.

D. Turnaround time

Data were made available from system Health check reports undertaken as part of the service provision by Siemens Diagnostics. It shows that overall daily TAT for test results in Niagara Health is below 1 hour for 95% of all tests performed. The median time here is 43 min. This is consistent with the data obtained for the indicator tests discussed earlier (Table 3 & 4) all test results are below 60 min TAT. NHS Tayside also demonstrated improvement on comparison with TAT data obtained from the previous score automation replaced by Aptio and improvements in production. The Healthcheck data indicated a median TAT of 41 min with 95% of the work completed within 60 minutes.

E. Innovation

NHS Tayside have capitalized on the availability of automation, the re-profiling of its skilled laboratory workforce, the consolidation of its Clinical laboratory operations to address the issue of direct and rapid access to diagnostics, to improve patient outcome by developing early diagnostic techniques. In this research we focused on understanding how intelligent Liver Pathway study, also known as (iLFT) that is being conducted at Ninewells Hospital, Dundee, using the APTIO automation, to investigate abnormal Liver Function tests (LFTs) (Miller, et al., 2018). The NHS Tayside team, argue that there is an urgent need to shift toward faster and less restrictive investigative testing to better manage specific diseases such as liver, heart, cancers, etc. Early diagnosis of serious diseases where effective interventions are available has been proven to increase survival rates and quality of life while reducing mortality. As a result, the total cost of managing the disease decreases.

IV. Conclusions

Laboratory automation has created resilience, flexibility and culture change by laboratory staff in both healthcare systems. It allowed disciplines that traditionally worked in silos to work side by side and across boundaries while on the same track system. As a result, consolidation has improved collaboration, improved general knowledge and development of generic skills, to enabled introduction of new management structures for clinical laboratories.

Co-production is the key to delivery of added value from development and applications of complex systems that are the product of advanced Clinical Engineering. Innovative use of technology that combine engineering solutions and laboratory medicine to enable creation of new diagnostic and therapeutic pathways that will deliver opportunities to enhance patient care.

NHS Tayside managed to improve the effectiveness of its service delivery through combination of technology, availability of data and innovation. They maximized the functionality of laboratory automation and IT systems to facilitate the development of new diagnostic pathways. The intelligent liver diagnostic pathway developed by NHS Tayside can be shared with Niagara Health as part of collaboration and sharing best practices.

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Conflict of Interest

The authors declare that they have no conflict of interest.

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