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Consolidation of Medical Laboratory Services in Hospital Universiti Sains Malaysia through the Establishment of Central Diagnostic Laboratory - Planning, Challenges, and Benefits

Abstract – Medical laboratory (ML) is the backbone and one of the main components of hospital services. ML provides analytical test results and pathology reports to assist clinicians to treat patients with reliable diagnostic data and evidence for appropriate interventions or therapies. For over three-decade since its establishment, Hospital Universiti Sains Malaysia (HUSM) has grown beyond its foundation. A reimagining of HUSM ML is important to provide a safe and quality experience to patients. This article outlines the history, driving factors, objectives, design and structure, challenges, potential benefits, and steering team of HUSM ML routine tests consolidation into the Central Diagnostic Laboratory (CDL). In summary, CDL is anticipated to enhance HUSM's ML service, research, and teaching using its own sustainable, efficient, and innovative approaches.

Keywords – Automation, centralisation, diagnostic service, Hospital USM

1. INTRODUCTION

A hospital is comprised of a wide range of services. These include ambulatory, emergency, out-patient, in-patient, surgery, radiology, pharmacy, laboratory, and mortuary services. These services operate interdependently and in synergy to provide holistic healthcare [1]. Medical laboratory (ML) is one of the important hospital services where tests are performed. Tests on patient specimens involve analytical and interpretation of human biological systems and functions. Also, transfusion ML provides blood transfusion, blood components preparations, blood donation, and other blood-related services. These results assist clinicians in patient screening, monitoring, and intervention.

Over the years, Hospital USM (HUSM) facility has been expanding its facilities to accommodate the increasing demand from the rapidly growing population of the region. Cost-saving measures were enforced due to the resource planning policy. However, ML ought to maintain its test quality, safety, and accuracy. Therefore, ML services has been aiming to be lean, centralized, and fully optimized.

2. HISTORY OF ML SERVICES IN HUSM

Universiti Sains Malaysia (USM)'s School of Medical Sciences (SMS) was established in USM Main Campus on Penang Island in June 1979. The school has since then recruited, trained, and graduated many skilful Medical Laboratory Technologist (MLT), among others. In 1977, the government provides USM with a plan of teaching hospital in Kubang Kerian, Kelantan. The hospital is known as Hospital USM. In June 1990, School of Medical Sciences was relocated to the Kubang Kerian, Kelantan, after eleven years in Penang. HUSM and the SMS complement each other in teaching and services [2,3].

HUSM ML operation began on August 1st, 1983, after the hospital's completion. In the beginning, the HUSM Department of Pathology (DP) was responsible for the management of ML. Services provided to HUSM (initially with 36 beds) include blood banking, chemical pathology, microbiology, and haematology diagnostic tests [4–6]. The tests were performed by MLTs who were trained in the medical school. In 1998, ML was integrated into SMS's medical department (MD) to provide vertical integration with medical department and expand its sub-speciality training and research programmes. Now, there are twelve ML in nine MDs of the medical school (Figure 1) [4–6].

ML organization structure is different in each hospital, especially in a university hospital. In HUSM, ML is integrated with the MD of its discipline. Besides academics and research, the MD is also involved with ML operation and service. The MD is led by a head of the department (HOD), usually an SMS academician or medical lecturer. The MD is staffed with academicians (medical lecturers and university lecturers from SMS), non-academicians (administrative and professional staffs), science officers, and support staffs (MLT, laboratory assistants, and office assistants). Non-academic staffs are either from HUSM or SMS. This hybrid structure and environment have existed since the integration.

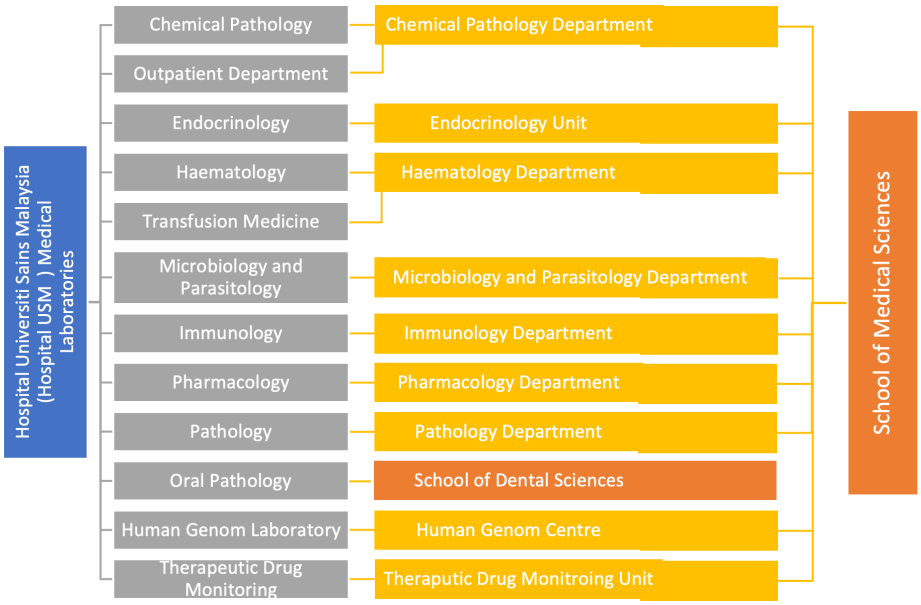

Figure 1. Diagram showing the hybrid relationship between HUSM ML and SMS MD

3. CENTRALIZATION OF ML SERVICES IN HUSM THROUGH THE ESTABLISHMENT OF CDL

The concept of centralised Medical Laboratory (ML) services is not new; many of the ML in Malaysian hospitals were centralized. Establishing Central Diagnostic Laboratory (CDL) through ML centralization is challenging as it requires vision, mindset change, efforts, resources, coordination, and support among the stakeholders. HUSM CDL's establishment was aimed at centralising resources, improving efficiency, and saving costs. Table 1 shows the list of ML tests potentially to be centralized and offered in CDL. However, this centralization proposal was not successful. In 2020, HUSM MS ISO (International Standard of Organization) 15189 ML Management Representative (MR), Associate Professor Dr. Rosnah Bahar, supported by all MD HOD, reproposed CDL to the hospital management. The proposal stressed the redundancy of analysers, human resources, maintenance, consumables, laboratory information system (LIS), and standard technical manual in twelve ML. Former HUSM Director and USM Vice Chancellor, Professor Dato' Dr. Ahmad Sukari Bin Halim and Professor Dato' Dr. Faisal Rafiq Bin Mahamd Adikan, respectively approved the proposal due to the benefits highlighted. The former USM Vice Chancellor included HUSM CDL as one of the USM finance key strategies for 2021-2022 in his 2021 annual talk and sharing with USM staff and

students. It stated that CDL is expected to sustain USM and HUSM operations, and increase revenue by streamlining and aligning more than 20 MS ISO 15189 accredited ML.

4. DRIVING FACTORS FOR ML SERVICES CENTRALIZATION IN HUSM

Currently, HUSM ML is managed under nine different MDs (Medical Department). There are overlapping of services because some of the MLs are using the same analysers to perform tests. For example, there are six chemistry analysers in chemical pathology, pharmacology, and therapeutic drug monitoring combined. There are four haematology analysers in the haematology and emergency department, and fourteen immunoassay analysers in endocrinology, chemical pathology, transfusion medicine, immunology, microbiology, and haematology combined. An asset is a cost. For example, a haematology analyser's cost is up to RM400,000, and its yearly maintenance is up to RM8,000. Thus, four units of haematology analysers would cost HUSM RM 1.7 million for three years. Purchasing and maintaining redundant analysers are a burden on the hospital's operational budget.

Redundancy is also observed in hospitals' staffing and on-call claims. Human resource is critical due to the shrinking emolument budget and hiring freeze of new or retired staff. Meanwhile, emoluments and claims increased as staff gained seniority, promotion, and increment. Furthermore, ML must provide 24-hour service, and currently, four ML have at least one on-call staff working daily. Thus, a total of 30 to 40 staff were required to ensure smooth on-call rotation, which cost RM 800,000 in on-call claims in 2019. HUSM CDL is estimated to reduce the cost up to 17%. Meanwhile, sharing of CDL internal and external quality assurance programmes may reduce enrolment costs by 10 to 20%. Besides, CDL reagents and chemicals procurement via an open multi-year cost per reportable tender contract will save a million ringgit for three years. Centralization of ML services makes CDL a one-stop centre for ML blood tubes and specimen collection, sample processing, LIS, accreditation, and standard operating procedure (SOP). Consequently, CDL total laboratory automation (TLA) integrates pre-analytical, analytical, and post-analytical processes from all ML into a single system [7], thus reducing redundant containers and consolidating chemistry, immunochemistry, haematology, and haemostasis analysers. This was accomplished by the San Bassano Hospital Laboratory Medicine service [8]. Similarly, Italian Brescia Spedali Civili healthcare Core-Lab CDL staff costs was reduced by 15%, slightly eliminated analyser costs and gradually improved test turn-around time using TLA [9]. Meanwhile, due to the Alberta health restructuring, thirty percent was cut from the Calgary city ML service sector budget which forced Calgary Laboratory Service to implement centralization. However, it turned to be a successful centralized laboratory [10].

Centralization of routine tests to CDL drives ML and MD to eliminate routine test burdens. A routine test is a standard test requested to detect common clinical conditions, and screening for subsequent testing, it can be requested during office hours and outside office hours [11]. Meanwhile, the STAT (short turnaround time) test is expedited testing for emergency reasons only, in which it will be given priority in the process of analysis and production of test results and can be requested during office hours or outside office hours [11]. Routine tests are burdensome because of high volume, repetitive processes, manual labour, high budget consumption and confined ML capacity to expand its specialized tests. ML can focus on specialized tests when its routine tests are outsourced to CDL.

Increased hospital inpatient occupancy and new outpatient clinics opening also drive ML for centralization. Started with 36 beds initially, HUSM has grown into a 747-beded hospital in 2009. [2]. Besides, HUSM regularly faces emergency and disaster events which increase ML burden [12,13]. Haematology Laboratory recorded a 30% increment in routine test requests in 2010 and 2020, an average of 3% year-to-year increment. It comprises of full blood count, differential count, reticulocyte count, full blood picture, erythrocyte sedimentation rate, glucose-6-phosphate deficiency screening tests; prothrombin time, activated partial thromboplastin time, fibrinogen level and D-dimer tests. Meanwhile, Chemical Pathology Laboratory recorded a 52.16% increment in 2010 and 2020 (Figure 2). HUSM plans to recover the ML operation budget by offering ML tests in the corporate, private wing, executive clinics, and new clinics.

Table1. Central Diagnostic Laboratory (CDL) Test Menu

No.	ML	Test
1.	Chemical Pathology	BUSE, Fasting Lipid Profile, LFT (Liver Function Test) RFT (Renal Function Test), Bilirubin, Albumin, Alkaline Phosphatase, ALT, Ammonia, Amylase, AST, ABG, Ca, HDL (High-Density Lipoprotein), Creatine Kinase, Creatinine, Cerebrospinal Fluid, CLDH (Lactate Dehydrogenase) Glucose, Lactate, LDH (Lactate Dehydrogenase), Lithium, Mg, PO4, Protein, TG, Troponin , Total Iron Binding Capacity, Unsaturated Iron Binding Capacity, Urea, UA, CA 125, Carcinoembryonic Antigen, Prostate-Specific Antigen, Pleural Fluid, Pericardial Fluid, Osmolarity, 24h urine, UFEME, Dialysate
2.	Out-Patient Department	UFEME, RME
3.	Endocrinology	Free T4, Thyroxine Stimulating Hormone, Free T3, Cortisol, Anti Thyroglobin, Total HCG, Thyroglobulin, Follicle Stimulating Hormone, Luteinising Hormone, PTH, Testosterone, Prolactin, Anti-Thyroid Peroxidase, Progesterone, Insulin, Oestradiol, Growth hormone
4.	Immunology	C-peptide, ACTH, DHEA.SO4, CRP, C3C4 (Complement 3, Complement 4), Ig G A M, Alpha Feto Protein, Urine Pregnancy Test.
5.	Pharmacology	Drug of Abuse test.
6.	Microbiology (Serology)	HbsAg, Anti Hbs, HBeAg, Anti Hbe, Anti HCV, Human Immunodeficiency Virus Ag/Ab, Syphilis, Toxoplasma IgM IgG, CMV, HSV IgG
7.	Haematology	Full Blood Count, Differential Count, Retic, Full Blood Picture, Erythrocyte Sedimentation Rate, Glucose 6 Phosphate Deficiency, Ferritin, B12 folate
8.	Coagulation	Prothrombin Time, Activated Partial Thromboplastin Time, DD, Fib, Disseminated Intravascular Coagulation
9.	Pathology	Fine Needle Aspiration Cytology
10.	Therapeutic Drug Monitoring	Acetaminophen, Amikacin, Carbamazepine, Cyclosporine, Digoxin, Gentamicin, Lamotrigine, Methotrexate, Phenobarbital, Phenytoin, Salicylate, Steroid, Theophylline, Valproic Acid, Vancomycin

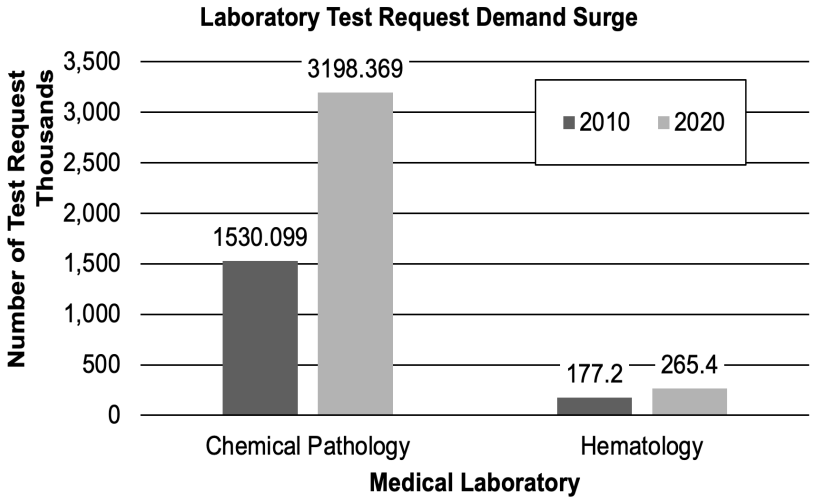

Figure 2. Comparison of Medical Laboratory (ML) test requests in 2010 and 2020

5. CDL ESTABLISHMENT OBJECTIVES

The objective to establish CDL vary for institutions, healthcare, and hospitals. For HUSM, CDL is established to consolidate all ML services for efficiency, capacity, sustainable operation, budget, emolument, maintenance, and utility use. HUSM ML is also catching up and adopting new and advanced laboratory automation technology. These technologies may be costly, but they are necessary, as automation, artificial intelligence and machine learning are the future of healthcare. To achieve that, HUSM CDL establishment aims to optimize operational costs and generate revenue to recover test costs. The operation is optimized by eliminating six current ML operation cost problems which are to (i) eliminate new asset procurement and management, (ii) eliminate asset liability for repair and maintenance, (iii) streamline specimen preparation, collection, transportation, and pre-analytical process, (iv) change procurement of reagents to multiyear tender of tests cost per reportable, (v) centralize and minimize ML workforce for efficiency, and (vi) merge TDM into CDL. The second CDL establishment objective is to generate revenue from specialized tests to cover its test costs. CDL establishment consolidates all routine ML tests to CDL and allows ML to focus, introduce and offer highly specialized tests to attract current and new, internal, and external customers on par with the private or public medical laboratories in the country such as Gribbles Pathology Malaysia or Institute of Medical Research.

6. HUSM'S CDL DESIGN, ORGANIZATION AND MANAGEMENT STRUCTURE

HUSM CDL was designed based on its objectives which were to create a centralized laboratory that can reduce operational costs and opportunity to recover costs. The physical and structural design was finalized after discussion with its stakeholders and end-users. HUSM management designated CDL organizational structure as a new unit under the Hospital Deputy Director (Clinical). A CDL coordinator which is a chemical pathologist was appointed to manage it. The coordinator will report to the Head Coordinator for Laboratory and Hospital Deputy Director (Clinical). The CDL coordinator will be assisted by two seniors SO (Scientific Officer) and about 20 MLTs (Medical Laboratory Technologists), LA (Laboratory Assistants) and operation assistants (OA) (Figure 3).

CDL's physical floor plan layout design was discussed after Jawatankuasa Pengurusan Hospital Universiti (JKPH) approved its establishment. The physical design planning involves all stakeholders, such as end users – ML and MD staff, Jabatan Pembangunan & Pengurusan Aset (JPPA) Kampus Kesihatan and potential CDL TLA vendors. Many layout design proposals were received from vendors but could not be disclosed due to potential conflicts of interest, and confidentiality. All layout design proposals must fit in the 1,800 square feet of space designated for CDL (Figure 4).

HUSM CDL development and operation must be completed within the space, budget, saving, redundancy elimination and tender process. HUSM or USM do not allocate additional budget for CDL. Thus, it was pooled from all ML routine tests budget. The annual operation budget for chemical pathology, haematology, immunology, microbiology, and pharmacology ML routine tests is RM 2.8 million. For three years, it amounted to RM 8.8 million, inclusive of a five percent yearly increment. CDL development and operation must be within this existing budget.

CDL offers 155 routine tests which consist of routine biochemistry, immunology, haematology, coagulation, therapeutic drug monitoring, pharmacology, tumour markers, cardiac markers, serology, and endocrinology discipline. Essential routine tests are performed immediately, meanwhile batch routine tests are collected anytime and performed periodically by batches at their predetermined time. Table 1 lists the tests offered in the initial operation of CDL and more will be added in the future.

7. APPLICATION OF TLA IN CDL

In the 1980s, Dr. Masahide Saski and a team of medical technologists in Kochi, Japan conceptualized and developed TLA [14]. After more than three decades, medical technology instrument companies have continually improved, perfected, and commercialize TLA. TLA automate laborious and repetitious tasks in specimen pre-analytical, analytical, and post-analytical processes in ML. These tasks are crucial and sensitive to ensure an accurate and timely reporting of results as they are prone to human errors, require skilled operators, and time-consuming.

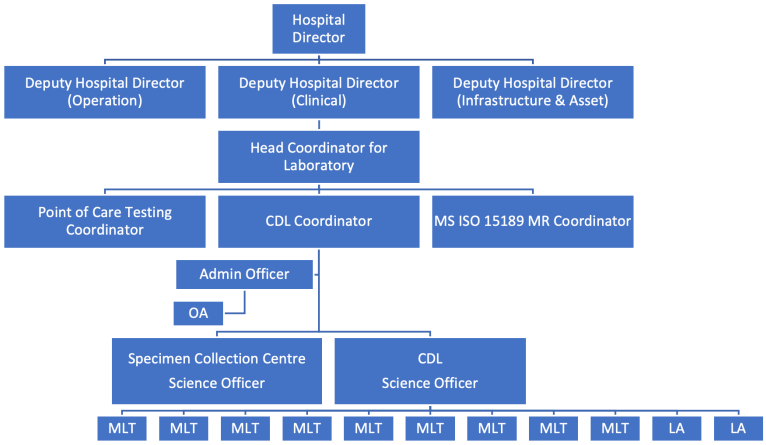

Figure 3. HUSM CDL proposed organizational structure

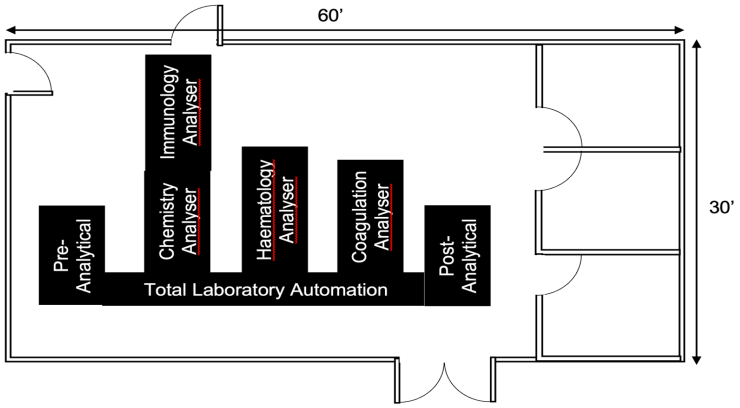

Figure 4. HUSM's CDL proposed floor plan and equipment placement layout

Table 2. List of hospitals and TLA used in their laboratory

Hospital	Type	TLA solution
Hospital Kuala Lumpur	Ministry of Health, General Hospital	Cobas® infinity
Hospital Sultanah Aminah	Ministry of Health, General Hospital	Cobas® infinity
Hospital Sultan Ismail	Ministry of Health, General Hospital	Cobas® infinity
Hospital Melaka	Ministry of Health, General Hospital	SIEMENS Atellica®
Hospital Raja Perempuan Zainab II, Kota Bharu.	Ministry of Health, General Hospital	Beckman DxA
Hospital Selayang	Ministry of Health, District Hospital	Cobas® infinity
Hospital Temerloh	Ministry of Health, District Hospital	Cobas® infinity
University Malaya Medical Centre	University Hospital	Cobas® infinity
Pusat Perubatan Universiti Kebangssan Malaysia	University Hospital	Cobas® infinity
Sultan Ahmad Shah Medical Education City at International Islamic University Malaysia	University Hospital	Beckman DxA
Hospital Tung Shin	Private Hospital	Cobas® infinity
Normah Medical Centre	Private Hospital	Cobas® infinity
Hospital Loh Guan Lye	Private Hospital	Cobas® infinity

As CDL consolidates all routine ML tests in HUSM, an estimated 10,000 test request is expected daily in CDL. HUSM must be prepared with a solution to address current and future demands as they surged over the years. And TLA is an ideal technology for CDL automation solutions to handle current and future routine test demands. A CDL equipped with TLA can keep up with the current test demand and provide a foundation for future hospital, ward, and clinic expansions. TLA can handle thousands of samples [14] with minimal staff [8,15], efficient specimen management [8], shrink working area, error-free [7,8], high quality and shorten TAT [7,8].

There are four TLA solutions in the market provided by local vendors to governments, universities, and private hospitals in Malaysia. They are Cobas® infinity laboratory solution from Roche Diagnostics, Basel Switzerland [16–18], Abbot Alinity core laboratory automation from Abbot, Illinois, United States of America (USA) [19], Beckman Coulter DxA 5000 laboratory automation systems from Beckman Coulter, California, USA [20], and Siemens Healthineers Atellica® laboratory automation solutions from SIEMENS, Munich, Germany [21]. Table 2 lists all Ministry of Health, teaching and research university and private hospitals which uses TLA.

With TLA in CDL, the human resource issue could be solved as it would be possible to reduce the number of on-call staff from different labs, thus reducing on-call claims and utility costs. It also provides on-call staff safety and compliance with ISO requirements in CDL. Consolidation of routine tests in CDL reduces up to 50 per cent of the staff and allows staff to focus on providing routine tests around the clock. TLA in CDL permits automation and walk-away operation in many current pre-analytical, analytical, and post-analytical steps, which required an operator's hands-on (Figure 5) [22]. TLA will automate manual, repetitious, and laborious tasks in the pre-analytical and post-analytical process and integrate different analytical analysers such as chemistry, immunoassay, serology, haematology, coagulation and in one single integrated or modular automation systems [14,23]. Figure 5 shows pre-analytical processes (steps 1, 2 and 3) which are specimen receiving, barcoding, sorting, transporting using the TLA specimen track system, specimen quality checking, centrifugation, de-capping, and aliquoting. The analytical process occurs in the TLA-connected analysers such as in A, B, C and D which are the haematology, chemistry, immuno-chemistry, and coagulation analysers, respectively. Finally, the post-analytical process (steps 4, 5 and 6) which are re-capping of the specimen tubes, sorting, transporting, storing the specimen in the refrigerated specimen stockyard and reporting, and releasing the test results.

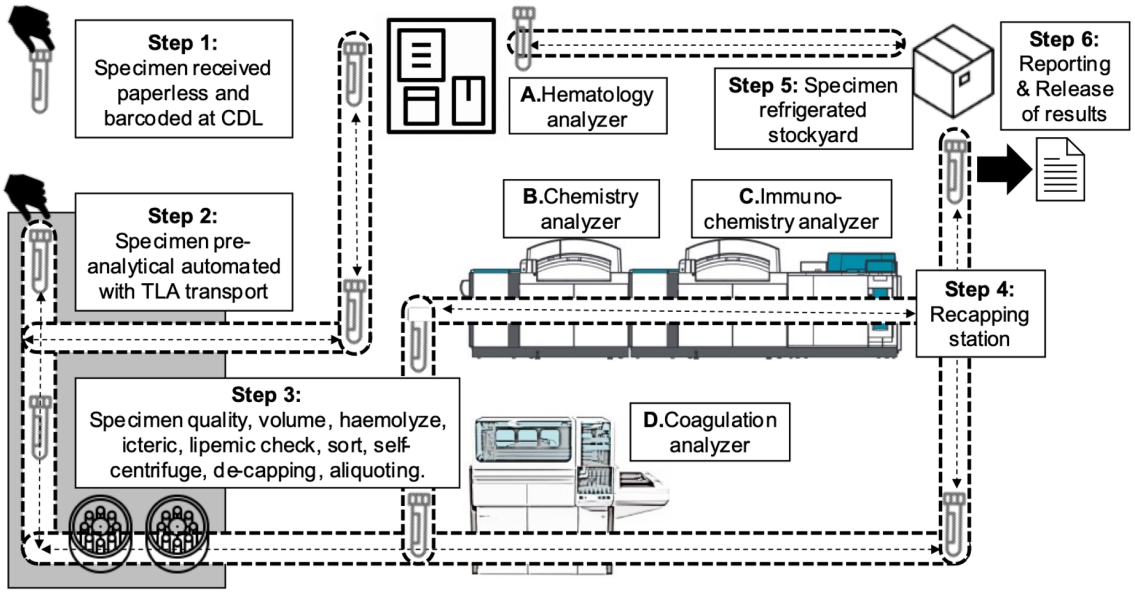

Figure 5. Automation of manual tasks in CDL TLA [8,14,22,24]

Challenges of CDL Establishment

To establish the CDL, collaboration among the Chemical Pathology, Haematology, Microbiology, Parasitology, Pathology, Immunology, Pharmacology, Therapeutic Drug Monitoring, and Endocrinology ML is of utmost importance. It is challenging for the task force team to explain and ensure the idea and needs to establish CDL are understood and supported by all ML. Thus, a briefing session was conducted with all MD HOD and relevant ML personnel involved with CDL. It received good feedback and increased all parties' understanding and cooperation.

The CDL project is new to HUSM, and the task force team had a challenge as none had prior experience in managing and executing a CDL. The team is concerned with the Hospital Information System (HIS), LIS, middleware, analyser interfacing, and IT (Information Technology) requirements that the vendor provides to CDL. Thus, HUSM must obtain a thorough solution that offers an end-to-end CDL IT solution to ensure smooth operation.

In other hospitals, challenges come from external forces to change the ML status quo leading to ML centralization. These forces were analyser tender or contract expiration [8], changes in public healthcare fund dispersion [10], demand in the healthcare and laboratory test cost reduction [25], economic stimuli and current financial constraints [26], economic sustainability [9], growing costs of healthcare and laboratory-related expenditures [27], and limitation of the current point of care testing technology or another diagnostic system [28].

Lastly, the challenge to establishing CDL is that it takes a longer laboratory turn-around time (TAT) compared to Point of Care Testing (POCT). This is because additional time is required for specimen transport, pre-analytical, analytical, post-analytical and validation of test results. Thus, hospital management must carefully decide and determine which test should be performed as POCT or in CDL to provide reliable, accurate, and efficient diagnostic testing [25].

8. POTENTIAL BENEFITS OF CONSOLIDATING THE ML SERVICES

The benefit of ML consolidation into CDL enables the transfer of current advancement and innovation in laboratory analytical and automation technology to HUSM to establish an efficient, automated, and productive CDL. This indirectly relieves HUSM's financial constraints to advance ML technology and provide better healthcare services, saving utility, staff, and operational costs. The benefit of CDL also potentially lifts HUSM ML's routine workload and enables it to focus on expanding and commercialising specialized tests.

Literature has reported positive benefits from ML centralization and automation. However, there were also some initial setbacks and challenges at the beginning of the centralization implementation. The benefits and challenges of centralizing ML are summarised in Table 3. For example, Alberta Health's restructuring in Canada forces Calgary Regional Health Authority to centralize its clinical microbiology service. The regional clinical microbiology services centralization was met with pros and cons. Still, the benefit of its centralization was a standardized process and procedure in its clinical microbiology services. The centralization also provides an efficient integrated service, cost-effective operation, and opportunities for growth and expansion into new markets [10].

Meanwhile, San Bassano Hospital, a medium-sized hospital in the northeast of Italy aim to implement a centralized laboratory based on TLA in its laboratory new vendor selection criteria. The potential benefits of this aim were to improve ML service quality, enhance patient safety, improve job satisfaction, offset technical staff shortages, increase productivity with limited cost, consolidate and improve chemistry, immunochemistry, haematology, and coagulation in a single functional platform [8].

Brescia University's Spedali Civili hospital is a large urban academic teaching university and one of the best public healthcare in Brescia, a city in the North of Italy [29]. The hospital reported good impact and economic performance benefits by merging its four ML into an integrated, centralized, and unified automated laboratory called Core-Lab. Its case study of a tertiary university hospital with academic teaching and research ML setting is closely similar to HUSM. It experienced benefits from improved efficiency, lowered operational costs, and reduced staff after the integration [9]. Procurement of new automation technology and equipment initially causes an increase in equipment cost. However, if an appropriate procurement and financial model were applied, the cost could be alleviated or reduced. The integrated laboratory and automation investment in Spedali Civili shows a reduction in laboratory staff costs while providing 24-hour service, and improved laboratory turn-around time for urgent and routine test examinations with short-term benefits. Long-term benefits of Spedali Civil hospital and Brescia

Core-Lab centralization and automation were expected [9].

Ingolf and Trenti reported that synergy, quality, and timeliness in CDL offer efficiency, scalability, and quality test results in addition to optimized operation cost. The value of a test is determined outside the laboratory, which is by providing all diagnostic information and confidence to the clinicians. The utility and usefulness of test results from CDL are beneficial to the whole hospital patient clinical pathway, thus CDL plays a role in the design of an effective and valuable healthcare system [28].

The benefits of CDL to achieve, conserve and manage cost-effectiveness make it a rational decision for other hospitals to adopt it to consolidate routine tests. Besides routine tests, CDL allows an efficient, accurate performance for low-volume, specialized testing, for both inpatient and outpatient to be performed together for lower cost as it eliminates duplication and shares facilities. And some testing delays or longer test TAT drawbacks in CDL due to its higher volume of workload were tolerable with higher professional satisfaction and confidence in CDL than in smaller or private ML [27]. Moreover, consolidation of haemostasis tests in CDL requires special attention to the requirements of anticoagulated blood collection tubes, pre-analytical variables and errors, stages of an analytical procedure for screening, confirmatory diagnostic tests, and importantly qualified and skilled technicians and specialists [26].

Table 3. Benefits and challenges of implementing CDL in other places

Author	Benefits/Challenges
D. Church, P. Hall [10]	Standardized processes and procedures, efficient integrated service, cost-effective, growth into a new market
C. Archetti, A. Montanelli, D. Finazzi et al. [9]	Automation increases equipment costs but is compensated by reduced staff costs. In total, operational costs were down twelve percent
R. Scharf [26]	Haemostasis diagnostic tests are delicate and difficult to be integrated with a centralized diagnostic laboratory. The Educational, training, and competencies of clinicians and technicians are highly recommended
Ingolf Schimke [25]	Centralized laboratory medicine offers high-quality results in a highly economical and efficient way, with adequate timeliness for optimal patient care
A. Robinson [27]	Centralized laboratory services help conserve resources and provide an efficient and accurate performance of low-volume, specialized tests
Tommaso Trenti [28]	Centralized clinical laboratories offer an improved number of diagnostic test services, higher automation quality, and higher productivity summarised as 'do more with less'
Rin, Giorgio Da Zoppelletto, Maira Lippi, Giuseppe [8]	Laboratory automation improves lab testing quality, job satisfaction, standardization, shorter lab turnaround time, reduces human resources, optimizes staff management, and minimizes errors

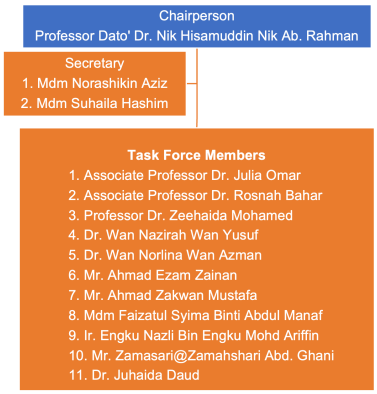

Figure 6. Hospital USM JK TF CDL organization structure

Table 4. The name, position, roles, and responsibilities of the JK TF CDL members

Position	Role and responsibility
JK TF CDL Chairperson	To lead, direct and coordinate the development of CDL
JK TF CDL member (Medical Lecturers)	To provide user input, feedback, update, and expertise in chemical pathology, haematology, microbiology, and immunology tests. Communicate CDL project to internal staff. Prepare staffing and organizational structure
JK TF CDL member (Science Officer)	To provide input and prepare the specification for CDL Inform the vendor to submit a proposal. Budget planning, risk analysis, SOP preparation, IT, LIS, middleware. Staff training
JK TF CDL member (Engineering)	To provide input, feedback, update, and prepare the infrastructure. Perform the space renovation for CDL
JK TF CDL member (Finance Officer)	To provide financial input, feedback, update, and preparation. Budget planning
JK TF CDL member (Medical Officer)	To provide clinical input, feedback, update, and preparation
JK TF CDL member, Secretary, Assistant Administrator	To provide the committee secretariat and administrative works

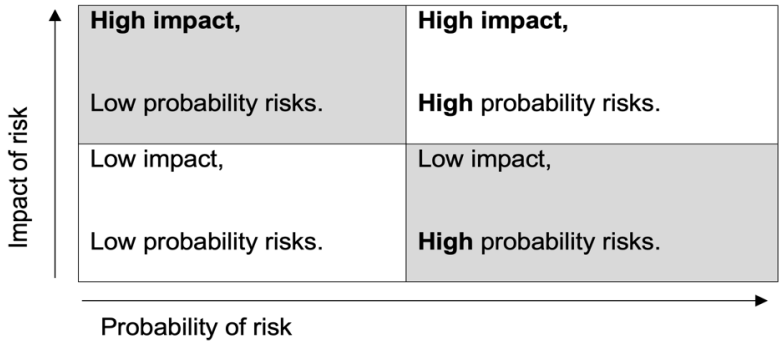

Figure 7. Risk probability and impact quadrant matrix

Table 5. CDL project risk probability and impact assessment

Project risks	Probability	Impact
1. LIS and interfacing issue	Very High	Very High
2. Project delay	Very High	High
3. Cost overruns	High	Very High
4. Missed target or objectives	Moderate	Moderate
5. High expectation	Low	Low

9. HUSM'S CDL TASK FORCE

To ensure the CDL implementation was executed, managed, and monitored effectively, HUSM set up a task force in 2021 chaired by the former Deputy Director (Asset and Infrastructure), Professor Dato' Dr. Nik Hisamuddin Bin Nik Ab. Rahman. The task force was named Jawatankuasa Task Force Central Diagnostic Laboratory (JK TF CDL) Hospital USM (Figure 6).

JK TF CDL began its preparation for many diverse tasks (Table 4). One of the task force's roles was to perform a risk assessment to determine the project's possible threats and strengths. The probability of risk occurrence and impact towards the project was assessed using a four-quadrant matrix analysis, categorizing risks into four types (Figure 7) [30,31]. The list of possible risks in this CDL project were LIS and interfacing issues, project delays, cost overruns, high expectations, and missed targets or objectives. The risk and impact of each risk were analysed and ranked according to the probability and impact scale (Table 5). It was concluded that project risks 1 (LIS and interfacing issue) has very high probability and very high impact, followed by very high probability and high impact of project risk 2 (Project delay) and project risk 3 (Cost overrun) which was high probability and very high impact. CDL project risk 3 (Missed targets or objectives) and 4 (high expectation) probability and impact factor were assessed as moderate and low, respectively. From the risk assessment conducted, it was concluded that assurance and peace of mind solutions for CDL LIS and interfacing issues need to be ironed out and solved between the JK TF CDL and potential vendors. Thus, to address this risk, JK TF CDL and the vendors have conducted consecutive discussions, product presentations, site visits, and brainstorming sessions. Moreover, to manage project delay and cost overrun risks, the JK TF CDL team have moved quickly and precisely with its planned project milestone and monitored the preparation of the tender specification and scope of the project within its allowable budget and timeframe.

10. CONCLUSION

After more than 30 years of establishment of HUSM, the role of ML has grown to be very crucial. This is an opportunity for HUSM to reimagine its ML and create a sustainable, efficient, and innovative ML. Justified by the driving factors, objectives, challenges, and potential benefits, CDL establishment was taken by HUSM. Learning from the valuable experiences and ideas reported in the previous literature and site visits of other hospitals around the world and inside the country with CDL-like ML respectively, HUSM JK TF CDL has learned and improved upon others who have failed or succeeded. The result of CDL is the consolidation of all routine tests in a one-stop centre for specimen collection, processing and results released. CDL TLA will automate many laborious manual tasks in the previous ML. Furthermore, integration would reduce redundancy in assets, resources, workforces, and financial expenditures and liabilities with CDL diagnostic testing services.

JK TF CDL faces challenges and risks to establish HUSM CDL. All the challenges faced were handled efficiently with the right planning and right personnel in USM, HUSM, ML, and important support from the Centre for Knowledge, Communication and Technology and JPPA. The risks related to CDL establishment were managed systematically using suitable tools and analysis.

HUSM CDL is expected to be completed in the middle of 2023 and showcase HUSM's accomplishment in completing an ML consolidation and automation project. HUSM is optimistic that CDL will achieve its objective and transform hospital ML to become lean, efficient, and affordable to be operated. Comparative study of cost, efficiency, and the performance of ML services pre-and post-CDL integration will be conducted from time to time to ensure efficiency of this project.

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