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# Promoting Laboratory Quality Management Programs in Cuenca, Ecuador

An Interactive Qualifying Project Report

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by:

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Ryan Choate

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Calvin Downey

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Ravneet Kaur

Sponsored by:

Dr. Jaime M. Moreno A.  
Hematología Laboratorio



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Professor Laureen Elgert, Co-Advisor

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Professor Gary Pollice, Co-Advisor

## **Abstract**

The advancement of healthcare via implementation of international standards encourages the adoption of quality assurance mechanisms that are designed to increase patient access to quality health services and care through safe medical practices. In an attempt to improve standard of care and comply with 5S and Lean Six Sigma principles, a set of international standards that specifies requirements for a quality management system, a group of specialty laboratories (*Bioncogen, CytoLab, Hematología Laboratorio, and NeoLab*) in Cuenca, Ecuador seek to implement framework for quality improvement models. The goal of this project, sponsored by Dr. Jaime M. Moreno A. of *Hematología Laboratorio* (HL), is to promote quality management in the laboratory setting and to support clinical laboratories in Cuenca in improving quality management systems. To achieve this goal, we satisfied four objectives: (1) establish professional relationships through informed and meaningful communication, (2) understand current laboratory means of operation and the state of quality management systems, (3) inform laboratories on the importance of quality and provide immediate recommendations for potential quality management improvement, and (4) evaluate project outcomes and assess opportunities for future developments. Through this project, participating laboratory administrators and personnel became more motivated and prepared to integrate forms of quality management systems into their existing workflow.

## **El resumen**

El avance de la atención médica por medio de la implementación de estándares internacionales fomenta la adopción de mecanismos de aseguramiento de la calidad diseñados para mejorar el acceso de los pacientes a servicios de salud y atención de calidad a través de prácticas médicas seguras. En un intento de mejorar el nivel de cuidado y cumplir con principios de 5S y Lean Six Sigma, un grupo de laboratorios especializados (*Bioncogen, CytoLab, Hematología Laboratorio, y NeoLab*) en Cuenca, Ecuador tratan implementar un marco para los modelos de mejora de calidad. La meta de este proyecto, patrocinado por Dr. Jaime M. Moreno A. de *Hematología Laboratorio* (HL), es apoyar a los laboratorios clínicos de cuenca en la mejora de los sistemas de gestión de la calidad. Para lograr esta meta, el equipo debe cumplir cuatro objetivos: (1) establecer relaciones profesionales a través comunicación informada y significativa, (2) entender los medios de funcionamiento actuales del laboratorio y el estado de los sistemas de gestión de la calidad, (3) informar a los laboratorios sobre la importancia de la calidad y ofrecer recomendaciones inmediatas para la mejora de la gestión de la calidad, y (4) evaluar los resultados del proyecto y evaluar las oportunidades para futuros desarrollos. A través de este proyecto, el personal de laboratorio de cuenca estará más motivado y preparado para integrar formas de sistemas de gestión de calidad en su flujo de trabajo existente.

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Lastly, we would like to extend our thanks to our peers from the Cuenca, Ecuador IQP team as they helped critique our work and provide useful recommendations when needed. Specifically, we would like Muhammad Hussain for working with us during the preliminary research phase of our project as a member of the team.

## **Authorship and Contributions**

### **Ryan Choate**

Ryan authored large portions of the introduction, methodologies for the first objective, and the quality measurement research done for the background. Additionally, he assisted in developing sample interview questions for the methods, and managing the interviews and focus groups that we conducted throughout the project. Throughout the execution of the methodologies, he also served as the primary note taker. Ryan designed and developed the majority of the tangible recommendations that we made during our project. Lastly, he was also responsible for authoring the field guides that we provided for each laboratory.

### **Calvin Downey**

Calvin served as one of the chief researchers and authored large portions of the technical research done for the background. He utilized his background in process engineering and design to help guide the considerations of the project, as well as organize the bulk of the technical strategies for the implementation of the team's potential quality management recommendations. In addition, Calvin created Value Stream Maps during the observation phase of the methodology, and compiled the data to make sound, feasible recommendations. Lastly, he acted as the primary writer for the results and conclusions sections of the final project report, which required the compilation of all relevant project data.

### **Ravneet Kaur**

As designated project manager, Ravneet was responsible for managing and notifying members about upcoming deadlines and scheduled appointments. She also managed the content submissions and notified the team and advisors when content was submitted. Additionally, she maintained contact with the advisors, sponsor, and liaisons of each of the participating laboratories to arrange meetings as necessary. Throughout the execution of the methodologies, she served as the primary Spanish speaker and translator. As for writing content, Ravneet served as the primary writer for content related to administrative involvement. She was also responsible for designing the infographics throughout the report. Lastly, she compiled the appendices that supplement the content included in the final report.

## **Executive Summary**

An acceptable definition for quality healthcare includes an emphasis on patient care and accessibility, as well as a dependence on internal improvement. Poor quality in a laboratory setting can lead to inappropriate interventions, questionable credibility, and may also invite legal action. Therefore, it is imperative to develop and implement a policy on quality in medical laboratories. Confronting quality control issues is very important in the identification and correction of flaws in pre-analytical and post-analytics lab processes prior to the release of inaccurate patient test results. Through quality control practices, laboratory personnel are able to regulate their testing and ensure that their diagnostic results are precise and accurate.

## **Project Goals and Objectives**

The goal of this project is to promote quality management in the laboratory setting and to support clinical laboratories in Cuenca in improving quality management systems. The four objectives that we satisfied to accomplish our goal are: 1) establish professional relationships through informed and meaningful communication, 2) understand current laboratory means of operation and the state of quality management systems, 3) inform laboratories on the importance of quality and provide recommendations for potential quality management improvement, and 4) evaluate project outcomes and assess opportunities for future developments.

## **Methodology**

The purpose of first objective was to: 1) gain a better understanding of why there is a demand for quality improvement in clinical laboratories and 2) engage with laboratory administrators and personnel. To satisfy this objective, we arranged unstructured and semi-formal meetings with the participating laboratories where we introduced ourselves, our project, and our goals.

The purpose of the second objective was to gain a deeper knowledge and understanding of operations of the specialty laboratories in Cuenca. We shadowed the medical personnel and made observations while helping with laboratory maintenance processes that seemed fit. Throughout the immersion, apart from active observation, we inquired about patient care practices and procedures at the laboratories by engaging with the staff in an effort to reduce any misinterpretation. In our observations, we focused on both the pre-analytical and post-analytical processes. We chose to focus on these two phases because, despite their importance, they are often overlooked and are a large source of errors in clinical laboratories. In order for us to compile, analyze, and interpret the collected process data, we utilized Lucidchart, a free online concept mapping software, to create value stream maps (VSMs). By organizing the collected data from a given lab in a VSM, we located areas of inefficiencies to improve.

The purpose of the third objective was to discuss the significance of quality, the principles of quality management, and reviewed tools such as 5S and Plan-Do-Study-Act

(PDSA) that help guide improvement. We discussed and presented these concepts through the use of a series of focus groups. In Focus Group 1, we presented the VSMS that we made to each of the laboratories. In Focus Group 2, we had the laboratory administrators and personnel complete a 5S checklist. In the checklist, we asked the laboratory staff to rate certain areas in their processes on a scale of “poor”, “satisfactory”, “good”, or “excellent”. In Focus Group 3, we presented a PDSA checklist to all of the laboratories and informed them on how they can use the two checklists together to initiate and evaluate procedure changes to improve quality management. After the focus groups, we created a guide for each individual laboratory which described the importance of quality, its measurement, and the outcomes of implementing programs for its improvement. The purpose of the guide was to provide participating laboratories with a reference for the implementation of future quality management programs and projects.

The purpose of the final objective was to discuss each laboratory’s future plans and the retention of the topics covered during our focus groups in order to gauge the relative success and results of the project. In order to assess the success of the three focus groups, a final evaluative workshop was conducted. As for the structure of the evaluation, we utilized Poll Everywhere as a means of live audience participation. Using Poll Everywhere for this method allowed our workshop to stimulate discussion and add a sense of interactivity. This workshop also focused on discussing potential future developments, including the costs and benefits of forming a medical consortium.

### **Findings**

Through our initial meetings with all of the laboratories, we not only motivated the administrators and personnel to participate in our project but also started making personal connections and relationships with the personnel. After these meetings, we learned that the participating laboratories are distinct in terms of laboratory space, infrastructure, staff size, primary and secondary medical interests, and ongoing laboratory projects.

During the interactive immersion phase, we collected data regarding pre-analytical processes such as documentation and procedures, equipment maintenance, and inventory and procurement. Our VSMS inferred that none of the four laboratories had a formal system for recording any errors that occur in their processes. In addition, all of the laboratories lacked a well-established inventory management system. Other weak areas for the laboratories included equipment maintenance documentation, digital documentation of patient records, and long patient wait times. As a result of our observed data, we recognized that each laboratory was at a different stage of quality.

After Focus Group 1, we found that the VSMS for Labs A and B were accurate, the VSM for Lab C had some missing details regarding equipment maintenance, and Lab D already had existing plans to improve the inefficient areas. After completing the 5S checklists in Focus Group 2, we discovered that there was a correlation between the inefficiencies that we identified and the areas that laboratory administrators and personnel had self-rated lowly. Additionally, we

observed that all of the laboratories had different perceptions of what constitutes excellent, good, or otherwise.

During the final evaluation meeting, the participants expressed that they enjoyed the “exchange of knowledge, [ideas], and experiences” that our project included. According to the Poll Everywhere results, 75% of the workshop participants regarded 5S as “necessary” for the improvement of their laboratories. Meanwhile, 33% believed the same for PDSA. The remaining participants ranked 5S and PDSA as “very useful.” Additionally, most of the participants believed that they, due to their new knowledge of 5S and PDSA, were comfortable enough to describe such concepts to a colleague.

### **Recommendations**

After identifying inefficiencies in the laboratories’ workflow, we made a series of recommendations that would improve their processes. The tangible recommendations we made are: 1) inventory management system, 2) test request form, 3) patient record system, 4) payment receipt, and 5) equipment maintenance documentation.

Some of the intangible recommendations that we made for the laboratories include patient wait time, laboratory sanitation, temperature control, and the reorganization of patient sample collection. Additionally, we recommended that all of the laboratories work together to form a consortium with each other. A consortium will aid the laboratories in terms of ordering inventory, public relations, patient referrals, external audits, and pursuing ISO accreditation. Lastly, we recommended that all of the laboratories continue using 5S and PDSA tools to improve their quality management programs. In addition to continuing to utilize these quality management tools, we hope that the laboratories will instruct and spread their knowledge to other laboratories in Cuenca.

### **Conclusions**

In terms of how this project can be carried out in future years, we believe that it would be beneficial to observe the laboratories to see if they are still using our initial recommendations or an updated version of our initial recommendations, and if they are using 5S and PDSA methods to identify and correct areas of inefficiency. If, through observation, the laboratories’ quality management shows improvement, then the next step will be to implement the consortium with all of the laboratories, if they have not done so already, and to expand the quality programs and consortium to other laboratories in Cuenca. However, if the laboratories’ quality management shows no improvement, then future projects should be centered on troubleshooting our recommendations and determining the cause of the problems.

## **El resumen ejecutivo**

Una definición aceptable para la atención médica de calidad incluye un énfasis en la atención al paciente y la accesibilidad, así como una dependencia de la mejora interna. La mala calidad en un entorno de laboratorio puede conducir a intervenciones inapropiadas, credibilidad cuestionable y también puede invitar a acciones legales. Por lo tanto, es imperativo desarrollar e implementar una política de calidad en los laboratorios médicos. La confrontación de los problemas de control de calidad es muy importante en la identificación y corrección de fallas en los procesos de laboratorio pre-analíticos y post-analíticos antes de la liberación de los resultados inexactos de la prueba del paciente. A través de prácticas de control de calidad, el personal de laboratorio puede regular sus pruebas y asegurar que sus resultados de diagnóstico sean precisos y precisos.

## **La meta y los objetivos del proyecto**

La meta de este proyecto es promover la gestión de la calidad en el entorno de laboratorio y de apoyo a los laboratorios clínicos en Cuenca en la mejora de los sistemas de gestión de calidad. Los cuatro objetivos que nos satisfacen son: 1) establecer relaciones profesionales a través de los medios actuales de laboratorio informados y comunicación significativa, 2) entender de funcionamiento y el estado de los sistemas de gestión de calidad, 3) informar a los laboratorios sobre la importancia de la calidad y ofrecer recomendaciones para la calidad potencial mejora de la gestión, y 4) evaluar los resultados del proyecto y evaluar oportunidades para desarrollos futuros.

## **La metodología**

El propósito de este objetivo era: 1) obtener una mejor comprensión de por qué existe una demanda de mejora de la calidad en los laboratorios clínicos y 2) colaborar con los administradores y el personal de laboratorio. Para satisfacer este objetivo, organizamos reuniones no estructurados y semi-formales con los laboratorios participantes, donde nos presentamos, nuestro proyecto y nuestras metas.

El propósito del segundo objetivo era obtener un conocimiento más profundo y la comprensión de las operaciones de los laboratorios especializados en Cuenca. Nos ensombrecido el personal médico y formuló observaciones al tiempo que ayuda a los procesos de mantenimiento de laboratorio que parecían ajuste. A lo largo de la inmersión, además de la observación activa, nos preguntó acerca de las prácticas de atención al paciente y procedimientos en los laboratorios mediante la participación con el personal en un esfuerzo por reducir cualquier mala interpretación. En nuestras observaciones, nos centramos en tanto los procesos de pre-analítica y post-analítica. Elegimos a centrarse en estas dos fases, ya que, a pesar de su importancia, a menudo se pasan por alto y son una gran fuente de errores en los laboratorios clínicos. A fin de que podemos elaborar, analizar e interpretar los datos de proceso recogidos, se utilizó Lucidchart, un software gratuito de mapas conceptuales en línea, para crear mapas de



flujo de valor (VSM). Mediante la organización de los datos recogidos de un laboratorio dado en una VSM, localizamos áreas de ineficiencias para mejorar.

El propósito del tercer objetivo era discutir la importancia de la calidad, los principios de la gestión de la calidad, y las herramientas revisadas como 5S y Plan-Do-Study-Act (PDSA) que ayudan a mejorar la guía. Estos conceptos fueron discutidos y presentados a través del uso de una serie de grupos de enfoque. En Grupo Focal 1, se presentaron los VSM que realizamos a cada uno de los laboratorios. En Grupo Focal 2, tuvimos los administradores de laboratorio y personal completan una lista de verificación 5S. En la lista de verificación, le preguntamos al personal de laboratorio para evaluar ciertas áreas en sus procesos en una escala de “malo”, “satisfactorio”, “bueno” o “excelente”. En Grupo Focal 3, presentamos una lista de control PDSA a todos los laboratorios y les informamos sobre cómo pueden utilizar las dos listas de verificación junto a iniciar y evaluar los cambios en el procedimiento para mejorar la gestión de la calidad. Después de que los grupos de enfoque, hemos creado una guía para cada laboratorio individual que describe la importancia de la calidad, su medición, y los resultados de la implementación de programas para su mejora. El propósito de la guía era para que los laboratorios participantes podrían hacer referencia a ella para la ejecución de programas y proyectos de gestión de la calidad en el futuro.

El propósito del objetivo final era para discutir los planes futuros de cada laboratorio y la retención de los temas tratados durante nuestros grupos de enfoque con el fin de la galga del relativo éxito y los resultados del proyecto. Con el fin de evaluar el éxito de los tres grupos de enfoque y examinar posibles planes de futuro, se llevó a cabo un taller de evaluación final. En cuanto a la estructura de la evaluación, Poll Everywhere se utilizó como medio de participación de la audiencia en vivo. Usando Poll Everywhere para este método permitido para nuestro taller para estimular la discusión y añadir una sensación de interactividad. Este taller fue principalmente centrado en conocer la opinión del personal de los laboratorios con respecto a la información que retienen a partir de los grupos de enfoque, los temas que ellos estaban interesados en, y lo que están pensando de perseguir en términos de sus propias mejoras en la gestión de calidad.

## **Los hallazgos**

A través de nuestras reuniones iniciales con todos los laboratorios, que no sólo motivó a los administradores y al personal a participar en nuestro proyecto, sino también a partir de hacer las conexiones personales y las relaciones con el personal. Después de las reuniones con los laboratorios, hemos aprendido que los laboratorios participantes son distintos en términos de espacio de laboratorio, la infraestructura, la cantidad de personal, primaria y secundaria intereses médicos, y los proyectos en curso.

A través de nuestra fase de inmersión interactiva, se recogieron los datos relativos a los procesos de pre-analíticos, tales como documentación y procedimientos, mantenimiento de equipos, y el inventario y las adquisiciones. Nuestros VSM infiere que ninguno de los cuatro laboratorios tenía un sistema formal para el registro de los errores que se producen en sus

procesos. Además, todos los laboratorios carecían de un sistema de gestión de inventario bien establecida. Otras áreas débiles de los laboratorios incluyen la documentación de mantenimiento de equipos, documentación digital de los registros de los pacientes, y los tiempos de espera de los pacientes. Como resultado de nuestros datos observados, se analizó que cada laboratorio estaba en una etapa diferente de calidad.

Después de presentar nuestros VSM a los laboratorios en el Grupo de enfoque 1, se encontró que los VSM para los laboratorios A y B eran exactos, la VSM para Lab C tenía algunos detalles que faltan en relación con el mantenimiento del equipo y de laboratorio D había planes para mejorar las áreas ineficientes ya existente. Después de la lista de verificación 5S se completó en Foco Grupo 2, descubrimos que había una correlación entre las ineficiencias que hemos identificado y las áreas que los administradores y el personal de laboratorio tenían humilde autopercepción en la lista de verificación 5S. Además, se observó que todos los laboratorios tienen diferentes percepciones de lo que constituye una excelente o buena o de otra manera.

Durante la reunión de evaluación final, los participantes expresaron que les gustaba el “intercambio de conocimientos, [las ideas] y experiencias” que nuestro proyecto incluyó. De acuerdo con resultados de encuesta en todas partes, el 75% de los participantes del taller 5S considerado como “necesario” para la mejora de sus laboratorios. Mientras tanto, el 33% creía que el mismo para PDSA. Para el 25% restante y el 67%, por 5S y PDSA, respectivamente, a los participantes les clasifican como “muy útil”. Además, la mayoría de los participantes consideraron que, debido a su nuevo conocimiento de 5S y PDSA, que fueron suficientes para cómoda describir tales conceptos a un colega.

## **Las recomendaciones**

Después de identificar las ineficiencias en el flujo de trabajo de los laboratorios, hemos hecho una serie de recomendaciones que harían que sus procesos sean más eficientes. Las recomendaciones que hicimos son: 1) el sistema de gestión del inventario, 2) el formulario de solicitud de las pruebas, el sistema de registro de pacientes, 4) la factura de pago, y 5) la documentación de mantenimiento del equipo.

Algunas de las recomendaciones intangibles que hicimos para los laboratorios incluyen el tiempo de espera del paciente, el saneamiento de laboratorio, control de temperatura, y la reorganización de la recogida de muestras. Además, se recomienda que todos los laboratorios trabajen juntos para formar un consorcio entre sí. La formación de un consorcio ayudará a los laboratorios en términos de inventario de realizar el pedido, las relaciones públicas, las referencias de pacientes, auditorías externas, y la búsqueda de la acreditación ISO. Por último, se recomienda que todos los laboratorios sigan utilizando herramientas 5S y PDSA para mejorar sus programas de gestión de calidad. Además de continuar a utilizar estas herramientas de gestión de la calidad, esperamos que los laboratorios darán instrucciones a los demás y difundir sus conocimientos a otros laboratorios en Cuenca.

## **Las conclusiones**

En términos de cómo este proyecto puede llevarse a cabo en los próximos años, creemos que sería beneficioso para observar los laboratorios para ver si todavía están utilizando nuestras recomendaciones iniciales o una versión actualizada de nuestras recomendaciones iniciales, y si están utilizando 5S y métodos PDSA para identificar y corregir las áreas de ineficiencia. Si, a través de la observación, la gestión de calidad de los laboratorios muestra una mejora, entonces el siguiente paso será implementar el consorcio con todos los laboratorios, si no lo han hecho ya, y para ampliar los programas de calidad y consorcio a otros laboratorios en Cuenca. Si la gestión de calidad de los laboratorios no muestra ninguna mejora, entonces los proyectos futuros deberían centrarse en la solución de problemas de nuestras recomendaciones y determinar la causa del problema.

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## 1. Introduction

As medical advancements continue to improve standards of the healthcare industry, there is an increased demand for institutions to refine their practice of quality. Globally, quality plays an important role in the function of healthcare facilities as standards of care and positive health outcomes are closely related. Though the definition and perception of quality is multi-dimensional and subjective, healthcare facilities, regardless of specific practice, must be safe, effective, timely, efficient, equitable, and people-centered to demonstrate quality practice (World Health Organization [WHO], n.d).

Through quality control practices, laboratory personnel can verify that their diagnostic results are precise and accurate, and that their processes are free of errors. Confronting quality control issues is important in the identification and correction of flaws in lab processes prior to the release of inaccurate patient test results (Eden, 2015). Unfortunately, poor quality in laboratories can lead to inappropriate interventions, questionable credibility, and may also invite legal action. Therefore, it is imperative to develop and implement a policy on quality in such institutions.

Ecuador currently stands as one of the top five nations in Latin America in terms of efficient healthcare services. The country has increased direct healthcare spending from \$2.3 million in 2000 to \$6.8 million in 2013 (Coffey, 2016). Additionally, Ecuador's mortality rate has decreased from 6.7 deaths per 1000 people in 1981 to 4.3 deaths per 1000 in 2008. Under the past presidency of Rafael Correa, the Ecuadorian government has implemented strict legislation to prosecute cases of medical malpractice. Article 146 of the Ecuadorian Criminal Code states that if a doctor, "in the exercise or practice of their profession, causes the death of another, [he or she] shall be punished with imprisonment of one to three years." (*Código Orgánico Integral Penal*, 2014). Overall, Ecuador is in a state of social and economic progress, and must continue to reflect this culture of change and reflexivity in the medical field. Therefore, medical professionals who aim to continually improve their standard of care and wish to avoid mistakes should implement quality management systems.

The goal of our project is to promote quality management in the laboratory setting and to support clinical laboratories in Cuenca in improving quality management systems. Our project incorporates 5S and Plan-Do-Study-Act (PDSA) systems as recommended tools to examine and optimize pre-analytical and post-analytical processes. Understanding how the specialty laboratories are currently operating helps provide recommendations and suggest a system for implementation. In order to fulfill our goal, it is important that we accomplish the following objectives:

- Establish professional relationships through informed and meaningful communication
- Understand current laboratory means of operation and the state of quality management systems
- Inform laboratories on the importance of quality and provide immediate recommendations for potential quality management improvement
- Evaluate result outcomes and identify opportunities for future developments

## 2. Literature Review

The goal and objectives bring about many affiliated questions. They are as follows:

- What is the definition of *quality* and who determines when something is or is not of *quality*? Why is it important? How do you measure it?
- What strategies currently exist to improve quality? How can they be applied in the laboratory setting?
- What metrics contribute in defining quality management? What role do the metrics play in determining the success of quality management systems with respect to health care?

This section provides answers to these questions as well as an outline of relevant research useful for the project.

### 2.1. Overview of Healthcare in Ecuador

The healthcare system in Ecuador can be categorized into three main branches: social security medical care, public health services, and private healthcare institutions. The Ecuadorian Institute of Social Security (IESS) is an autonomous entity that is in charge of the social security and universal healthcare in Ecuador. The IESS provides full-service hospitals in many large towns and cities for those who have paid into the social security system. Meanwhile, the Ecuadorian Ministry of Health (MOH), now known as Ministry of Public Health or *Ministerio de Salud Pública del Ecuador* (MSP), has large hospitals in major cities and small clinics in rural areas, which provide free healthcare to everyone, including visitors of Ecuador. This branch of healthcare reflects Article 34 of the *Constitución de la República del Ecuador*, which states that one's social security, including one's healthcare, is an inalienable right (The Constitution of Ecuador, 2008). To put Ecuador's healthcare in perspective, a 2014 Bloomberg survey of overall healthcare efficiency, which primarily factored in quality with respect to cost, listed Ecuador as 20<sup>th</sup> in the world; the United States was ranked 46<sup>th</sup> (Morrill & Medeiros, 2016). According to Morrill and Medeiros, health services in Ecuador cost only 10% to 30% of what the services would cost in the United States.

### 2.2. Defining Quality in a Medical Setting

Quality in healthcare is largely subjective and continuously changing. However, it is generally interpreted as a degree of excellence in key areas of the workplace and in continuous improvement to provide accessible, comprehensive, and effective care to the community (Porter, 2010). Understanding the topic of quality in this context is vital to the implementation of any form of quality management system. The Institute of Medicine describes quality in health care as “the degree to which health services increase the likelihood of desired [health] outcomes for individuals and populations” (Lohr & Institute of Medicine, 1990). Conceptually, quality is the ability of an institution to provide optimal care given the current understanding of best practices. However, this definition is limited in terms of accessibility, documentation, and improvement. Quality can describe a system that



“ensures that a product or service is consistent”, which depends on “quality planning, quality assurance, quality control, and quality improvement” (Rose, 2005). The most important aspect of this definition is the addition of internal improvement. This definition should be applied over the three main phases of testing in the laboratory setting: pre-analytical sample handling and organization, analytical testing, and post-analytical diagnostics.

### **2.3. Measurement and Significance of Quality in Healthcare**

An important aspect of defining quality is measuring and determining its significance in healthcare. An example of how quality can be measured is through outcomes in comparison to costs. Although the cost is considered a measurement of value, the outcomes of services should serve as the main criteria for value in certain areas such as healthcare. For example, if an individual were to seek a reduced cost with no regard to accurate results, he or she would be subject to limited effective care. Reporting and comparing outcomes are important steps to improve outcomes and reduce costs for services.

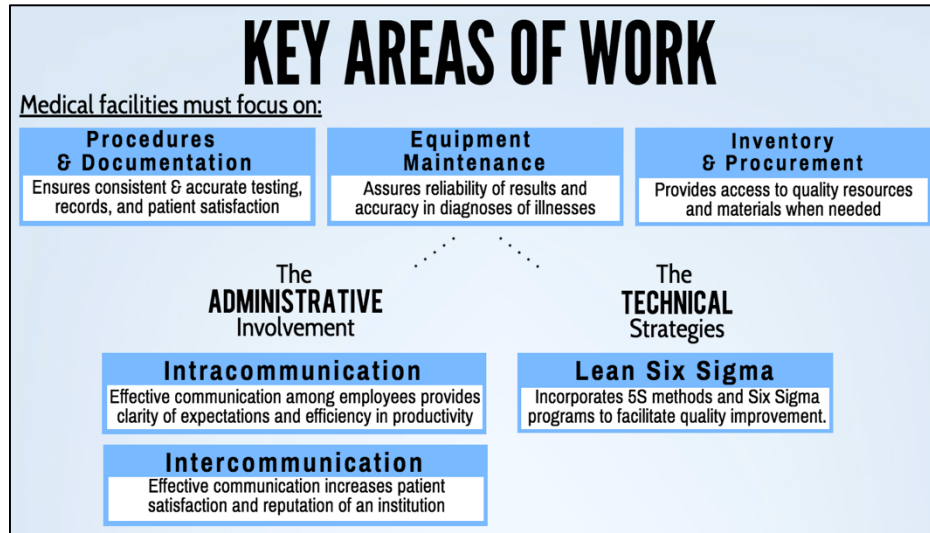
The first major step in measuring and understanding the significance of quality is to investigate the prevalence of errors and their reduction. A study of diagnostic laboratories in Iraqi Kurdistan, which focused on collecting data on the sources of error in their processes, found that 70% of all analytical mistakes reflected errors in the pre-analytical phase. The study collected 5500 blood samples and categorized the rejected samples by the form of error that occurred. This collected data was useful in identifying phases of procedures that needed to increase in quality, and in justifying the training of quality management (Najat, 2017). An additional study in Thailand determined that the rate of pre-analytical mistakes is representative of quality in the laboratory (Wiwanitkit, 2001).

Although quality management is significant in an institution, the metric that determines the success of quality programs is non-uniform. Generally, the continual improvement of both an institution and its goods and services determines a useful quality management program. A study by the Health Services Research Center (HSRC) analyzed the relationships between organizational culture and quality improvement outcomes in 61 hospitals in the United States. The study found that in flexible work environments with high staff participation, “quality improvement implementation...was positively associated with greater perceived patient outcomes and human resource development” (Shortell et. al., 1995). Ultimately, if institutions want to progress, an influential factor is the implementation of quality management programs.

### **2.4. Considerations of Quality Management Programs in Laboratories**

Quality management programs assist clinical laboratories in improving overall standards of patient care services. Through healthcare administration and technical strategies, developments in key areas of work (procedures and documentation, equipment

maintenance, and inventory and procurement) aim to enhance quality (see Figure I). These considerations are useful in setting a framework for achieving an effective quality management system in clinical laboratories.



**Figure I. Key Areas of Work and Aspects of QMS**

**2.4.1. Key areas of work** Quality management programs can be designed to address improvements made in individual areas of work. For the purposes of our project scope, these areas were prioritized into three main categories of quality management systems: procedures and documentation, equipment maintenance, and inventory and procurement.

One of the most important factors in a successful quality management program is the creation, implementation, and documentation of procedural standards. This ensures that the institution has consistent testing, recordkeeping, and patient satisfaction. Every sample should be properly collected, standardly labeled, and stored or disposed, which occur in pre-analytical phase of processing (Simoes, Dias, Santos, & Lima, 2016). All testing should be prompt and efficient, and all results should be valid, which is dependent on the analytical and post-analytical phases. Laboratories should securely store files and accumulated data for the privacy of the patients, but also place them in accessible areas for reference. Ultimately, successful institutions create procedural standards that are documented, which assure quality care to patients.

Equipment maintenance is also an integral factor in quality management systems in health care. The World Health Organization (WHO) states, “Medical devices are assets that directly affect human lives. They are considerable investments and, in many cases, have high maintenance costs” (WHO, n.d.). Improving equipment management involves the establishment of a preventative maintenance and inspection program. In an interview with Elyse Favreau and Lisa Wall, the two lab managers of the Worcester Polytechnic Institute (WPI) Biomedical Engineering (BME) laboratories, made it clear that having

functional equipment and instrumentation is a vital aspect of quality management. Through routine inspections (weekly, monthly, and yearly) of equipment (see Appendix A), the lab managers address proper calibration and functioning of equipment, which produces accurate results and avoids costly equipment replacement. Therefore, it is important to have a “well-planned and managed maintenance program that is able to keep the medical equipment in a healthcare institution reliable” (WHO, n.d.).

Another prioritized focus in quality is inventory management and procurement. Because the access and acquisition of supplies is an essential part of the workflow of any institution, laboratories should clearly label inventory items and place them in accessible areas. Laboratory personnel should constantly assess, standardize, log, and maintain storing conditions to avoid inconsistencies in stock. For procurement, there should always be adequate supplies available for continuous service. Personnel must evaluate existing supplies in a timely manner, which directly relates back to inventory management. In the BME department at WPI, the laboratory managers implement a schedule for inventory checks and supply orders.

**2.4.2. Administrative involvement in quality management programs** Due to the ever-changing, qualitative definition of healthcare, the role of administration in assuring and delivering quality care to patients is multi-dimensional. Because “leaders [often] struggle to adapt and develop their skill sets to meet the changing demands of an increasingly difficult work environment,” effective leadership in a medical laboratory is key in determining the level of quality provided to patients (Lee & Herring, 2009).

It is important for administrative staff to keep open communication within the institution so that proper laboratory standards are being met. For example, laboratories need to regularly inspect and calibrate equipment to both assure proper functionality and identify the need for any preventative or corrective maintenance procedures. However, a lack of communication amongst staff can lead to inattention to schedule equipment maintenance, which can produce inaccurate data and improper illness diagnosis. Gaps in intracommunication can jeopardize compliance, results, accuracy and patient safety. Ultimately, without intracommunication, a medical laboratory will not be able to function effectively.

In the case where healthcare may not be centralized to one specific location, institutions may be limited to a certain specialty. In this instance, it is important for medical institutions to create a communication network, or a consortium. By maintaining effective communication, patients could be easily referred to services within the network for further testing. Furthermore, if a particular staff member is in need of medical advice, he or she will have a network of medical professionals for guidance and recommendations. Because medical facilities are designed to provide quality service, emphasizing the importance of intercommunication with other medical institutions positively impacts health outcomes. The benefits of creating a consortium include, but are

not limited to, sharing resources, achieving common goals, improving patient care and satisfaction, improving standards of quality, and working together towards laboratory accreditation (Myers & Miller, 2016).

In their effort to create an effective administration, medical facilities could face several challenges that impede progress. For example, integrating new technologies and advanced procedures may not be a financial option (Poulin, 2013). Apart from the financial aspect, medical administrations have to assess whether they will or can have the appropriate staffing and staff response to the new technology. If a laboratory implements a new methodology for a certain procedure, there could be difficulties in the staff in assimilating to the new protocol. Although such challenges may exist, it is important for laboratory administration to thoroughly review the benefits and drawbacks of adapting to new advancements.

**2.4.3. Technical strategies for quality management** Some of the largest industries in the world rely on quality management systems to improve their processes and products. These systems utilize methods and concepts that cover process control and optimization, waste elimination, continuous improvement, and customer satisfaction. By far, the most widely used quality management program is a collection of tools and techniques known as Lean Six Sigma (Pepper & Spedding, 2010). The Lean Six Sigma method is a union between Lean Manufacturing and Six Sigma. Healthcare industries can apply these systems to increase the efficiency of medical procedures and decrease the amount of waste.

In the article *Triumph of the Lean Production System*, Toyota Quality Engineer John F. Krafcik introduced the word “lean” as a description of industry (Krafcik, 1988). With roots in the Japanese manufacturing industry, “lean” describes a set of tools used to identify the 7 Wastes (see Figure II) and the continuous removal of them (El-Namrouy & AbuShaaban, 2013). In practice, lean manufacturing is a program that aims at solving issues with waste reduction and process fluidity.

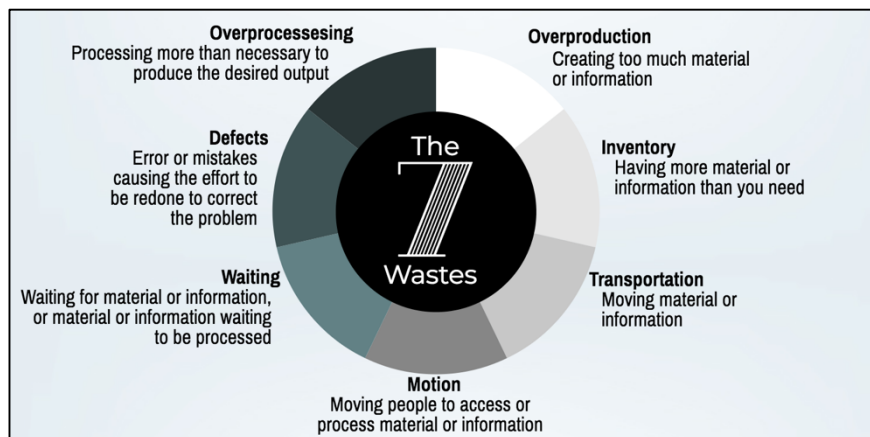
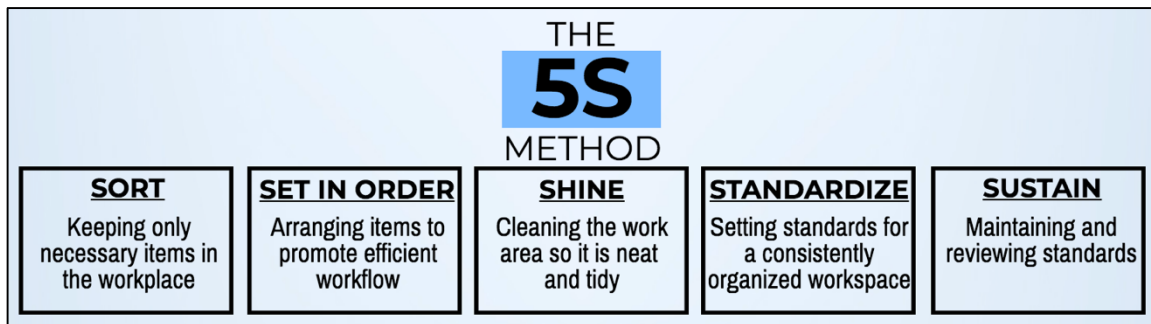


Figure II. The 7 Wastes of Lean

The most notable tool in the lean model is the 5S method (see Figure III), which is based upon five Japanese words: *seiri*, *seiton*, *seiso*, *seiketsu*, and *shitsuke*. Respectively translated, the terms *sort*, *set in order*, *shine*, *standardize*, and *sustain* collectively describe the optimal work environment. An institution can take these terms and create a procedural framework that reflects 5S. For instance, placing tools and materials that are not being used in an organized storage space would be an example of *sort*. Although there are various methodologies that can be employed to reduce waste, a common visual tool used in the process of waste reduction is known as value stream mapping.



**Figure III. 5S Methods and Some of their Principles**

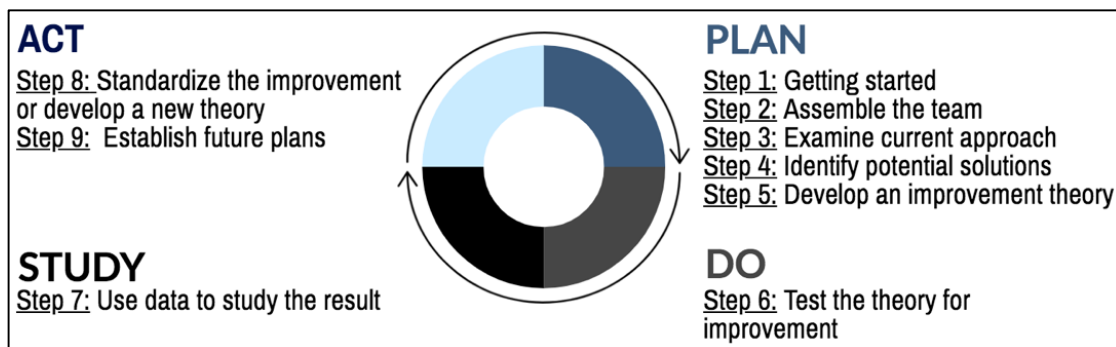
Value stream maps (VSMs) identify all the tasks or processes necessary in producing specific outputs as they accurately describe the current state of operation. Private health facilities in Nairobi, Kenya found that VSMs were useful as “a simple visual tool to engage staff at all levels in the organization” as they “provided novel insights” (Ramaswamy, 2017). A VSM outlines a process flow from start to finish, taking into account every step, and assigning it to either a “value added” or “non-value adding” category. This method is useful for identifying bottlenecks or points of waste creation in a process. By removing these wastes, or *muda* in Japanese, a process fundamentally becomes more “lean.” Successful application and sustained performance require continuous improvement (Culcuoglu, 2018). *Kaizen*, or continuous improvement mechanism, is a concept popularized by Toyota that has gradually found its way into the healthcare sector. After identifying specific errors and waste, medical institutions can implement a continuous improvement project in an effort to improve issues in workflow or processes.

In parallel, Motorola first introduced their concept of Six Sigma in 1986. It is a program created with the sole purpose of minimizing product defects and reducing variance in manufacturing and business processes. A “sigma” rating is given to a process based on either how many defects occur in a certain population or the difference of standard deviations between the mean of the outcomes and the specification. A Six Sigma process is one which yields 99.9997% defect-free products, which is otherwise described

as 3.4 defective features per one million opportunities. In comparison, a Three Sigma process would yield around 93% success rate with 66,800 defects per million opportunities (Kwak, 2006). By the early 1990s, over two-thirds of fortune 500 companies implemented some form of Six Sigma initiative, reporting billions in savings (De Feo, 2005).

The combination of these two quality management techniques more comprehensively addresses aspects of the success of an institution. It combines the waste reduction and process flow of “lean” with the process output control and variance minimization of Six Sigma. The core strategy of Lean Six Sigma is to implement a closed-loop, data-driven process which inherently creates sustainable, continuous improvement. Overall, the principles that are applied in Lean Six Sigma are appealing in the healthcare industry because of its focus reduction of mistakes and defects, as well as the streamlining of processes (Kwak, 2006). Lean Six Sigma initiatives improve internal progress, and become indicators of future performance and growth, and as such are effective in producing benefits in healthcare organizations.

Plan-Do-Study-Act (PDSA) is a similar tool aimed at accelerating quality improvement. Part of the Institute for Healthcare Improvement (IHI) model for advancement, PDSA (see Figure IV) is an approach to test a change that is implemented through following four steps: plan, do, study, and act (Tribal Evaluation Institute, 2016). Following these four steps guides the thinking process into breaking down the task into steps and then evaluating the outcome, improving on the change, and testing again. Usually, most organizations and individuals go through some or all of these steps when implementing a change without even realizing it. However, having the steps thoroughly documented and visually displayed often helps to analyze the entire process and learn more about it. The PDSA process can be used to organize a *kaizen*, an organized improvement project, and address issues found in a VSM.



**Figure IV. PDSA: Plan-Do-Study-Act**

**2.4.4. ISO accreditation** Established during the manufacturing industry boom after the end of World War II in 1947, the International Organization for Standards (ISO) is an independent, non-governmental organizational network that develops international standards. According to the organization, international standards “make things work” as

they provide world-class specifications for products, services, and systems to ensure quality, safety, and efficiency (ISO, n.d.). Furthermore, the organization believes that adopting a quality management system is a strategic decision for an organization as it can help improve the institution's overall performance and provide a sound basis for sustainable development initiatives. ISO's quality management standards are based upon seven quality management principles (QMPs) (ISO, 2015). The seven QMPs are customer focus, leadership, engagement of people, process approach, improvement, evidence-based decision making, and relationship management. According to ISO, one of the primary focuses of quality management is to meet expectations from customers; therefore, the customer focus principle seems to be the focus of ISO's quality management standards.

On the topic of quality management, ISO 9001:2015 is a set of international standards that specify broad requirements for gaining an accredited quality management system. This standard is useful for demonstrating an institution's ability to meet the requirements that reflect a successful implementation of a quality management system. These requirements cover the creation and organization of documentation and records, resources, the responsibilities of management, customer focus, process control, and the implementation of a continuous improvement system (ISO, 2015). In order to reap the benefits of long-term success, companies need to participate in a time extensive process to become ISO accredited. However, depending on the needs of the institution and the amount of preexisting quality framework, the process of certification can be lengthy and resource intensive. A systematic review done by the Annals of Saudi Medicine showed "that general accreditation programs significantly improve clinical outcomes and the quality of care" (Alkhenizan, 2011). It concluded that there is considerable evidence that shows that the processes involved in the accreditation, and the systems created, improve clinical outcomes in various subspecialties, and should be supported.

### **3. Methodology**

The goal of this project is to promote quality management in the laboratory setting and to support clinical laboratories in Cuenca in improving quality management systems. We executed various methodologies (see Appendix B) to satisfy the following four objectives:

1. Establish professional relationships through informed and meaningful communication
2. Understand current laboratory means of operation and the state of quality management systems
3. Inform laboratories on the importance of quality and provide recommendations for potential quality management improvement
4. Evaluate project outcomes and assess opportunities for future developments

### **3.1. Meeting Laboratory Administrators and Personnel**

The first objective of our project is to establish professional relationships through research and meaningful communication with a multifaceted purpose of: 1) gaining a better understanding of *why* there is a demand for quality improvement in clinical laboratories and 2) engaging with laboratory administrators and personnel.

**3.1.1. Unstructured meetings with participating laboratories** With the future methodology in mind, it was necessary for us to present ourselves to the laboratory administrators and personnel as a research team that is knowledgeable, yet eager to learn more about their laboratories. Through our effort to create such relationships, we hoped to foster a sense of teamwork within the laboratories because trust among individuals encourages increased productivity and the ability to work more effectively (Towers, 2017). Additionally, we wanted to avoid the creation of a potential barrier between us, as less-experienced researchers, and the laboratory personnel who have multiple years of experience towards their profession.

In order to build a successful relationship, we planned to seek every opportunity that would allow us to spend time with the laboratory personnel during and after laboratory hours of operation. Embracing the Ecuadorian culture, especially in terms of language, dress code, and greeting style helped reduce the amount potential language barrier. After our preparation, we arranged unstructured and semi-formal meetings with the participating laboratories where we introduced ourselves, our project, and our goals.

### **3.2. Observing the Laboratories and Collecting Data**

In order to gain a deeper knowledge and understanding of operations of the participating laboratories, our second objective is to understand current laboratory means of operation and the state of quality management systems in order. Means of operation include, but are not limited to, treating and managing patients, conducting tests, diagnosing treatment, and work area management. Particularly, we are focusing on the pre-analytical and post-analytical stages of the laboratory processes. Information gathered from interviews with laboratory personnel and laboratory immersion helps guide us in making feasible recommendations towards improving quality in the laboratories.

**3.2.1. Interactive immersion with laboratory personnel** To avoid making recommendations solely based on preliminary research, it was important for us to listen to the firsthand knowledge and expertise of the laboratory personnel. Having an understanding of the laboratories' interests was important because it enabled our research and future interactions to be more relevant and meaningful to the stakeholders. Therefore, we shadowed the medical personnel and made observations while helping with laboratory maintenance processes that seemed fit (e.g. restocking supplies, cleaning and organizing



prior to and after patient visits). Going through the laboratory maintenance procedure allowed us to self-realize the tasks that are challenging to complete in a quality manner.

First-hand laboratory experience played a key role in helping us understand which areas of the facility needed improvement and what appropriate recommendations could be made based on feasibility. Throughout the immersion, apart from active observation, we inquired about patient care practices and procedures at the laboratories by engaging with the staff in an effort to reduce any misinterpretation. Unstructured interview questions and visual observations allowed us to understand the perspective of the laboratory personnel while developing our own interpretations of the pre-analytical and post-analytical processes. Responses to certain questions answered by the personnel provided us with important information that helped provide guidance in assessing the administrations' strengths and weaknesses in current means of operation. For the identification of inefficient and error-prone areas of work, we created value stream maps for the processes we observed to visually highlight areas of laboratory improvement.

### **3.3. Recommending Improvements and QM Tools**

The third objective of the project is to inform laboratories on the importance of quality and provide recommendations for potential quality management improvement. For this objective, we discuss the significance of quality, the principles of quality management, and review tools such as 5S and PDSA that help guide quality improvement. By compiling information gathered from previous methodologies we are able to provide feasible recommendations and initiate a framework for quality improvement for the participating clinical laboratories. The purpose is to promote a quality management environment that will help in guiding laboratory practices and projects. Lastly, creating a reference guide that summarizes our findings and recommendations will assist in facilitating future quality management.

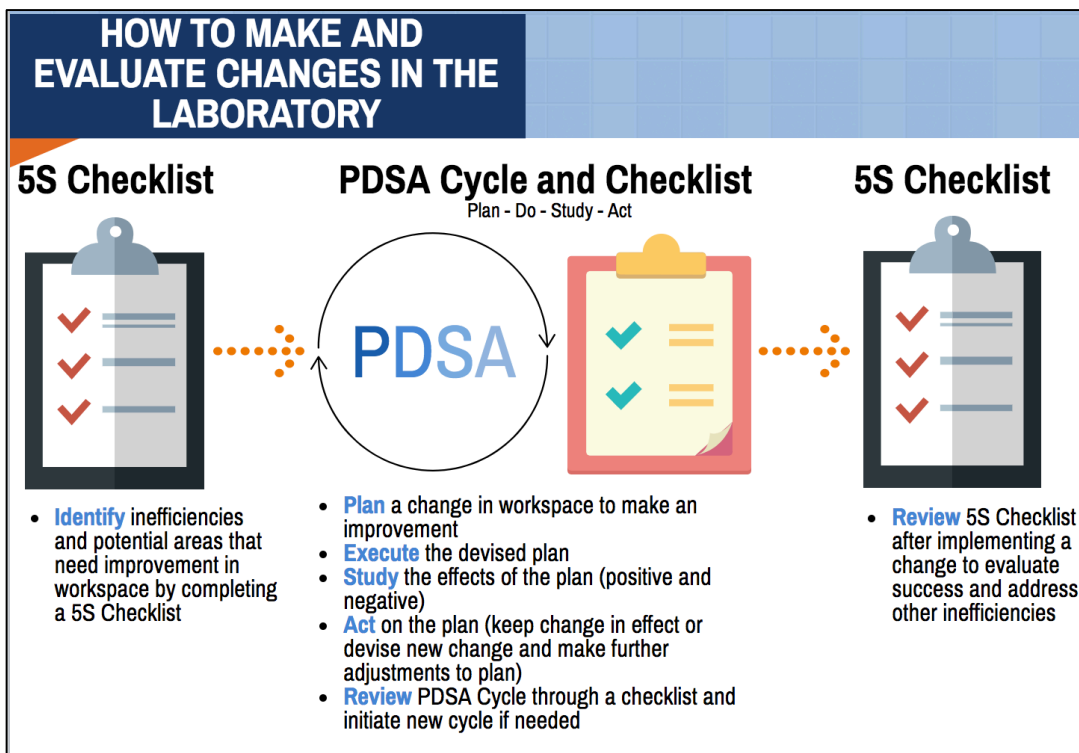
**3.3.1. Conduct focus groups** In an effort to present our understanding of quality management and findings from previous methodologies in an effective manner, we designed a series of focus groups. Focus groups are helpful as they allow for discussion between both parties (the audience and the moderators) rather than a unidirectional presentation from the moderators alone. We designed the focus groups with the intention of encouraging conversation, interaction, and the exchange of information. When designing the focus groups to be as worthwhile as possible for both parties, we took availability, duration, location, and context into consideration. To avoid lengthy meetings, the content we presented was divided into three focus groups.

The first semi-structured focus group was designed to further initiate interest and conversation about quality management. To begin, we engaged the audience by asking open-ended questions regarding the definition, context, and importance of quality. In order to present our research, we reviewed case studies that highlighted how delivering

quality practice can be measured both quantitatively and qualitatively. We presented the VSMS that we created because they clearly illustrated our understanding of the current means of laboratory operation and the areas that we believed that the laboratories could improve.

The second interactive focus group was centered on discussing the feasibility of the 5S method. We proposed this method of quality management and explained how they fit the financial, physical, and operational means of the laboratories. Based on the previously discussed VSMS, the second focus group addressed how 5S is a supplementary tool that helps identify inefficiencies. In collaboration with the participants, we completed a sample 5S action checklist (see Appendix C) that explicitly states the specific steps and action items institutions must complete in order to maintain quality. After identifying areas that the laboratories are performing poorly in, we revealed a series of recommendations that we devised. When presenting our recommendations, we gave short tutorials on how they can be used in hopes that the personnel would give us feedback on their feasibility.

For the third focus group, we explained the Plan-Do-Study-Act (PDSA) method and how it can be employed to organize a project designed to correct the inefficiencies discussed in the previous focus group. We introduced a PDSA Checklist (see Appendix D) to each laboratory, explained how it could be used in conjunction with the 5S Checklist, and reviewed a general outline for quality management for the laboratories to follow (see Figure V).



**Figure V. Potential Outline to Follow When Implementing a Change**

Together, we and the laboratory personnel from Lab A, B, and C devised a plan that could be used to monitor the points of success and failure of our recommendations. Ideally, if the laboratories were to follow our suggested outline, they would: 1) complete the 5S checklist, 2) plan, execute, study, and act on a specific change, 3) complete the PDSA checklist to determine the success of the specific change, and 4) complete a new 5S checklist after the change is permanently in effect to assess how the plan impacted the quality of the laboratory. While completing the PDSA checklist with laboratory administrators, we explained that if our recommendations are not as successful as intended, then a new PDSA cycle can be completed with a new plan to correct any trouble areas of the original plan.

**3.3.2. Provide quality guidance and awareness deliverables** Providing meaningful deliverables that highlight the entirety of our research and disseminating general recommendations for quality improvement was an essential stage of the final weeks of the project. We created a guide for each individual laboratory that described the importance of quality, its measurement, and the outcomes of implementing programs for its improvement. Most of the document focuses on tools and techniques that will be helpful in quality management programs, including example models and uses of tools in other laboratories, as well as the impact of non-technical factors such as administration. Mainly the topics discussed were the Lean Six Sigma technique, specifically the 5S method, as well as the use of a model such as IHI's PDSA model (Langley, 2009). In addition, the guide includes a copy of the data collected during the immersion phase of the methodology and the feasible recommendations that we gave. Finally, the packet includes a broad guide on the continuation of quality management, and how it can eventually lead to ISO accreditation.

Overall, this guide is comprehensive of the entire project, but also compact. It is centered around the areas in which the laboratories aim to improve, based upon the information gathered in previous methodologies. The participating laboratories will be able to reference this short guide for the implementation of future quality management programs and projects.

### **3.4. Assessment of Methodology and Future Plans**

For this project, we utilized Lean Six Sigma for improvements in quality management. However, a thorough project of this type can take companies months to complete and up to a year to see permanent implementation of changes in workflow. Many of the developments regarding workflow changes and quality management systems will occur well after our project's end. For this reason, it is important to discuss each laboratory's future plans and the retention of the topics covered during our focus groups in order to gauge the relative success and results of the project.

**3.4.1. Final evaluation workshop** In order to assess the success of the three focus groups and review potential future plans, a final evaluative workshop was conducted. This workshop primarily focused on getting feedback from the laboratory personnel regarding the information they retained from the focus groups, the topics that they were interested in, and what they are thinking of pursuing in terms of their own quality management improvements. Specifically, we asked questions regarding their experience with our project, how much they learned and retained, and the possible mutual benefits of forming a consortium.

As for the structure of the evaluation, Poll Everywhere was utilized as a means of live audience participation. Using Poll Everywhere for this method allowed for our workshop to stimulate discussion and add a sense of interactivity (University of Brighton, n.d.). Once a question (multiple choice or short answer) was live, the participants responded immediately through the use of a smartphone or computer. There were two main benefits of using this software:

- We are able to record and display the results of the poll in an anonymous fashion that does not disclose the identity of the participants. Thus, participants will hopefully not feel like they are being coerced when submitting their response.
- The results can be visually analyzed through graphs, which helps to statistically review the responses.

Additionally, the goal of the evaluation workshop was to gauge interest in pursuing ISO or similar accreditations, as well as pursuing a formal consortium between all of the participating laboratories. We wanted to learn more about the laboratories' thoughts about the project as a whole, and whether they think similar projects or a project continuation could be viable in the future, either sponsored through WPI or between laboratories.

## 4. Results

Analyzing the data collected from the methodologies indicated that each laboratory was at a different stage of quality. Thus, it was evident that our methodologies would have to be carried out using a more individualistic approach to support the laboratories. For confidentiality reasons, they will be denoted as Labs A, B, C, and D for the results and recommendations sections of this paper.

### 4.1. Meeting Laboratory Administrators and Personnel

Through our initial meetings, we motivated the administrators and personnel to participate in our project and started making personal connections, which eased the implementation of methodology and the participation of the laboratories. After a general tour of each space, we learned that the participating laboratories are distinct in terms of: space, infrastructure, staff size, primary and secondary medical interests, and current projects. In addition, we learned about two significant circumstances: 1) CytoLab was actively undergoing major construction and renovations to expand their laboratory, and 2) Neo Lab was following a defined timeline toward ISO 9001:2015 accreditation through the help of a certified team of auditors. To illustrate a better concept of the project sites, we created a visual site description (see Figure VI).

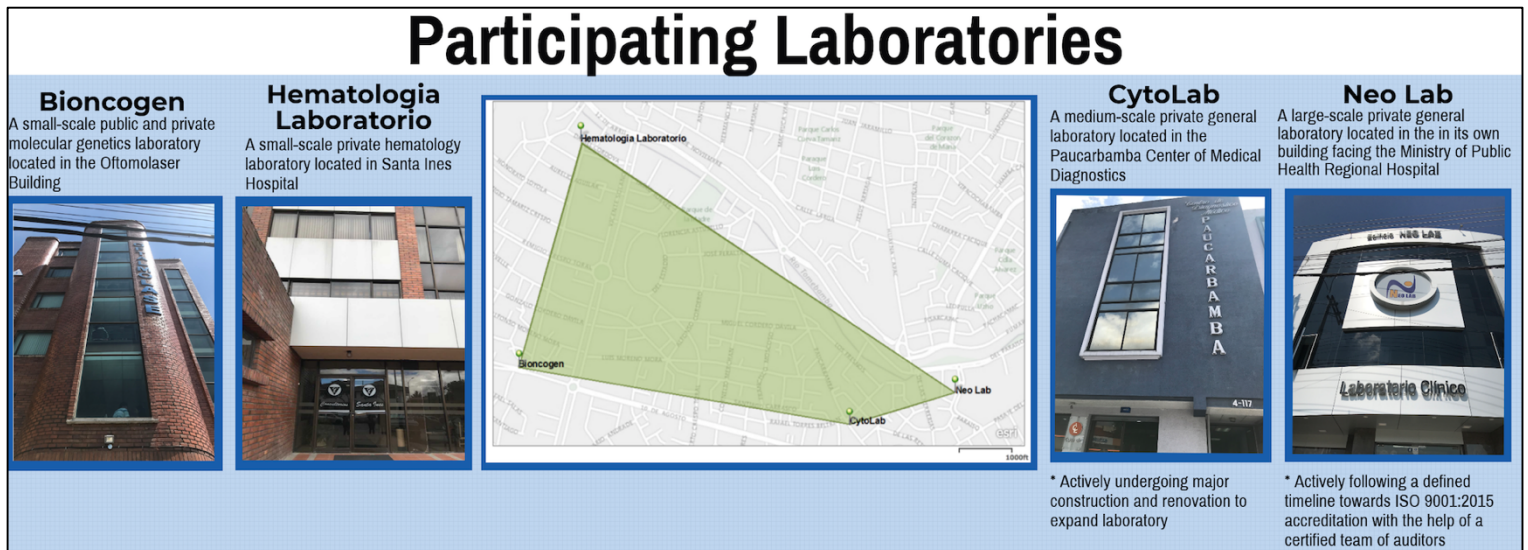
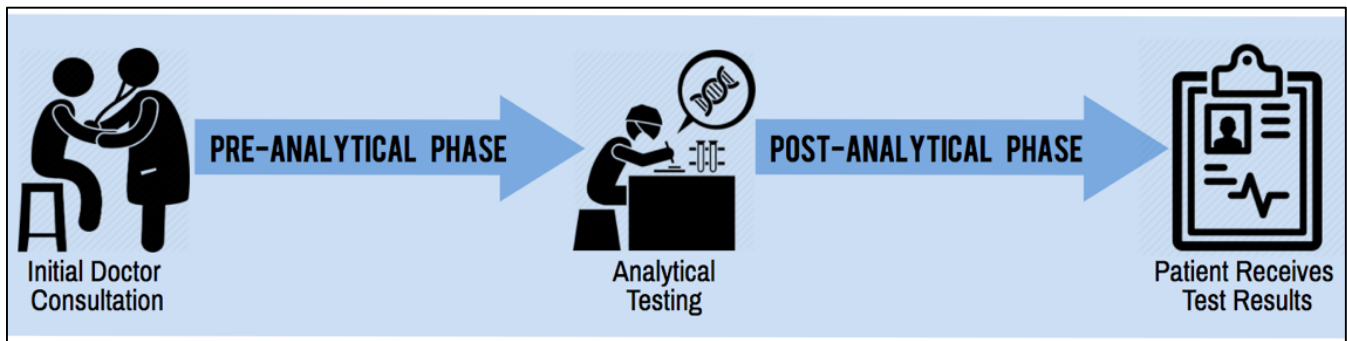


Figure VI. Site Description of Participating Laboratories

## 4.2. Observations and Collected Data

During the scheduled immersions, the laboratory personnel naturally focused on analytical processes while our team focused predominantly on pre-analytical and post-analytical processes (see Figure VII). We collected data regarding the pre-analytical processes of procedures and documentation, equipment maintenance, and inventory and procurement. With the personal connections we had created prior to the immersion, we found that the laboratory personnel were very open to answering questions and explaining their processes to us. Foremost, our team gained general information about the current level of quality management, and the current capabilities of the laboratories. For instance, all of the participating laboratories had documentation outlining their analytical processes, all of them had a form of equipment maintenance and calibration program, and all had methods of patient record and result storage. However, the efficiency of their existing quality management differed, ranging from a mostly paper-based system in Lab C to a personalized software used in Lab D.



**Figure VII. General Workflow in Clinical Laboratories**

In order to compile, analyze, and interpret the collected process data, we utilized Lucidchart, a free online concept mapping software, to create value stream maps (VSMs). By organizing the collected data from a given laboratory in a VSM (see Figure VIII and Appendix E), we located areas of inefficiencies to improve. The typical testing process was represented by a primary rectangular loop, which includes principle pre-analytical, analytical, and post-analytical processes; all laboratories operated using a very similar, if not nearly identical, primary workflow. Everything outside of this primary loop was what we considered to be processes that were not directly part of the workflow, but were vital to complete processes on the primary loop. These “secondary” processes were what differed between each laboratory depending on what systems they had in place. For example, Lab B and Lab D have software that automates many of their pre-analytical and post-analytical processes, reducing the need of many secondary processes. Thus, their VSM reflects a more efficient and streamlined process. Lastly, we denoted processes that we found to be inefficient in red, and described the negatives that we perceived.

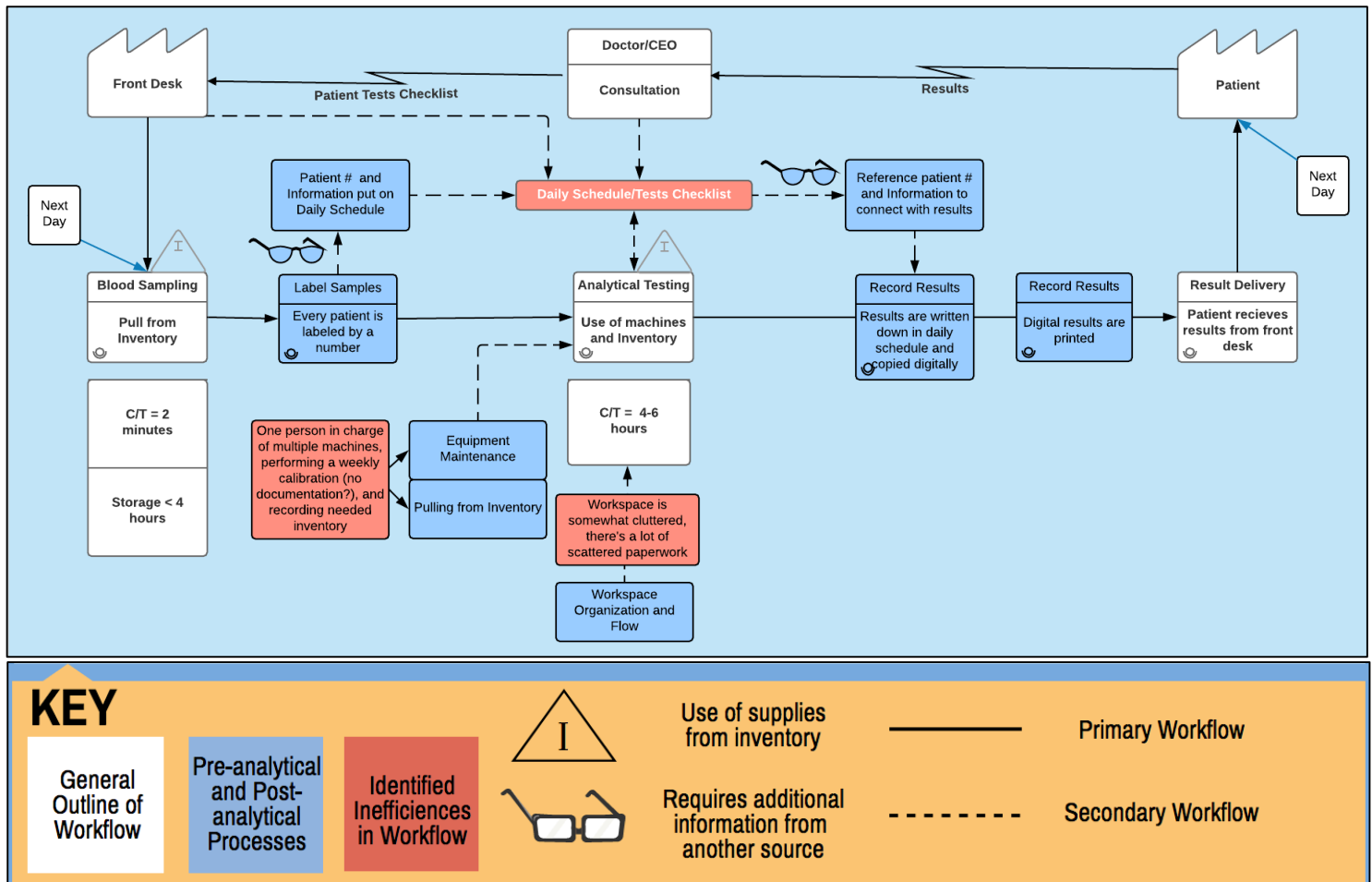


Figure VIII. Value Stream Map of Lab C

From the collected data, we recognized differences in the quality of pre-analytical and post-analytical processes in each laboratory. First, they lack a formal system for recording process errors in all four laboratories. In other words, there is no internal record of observations. Second, Lab D does not have a secure patient sample drop-off location. Currently, samples are placed near the reception desk where there is no permanent receptionist to collect them. This presents opportunity for the samples to be misplaced or stolen. Third, in Lab A, C, and D, all of the test results are printed immediately after the testing is complete and then given to the patient. Meanwhile, Lab B waits to print the tests results until the patient arrives to collect them. By following this procedure, Lab B reduces the amount of wasted resources (e.g. paper, ink, envelopes, and space) because it is common for patients to not return to retrieve their results. Fourth, all of the laboratories lack a well-established inventory management system. Other weak areas for the laboratories included, digital documentation of patient records and equipment maintenance, and patient wait times. In an effort to meet the personal needs of each laboratory,

the VSMs helped us in taking a more heterogeneous approach with our project recommendations that would be designed to address weak areas.

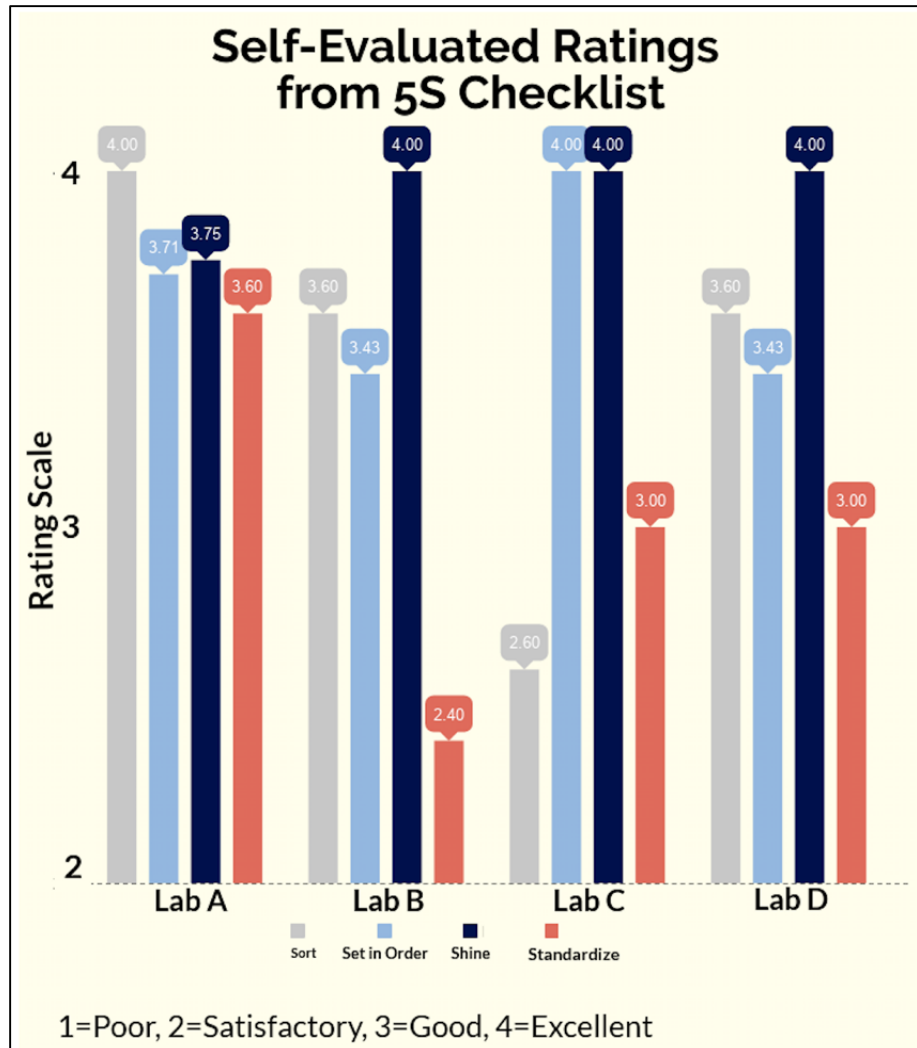
### 4.3. Recommending Improvements and QM Tools

Focus Group 1 covered the importance of quality and our collected case studies, as well as our VSMs from the immersion phase. For the purposes of organization, we prepared a slideshow to guide conversations for each of the laboratories. The presented VSMs for each laboratory were a point of major interest and conversation in the focus groups. With Lab C, there was a lengthy unstructured discussion and all of the laboratory personnel actively participated in providing feedback and sharing their thoughts. Specifically, the personnel of Lab C needed further explanation about the identified inefficiencies in workspace organization and documentation of laboratory equipment. Overall, the VSMs for Labs A and B were accurate, Lab C had some missing details regarding equipment maintenance, and Lab D had already existing plans to improve the inefficient areas. Despite such inconsistencies, all of the laboratories agreed with the observations we made and were genuinely interested in our findings. However, this showed that it was essential to have open discussions with participants about areas of work in their *own* clinical laboratories because they are the experienced professionals and will see the direct impact of our recommendations.

Focus Group 2 concentrated on presenting specific recommendations and quality improvement methods. Prior to introducing potential recommendations based on our field observations, we completed a 5S checklist (see Appendix F) with the laboratory administrators and personnel. With this checklist, we asked the laboratory staff to rate certain areas in their processes on a scale of “poor”, “satisfactory”, “good”, or “excellent”. To make the process as interactive as possible, we requested the audience to discuss their opinions amongst each other in an effort to reach a similar consensus on how they should evaluate the performance of their laboratory for each 5S criteria.

To quantify the laboratories’ responses of the checklist, each of the ratings were assigned a numerical value (poor=1, satisfactory=2, good=3, excellent=4). Then, the responses of 5S criteria were averaged for their respective categories (see Figure IX). For example, Lab A averaged 4.00 in the “sort” category; therefore, that means the personnel evaluated their lab’s performance in that discipline as excellent. It was helpful for us to view their responses in this format because it differentiates how all of the laboratories view their own processes. Additionally, this graph portrays how the laboratories have varying perspectives on what excellent practices consist of. The final “s” of the checklist, sustain, was disregarded because it is more suitable to assess an institution’s performance for that criteria once 5S practices are implemented.





**Figure IX. Results from the 5S Checklist Completed by All Laboratories**

After all of the laboratories completed their 5S checklist, we discovered a correlation between the inefficiencies that we identified and the areas that laboratory administrators and personnel had self-rated lowly. This result allowed us to triangulate on the areas of priority. For example, personnel from Lab C rated their workspace below “excellent” in the following categories: sort, set in order, and standardize. The low ranking of these categories correlated with our observations of poor patient recordkeeping, error documentation, inventory management, and equipment maintenance. Thus, we determined the specific areas that require improvement. When revealing our recommendations after the 5S checklist was completed, the laboratory representatives were receptive to our suggestions. They easily made connections with their ratings on the checklist and how each recommendation was designed to help improve the current state of workflow in their laboratory. Through the demonstration of our recommendations, the laboratories were able to visualize and

conceptualize how our recommendations could be implemented and how they could facilitate improvement.

During Focus Group 3, the participating laboratories confirmed to incorporate our initial recommendations. Thus, we and the laboratory personnel, filled out the first step of the PDSA checklist for the implementation of one of our recommendations (see Appendix G). We found that the laboratories were not only receptive to our proposed system but also put serious thought into the “plan” step of PDSA. Through these checklists, laboratory administrators and personnel hope to: 1) monitor both positive and negative effects of the recommendations, and 2) determine whether the change should be permanently integrated into their workflow or whether the PDSA cycle must be repeated to address and resolve potential issues.

#### **4.4. Assessment of Methodology and Future Plans**

Our final evaluation workshop helped us gain feedback on our methodology and discuss intangible recommendations for the laboratories to pursue in the future, notably the formation of a consortium. Through Poll Everywhere, we reviewed both quantitative and qualitative responses (see Appendix H). Furthermore, this final evaluation workshop also provided opportunity for us to initiate conversation between the laboratories based on the results that were displayed on the screen.

During this final meeting, the participants expressed that they enjoyed the “exchange of knowledge, [ideas], and experiences” that our project included. Furthermore, they conveyed appreciation for our enthusiasm, professionalism, and motivation in working with the laboratories. The participating laboratories believed that the most important aspect of our project was informing them about 5S and PDSA and how such tools can facilitate advancement. According to our Poll Everywhere results, 75% of the workshop participants regarded 5S as “necessary” for the improvement of their laboratories. Meanwhile, 33% believed the same for PDSA. The remaining participants ranked 5S and PDSA as being “very useful.” In relation to our goal of promoting quality management systems, the personnel reported that they learned a great deal about 5S and PDSA, especially since they did not have knowledge on such concepts prior to this project. Consequently, the majority of participants claimed that they now feel comfortable enough to describe the material to a colleague.

When prompted to provide opinions on the benefits of forming a consortium, the participants gave responses that reflected the importance of patient-centered care. Representatives from the laboratories believe that creating a network ensures the integrity of results throughout the participating laboratories and reliability of patient referrals. Specifically, one participant stated, “With a union comes strength. A consortium can bring better service to the community.” Participants also noted that cooperation may yield an economic benefit in terms of bulk inventory orders and reduction of waste. Ultimately, the

personnel agreed that a consortium can mutually benefit *all* laboratories, especially as it signifies the importance of a supportive and collaborative environment.

## 5. Conclusions and Recommendations

The purpose of this project was to promote quality management in the laboratory setting and to support clinical laboratories in Cuenca in improving quality management systems. We formed personal connections with laboratory administrators and personnel, comprehensively collected data on the current means of operation of the laboratories, and designed personalized deliverables and recommendations for the needs of each laboratory. Apart from providing recommendations, we created a quality management guide for each laboratory and organized a final workshop that encouraged the continual improvement of quality. Through our methodology, we provided the laboratories with tools to create a sustainable quality management program and, thus, increase their overall quality of patient care.

### 5.1. Project Evaluation and Evidence of Sustainability

Although we could not analyze the long-term effects of our project in the allotted time, several key observations display substantial impact. In relation to our project goal, we noticed improved participation of the laboratories in discussions on quality management and the active implementation of some of our recommendations. We also received positive feedback from our final evaluation workshop regarding the impact of our project and reviewed each laboratory's plans for future quality management programs. This suggested the prevalence of a positive quality management mentality moving forward. Therefore, we believe that there is sufficient evidence that the participating laboratories will continue pursuing sustainable quality management endeavors.

First, our evidence for this conclusion was the active participation of laboratories in our methodologies. Many of the laboratories started to analyze their own processes, and began to offer their own ideas for improvements. For example, after our use of a VSM for Lab C, laboratory administrators created their own process map (see Appendix I). Similarly, personnel from Lab A also presented a VSM that they created for their analytical processes, as well as a table outlining the processes where errors can occur and how the laboratory can address such inefficiencies (see Appendix J). During Focus Group 2 with Lab C, the personnel suggested that having a digital version of their receipt system would be beneficial for organizing their billing records. This showed not only that the laboratory personnel have the capacity to analyze their own processes, but also that they are interested in using our suggested tools.

Second, the final evaluation workshop demonstrated that the laboratories comprehended the entirety of the subject of 5S and PDSA, to the point of being able to describe the system to a colleague. This was significant because these results showed the laboratories' ability to spread their newfound knowledge to other laboratories. In addition,

the efforts of the laboratories to improve are highlighted by their plans for eventual quality management developments using 5S and PDSA, especially in their analytical processes.

From our observations and discussions, we feel that the personnel have a mindset intended for successful quality management, and that our project was merely a catalyst for immediate change. All of the laboratories are very organized, clean, patient-oriented, and the personnel truly care about their work. At the same time, all of the laboratories understood that there will always be room for improvement. Our experience with the laboratories assured that they will actively continue to use 5S and PDSA in conjunction with our quality management guide as a reference and the creation of a consortium. Ultimately, we hope that they will continue to improve their quality, and spread the culture of quality management to other laboratories in Cuenca.

## 5.2. Recommendations Moving Forward

After analyzing our findings, we created recommendations aimed towards both creating immediate quality management improvements and facilitating future efforts. The recommendations that we designed are based on two sources: 1) the areas of inefficiency that we discovered through our interactive immersions and VSMS, and 2) the information provided by the laboratory administrators and personnel through their self-evaluations in the 5S checklist. In particular, our immediate recommendations include systems to digitize documents, which will act as the bulk of our deliverables. Additionally, we proposed future recommendations for areas of work that we believe laboratories can improve upon, but have no direct solution from us. These recommendations address quality improvements to be made over a long period of time, and the concepts from our project that can be utilized to accomplish them.

- 1. We recommend that the participating laboratories digitize essential documentation, including, but not limited to, patient records, test requests, inventory and equipment maintenance, and receipts in order to reduce workspace clutter, increase security of patient information, and have more extensive documentation.**

We found that, in order to make the greatest impact during our time with the four laboratories, the best course of action would be to decrease as much physical paperwork as possible, and to give them examples of automated inventory and equipment maintenance documents. These recommendations assist with decreasing benchtop clutter, and allow laboratories to more easily keep track of aspects of their pre-analytical and post-analytical work.

We recommend the use of our deliverables (see Appendix K-O) as a way to digitize their current pre-analytical and post-analytical processes, or as templates for the laboratories to create their own digital documents. These deliverables are particularly useful for Lab C where patient record software is not readily available, and is not a

feasible economic investment. Our master patient record, made in Excel, allows laboratory personnel to more easily keep track of each patient's required tests, their results, and the costs of testing. A test request sheet, results record, and payment receipt are all available in the patient records through the use of hyperlinks. This master patient record sheet will make the workflow of the laboratory more streamline, and create a more complete record system.

Additionally, we recommend the use of our created inventory management form in Labs A, B, and C in order to better maintain their stock and acquisitions. This form allows laboratories to keep track of their current amount of inventory and automatically indicates if that current amount is below an inputted boundary amount. This recommendation also includes an inventory request form and a list of suppliers attached to it for easy access. The system will allow each laboratory to have full control over their inventory and never run into a lack of supplies from a late shipment or a lapse in memory.

- 2. We recommend that the laboratories continue with 5S and PDSA initiatives to improve the efficiency of processes (pre-analytical, analytical, and post-analytical processes) such as patient wait times, laboratory sanitation, temperature control, and sample drop-off locations.**

Our results show that there is sufficient evidence that suggests that each of the laboratory's quality management program will continue. However, our team would like to recommend the continued use of 5S, PDSA, VSMs, and audits as tools for quality management and improvement. Specifically, our results showed that 3 out of 4 laboratories lacked a system for proper temperature and climate control. Furthermore, Lab D did not have a system for immediate patient reception or a secure sample drop-off location. Therefore, we recommend that, in the coming months, the laboratories focus on the areas of patient wait time, control of the laboratory environment, and sample collection.

- 3. We recommend that the participating laboratories form a consortium with the objective of continuous quality improvement and the eventual goal of ISO accreditation.**

In order to create a system for continuous quality improvement, we believe that a consortium or network should be created between the participating laboratories. By creating a consortium, personnel will be able to support each other in not only quality management projects and initiatives, but also with patient referrals, more comprehensive medical support, and analytical studies. A consortium will also make ordering common materials easier through the process of bulk ordering between all of the participating laboratories. It also strengthens the public relations of the laboratories if all are represented by a network that is pursuing an improved quality management

program. Additionally, we see a consortium being especially useful as a form of external auditing, similar to our role during this project. Having an external opinion that is invested in a laboratory's success is useful in analyzing processes and finding areas of inefficiencies and errors, as well as coming up with possible solutions to those issues.

Laboratory administrators and personnel can organize monthly or bi-monthly meetings to talk about their current quality management initiatives, the results of a PDSA assessment on a previous change, or even share interesting papers on the topic of quality management. Additionally, this consortium can be especially useful for discussing required documents or methods for future ISO accreditation. Participating laboratories can share their experiences with the process of accreditation and assist others with the process while maintaining confidentiality.

**4. We recommend that the participating laboratories spread their knowledge of 5S, PDSA, and VSMs to surrounding laboratories and the general medical community.**

Although outreach to other laboratories was not directly part of our goal, the overall theme of our project was the promotion of quality management in Cuenca as a whole. All of the laboratories which participated in our project were interested in improving and our project was purely a way to give them the tools to do so. It is possible, however, that many other laboratories lack the same quality management infrastructure as the participating laboratories in this project. Thus, the impact from these quality management tools would be greater. If the participating laboratories were to have focus groups with other laboratories in the area, then they would be able to have a positive impact on the medical community. The participating laboratories could lecture to other laboratories and take a similar methodological approach to what we did with them, ensuring the promotion of a culture of quality management in Cuenca.

### **5.3. Project Conclusion**

Based on our results and the reception of our recommendations, we believe that our goal of promoting quality management in the laboratory setting and supporting clinical laboratories in Cuenca in improving quality management systems was an overall success. We achieved our goals and met objectives in the allotted time through an effective, efficient, and mindful manner. Throughout the execution of our methodologies, personnel from each laboratory showed enthusiasm towards our project, a motivation to improve, and the initiative to begin the implementation of our tangible recommendations. Thus, we expect that the laboratories will continue their quality management endeavors based on the systems outlined during our project. Lastly, we postulate that there will be opportunities in the future to work with the participating laboratories regarding their pending consortium, especially in terms of creating a digital network, finance systems, and plans for expansion.

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## **7. Appendix**

### **Appendix A: Inventory Management Documents**

## Promoting Laboratory Quality Management Systems in Cuenca, Ecuador

The documents below were provided by Lisa Wall and Elyse Favreau, the lab managers of the WPI BME department. These documents are routinely used by the managers to maintain quality within the laboratories they manage. More detail as to what each document contains and aids in can be found in the text below each document.

<b><u>Biohazard Waste Check – SL219</u></b>	
<b>Task</b>	<b>✓ or Comment</b>
Check small benchtop biohazard bags and replace if needed.	
Check 2 biohazard boxes – are any 3/4 full or more?	
Check large 8 gallon sharps containers next to each hood. If any are full, close securely and replace with empty one.	
# of EMPTY 8 gallon sharps containers remaining	
Check small 2 gallon sharps containers – do any need to be replaced? (Look for “fill” line on container.)	
<b><u>Biohazard Waste Check – Goddard Hall</u></b>	
<b>Task</b>	<b>✓ or Comment</b>
<b>GH006</b> – check biohazard box. Replace if needed.	
<b>GH006</b> – check 8 gallon sharps containers next to hoods. Replace if needed.	
<b>GH207</b> – check biohazard box. Replace if needed.	
<b>GH207</b> – check small 2 gallon sharps containers. Replace if needed. (Look for “fill” line on container.)	
<b>GH207</b> – check freezer AND fridge for biohazard waste (red bags). Bring to 007A freezer.	
<b>GH306</b> – check biohazard boxes. Replace if needed.	
<b>GH306</b> – check 8 gallon sharps containers. Replace if needed.	
<b>GH306</b> – check 2 gallon sharps containers. Replace if needed.	

The Biohazard Waste Check sheet above outlines tasks according to each laboratory (i.e. SL219, GH006, GH207, and GH306) managed by the lab managers. These tasks are typically completed on a weekly basis. Tasks mainly include checking different areas of waste and replacing waste storage containers as needed.

Promoting Laboratory Quality Management Systems in Cuenca, Ecuador

BME Labs Inspection Chart					
WEEKLY					
Lab _____					
	Date	Date	Date	Date	Date
<b>Biohazard Waste –</b> Check all biohazard containers and replace as needed.					
<b>Chemical Hazard Waste –</b> If the lab has a chemical waste collection area, check to see if there is waste needing to be picked up. Check labels.					
<b>Sharps –</b> Check all sharps containers, including broken glass containers. Replace as needed.					
<b>Aspiration Flasks –</b> Check all collection flasks. Replace with empty flask as needed.					
<b>CO2 Incubators –</b> Check water level inside incubators. Add DI water if needed. Also check temperature and CO2%.					
<b>Compressed gas cylinders –</b> Check levels in tanks. Replace if needed. Check tanks are secured properly.					
<b>Biosafety Cabinets –</b> Check that UV and fluorescent lamps are working. Check blower fan for operation.					
<b>Eye Wash Stations –</b> Check eye wash stations for operation.					
<b>Students –</b> Check that students are complying to all lab safety rules, like PPE, etc.					
<b>Housekeeping –</b> Check bins next to sinks for dirty dishware. Clean when necessary.					
<b>Fume Hoods –</b> Check that sashes are closed when not in use, and that exhaust fan is working and not alarming.					
<b>Refrigerator/Freezers –</b> Check that they are working properly.					
<b>Electrical Safety –</b> Check for condition of outlets, and excessive use of power strips and extension cords, etc.					
MONTHLY					
<b>Biohazard Waste –</b> Collect all biohazard waste including freezers for monthly pickup.					
YEARLY					
<b>Biosafety Cabinets –</b> Check for certification. Get recertified as needed.					
<b>Fume Hoods –</b> Check date for inspection. Notify Campus Safety Officer if past due.					
<b>Freezers –</b> Manually defrost freezer.					
<b>Eye Wash &amp; Showers –</b> Check for inspection date. If overdue, contact Facilities.					
<b>Fire Extinguisher –</b> Check for inspection date. If overdue, contact Campus Safety Officer.					

Revised Nov 2013

The BME Labs Inspection sheet above is the laboratory inspection sheet that covers all levels of inspection. It covers weekly checks, month checks, and year checks. Checks are in relation to equipment, inventory, and safety procedure.

<b><u>GH 006 Supplies Checklist</u></b>	
<b>DATE:</b>	_____
<b><u>On bench shelves closest to biosafety cabinets</u></b>	
<input type="checkbox"/>	100 mm plates – at least 6 sleeves
<input type="checkbox"/>	Centrifuge tubes - 15 mL, 50 mL (2 packs of each out)
<input type="checkbox"/>	Serological pipets – 1, 5, 10, 25 mL (2 boxes of each)
<input type="checkbox"/>	Tissue culture flasks (1 box of each size – check fullness of box) <ul style="list-style-type: none"><li><input type="checkbox"/> Sizes: 25, 75, 182 cm<sup>2</sup></li></ul>
<input type="checkbox"/>	DPBS(+) and DPBS(-) – at least 4-5 bottles of each
<input type="checkbox"/>	Pipet tips (all sizes, at least 4 boxes of each size – 10, 20, 200, 1250 µL)
<input type="checkbox"/>	Backup packs of pipet tips – 1 pack of each size <b>(in cabinet under centrifuge)</b>
<input type="checkbox"/>	Pasteur pipets – at least 6 sterile boxes <b>(in drawer underneath microscope)</b>
<b><u>On next set of bench shelves (next to freezers)</u></b>	
<input type="checkbox"/>	Tissue culture plates (1 box of each size – check fullness of box) <ul style="list-style-type: none"><li><input type="checkbox"/> Sizes: 100 mm, 4-well, 6-well, 12-well, 24-well, 96-well (Note: 4-well plates are labeled “Nunclon” plates – in a brown box)</li></ul>
<b><u>White drawers in front of biosafety cabinets</u></b>	
<input type="checkbox"/>	Centrifuge tubes – 1 pack each of 15 mL and 50 mL
<input type="checkbox"/>	100 mm plates – 2 sleeves
<input type="checkbox"/>	Roll or stack of paper towels
<b><u>Refrigerator</u></b>	
<input type="checkbox"/>	DMEM cell media – at least 6 unopened bottles (on door of fridge, label “BME”)
<b><u>Other</u></b>	
<input type="checkbox"/>	2 boxes of each size glove on table (XS, S, M, L, XL)
<input type="checkbox"/>	2 extra rolls (or 4 tri-fold stacks) of paper towels on the gloves table
<input type="checkbox"/>	Look around lab area for empty Pasteur pipet boxes – fill/autoclave
<input type="checkbox"/>	Check sink area for dirty dishes – clean, dry, and put away
<input type="checkbox"/>	Check DI water carboy; fill if necessary
<input type="checkbox"/>	Check 70% isopropanol carboy; fill if necessary

The GH006 Supplies Checklist document above covers the current inventory of the GH006 laboratory in terms of what is to be in stock in different areas of the laboratory at all times. This checklist is typically completed on a weekly basis.

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<b>SL219 Lab Supplies Check</b>		Date: _____
		Door code: 3214
<b>Pipet Cabinet</b>	<b>Fully Stocked Amount</b>	<b>Amount in Lab</b>
5 mL serological pipets	12 boxes	
10 mL serological pipets	6 boxes	
25 mL serological pipets	6 boxes	
50 mL centrifuge tubes	20 packs (fill shelf)	
15 mL centrifuge tubes	10-20 packs (fill shelf)	
10 uL pipet tips	3 boxes	
200 uL pipet tips	3 boxes	
1250 uL pipet tips	3 boxes	
<b>Cell Culture Plates Cabinet</b>	<b>Fully Stocked Amount</b>	<b>Amount in Lab</b>
4-well Nunclon plates	1 box	
100 mm plates	1 full shelf	
60 mm plates	~1 case	
35 mm plates	~1 case	
T-75 flasks	1 case	
T-182 flasks	1 case	
T-25 flasks	2 cases	
T-12.5 flasks	2 cases	
<b>Multi-Well Plates - Drawers</b>	<b>Fully Stocked Amount</b>	<b>Amount in Lab</b>
6 well plates	1 full drawer	
12 well plates	1 full drawer	
24 well plates	1 full drawer	
96 well plates	1 full drawer	
<b>Miscellaneous</b>	<b>Fully Stocked Amount</b>	<b>Amount in Lab</b>
Gloves (XS, S, M, L, XL)	2 in backup drawers	
Sterile Pasteur Pipet Boxes	~10 or more (in drawer)	
Hemocytometers	3 full boxes	
DPBS(+)	6 full bottles	
DPBS(-)	6 full bottles	
DMEM (Instructor's refrigerator)	6 full bottles	
Trypsin (Freezer)	1 case (6 full bottles)	

**Other:**

<input type="checkbox"/> Make sure there are 2 boxes of each size glove on the bench <input type="checkbox"/> Check for empty Pasteur pipet boxes and bring back to fill <input type="checkbox"/> Check 2 carboys of DI water – are they at least half full? <input type="checkbox"/> Check isopropanol spray bottles – fill if needed	<input type="checkbox"/> Make sure each set of white drawers next to the hoods have: <ul style="list-style-type: none"> <li>○ 1 sleeve of 100 mm plates</li> <li>○ 1 pack 50 mL centrifuge tubes</li> <li>○ 1 pack 15 mL centrifuge tubes</li> <li>○ 1 pack tri-fold paper towels</li> </ul>
---	--

The SL219 Lab Supplies Check document covers large quantities of inventory for the SL219 laboratory. The document states what the full inventory amount it and what the current inventory state is. When items are understocked, they need to be procured.

<b>Storage Room Inventory – 007A</b>							
<b>Item</b>		<b>Qty (cases/boxes)</b>		<b>Item</b>		<b>Qty (cases/boxes)</b>	
<b><u>Serological Pipets</u></b>				<b><u>Gloves</u></b>			
1 mL				XS			
5 mL				S			
10 mL				M			
25 mL				L			
50 mL				XL			
<b><u>Centrifuge Tubes</u></b>				<b><u>Pipet Tips</u></b>			
15 mL				1250 µL			
50 mL				10 µL			
				20 µL			
<b><u>Tissue Culture Plates</u></b>				200 µL			
6 well							
12 well				<b><u>Tissue Culture Flasks</u></b>			
24 well				T-25			
96 well				T-75			
35 mm				T-182			
60 mm							
100 mm							
<b><u>Miscellaneous</u></b>							
Bleach							
Saline							

The Storage Room Inventory – 007A document covers the inventory of items stored in the storage room designated for laboratory supplies. This document aids in making note of what items needs to be ordered (item name and quantity).

## Appendix B: Timeline of Methodology Execution


The infographic below provides a general outline of how the methodology was executed on a weekly basis. However, this methodology varied between each laboratory based on the administrators' and personnel's availability. Following a general timeline allowed us to maintain a routine and troubleshoot any delays that occurred.

<b>Methodology</b>	
<b>Jan. 17 - 19</b>	<b>Pre-Method:</b> <ul style="list-style-type: none"><li>• Initial meeting with doctors</li><li>• Brainstorming, and project-planning</li></ul>
<b>Jan. 22 - 26</b>	<b>Pre-interview with doctors from each laboratory:</b> <ul style="list-style-type: none"><li>• Current state of understanding</li><li>• Pre-analytical procedure and documentation</li><li>• Primary/secondary interests</li><li>• Importance of networking/consortium</li></ul>
<b>Jan. 29 - Feb. 2</b>	<b>Focus Group 1:</b> <ul style="list-style-type: none"><li>• Why is quality important?</li><li>• The "costs" of good quality and poor quality</li></ul>
<b>Feb. 5 - 9</b>	<b>Focus Group 2:</b> <ul style="list-style-type: none"><li>• Recommended 5S approach</li><li>• Introduction of recommendations</li></ul>
<b>Feb. 12 - 16</b>	<b>Focus Group 3:</b> <ul style="list-style-type: none"><li>• Recommended PDSA approach</li><li>• Review of recommendations</li></ul>
<b>Feb. 19 - 23</b>	<b>Evaluation Workshop</b> <ul style="list-style-type: none"><li>• What did you retain from the focus groups?</li><li>• Forming a consortium among labororaties</li></ul>
<b>Feb. 26 - Mar. 1</b>	<b>Post-Method</b> <ul style="list-style-type: none"><li>• Submission of final project recommendations summary/research</li></ul>
<b>*Immersion will take place throughout but we plan on having designated times/hours*</b>	

### Appendix C: 5S Action Checklist

The series of documents below represent the 5S Action Checklist that was created for Focus Group 2 (English and Spanish version can be found below). The purpose of this checklist was to assess the state of quality in each laboratory according to 5S standards. During the second focus group, administrators and personnel evaluated their respective laboratory to determine areas of improvement. This checklist is also a useful resource to rely on before and after a PDSA cycle is carried out with the intention to reevaluate the state of quality in the laboratory after a change has been made and carried out.

#### 5S Action Checklist (English)



**LABORATORY:** \_\_\_\_\_ **DATE:** \_\_\_\_\_

SORT					
Area of Laboratory	Criteria	Poor	Satisfactory	Good	Excellent
Cabinets and Shelves	1. No irrelevant reference materials, documents, drawings, etc.				
Desks and Tables	2. No irrelevant reference materials, documents, etc.				
Drawers	3. No excess pieces of equipment, documents, etc.				
Other Storage Area	4. Storage area is defined to store unneeded items and out-dated documents.				
Standards for Disposal	5. Standards for eliminating unnecessary items exist and are being followed.				
<b>COMMENTS:</b>   					

1



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SET IN ORDER					
Area of Laboratory	Criteria	Poor	Satisfactory	Good	Excellent
Desks, Shelves, y Cabinets	1. Desks and cabinets are free of accumulations of papers and other objects.				
Tools and Equipment	2. All tools and equipment are stored in a fixed place.				
Ease of Take and Return	3. Tools and equipment are well organized for ease of take and return.				
Storage Labels	4. Labeling of cabinets, shelves and files allows immediate identification.				
Documents	5. Documents are filed in accordance with the Record Retention Guidelines.				
Display Areas	6. Displays are tidy, free of clutter, labeled and up-to-date.				
Safety	7. Safety equipment easily accessible and in good condition.				
<b>COMMENTS:</b>					

2

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SHINE					
Area of Laboratory	Criteria	Poor	Satisfactory	Good	Excellent
Floor	1. The floor is kept clean and no signs of damage.				
Building Structure	2. Walls and ceilings are in good condition and free from dirt and dust.				
Racks and Cabinets	3. Racks and cabinets are kept clean and in good condition.				
Equipment y Tools	4. Equipment and tools are kept clean and in good condition.				
Furniture	5. Desks, tables and other furniture are kept clean				
Lighting	6. Lighting is enough and the angle and intensity of illumination are appropriate.				
Ventilation	7. Good movement of air exists through the room.				
Trash Containers	8. Trash containers are emptied on a regular basis.				
<b>COMMENTS:</b>					

## Promoting Laboratory Quality Management Systems in Cuenca, Ecuador

STANDARDIZE					
Area of Laboratory	Criteria	Poor	Satisfactory	Good	Excellent
Display Boards	1. Visual controls and display boards are used and regularly updated.				
Procedures	2. Procedures for maintaining the first three S's are being displayed.				
5S Documentation	3. 5S checklists, schedules and routines are defined and being used.				
Responsibilities	4. Everyone knows his responsibilities, when and how.				
Regular Audits	5. Regular audits are taking place using checklists and measures.				
<b>COMMENTS:</b>					

## Promoting Laboratory Quality Management Systems in Cuenca, Ecuador

SUSTAIN					
Area of Laboratory	Criteria	Poor	Satisfactory	Good	Excellent
5S System	1. 5S seems to be the way of life rather than just a routine.				
Success Stories	2. Success stories are being displayed (i.e. before and after pictures).				
Rewards y Recognition	3. Rewards and recognition is part of the 5S system.				
<b>COMMENTS:</b>					

**5S Action Checklist (Spanish)**

**La Lista  
de Acción  
5S**

**EL LABORATORIO:**

**FECHA:**

**AUDITOR(ES):**

<b>ORDENAR</b>					
<b>Área del Laboratorio</b>	<b>El Criterio</b>	<b>Malo</b>	<b>Satisfactorio</b>	<b>Bueno</b>	<b>Excelente</b>
Gabinetes y Estantes	1. Ningunos materiales de la referencia irrelevantes, documentos, dibujos, etc.				
Escritorios y Mesas	2. Ningunos materiales de la referencia irrelevantes, documentos, etc.				
Cajones	3. Ninguna pieza excedente de equipo, documentos, etc.				
Otras Áreas de Alimentación	4. El área de almacenamiento está definida para almacenar innecesarias de elementos y documentos fechados.				
Estándares de Disposición	5. Las normas para la eliminación de artículos innecesarios existen y se están siguiendo.				
<b>COMENTARIOS:</b>					

## Promoting Laboratory Quality Management Systems in Cuenca, Ecuador

<b>ARREGLAR</b>					
<b>Área del Laboratorio</b>	<b>El Criterio</b>	<b>Malo</b>	<b>Satisfactorio</b>	<b>Bueno</b>	<b>Excelente</b>
Escritorios, Estantes, y Gabinetes	1. Los escritorios y los gabinetes están libres de acumulaciones de papeles y otros objetos.				
Herramientas y Equipo	2. Todas las herramientas y el equipo se almacenan en un lugar fijo.				
Facilidad de Tomar y Devolver	3. Las herramientas y el equipo se organizan bien para la facilidad de la toma y de la vuelta.				
Etiquetas de Almacenamiento	4. El etiquetado de los gabinetes, estantes y archivos permite la identificación inmediata.				
Documentos	5. Los documentos se archivan de acuerdo con las pautas de retención de registros.				
Áreas de Visualización	6. Las exhibiciones son ordenadas, libres de desorden, etiquetados y actualizados.				
Seguridad	7. Equipo de seguridad fácilmente accesible y en buenas condiciones.				
<b>COMMENTARIOS:</b>					

## Promoting Laboratory Quality Management Systems in Cuenca, Ecuador

<b>LIMPIAR</b>					
<b>Área del Laboratorio</b>	<b>El Criterio</b>	<b>Malo</b>	<b>Satisfactorio</b>	<b>Bueno</b>	<b>Excelente</b>
Piso	1. El piso se mantiene limpio y no hay señales de daños.				
Estructura del Edificio	2. Las paredes y los techos de están en buenas condiciones y libres de la suciedad y del polvo.				
Bastidores y Gabinetes	3. Los bastidores y los gabinetes de se mantienen limpios y en buenas condiciones.				
Equipo y Herramientas	4. El equipo y las herramientas de se mantienen limpios y en buenas condiciones.				
Muebles	5. Los escritorios, las tablas y otros muebles se mantienen limpios				
Iluminación	6. La iluminación es bastante y el ángulo y la intensidad de la iluminación son apropiados.				
Ventilación	7. El buen movimiento del aire existe a través de la habitación.				
Contenedores de Basura	8. Los contenedores de basura se vacían regularmente.				
<b>COMENTARIOS:</b>					

## Promoting Laboratory Quality Management Systems in Cuenca, Ecuador

ESTANDARIZAR					
Área del Laboratorio	El Criterio	Malo	Satisfactorio	Bueno	Excelente
Tableros de Exhibición	1. Los controles visuales y los tableros de exhibición se utilizan y se actualizan regularmente.				
Procedimientos	2. Procedimientos para mantener los tres primeros S's se están mostrando.				
Documentación de 5S	3. Listas de 5S, horarios y rutinas son definidos y utilizados.				
Responsabilidades	4. Cada uno sabe sus responsabilidades, cuándo y cómo.				
Auditorías Regulares	5. Las auditorías regulares ocurren usando listas de comprobaciones y medidas.				
<b>COMENTARIOS:</b>					



Promoting Laboratory Quality Management Systems in Cuenca, Ecuador

CONTINUAR					
Área del Laboratorio	El Criterio	Malo	Satisfactorio	Bueno	Excelente
Sistema de 5S	1. 5S parece ser la forma de vida más que una rutina.				
Historias de Éxito	2. Historias de éxito se muestran (las fotografías de antes y después).				
Recompensas y Reconocimiento	3. Recompensas y reconocimiento es parte del sistema 5S.				
<b>COMMENTARIOS:</b>					

5

### Appendix D: PDSA Checklist

The series of documents below represent the PDSA Checklist that was created for Focus Group 3 (English and Spanish version can be found below). The purpose of this checklist was to provide laboratories with a tool that can be used when improving a process or creating a change in the lab.

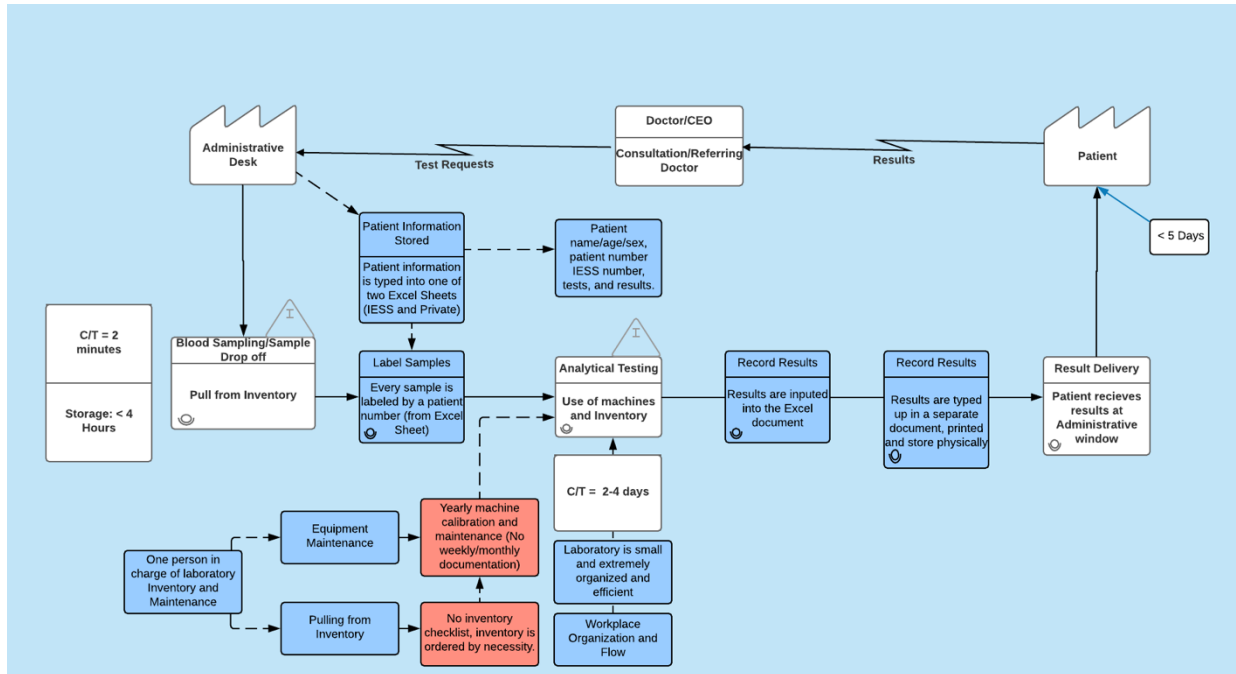
<b>Objective</b>		<b>Your Response</b>
<b>Plan</b>	What exactly will you do?	
	Who will be involved and how?	
	When will it take place?	
	Where will it take place?	
	What will you measure?	
	What do you predict will happen?	
<b>Do</b>	<b>Implement the plan and record:</b>	
	• What was actually done and when?	
	• Any unexpected observations or problems?	
	Collate and begin to analyze the data	
<b>Study</b>	What were the results?	
	Did they differ from your expectations? (If so how/why?)	
	What have you learned from completing this cycle?	
<b>Act</b>	<b>What action will you now take to:</b>	
	• Refine your improvement idea and re-test it? or	
	• Implement it and embed the change? or	
	• Reject the idea and prepare to test a new one?	

## Lista de PDSA

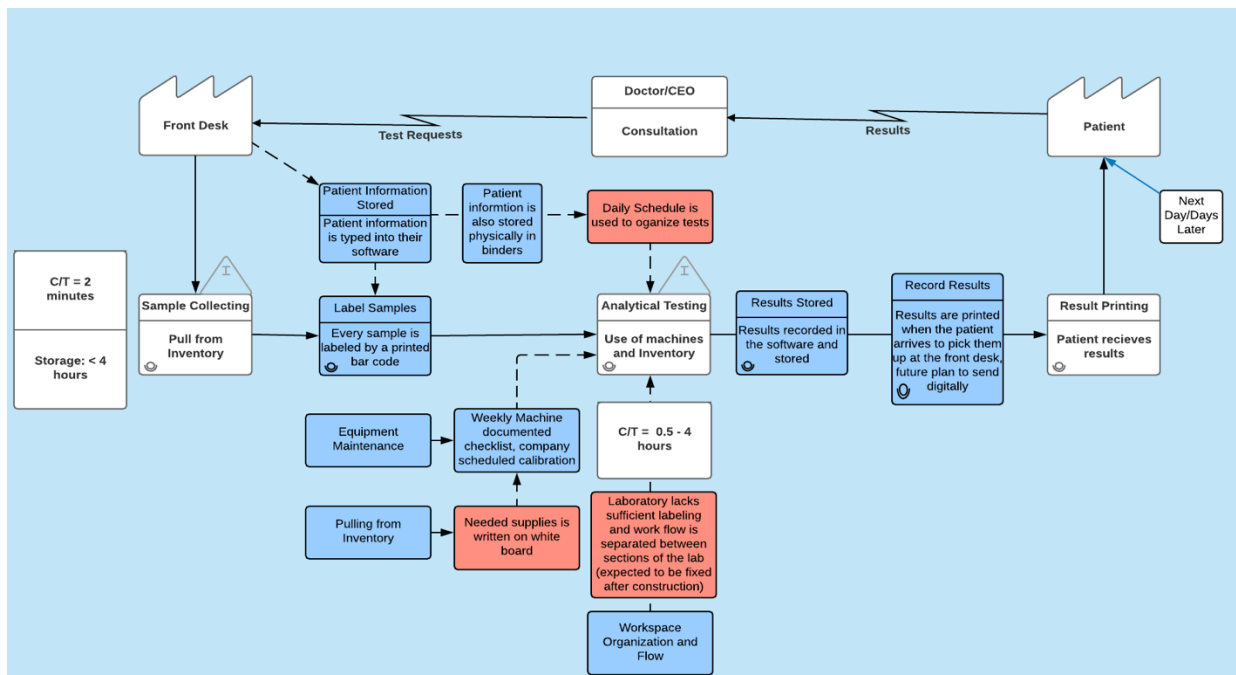
Objetivo		Su Respuesta
<b>Planear</b>	¿Qué hará exactamente?	
	¿Quién estará involucrado y cómo?	
	¿Cuándo ocurrirá?	
	¿Dónde ocurrirá?	
	¿Qué medirá?	
	¿Qué predice que pasará?	
<b>Hacer</b>	<b>Implemente el plan y registre:</b>	
	¿Qué fue hecho y cuándo?	
	¿Alguna observación o problema inesperado?	
	Cotejar y comenzar a analizar los datos	
<b>Estudiar</b>	¿Cuáles fueron los resultados?	
	¿Se diferenciaron de sus expectativas? (¿Si, así pues, cómo/por qué?)	
	¿Qué ha aprendido de completar este ciclo?	
<b>Actuar</b>	<b>A qué la acción le va ahora tomar:</b>	
	¿Refinar su idea de la mejora y probarla de nuevo? o	
	¿Implementarlo e incrustar el cambio? o	
	¿Rechazar la idea y prepararse para probar uno nuevo?	

### Appendix E: Value Stream Maps of All Laboratories

The value stream maps (VSMs) below were created to better understand the flow of work through each laboratory. Using these VSMs, we were able to highlight (shown in red) which pre-analytical and post-analytical areas of the laboratories could be improved.

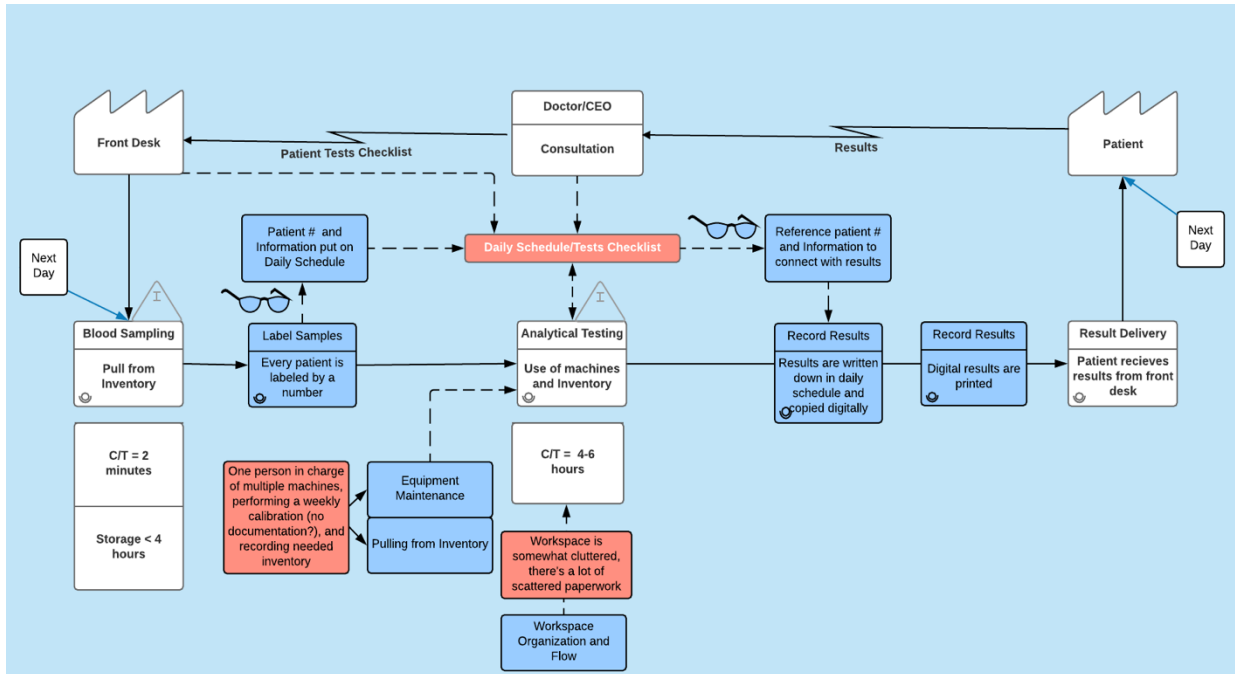


**Value Stream Map for Lab A**

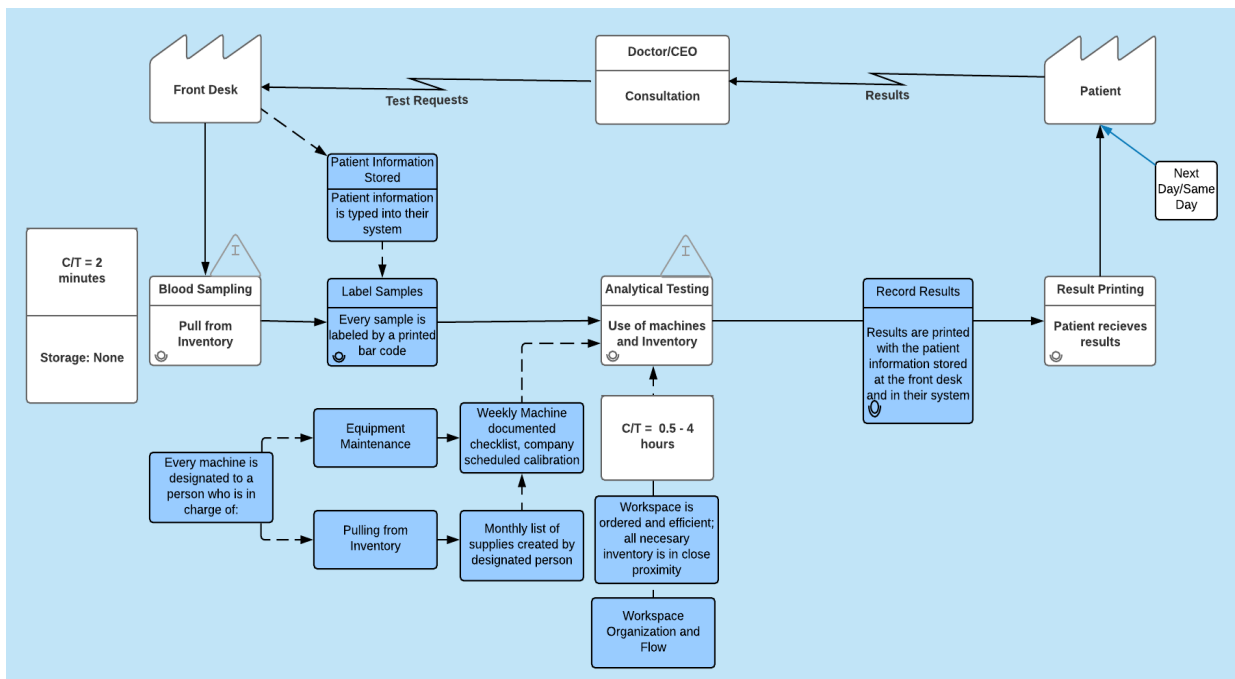


**Value Stream Map for Lab B**

# Promoting Laboratory Quality Management Systems in Cuenca, Ecuador



**Value Stream Map for Lab C**




**Value Stream Map for Lab D**

## Appendix F: 5S Action Checklist Completed by All Laboratories

In Focus Group 2, the administrators and personnel from each laboratory completed a 5S Action Checklist. This checklist was a useful analytical tool for the participating laboratories to self-assess the performance of their respective laboratory according to the criteria included in the checklist. Checklists filled out by each laboratory are included below. The final “S”, *continuar*, or sustain, for the checklist was not filled out by the laboratories because it is more suitable to assess an institution’s performance for that criteria once 5S practices have been implemented into the laboratory.

### 5S Checklist Completed by Lab A



**EL LABORATORIO: LAB A** **FECHA: Feb. 19, 2018**

ORDENAR					
Área del Laboratorio	El Criterio	Malo	Satisfactorio	Bueno	Excelente
Gabinetes y Estantes	1. Ningunos materiales de la referencia irrelevantes, documentos, dibujos, etc.				✓
Escritorios y Mesas	2. Ningunos materiales de la referencia irrelevantes, documentos, etc.				✓
Cajones	3. Ninguna pieza excedente de equipo, documentos, etc.				✓
Otras Áreas de Alimentación	4. El área de almacenamiento está definida para almacenar innecesarias de elementos y documentos fechados.				✓
Estándares de Disposición	5. Las normas para la eliminación de artículos innecesarios existen y se están siguiendo.				✓
<b>COMENTARIOS:</b>					

1

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ARREGLAR					
Área del Laboratorio	El Criterio	Malo	Satisfactorio	Bueno	Excelente
Escritorios, Estantes, y Gabinetes	1. Los escritorios y los gabinetes están libres de acumulaciones de papeles y otros objetos.				✓
Herramientas y Equipo	2. Todas las herramientas y el equipo se almacenan en un lugar fijo.				✓
Facilidad de Tomar y Devolver	3. Las herramientas y el equipo se organizan bien para la facilidad de la toma y de la vuelta.				✓
Etiquetas de Almacenamiento	4. El etiquetado de los gabinetes, estantes y archivos permite la identificación inmediata.				✓
Documentos	5. Los documentos se archivan de acuerdo con las pautas de retención de registros.		✓		
Áreas de Visualización	6. Las exhibiciones son ordenadas, libres de desorden, etiquetados y actualizados.				✓
Seguridad	7. Equipo de seguridad fácilmente accesible y en buenas condiciones.				✓
<b>COMENTARIOS:</b>					

<b>LIMPIAR</b>					
<b>Área del Laboratorio</b>	<b>El Criterio</b>	<b>Malo</b>	<b>Satisfactorio</b>	<b>Bueno</b>	<b>Excelente</b>
Piso	1. El piso se mantiene limpio y no hay señales de daños.				✓
Estructura del Edificio	2. Las paredes y los techos de están en buenas condiciones y libres de la suciedad y del polvo.				✓
Bastidores y Gabinetes	3. Los bastidores y los gabinetes de se mantienen limpios y en buenas condiciones.				✓
Equipo y Herramientas	4. El equipo y las herramientas de se mantienen limpios y en buenas condiciones.				✓
Muebles	5. Los escritorios, las tablas y otros muebles se mantienen limpios				✓
Iluminación	6. La iluminación es bastante y el ángulo y la intensidad de la iluminación son apropiados.				✓
Ventilación	7. El buen movimiento del aire existe a través de la habitación.		✓		
Contenedores de Basura	8. Los contenedores de basura se vacían regularmente.				✓
<b>COMENTARIOS:</b>					



Promoting Laboratory Quality Management Systems in Cuenca, Ecuador

ESTANDARIZAR					
Área del Laboratorio	El Criterio	Malo	Satisfactorio	Bueno	Excelente
Tableros de Exhibición	1. Los controles visuales y los tableros de exhibición se utilizan y se actualizan regularmente.				✓
Procedimientos	2. Procedimientos para mantener los tres primeros S's se están mostrando.			✓	
Documentación de 5S	3. Listas de 5S, horarios y rutinas son definidos y utilizados.		✓		
Responsabilidades	4. Cada uno sabe sus responsabilidades, cuándo y cómo.				✓
Auditorías Regulares	5. Las auditorías regulares ocurren usando listas de comprobaciones y medidas.		✓		
<b>COMMENTARIOS:</b>					

## Promoting Laboratory Quality Management Systems in Cuenca, Ecuador

<b>ESTANDARIZAR</b>					
<b>Área del Laboratorio</b>	<b>El Criterio</b>	<b>Malo</b>	<b>Satisfactorio</b>	<b>Bueno</b>	<b>Excelente</b>
Tableros de Exhibición	1. Los controles visuales y los tableros de exhibición se utilizan y se actualizan regularmente.				✓
Procedimientos	2. Procedimientos para mantener los tres primeros S's se están mostrando.			✓	
Documentación de 5S	3. Listas de 5S, horarios y rutinas son definidos y utilizados.		✓		
Responsabilidades	4. Cada uno sabe sus responsabilidades, cuándo y cómo.				✓
Auditorías Regulares	5. Las auditorías regulares ocurren usando listas de comprobaciones y medidas.				✓
<b>COMENTARIOS:</b>					

**5S Checklist Completed by Lab B**

**La Lista  
de Acción  
5S**

**EL LABORATORIO: LAB B**

**FECHA: Feb. 9, 2017**

<b>ORDENAR</b>					
<b>Área del Laboratorio</b>	<b>El Criterio</b>	<b>Malo</b>	<b>Satisfactorio</b>	<b>Bueno</b>	<b>Excelente</b>
Gabinetes y Estantes	1. Ningunos materiales de la referencia irrelevantes, documentos, dibujos, etc.				✓
Escritorios y Mesas	2. Ningunos materiales de la referencia irrelevantes, documentos, etc.				✓
Cajones	3. Ninguna pieza excedente de equipo, documentos, etc.			✓	
Otras Áreas de Alimentación	4. El área de almacenamiento está definida para almacenar innecesarias de elementos y documentos fechados.			✓	
Estándares de Disposición	5. Las normas para la eliminación de artículos innecesarios existen y se están siguiendo.				✓
<b>COMENTARIOS:</b>					

## Promoting Laboratory Quality Management Systems in Cuenca, Ecuador

ARREGLAR					
Área del Laboratorio	El Criterio	Malo	Satisfactorio	Bueno	Excelente
Escritorios, Estantes, y Gabinetes	1. Los escritorios y los gabinetes están libres de acumulaciones de papeles y otros objetos.			✓	
Herramientas y Equipo	2. Todas las herramientas y el equipo se almacenan en un lugar fijo.				✓
Facilidad de Tomar y Devolver	3. Las herramientas y el equipo se organizan bien para la facilidad de la toma y de la vuelta.			✓	
Etiquetas de Almacenamiento	4. El etiquetado de los gabinetes, estantes y archivos permite la identificación inmediata.			✓	
Documentos	5. Los documentos se archivan de acuerdo con las pautas de retención de registros.				✓
Áreas de Visualización	6. Las exhibiciones son ordenadas, libres de desorden, etiquetados y actualizados.			✓	
Seguridad	7. Equipo de seguridad fácilmente accesible y en buenas condiciones.				✓
<b>COMENTARIOS:</b>					

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<b>LIMPIAR</b>					
<b>Área del Laboratorio</b>	<b>El Criterio</b>	<b>Malo</b>	<b>Satisfactorio</b>	<b>Bueno</b>	<b>Excelente</b>
Piso	1. El piso se mantiene limpio y no hay señales de daños.				✓
Estructura del Edificio	2. Las paredes y los techos de están en buenas condiciones y libres de la suciedad y del polvo.				✓
Bastidores y Gabinetes	3. Los bastidores y los gabinetes de se mantienen limpios y en buenas condiciones.				✓
Equipo y Herramientas	4. El equipo y las herramientas de se mantienen limpios y en buenas condiciones.				✓
Muebles	5. Los escritorios, las tablas y otros muebles se mantienen limpios				✓
Iluminación	6. La iluminación es bastante y el ángulo y la intensidad de la iluminación son apropiados.				✓
Ventilación	7. El buen movimiento del aire existe a través de la habitación.				✓
Contenedores de Basura	8. Los contenedores de basura se vacían regularmente.				✓
<b>COMENTARIOS:</b>					

## Promoting Laboratory Quality Management Systems in Cuenca, Ecuador

<b>ESTANDARIZAR</b>					
<b>Área del Laboratorio</b>	<b>El Criterio</b>	<b>Malo</b>	<b>Satisfactorio</b>	<b>Bueno</b>	<b>Excelente</b>
Tableros de Exhibición	1. Los controles visuales y los tableros de exhibición se utilizan y se actualizan regularmente.			✓	
Procedimientos	2. Procedimientos para mantener los tres primeros S's se están mostrando.		✓		
Documentación de 5S	3. Listas de 5S, horarios y rutinas son definidos y utilizados.		✓		
Responsabilidades	4. Cada uno sabe sus responsabilidades, cuándo y cómo.				✓
Auditorías Regulares	5. Las auditorías regulares ocurren usando listas de comprobaciones y medidas.	✓			
<b>COMMENTARIOS:</b>					

4

**5S Checklist Completed by Lab C**



**EL LABORATORIO: LAB C**

**FECHA: Feb 8, 2018**

ORDENAR					
Área del Laboratorio	El Criterio	Malo	Satisfactorio	Bueno	Excelente
Gabinets y Estantes	1. Ningunos materiales de la referencia irrelevantes, documentos, dibujos, etc.		✓		
Escritorios y Mesas	2. Ningunos materiales de la referencia irrelevantes, documentos, etc.		✓		
Cajones	3. Ninguna pieza excedente de equipo, documentos, etc.				✓
Otras Áreas de Alimentación	4. El área de almacenamiento está definida para almacenar innecesarias de elementos y documentos fechados.	✓			
Estándares de Disposición	5. Las normas para la eliminación de artículos innecesarios existen y se están siguiendo.				✓
<b>COMENTARIOS:</b>					

## Promoting Laboratory Quality Management Systems in Cuenca, Ecuador

ARREGLAR					
Área del Laboratorio	El Criterio	Malo	Satisfactorio	Bueno	Excelente
Escritorios, Estantes, y Gabinetes	1. Los escritorios y los gabinetes están libres de acumulaciones de papeles y otros objetos.				✓
Herramientas y Equipo	2. Todas las herramientas y el equipo se almacenan en un lugar fijo.				✓
Facilidad de Tomar y Devolver	3. Las herramientas y el equipo se organizan bien para la facilidad de la toma y de la vuelta.				✓
Etiquetas de Almacenamiento	4. El etiquetado de los gabinetes, estantes y archivos permite la identificación inmediata.				✓
Documentos	5. Los documentos se archivan de acuerdo con las pautas de retención de registros.				✓
Áreas de Visualización	6. Las exhibiciones son ordenadas, libres de desorden, etiquetados y actualizados.				✓
Seguridad	7. Equipo de seguridad fácilmente accesible y en buenas condiciones.				✓
<b>COMENTARIOS:</b>					



<b>LIMPIAR</b>					
<b>Área del Laboratorio</b>	<b>El Criterio</b>	<b>Malo</b>	<b>Satisfactorio</b>	<b>Bueno</b>	<b>Excelente</b>
Piso	1. El piso se mantiene limpio y no hay señales de daños.				✓
Estructura del Edificio	2. Las paredes y los techos de están en buenas condiciones y libres de la suciedad y del polvo.				✓
Bastidores y Gabinetes	3. Los bastidores y los gabinetes de se mantienen limpios y en buenas condiciones.				✓
Equipo y Herramientas	4. El equipo y las herramientas de se mantienen limpios y en buenas condiciones.				✓
Muebles	5. Los escritorios, las tablas y otros muebles se mantienen limpios				✓
Iluminación	6. La iluminación es bastante y el ángulo y la intensidad de la iluminación son apropiados.				✓
Ventilación	7. El buen movimiento del aire existe a través de la habitación.				✓
Contenedores de Basura	8. Los contenedores de basura se vacían regularmente.				✓
<b>COMENTARIOS:</b>					

## Promoting Laboratory Quality Management Systems in Cuenca, Ecuador

ESTANDARIZAR					
Área del Laboratorio	El Criterio	Malo	Satisfactorio	Bueno	Excelente
Tableros de Exhibición	1. Los controles visuales y los tableros de exhibición se utilizan y se actualizan regularmente.			✓	
Procedimientos	2. Procedimientos para mantener los tres primeros S's se están mostrando.		✓		
Documentación de 5S	3. Listas de 5S, horarios y rutinas son definidos y utilizados.		✓		
Responsabilidades	4. Cada uno sabe sus responsabilidades, cuándo y cómo.				✓
Auditorías Regulares	5. Las auditorías regulares ocurren usando listas de comprobaciones y medidas.	✓			
<b>COMMENTARIOS:</b>   					

**5S Checklist Completed by Lab D**

**La Lista  
de Acción  
5S**

**EL LABORATORIO: LAB D**

**FECHA: Feb. 15, 2017**

<b>ORDENAR</b>					
<b>Área del Laboratorio</b>	<b>El Criterio</b>	<b>Malo</b>	<b>Satisfactorio</b>	<b>Bueno</b>	<b>Excelente</b>
Gabinetes y Estantes	1. Ningunos materiales de la referencia irrelevantes, documentos, dibujos, etc.				✓
Escritorios y Mesas	2. Ningunos materiales de la referencia irrelevantes, documentos, etc.				✓
Cajones	3. Ninguna pieza excedente de equipo, documentos, etc.			✓	
Otras Áreas de Alimentación	4. El área de almacenamiento está definida para almacenar innecesarias de elementos y documentos fechados.			✓	
Estándares de Disposición	5. Las normas para la eliminación de artículos innecesarios existen y se están siguiendo.				✓
<b>COMENTARIOS:</b>					

## Promoting Laboratory Quality Management Systems in Cuenca, Ecuador

ARREGLAR					
Área del Laboratorio	El Criterio	Malo	Satisfactorio	Bueno	Excelente
Escritorios, Estantes, y Gabinetes	1. Los escritorios y los gabinetes están libres de acumulaciones de papeles y otros objetos.			✓	
Herramientas y Equipo	2. Todas las herramientas y el equipo se almacenan en un lugar fijo.				✓
Facilidad de Tomar y Devolver	3. Las herramientas y el equipo se organizan bien para la facilidad de la toma y de la vuelta.			✓	
Etiquetas de Almacenamiento	4. El etiquetado de los gabinetes, estantes y archivos permite la identificación inmediata.			✓	
Documentos	5. Los documentos se archivan de acuerdo con las pautas de retención de registros.				✓
Áreas de Visualización	6. Las exhibiciones son ordenadas, libres de desorden, etiquetados y actualizados.			✓	
Seguridad	7. Equipo de seguridad fácilmente accesible y en buenas condiciones.				✓
<b>COMENTARIOS:</b>					

## Promoting Laboratory Quality Management Systems in Cuenca, Ecuador

<b>LIMPIAR</b>					
<b>Área del Laboratorio</b>	<b>El Criterio</b>	<b>Malo</b>	<b>Satisfactorio</b>	<b>Bueno</b>	<b>Excelente</b>
Piso	1. El piso se mantiene limpio y no hay señales de daños.				✓
Estructura del Edificio	2. Las paredes y los techos de están en buenas condiciones y libres de la suciedad y del polvo.				✓
Bastidores y Gabinetes	3. Los bastidores y los gabinetes de se mantienen limpios y en buenas condiciones.				✓
Equipo y Herramientas	4. El equipo y las herramientas de se mantienen limpios y en buenas condiciones.				✓
Muebles	5. Los escritorios, las tablas y otros muebles se mantienen limpios				✓
Iluminación	6. La iluminación es bastante y el ángulo y la intensidad de la iluminación son apropiados.				✓
Ventilación	7. El buen movimiento del aire existe a través de la habitación.				✓
Contenedores de Basura	8. Los contenedores de basura se vacían regularmente.				✓
<b>COMENTARIOS:</b>					

Promoting Laboratory Quality Management Systems in Cuenca, Ecuador

<b>ESTANDARIZAR</b>					
<b>Área del Laboratorio</b>	<b>El Criterio</b>	<b>Malo</b>	<b>Satisfactorio</b>	<b>Bueno</b>	<b>Excelente</b>
Tableros de Exhibición	1. Los controles visuales y los tableros de exhibición se utilizan y se actualizan regularmente.				✓
Procedimientos	2. Procedimientos para mantener los tres primeros S's se están mostrando.	✓			
Documentación de 5S	3. Listas de 5S, horarios y rutinas son definidos y utilizados.		✓		
Responsabilidades	4. Cada uno sabe sus responsabilidades, cuándo y cómo.				✓
Auditorías Regulares	5. Las auditorías regulares ocurren usando listas de comprobaciones y medidas.				✓
<b>COMMENTARIOS:</b>					

## Appendix G: Plan of Recommendation Implementation

During Focus Group 3, Lab A, B, and C completed the “plan” phase of PDSA for the implantation of the suggested inventory maintenance Excel sheets. Personnel requested to fill out this checklist reveals that they are proactive in using our recommendations in daily practice in their laboratories. Filling out this checklist with them allows them to follow a structured plan so that positives and negatives in the laboratory can be documented and measured once a change has been incorporated.

### Lista de PDSA

**LAB A**

Objetivo		Su Respuesta
<b>Planear</b>	¿Qué hará exactamente?	Vamos a implementar el sistema de inventario monitorearlo por 6 meses
	¿Quién estará involucrado y cómo?	CONFIDENTIAL INFORMATION
	¿Cuándo ocurrirá?	La actualización va a ocurrir mensualmente (cada mes)
	¿Dónde ocurrirá?	CONFIDENTIAL INFORMATION
	¿Qué medirá?	Queremos medir el stock de materiales y reactivos.
	¿Qué predice que pasará?	Vamos a facilitar la realización de pedidos y tener un registro formal de pedidos
<b>Implemente el plan y registre:</b>		
<b>Hacer</b>	¿Qué fue hecho y cuándo?	
	¿Alguna observación o problema inesperado?	
	Cotejar y comenzar a analizar los datos	
<b>Estudiar</b>	¿Cuáles fueron los resultados?	
	¿Se diferenciaron de sus expectativas? (¿Si, así pues, cómo/por qué?)	
	¿Qué ha aprendido de completar este ciclo?	
<b>A qué la acción le va ahora tomar:</b>		
<b>Actuar</b>	¿Refinar su idea de la mejora y probarla de nuevo? o	
	¿Implementarlo e incrustar el cambio? o	
	¿Rechazar la idea y prepararse para probar uno nuevo?	

# Lista de PDSA

## LAB B

Objetivo		Su Respuesta
<b>Planear</b>	¿Qué hará exactamente?	Vamos a implementar el sistema de inventario monitorearlo por 6 meses,
	¿Quién estará involucrado y cómo?	Todos los asistentes del va a actualizar datos
	¿Cuándo ocurrirá?	Cada semana para chequear Cada 15 días para el pedido
	¿Dónde ocurrirá?	<b>CONFIDENTIAL INFORMATION</b>
	¿Qué medirá?	Queremos medir el stock adecuado y queremos guardar el tiempo
	¿Qué predice que pasará?	Vamos a tener beneficios para el inventario
<b>Implemente el plan y registre:</b>		
<b>Hacer</b>	¿Qué fue hecho y cuándo?	
	¿Alguna observación o problema inesperado?	
	Cotejar y comenzar a analizar los datos	
<b>Estudiar</b>	¿Cuáles fueron los resultados?	
	¿Se diferenciaron de sus expectativas? (¿Si, así pues, cómo/por qué?)	
	¿Qué ha aprendido de completar este ciclo?	
<b>A qué la acción le va ahora tomar:</b>		
<b>Actuar</b>	¿Refinar su idea de la mejora y probarla de nuevo? o	
	¿Implementarlo e incrustar el cambio? o	
	¿Rechazar la idea y prepararse para probar uno nuevo?	



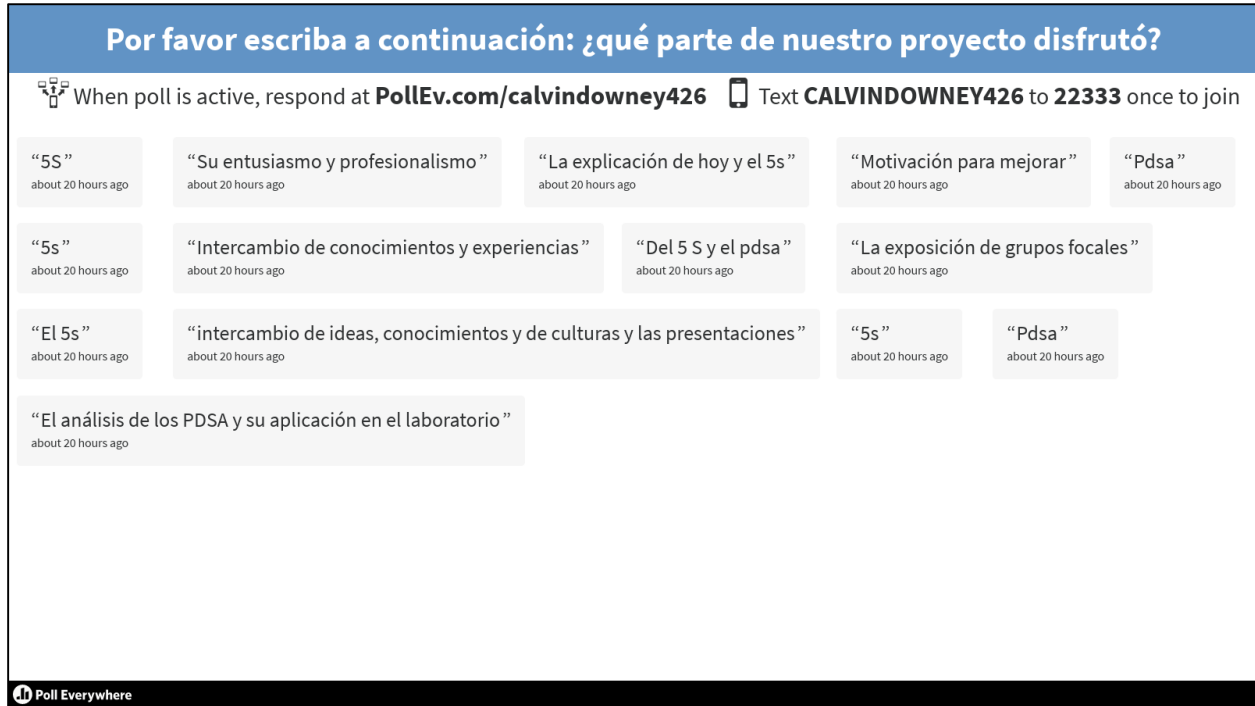
# Lista de PDSA

## LAB C

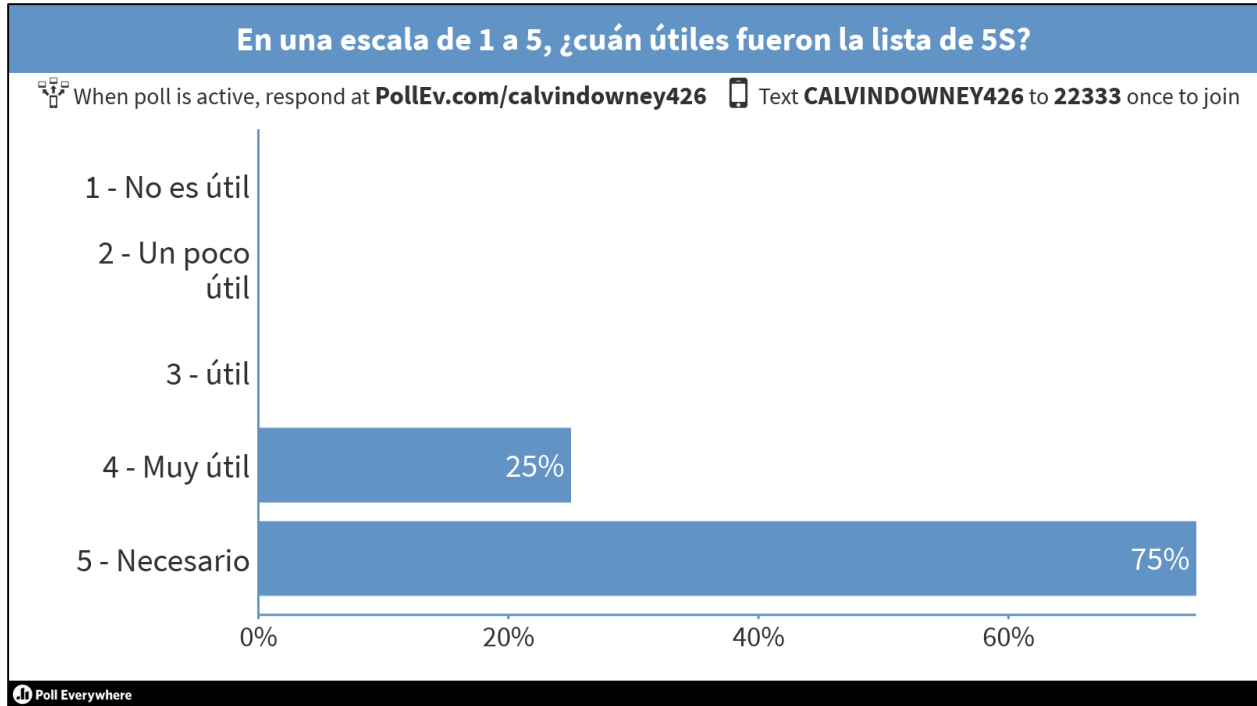
Objetivo		Su Respuesta
<b>Planear</b>	¿Qué hará exactamente?	Vamos a implementar el sistema de inventario monitorearlo por 1 año
	¿Quién estará involucrado y cómo?	Asistente de laboratorio a actualizar datos mensualmente y hacer pedidos
	¿Cuándo ocurrirá?	La actualización va a ocurrir mensualmente (cada mes)
	¿Dónde ocurrirá?	<b>CONFIDENTIAL INFORMATION</b>
	¿Qué medirá?	Queremos medir la duración y optimización del stock
	¿Qué predice que pasará?	Vamos a tener un proceso más fijo y formal que ayudará documentar nuestro inventario
<b>Hacer</b>	<b>Implemente el plan y registre:</b>	
	¿Qué fue hecho y cuándo?	
	¿Alguna observación o problema inesperado?	
	Cotejar y comenzar a analizar los datos	
<b>Estudiar</b>	¿Cuáles fueron los resultados?	
	¿Se diferenciaron de sus expectativas? (¿Si, así pues, cómo/por qué?)	
	¿Qué ha aprendido de completar este ciclo?	
<b>Actuar</b>	<b>A qué la acción le va ahora tomar:</b>	
	¿Refinar su idea de la mejora y probarla de nuevo? o	
	¿Implementarlo e incrustar el cambio? o	
	¿Rechazar la idea y prepararse para probar uno nuevo?	

## Appendix H: Results from Poll Everywhere

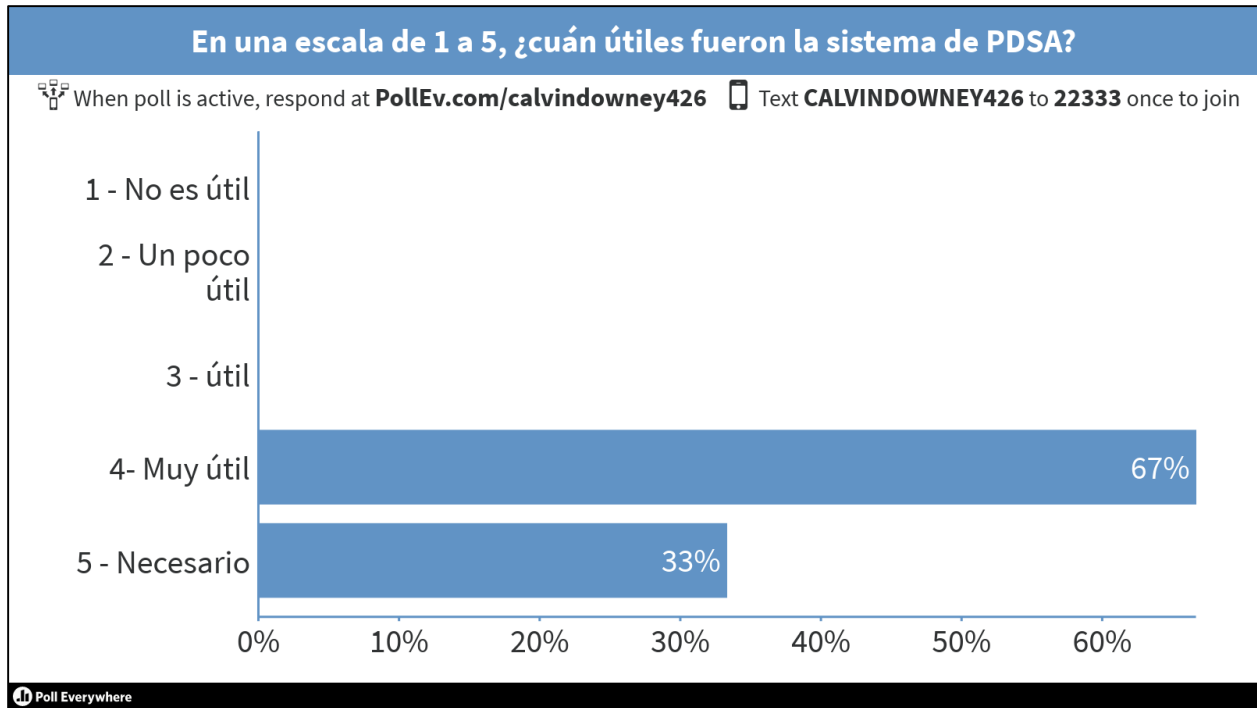
The following screenshots display the responses of the participants of our final evaluation workshop. Below each question, there is an English translation of the question, specific details regarding the question, and responses that we received.



Question	Answer
<p>Please write a response for the following: Which part of our project did you enjoy?</p>	<ul style="list-style-type: none"> <li>• 5S and PDSA</li> <li>• Your enthusiasm and professionalism</li> <li>• The explanations today and 5S</li> <li>• Motivation toward betterment</li> <li>• Exchange of knowledge and experiences</li> <li>• Focus group events</li> <li>• Exchange of ideas, knowledge, culture, and the presentations</li> <li>• The analysis of PDSA and its application to the laboratory</li> </ul>



Question	Answer
<p>On a scale of 1 to 5, how useful was the 5S Action Checklist?</p> <p>Scale:                      1: Not useful                      2: A little useful                      3: Useful                      4: Very useful                      5: Necessary</p>	<ul style="list-style-type: none"> <li>• 25% responded very useful</li> <li>• 75% responded necessary</li> </ul>



Question	Answer
<p>On a scale of 1 to 5, how useful was the system of PDSA?</p> <p>Scale:                      1: Not useful                      2: A little useful                      3: Useful                      4: Very useful                      5: Necessary</p>	<ul style="list-style-type: none"> <li>• 67% responded very useful</li> <li>• 33% responded necessary</li> </ul>

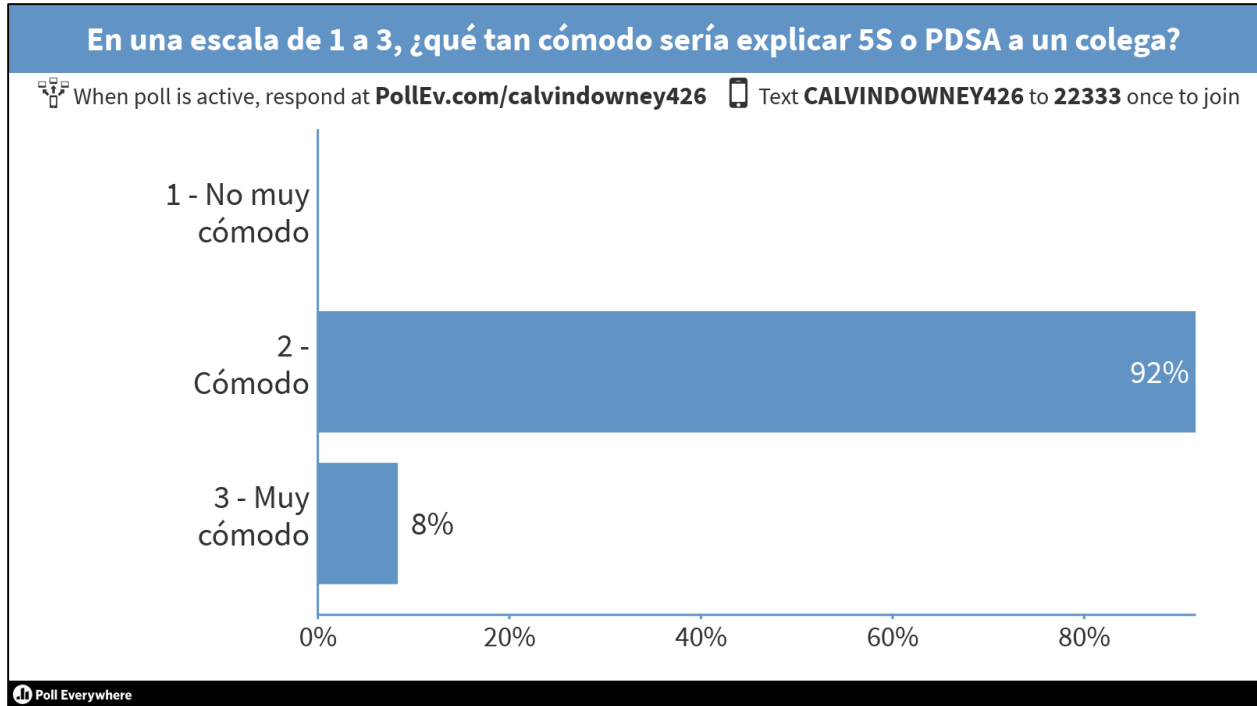
**Por favor escriba: ¿Dónde en sus procesos se puede ver la aplicación de 5S y PDSA en un futuro próximo? (EN UNA PALABRA)**

When poll is active, respond at [PollEv.com/calvindowney426](https://www.poll-ev.com/calvindowney426) Text **CALVINDOWNEY426** to **22333** once to join

A word cloud visualization of responses. The most prominent word is 'calidad' in large purple font. Other visible words include 'resultados', 'procesos', 'inventario', 'datos', 'confianza', 'satisfacción', 'procedimiento', and 'mejorar' in various sizes and colors (green, blue, purple).

Poll Everywhere

Question	Answer
Please write about the following: Where in your processes can you see the application of 5S and PDSA in the future? (in one word)	<ul style="list-style-type: none"> <li>• Results</li> <li>• Processes/Procedure</li> <li>• Inventory</li> <li>• Results</li> <li>• Trust</li> <li>• Satisfaction</li> <li>• Betterment</li> <li>• Quality</li> </ul>



Question	Answer
<p>On a scale of 1 to 3, how comfortable would you be in explaining 5S or PDSA to a colleague?</p> <p>Scale:                      1: Not very comfortable                      2: Comfortable                      3: Very comfortable</p>	<ul style="list-style-type: none"> <li>• 92% answered comfortable</li> <li>• 8% answered very comfortable</li> </ul>

**¿Cuál sería su objetivo para formar un consorcio? ¿Cuáles son algunos resultados positivos para la calidad, las finanzas y la imagen pública?**

Respond at [PollEv.com/calvindowney426](https://poll-ev.com/calvindowney426)  
Text **CALVINDOWNEY426** to **22333** once to join, then text your message

“Calidad”  
1 day ago

“Brindar mejor atención en lo referente a la calidad de atención a los paciente”  
1 day ago

“Acreditación”  
1 day ago

“Certeza”  
1 day ago

“La unión hace la fuerza. Un consorcio puede brindar mejor servicio a la comunidad”  
1 day ago

“Confiabilidad”  
1 day ago

“Confianza en resultados.”  
1 day ago

“Responsabilidad”  
1 day ago

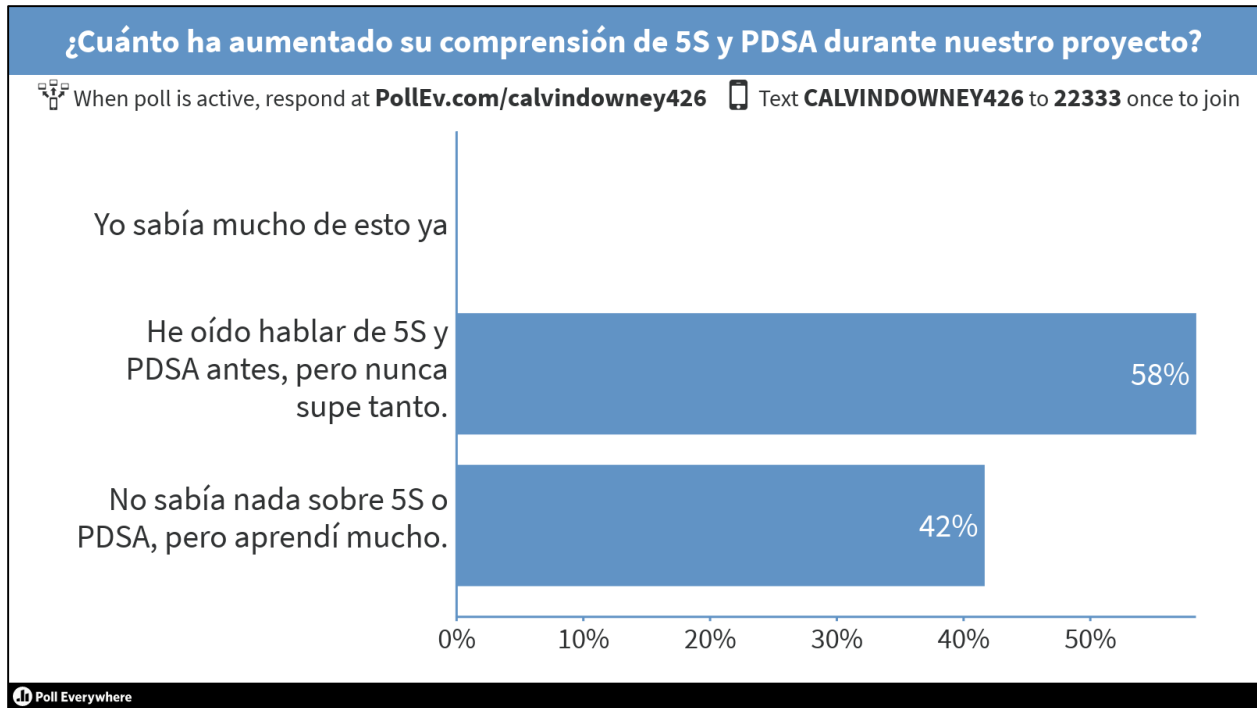
“Servicio integral”  
1 day ago

“reditos economicos y brindar el un servicio completo a la ciudadanía”  
1 day ago

“Calidad en resultados”  
1 day ago

Poll Everywhere

Question	Answer
<p>What would be your objective in forming a consortium? What are some positive results for quality, finances, and the public image?</p>	<ul style="list-style-type: none"> <li>• Quality</li> <li>• To provide better care in terms of the quality of patient care</li> <li>• Quality in results</li> <li>• Economic merits and provide full service to citizens</li> <li>• Certainty</li> <li>• Accreditation</li> <li>• Trust in results</li> <li>• Reliability</li> <li>• With a union comes strength. A consortium can provide better service to the community</li> <li>• Integral service</li> </ul>

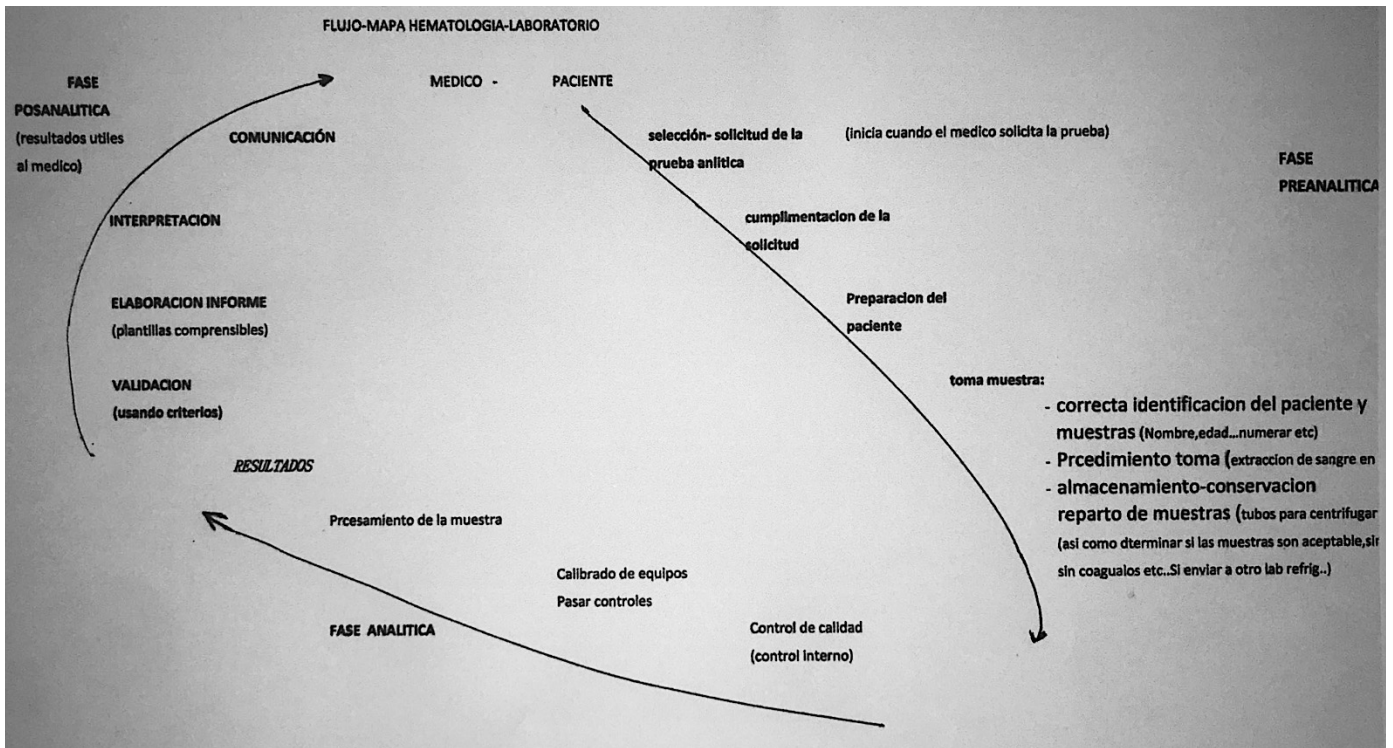


Question	Answer
<p>How much has your comprehension of 5S or PDS increased during our project?</p> <p>Answer Choices:                      “I had known about most of it already”                      “I had heard of 5S and PDSA before but never knew a lot about them”                      “I had known nothing about 5S or PDSA but I learned a lot”</p>	<ul style="list-style-type: none"> <li>• 58% answered “I had heard of 5S and PDSA before but never knew a lot about them”</li> <li>• 42% answered “I had known nothing about 5S or PDSA but I learned a lot”</li> </ul>



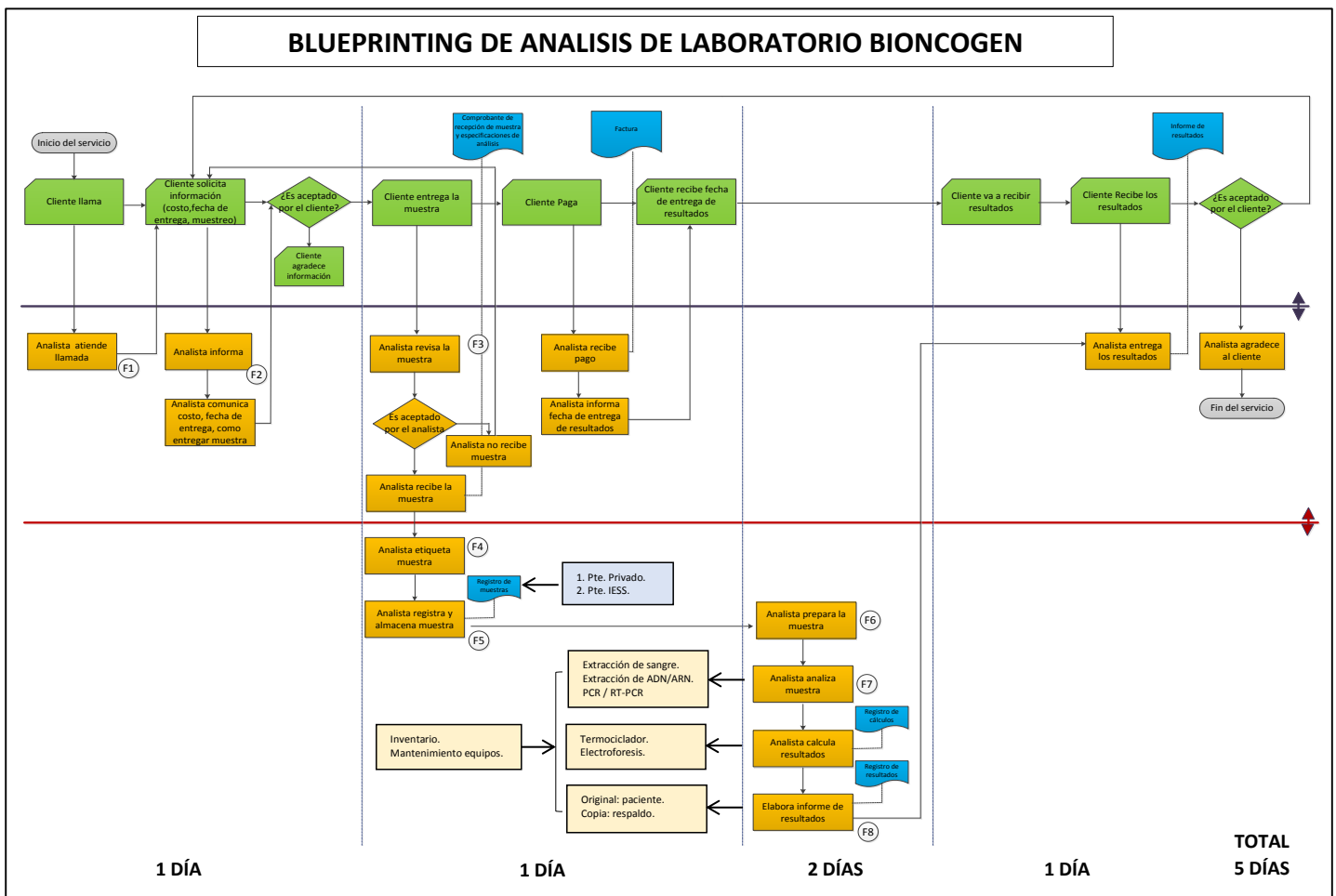
### Appendix I: Lab C's Recreation of Value Stream Map

Personnel from Lab C created their own version of a VSM to describe their workflow. In the VSM, they highlight the three phases of work in significant detail.



### Appendix J: Lab A's Recreation of VSM and Troubleshoot Chart

After attending Focus Group 1, in which we presented the laboratory with the VSM that we created after our observations, one of the personnel working at Lab A created her own VSM and well as a troubleshoot chart for the lab (see below). With the VSM and chart that was created by Lab A, we immediately interpreted that Focus Group 1 was a success as it motivated the laboratory personnel to further analyze their performance and make an effort to improve their quality. The VSM illustrates all 3 processes of work in the laboratory (pre-analytical, analytical, and post-analytical). On the VSM, the personnel added symbols (F1-F8), which correlate with the troubleshoot chart, to highlight processes that can be identified as weak areas in the laboratory. The troubleshoot chart goes into further detail about each weak area and provides information on the following: a description of the inefficiency, the effect of the inefficiency, the cause of the inefficiency, and finally measures that can be implemented to improve the laboratory's performance in such weak areas.



## Promoting Laboratory Quality Management Systems in Cuenca, Ecuador

No.	MODO	EFEECTO	CAUSA	PCC O MEDIDAS
F1: Analista atiende llamada	El cliente recibe una mala atención por parte del analista.	Cliente inconforme.	Analista realiza varias actividades al mismo tiempo.	M1: Capacitación sobre atención al cliente. M2: Contratar asistente.
F2: Analista informa	El cliente no recibe la suficiente información de su requerimiento.	Cliente descarta el servicio.	No se dispone de información clara y precisa sobre los análisis.	M1: Colocar lista de precios de análisis prestados. M2: Implementar calendario de recepción de muestras.
F3: Analista revisa la muestra	Analista recibe la muestra en malas condiciones.	Resultados inválidos.	No existe protocolo para recepción de muestras.	PCC: Inspeccionar procedimiento de recepción de muestras. M1: Implementar un protocolo de recepción de muestras.
F4: Analista etiqueta la muestra	Analista no coloca toda la información en la etiqueta de la muestra.	Etiqueta con datos faltantes.	Analista no sigue procedimiento correcto para el etiquetado.	M1: Establecer un sistema de verificación de etiquetas. M2: Exhibir formato de llenado de etiqueta.
F5: Analista registra y almacena la muestra	Analista no completa la información el registro de muestras que ingresan al laboratorio y no almacena adecuadamente la muestra.	Incompleto análisis de muestras. Pérdida de muestras. Contaminación cruzada.	Analista no pone atención durante el registro y almacenamiento de muestras.	PCC: Inspección al protocolo de recepción y almacenamiento de muestras.

F6: Analista prepara la muestra	Analista no cumple con el protocolo para preparación de la muestra.	Muestras inadecuadas para el análisis. Resultados no confiables	Exceso en el número de muestras a analizar por día.	PCC: Establecer un protocolo de verificación para preparación de muestra. M1. Determinar un límite de muestras para ser analizadas en el día.
F7: Analista analiza la muestra	Analista no sigue el método analítico.	Resultados falsos, no confiables.	Excesiva cantidad de muestras para ser analizadas el mismo día. No revisa método analítico a utilizar.	M1. Mantener al alcance los métodos analíticos. M2. Determinar un límite de muestras para ser analizadas en el día.
F8: Elaboración informe de resultados	Analista no verifica los resultados antes de imprimir informe.	Informe erróneo. Cliente inconforme	Excesiva cantidad de informes por entregar.	PCC: Revisión minuciosa de los datos que deben constar en el informe. M1: Determinar un límite de resultados a entregar.

## Appendix K: Patient Test Request Form for Lab C

The documents below were created for Lab C minimize the amount of manual paper that the laboratory needs to fill out, refer to, and store on a daily basis. This form was created using Adobe Acrobat Pro DC using the physical patient test request form as a guide. The reasoning behind minimizing paperwork is to reduce waste and to have documents stored and available for reference in one central location – the laboratory computer. Ideally, this patient test request form would be filled out by Dr. Moreno when a patient is in need of medical testing in his laboratory. When filled out electronically, he would be able to create a hyperlink to this form in the “Patient Record” Microsoft Excel sheet. Then, laboratory technicians in the laboratory (below his office) would be able to access them and attend the patient as soon as he/she visits the laboratory.

CONFIDENTIAL INFORMATION

Fecha:  Dr.(a):

Paciente:  Tel.:  Sexo:  Edad:

Historia Clínica:

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<p><b>HEMATOLOGIA</b></p> <p><input type="checkbox"/> Biometría</p> <p><input type="checkbox"/> Hemograma de Schilling</p> <p><input type="checkbox"/> Eritrosedimentación (VSG) Reticulocitos</p> <p><input type="checkbox"/> Haptoglobina</p> <p><input type="checkbox"/> Hierro, Captación, Saturación</p> <p><input type="checkbox"/> Ferritina</p> <p><input type="checkbox"/> Acido Fólico y Vitamina B12</p> <p><input type="checkbox"/> Grupo Sanguíneo y Factor Rh</p> <p><input type="checkbox"/> Estudio de Madurez de Líquido Amniótico</p> <p><input type="checkbox"/> Hemoglobina F</p> <p><input type="checkbox"/> Coombs Directo (DAT)</p> <p><input type="checkbox"/> Coombs Indirecto (IAT)</p> <p><input type="checkbox"/> Eluciones</p> <p><input type="checkbox"/> Crioaglutininas</p> <p><input type="checkbox"/> Células Falciformes</p> <p><input type="checkbox"/> Parásitos en Sangre</p> <p><input type="checkbox"/> Células L. E.</p> <p><input type="checkbox"/> Hemoglobina Glicosilada</p> <p><input type="checkbox"/> Fructosamina</p> <p><input type="checkbox"/> Glucosa-6-Fostato Heshidrogenasa</p> <p><input type="checkbox"/> Test de Hemólisis de Sucrosa</p> <p><input type="checkbox"/> Test de Ham</p> <p><input type="checkbox"/> Metahemoglobina</p> <p><input type="checkbox"/> Hemosiderina</p> <p><input type="checkbox"/> Electroforesis de Hemoglobina Fragilidad</p> <p><input type="checkbox"/> Osmótica</p> <p><input type="checkbox"/> Eosinófilos Nasales</p> <p><input type="checkbox"/> Citoquímico <input type="checkbox"/> S.P. <input type="checkbox"/> M.O.</p> <p><input type="checkbox"/> Inmunofenotipo <input type="checkbox"/> S.P. <input type="checkbox"/> M.O.</p> <p><input type="checkbox"/> Citogenética <input type="checkbox"/> S.P. <input type="checkbox"/> M.O.</p>	<p><b>QUIMICA Y ELECTROLITOS</b></p> <p><input type="checkbox"/> Glucosa</p> <p><input type="checkbox"/> Sodio</p> <p><input type="checkbox"/> Potasio</p> <p><input type="checkbox"/> Cloro</p> <p><input type="checkbox"/> CO2</p> <p><input type="checkbox"/> Urea</p> <p><input type="checkbox"/> BUN</p> <p><input type="checkbox"/> Creatinina</p> <p><input type="checkbox"/> Colesterol</p> <p><input type="checkbox"/> Triglicéridos</p> <p><input type="checkbox"/> HDL/LDL Colesterol</p> <p><input type="checkbox"/> Calcio <input type="checkbox"/> Total <input type="checkbox"/> Iónico</p> <p><input type="checkbox"/> Fósforo</p> <p><input type="checkbox"/> Magnesio</p> <p><input type="checkbox"/> Acido Úrico</p> <p><input type="checkbox"/> Billirumbinas</p> <p><input type="checkbox"/> Tolerancia a la Glucosa</p> <p><input type="checkbox"/> Tolerancia a la Glucosa Embarazadas</p> <p><input type="checkbox"/> Glucosa Postprandial</p> <p><input type="checkbox"/> Alcohol</p> <p><input type="checkbox"/> Electrolitos en Sudor (Na/Cl)</p> <p><input type="checkbox"/> Saturación de O2/Hb</p> <p><input type="checkbox"/> Clearance</p> <p><input type="checkbox"/> Exercción Fraccionada</p> <p><input type="checkbox"/> Osmolaridad <input type="checkbox"/> Suero <input type="checkbox"/> Orina</p> <p><input type="checkbox"/> Gasometría <input type="checkbox"/> Arterial <input type="checkbox"/> Venosa</p>	<p><b>HORMONAS</b></p> <p><input type="checkbox"/> TSH</p> <p><input type="checkbox"/> T3 Libre</p> <p><input type="checkbox"/> T4 Libre</p> <p><input type="checkbox"/> Anti TPO</p> <p><input type="checkbox"/> Tiroglobulina</p> <p><input type="checkbox"/> LH</p> <p><input type="checkbox"/> FSH</p> <p><input type="checkbox"/> Prolactina</p> <p><input type="checkbox"/> Estradiol (Estrógeno)</p> <p><input type="checkbox"/> 17 (OH) Progesterona</p> <p><input type="checkbox"/> Progesterona</p> <p><input type="checkbox"/> Beta hCG (BHCG Cualitativa)</p> <p><input type="checkbox"/> Beta hCG (BHCG Cuantitativa)</p> <p><input type="checkbox"/> Estriol</p> <p><input type="checkbox"/> Cortisol AM - PM</p> <p><input type="checkbox"/> Hormona del Crecimiento (HGH)</p> <p><input type="checkbox"/> Testosterona Total</p> <p><input type="checkbox"/> Paratohormona (PTH)</p> <p><input type="checkbox"/> Insulina Basal</p> <p><input type="checkbox"/> Dehidroepiandrosterona (DHEAS)</p> <p><input type="checkbox"/> Péptido C</p> <p><input type="checkbox"/> IGF - BPS</p>
<p><b>COAGULACION</b></p> <p><input type="checkbox"/> Control de Anticoagulantes (TP-INR)</p> <p><input type="checkbox"/> Tiempo de Protombina (TP)</p> <p><input type="checkbox"/> Tiempo de Coagulación</p> <p><input type="checkbox"/> T. Thromboplastina Parcial (aTPT)</p> <p><input type="checkbox"/> Fibrinógeno</p> <p><input type="checkbox"/> Tiempo de Trombina (TT)</p> <p><input type="checkbox"/> Contaje de Plaquetas</p> <p><input type="checkbox"/> Tiempo de Sangre</p> <p><input type="checkbox"/> Retracción de Coágulo</p> <p><input type="checkbox"/> Rumpel-Leede</p> <p><input type="checkbox"/> Anticoagulante Lúpico</p> <p><input type="checkbox"/> Antitrombina III, Proteína C, Proteína S</p> <p><input type="checkbox"/> Lisis de Euglobulinas</p> <p><input type="checkbox"/> Productos de Degradación Fibrinógeno</p> <p><input type="checkbox"/> Dímero</p>	<p><b>ENZIMAS</b></p> <p><input type="checkbox"/> TGO (AST)</p> <p><input type="checkbox"/> TGP (ALT)</p> <p><input type="checkbox"/> Fosfatasa Alcalina</p> <p><input type="checkbox"/> Gamma Glutamil</p> <p><input type="checkbox"/> Transpeptidasa (GGT)</p> <p><input type="checkbox"/> Deshidrogenasa Láctica (DHL)</p> <p><input type="checkbox"/> Amilasa</p> <p><input type="checkbox"/> Lipasa</p> <p><input type="checkbox"/> Troponina</p> <p><input type="checkbox"/> CK</p> <p><input type="checkbox"/> CK- MB</p> <p><input type="checkbox"/> Colinesterasa</p> <p><input type="checkbox"/> Mioglobina</p>	<p><b>MARCADORES TUMORALES</b></p> <p><input type="checkbox"/> Alfa Fetoproteína (AFP)</p> <p><input type="checkbox"/> Antígeno Carcino Embrionario (CEA)</p> <p><input type="checkbox"/> Beta hGC</p> <p><input type="checkbox"/> Fosfatasa Acida <input type="checkbox"/> Total <input type="checkbox"/> Prostática</p> <p><input type="checkbox"/> Antígeno Prostático Especifico Total (PSA)</p> <p><input type="checkbox"/> Antígeno Prostático Especifico Libre (PSA)</p> <p><input type="checkbox"/> CA 125</p> <p><input type="checkbox"/> Ferritina</p>

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<p><b>PROTEINAS</b></p> <p><input type="checkbox"/> Proteínas</p> <p><input type="checkbox"/> Albúmina</p> <p><input type="checkbox"/> Globulina</p> <p><input type="checkbox"/> Preatbúmina</p> <p><input type="checkbox"/> Electroforesis de Proteínas</p> <p><input type="checkbox"/> Suero <input type="checkbox"/> Orina</p> <p><input type="checkbox"/> Immunolectroforesis</p> <p><input type="checkbox"/> Suero <input type="checkbox"/> Orina</p> <p><b>REACTANTES DE FASE AGUADA/ SOROLOGIA/ANTICUERPOS</b></p> <p><b>VIRALES Y PARASITARIO</b></p> <p><input type="checkbox"/> Proteína C Reactiva</p> <p><input type="checkbox"/> Factor Reumatoideo (FR)</p> <p><input type="checkbox"/> ASTO</p> <p><input type="checkbox"/> VDRL/RPR</p> <p><input type="checkbox"/> FTA-ABS</p> <p><input type="checkbox"/> Widal y Weil Felix</p> <p><input type="checkbox"/> Brucella Abortus (Huddleson)</p> <p><input type="checkbox"/> Epstein - Barr <input type="checkbox"/> IgG <input type="checkbox"/> IgM</p> <p><input type="checkbox"/> Citomegalovirus <input type="checkbox"/> IgG <input type="checkbox"/> IgM</p> <p><input type="checkbox"/> Toxoplasma <input type="checkbox"/> IgG <input type="checkbox"/> IgM</p> <p><input type="checkbox"/> Rubéola <input type="checkbox"/> IgG <input type="checkbox"/> IgM</p> <p><input type="checkbox"/> Herpes 1 <input type="checkbox"/> IgG <input type="checkbox"/> IgM</p> <p><input type="checkbox"/> Herpes 2 <input type="checkbox"/> IgG <input type="checkbox"/> IgM</p> <p><input type="checkbox"/> VIH 1 y 2, ELISA screening</p> <p><input type="checkbox"/> Western Blot</p> <p><input type="checkbox"/> Sífilis <input type="checkbox"/> IgG <input type="checkbox"/> IgM</p> <p><input type="checkbox"/> HIV: Carga Viral</p> <p><input type="checkbox"/> Hepatitis A (anti HAV IgM)</p> <p><input type="checkbox"/> Hepatitis B (HBsAg, anti-HBs, Anti-HBc)</p> <p><input type="checkbox"/> Total, HBeAg, anti-HBe</p> <p><input type="checkbox"/> Hepatitis C (anti-HCV)</p> <p><input type="checkbox"/> Mycoplasma</p> <p><input type="checkbox"/> Coxiella Burnetti</p> <p><input type="checkbox"/> Legionella</p> <p><input type="checkbox"/> Chlamydia Psittasi</p> <p><input type="checkbox"/> Virus Sincitial Respiratorio</p> <p><input type="checkbox"/> Chagas</p> <p><input type="checkbox"/> Tularemia</p> <p><input type="checkbox"/> Lyme</p> <p><input type="checkbox"/> Helicobacter pylori</p> <p><input type="checkbox"/> Cysticercosis <input type="checkbox"/> IgG <input type="checkbox"/> IgM</p> <p><input type="checkbox"/> Ameba Histolitica</p>	<p><b>INMUNOLOGIA</b></p> <p><input type="checkbox"/> C3</p> <p><input type="checkbox"/> C4</p> <p><input type="checkbox"/> Anticuerpos Antinucleares (ANA)</p> <p><input type="checkbox"/> Anti-DNA-Nativo (ds)</p> <p><input type="checkbox"/> Anti-ENA-Sm-NRP</p> <p><input type="checkbox"/> Anti Ro (SSA) - La (SSB)</p> <p><input type="checkbox"/> Anti Sol 70</p> <p><input type="checkbox"/> c-ANCA</p> <p><input type="checkbox"/> p-ANCA</p> <p><input type="checkbox"/> Anticuerpos Anticardiolipina</p> <p><input type="checkbox"/> Anticuerpos Anticentómero</p> <p><input type="checkbox"/> IgE Total</p> <p><input type="checkbox"/> Western Blot</p> <p><input type="checkbox"/> FTA-ABS</p> <p><input type="checkbox"/> Anti Músculo Liso</p> <p><input type="checkbox"/> Anti Reticulina</p> <p><input type="checkbox"/> Anti Células Parietales</p> <p><input type="checkbox"/> Anti Mitocondriales</p> <p><input type="checkbox"/> Anti Plaquetarios</p> <p><input type="checkbox"/> Anti Neutrófilos</p> <p><input type="checkbox"/> Ig de Superficie Linfocitos B</p> <p><input type="checkbox"/> Ig Intracitoplasmáticos</p> <p><input type="checkbox"/> Anti Epidermis</p> <p><input type="checkbox"/> Anti Tiroides</p> <p><input type="checkbox"/> Anti Espermatozoides</p> <p><input type="checkbox"/> Inmunocomplejos Circulantes</p> <p><input type="checkbox"/> Quimiotaxis de PMN</p> <p><input type="checkbox"/> Fagocitosis de MN</p> <p><input type="checkbox"/> Test NBT</p> <p><input type="checkbox"/> Subpoblaciones infocitarias</p> <p><input type="checkbox"/> HLAB 27</p> <p><input type="checkbox"/> HLAB/DR</p> <p><input type="checkbox"/> HLab/ABC</p> <p><b>ORINA</b></p> <p>Muestra <input type="checkbox"/> Horas <input type="checkbox"/></p> <p><input type="checkbox"/> Elemental y Microscópico (EMO)</p> <p><input type="checkbox"/> Sedimento Urinario</p> <p><input type="checkbox"/> Gota Fresca</p> <p><input type="checkbox"/> Thayer Martin</p> <p><input type="checkbox"/> Prueba de embarazo</p> <p><input type="checkbox"/> Proteínas de Bence Jones</p> <p><input type="checkbox"/> Densidad Urinaria</p> <p><input type="checkbox"/> Sodio en Orina</p> <p><input type="checkbox"/> Potasio en Orina</p> <p><input type="checkbox"/> Creatinina en Orina</p> <p><input type="checkbox"/> Nitrógeno Ureico en Orina</p> <p><input type="checkbox"/> Calcio en Orina</p> <p><input type="checkbox"/> Fósforo en Orina</p> <p><input type="checkbox"/> Amilasa en Orina</p> <p><input type="checkbox"/> Fenilcetonuria</p> <p><input type="checkbox"/> Invest. de Ac. Hemogentísico</p> <p><input type="checkbox"/> Mioglobinauria</p> <p><input type="checkbox"/> Cistina en Orina</p> <p><input type="checkbox"/> Microalbuminuria</p>	<p><b>COPROANALISIS Y MALABSORCION</b></p> <p><input type="checkbox"/> Coproparasitario Seriado x 3</p> <p><input type="checkbox"/> Coproparasitario en Fresco, Simple</p> <p><input type="checkbox"/> Coproparasitario en Fresco, Concentrado</p> <p><input type="checkbox"/> Leucocitos en Heces</p> <p><input type="checkbox"/> pH</p> <p><input type="checkbox"/> Azúcares Reductores</p> <p><input type="checkbox"/> Sangre Oculta</p> <p><input type="checkbox"/> Actividad Triptica</p> <p><input type="checkbox"/> Adenovirus</p> <p><input type="checkbox"/> Criptosporidium</p> <p><input type="checkbox"/> Curva de Tolerancia a la Lactosa</p> <p><b>LIQUIDOS</b></p> <p><input type="checkbox"/> LC <input type="checkbox"/> Citoquímico <input type="checkbox"/> Bacteriológico</p> <p><input type="checkbox"/> Pleural <input type="checkbox"/> Citoquímico <input type="checkbox"/> Bacteriológico</p> <p><input type="checkbox"/> Ascítico <input type="checkbox"/> Citoquímico <input type="checkbox"/> Bacteriológico</p> <p><input type="checkbox"/> Pericárdio <input type="checkbox"/> Citoquímico <input type="checkbox"/> Bacteriológico</p> <p><input type="checkbox"/> Sinovial <input type="checkbox"/> Citoquímico <input type="checkbox"/> Bacteriológico</p> <p><b>MICROBIOLOGIA</b></p> <p>Muestra tomada de: <input type="text"/></p> <p><input type="checkbox"/> Estudio en fresco</p> <p><input type="checkbox"/> Gram</p> <p><input type="checkbox"/> Ziehl-Neelsen</p> <p><input type="checkbox"/> Cultivo</p> <p><input type="checkbox"/> Antibiograma</p> <p><input type="checkbox"/> PCR</p> <p><b>OTROS</b></p> <div style="border: 1px solid black; height: 80px; width: 100%;"></div>
<p><b>USO INTERNO DE LABORATORIO:</b></p> <p>Forma de Pago: <input type="text"/></p> <p>Nombres y Apellidos: <input type="text"/></p> <p>R.U.I.C. / C.I.: <input type="text"/> Dirección: <input type="text"/></p> <p>Teléfono: <input type="text"/> Costo (\$): <input type="text"/></p> <p>Código: <input type="text"/></p>		

### Appendix L: Patient Record Excel Sheet for Lab C

The Patient Record Excel sheet below (filled out with sample/false information) was designed for Lab C to further minimize their dependence of physical paperwork to keep records of patients. Having an electronic patient record is more reliable as it provides easy, yet secure, access to patient information (identity, test requests, and results). The test requests and results are intended to be filled out using hyperlinks that will directly lead to the patient test request form and the results form.

Patient Number	Date	Patient Full Name	Patient Contact Information	Gender	Age	Patient ID	Doctor of Reference	Tests Request	Results	Price	Observations
Código del Paciente	Fecha	Nombre Completo	Número de Teléfono	Edad	Sexo	Cédula	Médico Solicitante	Pruebas Necesarias	Resultados	Valor	Observaciones

## Appendix M: Inventory Maintenance Excel Sheets for All Laboratories

The Excel sheet below can be used to keep a record of what materials and supplies are available in the laboratories and which ones need to be ordered. To use this inventory maintenance sheet, the laboratory personnel will add every item that needs to be repurchased. On a weekly basis, when one updates this checklist with the new quantity of items that are available, the Excel sheet with automatically update and indicate which item needs to be reordered (item name, quantity, price) once the quantity falls below the minimum desired/required supplies by changing the cells from blue to red. This Excel sheet is useful to keep a real-time record of available and insufficient supplies in the laboratory. It will also help in prevent under- and over-ordering of items.

### INVENTARIO - CONTROL DE LA RESERVA

ESTADO ACTUAL (relleno automático)	FECHA DE ÚLTIMO DE ORDEN	NOMBRE DEL ARTÍCULO	VENDEDOR	DESCRIPCIÓN DEL ARTÍCULO	COSTE POR ARTÍCULO	CANTIDAD DE LA RESERVA	COSTE DE ORDEN	NIVEL DE NUEVO PEDIDO	CANTIDAD DE ORDEN DEL ARTÍCULO
BIEN	5/20/16	ITEM A	Cole	Item A description	\$10.00	200	\$1,000.00	50	100
BIEN	5/20/16	ITEM B	Cole	Item B description	\$20.00	100	\$400.00	50	20
ORDENAR	5/20/16	ITEM C	Cole	Item C description	\$30.00	45	\$1,500.00	50	50
ORDENAR	5/20/16	ITEM D	Cole	Item D description	\$10.00	40	\$100.00	50	10
BIEN	5/20/16	ITEM E	Cole	Item E description	\$20.00	75	\$2,000.00	50	100
BIEN	5/20/16	ITEM F	Cole	Item F description	\$30.00	100	\$600.00	50	20
ORDENAR	5/20/16	ITEM G	Cole	Item G description	\$10.00	10	\$500.00	50	50
BIEN	5/20/16	ITEM H	Cole	Item H description	\$20.00	60	\$200.00	50	10
BIEN							\$0.00		
BIEN							\$0.00		
BIEN							\$0.00		
BIEN							\$0.00		
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## Promoting Laboratory Quality Management Systems in Cuenca, Ecuador

The Excel sheet below is designed to be used when supplied need to be ordered. Because the ordering list is electronic, the laboratory can easily maintain a record of what supplies have been ordered at a given date.

INVENTARIO - PAPEL DE LA RESERVA DEL ARTÍCULO				
NOMBRE DE SU LABORATORIO				
INFORMACIÓN DEL ARTÍCULO				
VENDEDOR	NOMBRE Y DESCRIPCIÓN DEL ARTÍCULO	CANTIDAD DEL ARTÍCULO	COSTE POR ARTÍCULO	PRECIO TOTAL
INFORMACIÓN DEL EMPLEADO				
FECHA _____				
FIRMA DEL EMPLEADO _____				



Promoting Laboratory Quality Management Systems in Cuenca, Ecuador

The Excel sheet below can be used by the laboratories to keep a running list of vendors they contact when ordering new supplies. Having an electronic version reduces the need of have a physical phone book and also allows easy updates of contact information.

INVENTARIO - LISTA DEL VENDEDOR							
NOMBRE DEL VENDEDOR	EL ENLACE	NOMBRE DE CONTACTO	CORREO	NUMERO DE TELÉFONO	LA DIRRECIÓN POSTAL	CIUDAD	PAÍS
Cole	<a href="http://www.cole.com/itemA">www.cole.com/itemA</a>	Ms. Kelly Thomas	<a href="mailto:kelly@cole.com">kelly@cole.com</a>	321-456-7890	123 Main Street	Cuenca	Ecuador

### Appendix N: Electronic Payment Receipt for Patients at Lab C

The document below is designed to be used as an electronic payment receipt that Lab C can give to its patients. This receipt can be used whether the payment is pending or completed. Lab C requested us to create this for them after we presented our original set of recommendations to them in Focus Group 2. We are very grateful that Lab C actively participated and put forth a collaborative effort to self-report areas that could be improved in the laboratory.

<b>CONFIDENTIAL INFORMATION</b>	Fecha :														
	Médico :														
	<b>Paciente</b>														
	Nombre :														
Correo: hematologia.laboratorio@yahoo.com	Cedula :														
Consultorios Santa Ines Torre I, Consultorio #003	Correo :														
Cuenca-Ecuador	Celular :														
<table border="1" style="width: 100%; border-collapse: collapse;"> <thead> <tr style="background-color: #4F81BD; color: white;"> <th style="width: 15%;">Cantidad</th> <th style="width: 45%;">Descripción del Examen</th> <th style="width: 20%;">Precio por un Examen</th> <th style="width: 20%;">Precio por Todos Exámenes</th> </tr> </thead> <tbody> <tr> <td style="height: 100px;"></td> <td></td> <td></td> <td></td> </tr> <tr> <td style="text-align: center;">X</td> <td style="text-align: center;">Firma del Empleado</td> <td style="text-align: center;"><b>Precio Total</b></td> <td></td> </tr> </tbody> </table>				Cantidad	Descripción del Examen	Precio por un Examen	Precio por Todos Exámenes					X	Firma del Empleado	<b>Precio Total</b>	
Cantidad	Descripción del Examen	Precio por un Examen	Precio por Todos Exámenes												
X	Firma del Empleado	<b>Precio Total</b>													

### Appendix O: Equipment Maintenance Excel Sheet for Lab B and C

The document below is designed to be used as equipment maintenance that Lab B and C can use to keep record of the weekly and monthly maintenance checks that they perform. In this Excel sheet, personnel from Lab C can electronically record 2 types of information: 1) information about the specific equipment (machine name, serial number, company, etc.), and 2) information about the weekly and monthly maintenance checks (date, description of maintenance check, employee name, date of next maintenance check, etc.).

Mantenimiento de Equipos						
Nombre del Equipo:						
La Etiqueta:						
El Número de Serie:						
El Fabricante:						
El Contacto del Fabricante:						
Fecha de Compra:						
Fecha de Puesta en Servicio:						
Persona Responsable del Equipo:						
Iniciales de la Persona:						
Lugar del Equipo:						
Condición Física:						
Proveedor de servicios (para mantenimiento y calibración):						
Persona de contacto del proveedor de servicios y datos de contacto:						
Frecuencia de Mantenimiento:						
Fecha:	Descripción del Mantenimiento:	Mantenimiento Realizado Por:	Fecha de Validación Antes de Puesta en Servicio:	Validación Realizado Por:	Fecha de Mantenimiento Proximo:	Observaciones: