TIBA-VENT: A Case Study on the Application of Invention Education at Kenyatta University

Step 1: Proof of Concept and Prototyping

A team of 15 innovators from the Schools of Engineering & Architecture and Health Sciences at Kenyatta University developed a mechanical ventilator to address the clinical challenges during the COVID-19 pandemic. The initiative was approved and supported by the Dean of the School of Engineering and Architecture and by the Kenyatta University leadership team. A team of mentors was identified from the same schools and Chandaria Business Innovation and Incubation Centre (CBIIC) to guide the innovators through the engineering design process that included extensive proof of concept and prototyping for the high fidelity minimal viable product. The Schools of Engineering & Architecture and Health Sciences at Kenyatta University provided technical mentorship while CBIIC provided mentorship on intellectual property and market pathways.

Prior to the COVID pandemic, Kenya did not have standards for ventilators and relied on the European Union (EU) standards. The TIBA-Vent team used the EU Medical Device Directive standards for ventilator specifications. Following the development of TIBA-Vent, Kenya Bureau of Standards (KEBS) approved a set of standards for ventilators intended for use in critical care in 2020.

Step 2: Attaining KEBS Certification

The Pharmacy and Poisons Act Chapter 244 of 2002 designates The Pharmacy and Poisons Board (PPB) as the regulatory entity for all medical devices in Kenya. The Pharmacy and Poisons Board (PPB) is an agency under the Department of Medical Services at the Ministry of Health. KEBS is the national standards body responsible for the development of standards, testing and certification of devices. KEBS provided a detailed checklist, outlined below, of essential requirements that have to be fulfilled prior to device release to the market. These include:

International Medical Device Standards	
Device Life Cycle	
ISO 13486	Quality Systems
ISO 14971	Risk Management
ISO 14155	Clinical Investigations

Technical Regulations	
IE 60601-1	Electro Medical Devices
ISO 11137	Sterile Devices
ISO 10993	Devices in Contact with Body

1. Request permission from KEBS to be investigated. The KEBS Director grants this permission after determining that the applicant is adequately prepared for an audit.
2. Submit application with following documents:
    a. Standards Conformity Matrix found in the ISO Standard
    b. Risk Management Plan
    c. Risk Management Report
    d. Software Development Plan
    e. Software Architecture and Software Design
    f. System and Software Requirement Specification
3. KEBS reviews documents, accepts application & conducts facility and device inspection
4. Site Visit I: Quality Assurance Office
5. Site Visit II: Electrical Safety Office
6. Site Visit III: Operational Office

Through a letter to the Director of KEBS, Kenyatta University requested permission for investigation of the TIBA-Vent. Once this permission was granted KU submitted the application documents outlined below.

- The Tiba-Vent Standards Conformity matrix.
- Risk management plan.
- Risk Management report.
- Software development plan.
- Software Architecture and Software Design.
- System and Software Requirement Specification.

Step 3: KEBS Quality Assurance Office In-Person Site Visits to Assess TIBA-Vent's Safety and Standards Compliance

Following the successful KEBS application, the first group to visit the TIBA-Vent workspace at Kenyatta University was the Quality Assurance Office. This office determines the viability and quality of the production unit in reference to the initially submitted specifications. During the visit, their main focus was the following:

- Operations and safety of the production unit.
- Preparedness of the institution to meet the standards for the production of the ventilator.
- Understanding the proposed process of assembly and sterilization.
- Establishing that user manuals are in place.
- The observation of sterilization protocols across operations.
- Ensuring that good manufacturing practices are in place.

The quality assurance office determined that all these specifications surrounding the manufacturing process were adequate and in line with KEBS standards.

Step 4: KEBS Electrical Safety Office In-Person Site Visits to Assess TIBA-Vent's Electrical Compliance

A site visit by the Electrical Safety Office followed the successful visit by the Quality Assurance Office. This was the toughest stage. The Electrical Safety Office assessed the device against KEBS electrical standards and also assessed the device for mechanical stability. A part of the tests conducted included running the ventilator continuously for 14 days to assess for failure. The TIBA-Vent team had to modify circuits, display, battery, and safety alarms at the recommendation of the Electrical Safety Office.

Step 5: KEBS Operational Office In-Person Site Visits to Assess TIBA-Vent's Impact on Patient Safety

A site visit was conducted by KEBS to assess operational aspects of the device and determine how the device would impact patient safety. The test conducted included calibration of the ventilators by using a gas flow analyzer, verifying functionality until the required specifications were confirmed. This office also raised concerns on the user interface and device labeling. This was a 3-month long process.

Step 6: Clinical Trials

After receiving the certification from KEBS, TIBA-Vent submitted the following applications for clinical trials. The Pharmacy and Poison Board and Ministry of Health have a published guide for conducting clinical trials in Kenya. The Pharmacy and Poisons Board designed a protocol to guide clinical validation of the TIBA-Vent at Kenyatta University Teaching and Research Hospital Critical Care Unit.

1. Applications for clinical trial protocol approval and permission to conduct research through the Ethics Review Committee at Kenyatta University. The trial protocol is a guide that outlines how the trial will be conducted. All consent forms and questionnaires to be used for the trial are required at this stage. A certificate from the National Commission for University Education is also required.
2. Application to conduct a clinical trial in Kenya through the Pharmacy and Poison Board. This application is only possible with KEBS certification.
3. Application to conduct a clinical trial at the hospital of choice.

All these applications were approved.

Step 6: Compiling a Device Dossier

After clinical trials are conducted, TIBA-Vent will present the results for safety and efficacy to the regulatory entities which require a device dossier. A Device Dossier is a technical document required to prove compliance. It consists of drawings that outline technical features, device description and technical specifications, manufacturing and quality control, clinical data, labeling, packaging and instructions for use, risk assessment, post market surveillance plan, and bench testing results.

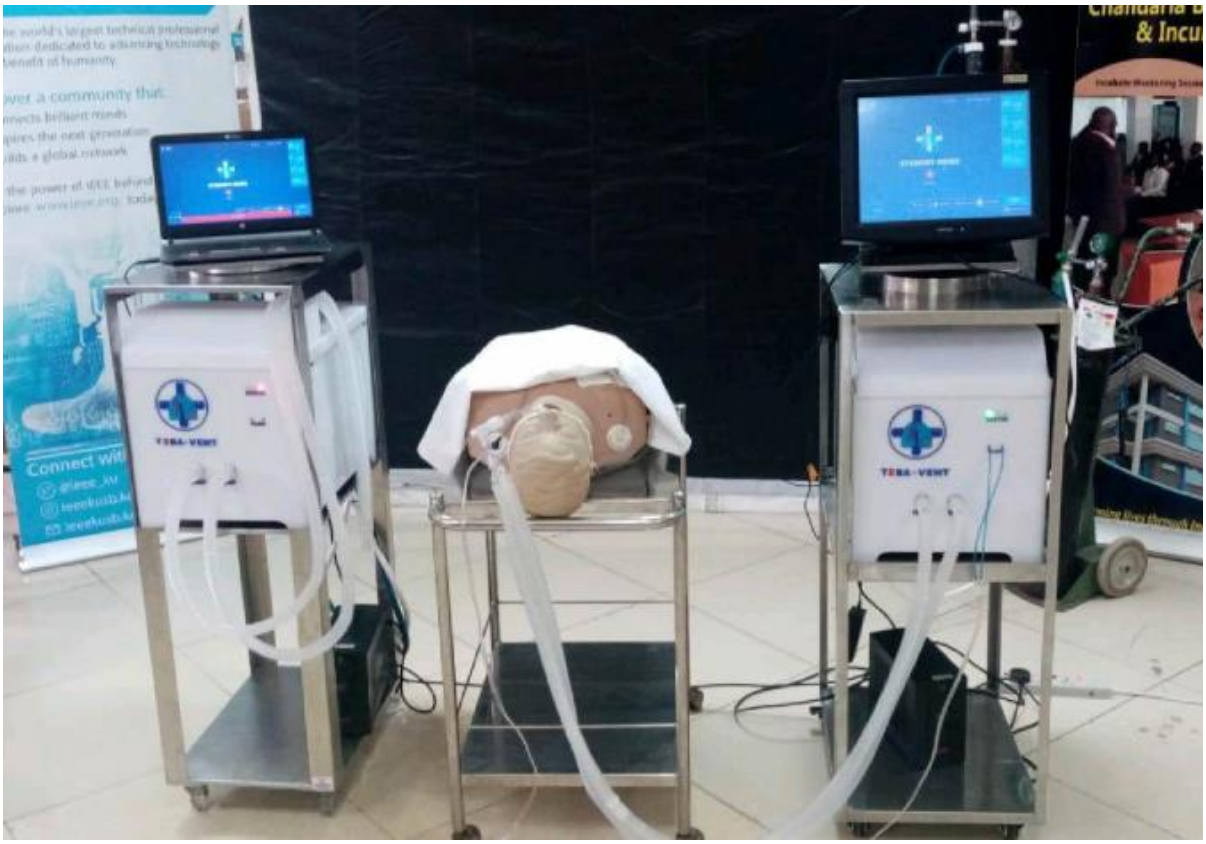

Figure 1: *TIBA-Vent*

Key Features and Specifications of TIBA-VENT

These standards are outlined in the Critical Care Ventilator Standard KPAS 2918: 2020

1. Two Modes - IPPV and SIMV
2. Medical Alarms
3. FiO2 control
4. Flow, pressure, and volume monitoring
5. Graphical user interface on a capacitive touch screen
6. Small, portable, mobile, compact with remote access capability
7. Battery charging unit with UPS support. Ventilator can function for 4 hours in instances of loss of power

Enabling Conditions for Development of the TIBA-Vent

A combination of factors enabled the development of TIBA-Vent. The urgency of the COVID-19 global health crisis galvanized the team's efforts, creating a shared sense of purpose and commitment. The university's robust research infrastructure provided access to advanced laboratories, cutting-edge equipment, and a network of experts across various disciplines. Collaborative partnerships with medical professionals, industry specialists, and regulatory authorities streamlined the development process,

ensuring that medical, engineering, and safety considerations were meticulously addressed. Open information sharing and the availability of relevant research data from around the world offered valuable insights and accelerated decision-making. Moreover, the team's agility, adaptability, and tireless dedication were key driving forces, allowing them to navigate challenges swiftly and refine the ventilator's design iteratively. Together, these enabling conditions converged to empower the university team in successfully developing a vital ventilator solution amidst the demanding circumstances of the COVID-19 pandemic.

Challenges in the Development Process

During the peak of the COVID-19 pandemic, sourcing ventilator consumables, parts and calibration equipment in Kenya posed unprecedented challenges. When available within the country, the prices were prohibitively expensive. The surge in global demand strained supply chains, causing shortages of critical components such as valves, sensors, and circuitry. With many countries prioritizing their domestic needs, international procurement became increasingly complex, leading to delayed shipments and competition for limited resources. Ventilator development is financially intensive, requiring significant funding for research, equipment, components, and skilled personnel.

Regulatory entities often operate within their own isolated spheres, creating a fragmented landscape that can significantly prolong the process of medical device certification. These entities, each responsible for specific aspects of safety, efficacy, and quality assurance, tend to work independently without seamless collaboration. This siloed approach leads to redundant evaluations, conflicting requirements, and inefficient information sharing. Consequently, TIBA Vent had to navigate a complex web of regulations and experienced lengthy delays in obtaining necessary certifications. To streamline and expedite the certification process, it is crucial for regulatory bodies to bridge these silos, fostering a more integrated and cooperative environment that ensures a higher level of patient safety and timely access to innovative medical technologies.

Lessons Learned

The development of the TIBA-Vent has yielded valuable lessons that extend beyond medical technology innovation. Firstly, collaboration between diverse fields, including clinicians, engineers, and manufacturers, is essential for successful and rapid development. The urgency of the COVID-19 pandemic highlighted the importance of flexibility and adaptability in design, manufacturing, and regulatory processes. The importance of regulatory compliance and adherence to safety standards cannot be overstated, as shortcuts can compromise patient well-being. It is important to consider standards and safety at the beginning of development. TIBA-Vent development also highlighted the importance of open-source sharing of designs and knowledge, fostering a global community of problem solvers.

Ultimately, the TIBA-Vent development process showcased the power of collaborative initiatives and demonstrated local capacity for development. At each stage of the medical device development and regulatory process, various fees are levied for the processes that cover the evaluation by regulatory agencies. Post-market surveillance and ongoing compliance necessitate continued financial commitments. While these fees are essential for maintaining robust oversight and safeguarding patient well-being, it's important to strike a balance that doesn't unduly burden developers, especially ones like the TIBA-Vent.

Comprehensive documentation throughout the prototyping process is of paramount importance, serving as a foundational pillar for success in medical device development. Thorough documentation captures every step, decision, and iteration taken during the prototyping journey. It provides an invaluable roadmap, enabling the team to retrace steps, troubleshoot issues, and refine designs with precision. Detailed records

ensure accountability and transparency, aiding in communication among team members, collaborators, and especially regulatory bodies. Moreover, documentation safeguards against potential risks by creating a well-documented history of the device's evolution, which can be vital in addressing safety concerns and liability considerations. In the context of TIBA-Vent development, documentation was especially important for supporting regulatory submissions, and informing future iterations.

Incorporating invention education and involving students in the development of medical devices holds immense significance in fostering innovation, nurturing talent, and addressing real-world healthcare challenges. By engaging students in the process, we tap into their fresh perspectives, boundless creativity, and untapped potential. Through hands-on experiences and exposure to real-world problems, students gain a deeper understanding of the complexities of medical device design, manufacturing, and regulatory considerations.

Budgeting for clinical trials during the research and development (R&D) phase of medical technologies is a pivotal aspect that ensures the successful advancement of innovations from the lab to real-world applications. Clinical trials represent a critical juncture where the safety, efficacy, and real-world performance of medical technology are rigorously evaluated. Adequate budget allocation for clinical trials allows for the recruitment of patients, proper infrastructure, qualified medical personnel, data collection, analysis, and compliance with regulatory requirements. Insufficient funding can lead to compromised trial quality, delayed timelines, or even premature discontinuation, thwarting the potential of promising medical technologies. Well-planned budgeting enables accurate planning, proactive problem-solving, and the ability to adapt to unforeseen challenges, safeguarding the integrity of the trial and the validity of the data generated. In essence, budgeting for clinical trials in the R&D phase is an investment in ensuring the viability and eventual success of medical technologies, underscoring its pivotal role in advancing healthcare innovation.

The TIBA-Vent team learned that it is important to engage financiers at the early stage of medical technology prototype development. The MedTech development requires substantial financial resources to move from lab to testing and to market. Early involvement of financiers is important as it accelerates the research and development process because it enables component sourcing, human resource for product development, pre-clinical testing, and funds for regulatory compliance. In addition to capital, financiers provide valuable industry insights and strategic guidance that can steer the development trajectory in alignment with market needs and trends. By fostering these crucial partnerships from the outset, Medtech innovators can optimize their chances of success, ensuring that groundbreaking technologies reach patients efficiently.

The Cabinet Secretary for the Ministry of Industrialization officiated the launch of the TIBA-Vent. Government support is of paramount importance in driving innovation at the university level. Through financial support, policy and regulatory frameworks, and strategic collaboration, the government creates an enabling environment for innovation and market pathways, conducive to groundbreaking research and transformative ideas. The launch by the Cabinet Secretary, Ministry of Industrialization demonstrated the government buy in. The presence of the Secretary also demonstrated a commitment from the government towards promoting innovation and technological advancement in MedTech development at the university level. The government’s support thus serves as a catalyst for additional funding opportunities, partnerships, and regulatory assistance, all of which are crucial for ensuring the success, scalability, and widespread adoption of medical technologies developed in the university.

Future Plans

The TIBA-Vent team's future plans encompass a commitment to sharing their insights with the medical technologies ecosystem. They will share challenges and opportunities that exist in the MedTech development pipeline. Through this transparency, they aim to contribute valuable lessons and experiences that can serve as a guide for others on a similar path. By openly sharing their journey and fostering collaboration, they envision a collective effort that enriches the medical technologies ecosystem and drives prototypes to products. The TIBA-Vent team, in collaboration with MedTech stakeholders, will subject the prototype to a methodical assessment. This assessment aims to enhance the prototype's value by identifying and eliminating unnecessary expenses whilst enhancing performance and functionality.

Despite the challenges and limitations, TIBA-Vent development at Kenyatta University is a testament of the innovation, skill and ingenuity of local researchers and innovators. They demonstrated that innovation requires a collaborative approach involving academia, industry, government, and international partners. Initiatives to enhance technological capabilities, improve infrastructure, secure adequate funding, streamline regulatory processes, and strengthen educational programs are essential for overcoming these challenges and realizing the potential of ventilator development in Kenya. By surmounting these obstacles, African innovators can contribute significantly to the advancement of medical technologies and the enhancement of healthcare outcomes in the region and beyond.

Members of the TIBA-Vent Team		
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TIBA-Vent Press

- Business Daily Africa
- Kenyatta University Media Page
- United Nations Magazine
- Borgen Project
- IEEE
- The Institution of Engineers of Kenya