

Global Clinical Engineering Journal

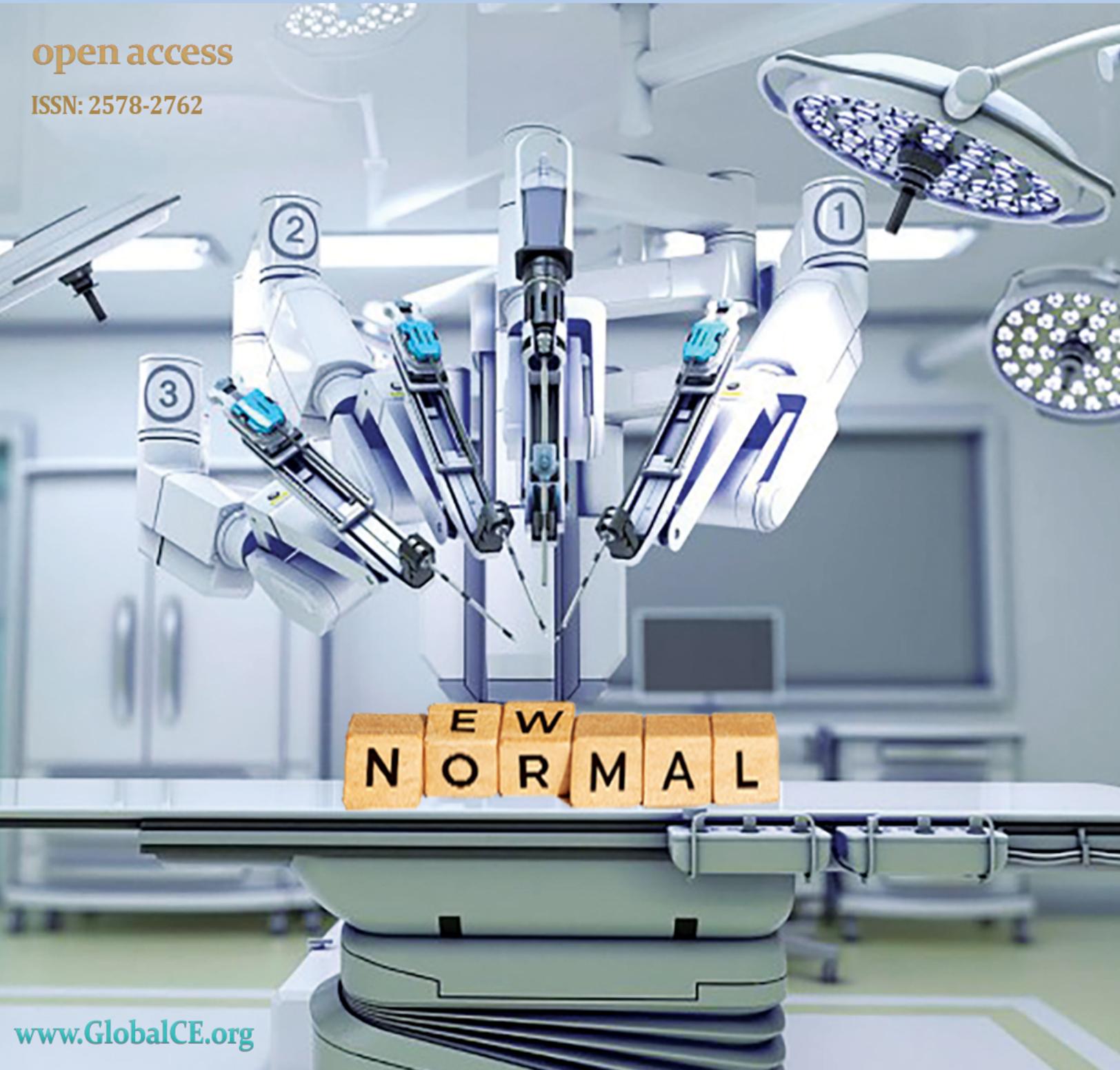
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Editor's Corner

Many readers of this Journal will be familiar with the field of Health Technology Assessment (HTA), at least in principle if not in detail. They may also be aware of the three main pillars of HTA: evaluating comparative effectiveness; cost-effectiveness, and organizational impact, and that HTA serves to inform decision-making in order to promote an equitable, efficient, and high-quality health system.

HTA activities often fall within the domain of specialized units or agencies – be these in the public or private health sectors - with health economists as lead practitioners. The questions posed relate primarily to allocative efficiency issues and related affordability of new medicines, drugs, and procedures for various target populations or groups. As such, HTA is downstream to assurance of regulatory compliance and upstream of technology dissemination and related life-cycle management.

HTA has recently been redefined by an international joint task group as a “multidisciplinary process that uses explicit methods to determine the value of a health technology at different points in its life cycle”.¹

It's useful to spend a minute unpacking that definition. What disciplines are involved and who are the primary drivers of the process? Health economists play an important role, as do health clinical professionals. For so-called hospital-based or ‘mini-HTA’, a broader mix of stakeholders – including clinical engineering (CE), or CE&HTM (Health Technology Management) professionals – would be involved. In all cases, it is the HT-related questions posed that are the crucial determinant of what the process entails and who is involved.

At this point, it's worth remembering that the first technology assessment in the healthcare space was that of the artificial human heart, and the second of the CT scanner – both conducted by the (then) Office of Technology Assessment of the US Congress and hence the birthplace of HTA. One can surmise the key questions posed in each

case: does the technology work and is it safe in the first instance, and can the health system afford the proliferation of this new and expensive medical imaging system in the second.

What are the ‘explicit methods’ and who gets to define these? There are several formal methodology frameworks, the most recent being the European collaboration of HTA (EUnetHTA) HTA Core Model.² The ‘value of a technology’ is a loaded term, since the needs and value systems of the different stakeholders in the outcome of the HTA process may not always be aligned. Lastly – and perhaps most importantly in our context – is to establish the ‘different points in a technology’s life-cycle’.

Current HTA practice commonly sees the technology life-cycle in the generic sense, from embryonic to early adoption to market acceptance to mature and eventual replacement and/or abandonment. Interestingly, a recent publication⁴ refers to 6 stages for Life-Cycle HTA: pre-assessment; safety and efficacy assessment; HTA; adoption; de-adoption, and reassessment.

What has all this got to do with CE&HTM? Everything! CE&HTM practitioners are key stakeholders in – and overseers of - the operational Life-Cycle Management (LCM) of medical devices, with decision-making an integral component of all phases, from needs assessment, planning, and budgeting to procurement, commissioning, maintenance, user support, and training, and eventual decommissioning and disposal. Numerous decisions are made by CE&HTM practitioners in consultation with other stakeholders along the device’s journey from cradle to grave. All of this can be done without mention of HTA.

Should this not be addressed - for both operational and strategic reasons - since the HTA ‘toolkit’ can be used to select the most appropriate approach in providing the evidence needed for specific decisions while also serving to support the standardization of institutional processes? In addition, by using the language of HTA,

CE&HTM practitioners can align themselves with existing HTA processes where these exist.

There are also broader benefits. As readers may well be aware, GCEA and the IFMBE's Clinical Engineering Division are engaged in the important exercise of defining the CE/HTM Bodies of Knowledge and Practice at the global level, both of which would benefit from the addition of HTA concepts and principles as being core to both CE/HTM knowledge and practice. On a related note, the IFMBE's Health Technology Assessment Division has recently suggested greater involvement of biomedical and clinical engineers in current HTA activities - and further explored related gaps and opportunities - in a recent publication.³ Another European-based in the HTA domain – EuroScan also known as the International HealthTechScan (i-HTS) has joined Global Clinical Engineering Alliance on a couple of World Health Organization projects.

Another benefit is linked to the challenges many colleagues are facing in raising the importance of CE/HTM in their respective countries, needing CE/HTM roles and contributions to be recognized in national policy and related support of professional recognition, capacity development, and appropriate resourcing.

A different perspective on HTA and related issues is informed by the reality that many lesser-resourced settings are well familiar with: *"...inefficiency (that) signifies the denial of additional citizens of opportunities to realise health improvements at zero extra cost. This makes inefficiency both immoral and unethical."*⁴

This begs the question: Are the resources currently invested (allocative efficiency) in the regulation, assessment, and management - individually and collectively - of health technologies in general and medical devices, in particular, achieving the highest return on investment when their actual impact is juxtaposed with their potential impact given the same levels of investment? There is anecdotal evidence that regulatory and assessment agencies in

some countries are pursuing the implementation of best global practices in upstream LCM activities, thereby consuming significant resources that could be better utilized in addressing proverbial orchards of low-hanging fruit associated with the downstream operational life-cycles of health technologies and medical devices, and related *technical efficiency*.

This in turn leads us to ask: Why not do an HTA on HTA, i.e. consider the cost-effectiveness of current HTA-related activities and their resourcing and impact, relative to their potential if their scope was broadened and a larger set of stakeholders were gathered at the decision-making table? Incidentally, the same question could be asked of Health Technology Regulation and CE/HTM activities and related resourcing.

Yours thoughts? Let me know at mladen.poluta@up.ac.za

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Together we are making it better!

Prof. Mladen Poluta

CONTENTS

Editor's Corner

By Mladen Poluta

2

Engineering Report

By Yadin David

5

Book Review

By Thomas Judd, Saide Calil and Yadin David

9

Application of Molecular Sieve Oxygen Generation Mini-plant under Harsh Environment

By Jixun Liu, Chao Qiu, Jianxiong Zuo, Xiaomin Lou

11

Analysis of 2022 Chinese Clinical Engineering Body of Knowledge and Body of Practice Survey

By Jing Tong, Kun Zheng, Bin Li

20

Sustainable Procurement of Medical Devices in an International Context: Part 1 - Background and Definitions

By Valerio Di Virgilio, Alexia Bouchard Saindon, Francisco Cesar Gerardo Becerra Posada

29

Engineering Report



By Yadin David

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New Normal and Year Reflections

As I sat to write this column during the 2022 holiday season between Xmas, Hanukah, and the new year celebrations, one cannot ignore the changing behavior of humanoids as the year came to a close. The elevated feeling from experiencing ubiquitous kindness shared by and among people, that of caring for one another, of conveying the season's joy to others around us near and far, and the realization that we all share this planet. This was magnified, and subconsciously visibly appeared, during our serious conversations as well as within the small talks we carried. You could hear it, smell it, see it, and above all you could feel it. It seemed like everyone partakes in forwarding good wishes, joining in the sharing

of fellowship, and gift exchange while getting prepared next to engage in making new year's resolutions. As the world population has surpassed at the end of the year 8 billion persons mark consequently to ongoing innovation, access to energy, food, water, and medical care becoming more reliable and available. Yet, the projected expectations for the more rapid growth¹ of the human population will contribute to the higher challenges we face together in order to meet our combined future needs as shown in figure 1 below.

Adopted from <https://population.un.org/wpp/Graphs/Probabilistic/POP/TOT/900>.

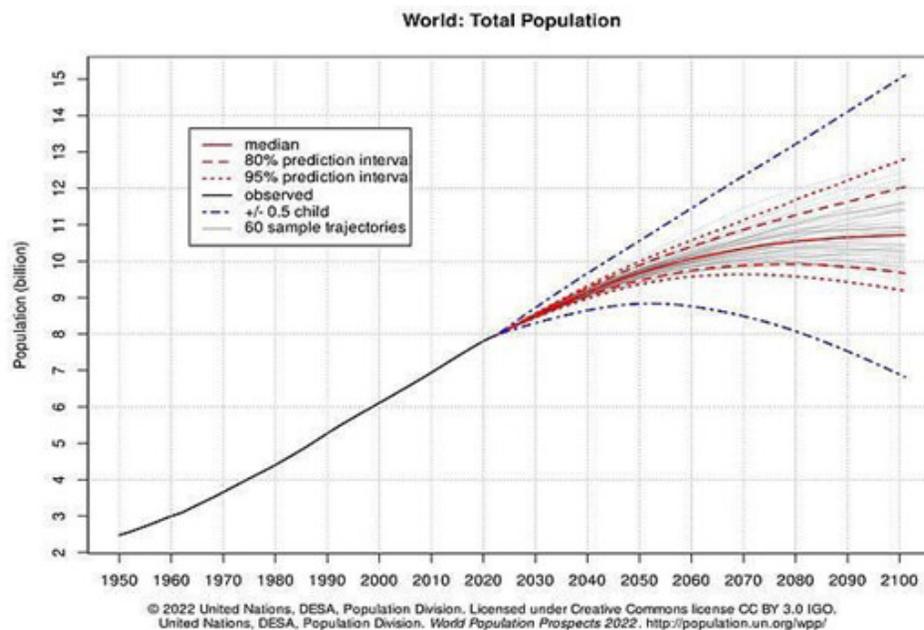


FIGURE 1. World Population surpassed 8 billion persons in 2022.

You could easily be confused that this beautiful seasonal period, as short as it may be, is normal compared with years past but in essence, this has been just a masking of the fear of the unknown - of uncertainty. Following three years of human suffering caused by the most devastating plague in the past 100 years that completely engulfed our globe and turned every normalcy on its head, the normalcy that until then we began to take for granted. Today, there are still regions where this disease is not contained.

Normalcy during this dreadful three-year period was only becoming a dream or a faint memory, with our aspiration not to forget the way we were. The normal world seems no more. Families lost loved ones, national economies were forced to shut down, schools were empty of students, social gatherings were curtailed, and travel was not an option. Grandparents could not hug their grandkids, and the only entertainment left to enjoy was from balconies or on the electronic display screens we kept becoming glued to at home. Science became somewhat of a political pawn, factories were closed, and the supply chain could not stand up to its gigantic challenge (we still are faced in some regions with the infant formula supply crisis) bringing the world to almost a standstill. Unfortunately, many difficult and sad lessons are still being debated and shared with the hope of never being faced with isolation and helplessness again.

Among the industries having a central role and perhaps the biggest impact on our lives is the healthcare delivery system. The system found itself in the middle of distress trying to meet the sudden rise in demand for its services and suffering from being unprepared, understaffed, and uncoordinated regarding its life-critical assets such as space, skilled personnel, drugs & vaccines, medical devices, and medical gases. That compelled healthcare systems to search for alternatives, workarounds, and innovative solutions to quickly produce the needed isolated patient care spaces, and obtain sufficient quality of personal protection equipment for their staff and patients, as well as mechanical ventilators, oxygen

concentrators, and oxygen supply. Healthcare providers and their support teams became exhausted, and fatigued but could not, for several reasons, be easily replaced by others. As history and global markets showed us, we are not good at predicting our future. We generally look for a brighter future, one that would not teach words like “new variant” or “subvariant”. What was normal before is no more, and in the vacuum, the new normal started to be created and has already begun to spread its roots.

As reported by KXAN² and the JAMA-Network Open publication “*Prevalence of and Factors Associated with Nurse Burnout in the US*”, almost 3% of practicing nurses, in the US, ages 49 and younger left their practice during the 2021 pandemic year. The figure below shows that in a short period between 2020 and 2021 over 100,000 caregivers (about 3%) left the workforce. However, their jobs had to be covered by other staff especially as patient volume has increased due to the pandemic. This condition, as difficult as can be imagined, gave rise to the new normal where potential partial relief can be derived from a new closer training between members of the healthcare team such as nurses and clinical engineering professionals.

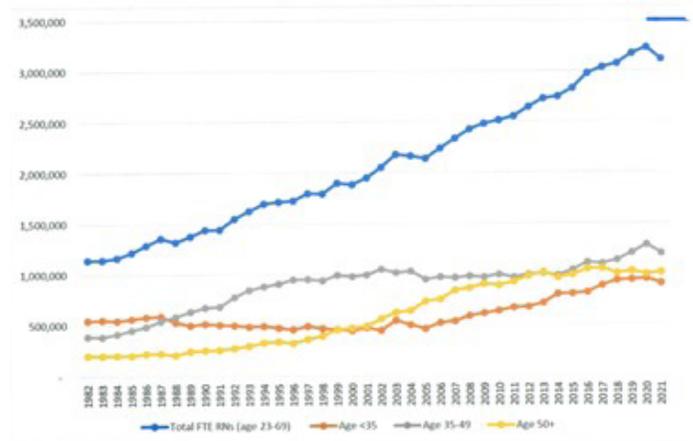


FIGURE 2. Over 100k nurses in the US left their job.

Clinical engineering professionals (engineers, technologists, and technicians) are team members of this stressed industry and are deserved to be counted within the silent hero's community that kept the healthcare delivery systems innovative, functioning, and safe under the extreme once-in-century challenge, brought about by the COVID-19 pandemic, and thus sustain the system of patient-ready and operationally safe technologies around the world.

The reality of the new normal was one of the reasons that in May 2022, T. Judd and I published in the National Academy of Engineering Perspectives an article discussing the *Growing Role of Clinical Engineering professionals in Merging Technology at the Point of Care*³ sharing with nursing staff new responsibilities.

To meet the needs of the new normal we included in this article a Call for Action for clinical engineering practitioners to transition from focusing on strategies addressing the localized point of care to those that meet larger population health needs, taking a bigger role in the healthcare delivery team, achieve certain systems competencies, and have a stronger contribution to national health technology policies. Such as:

1. **Education of the workforce** to create greater collaboration and resiliency within and between health team members. Collaborative interdisciplinary educational training⁴ will ensure the availability of systems skills needed to maximize the benefits of health technologies. With demonstrated competencies and internationally coordinated professional credentialing, CEs will be prepared to be equal partners with the other members of a healthcare team, participating in new clinical roles and workflows to free physicians and nurses for direct patient care.
2. **Participate in National health technology policy decisions** to address priority national challenges. Pandemic-related impacts necessitated the rapid implementation of national health technology policy in many countries.⁵ This and experiences with other disasters (e.g., floods, wildfires, earthquakes, power

outages) clearly show the need for international coordination of new national guidelines to sustain access to, availability of, and the transfer of critical healthcare technology tools. Clinical engineers can play an important role in informing and implementing such policies.

3. **Engage with National and international alliances and partnerships** to share expertise and lessons learned. Alliances, like the [Global Clinical Engineering Alliance](http://www.GlobalCEA.org) www.GlobalCEA.org, will coordinate meetings of healthcare stakeholders (e.g., clinicians, administrators, and ministry of health personnel with clinical engineers) to examine areas of concern where CEs can make a difference. For example, the [Global Clinical Engineering Alliance](http://www.GlobalCEA.org) has offered [webinars](#), a virtual [international congress](#), and a global CE summit to identify and rank common global challenges. Such alliances can help those in the health sector, industry, academia, and NGOs drive cost-effective and high-quality innovations in healthcare delivery and manage the performance of the technology used at both points of care and in regional and global populations.

As healthcare delivery systems around the world are increasingly dependent on technology⁶ for the provisioning of their services, the expertise of clinical engineering professionals in the development, use, and management of this asset is critical for achieving the best outcomes. For both point-of-care and population health, a systems approach can improve the delivery of health services through education, workforce collaboration, inclusion in policy development, and engagement in partnerships. Records from the pandemic era show that these professionals have much to be proud of and appreciated as they delivered solutions critical to sustaining the lives of patients all over the world. Nevertheless, the new normal is expecting that clinical engineering professionals will continue to raise the bar on their commitment to pursue career-long continued education, credentialing, and active engagement in national associations and international alliances. As a result, credentialed Clinical engineering professionals will continue to be indispensable partners

in achieving healthcare missions. The approach described here shows a pathway to achieve the outcomes during the new normal era we all desire.

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Book Review



Biomedical Device Technology Principles and Design,
(3rd Edition)
Anthony Y.K. Chan
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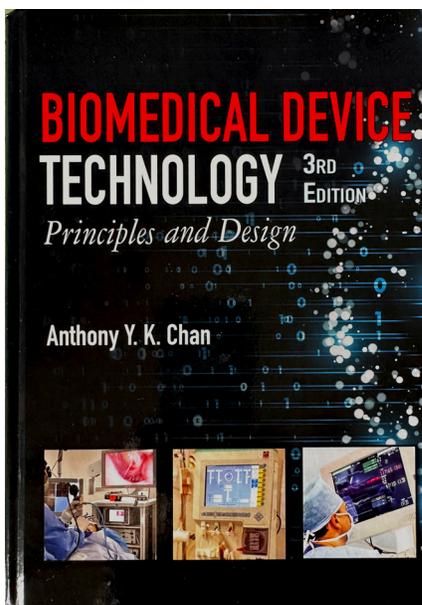
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In our continuous efforts to encourage sharing of knowledge and publication of engineering and scientific work related to the clinical engineering field, we were invited to review this newly published book. We hope that you will find it helpful to your career and at the same time promote the submission of other books for review by our community experts who serve the benefit of all our readers.

Biomedical Device Technology Principles and Design, (3rd Edition), by Anthony Y.K. Chan, ISBN 978-0-398-09392-1 (hard copy), ISBN 978-0-398-09393-8 (ebook), Charles C Thomas, Publisher, LTD., Published February 2023. Price \$79.95US. Biomedical Device Technology: Principles and Design: 9780398093921: Medicine & Health Science Books @ Amazon.com (last visited on April 26, 2023).



This book review is a combined summary of three practitioners from the Clinical Engineering global community. An academician, a national health technology and quality manager, and an international consultant. For this purpose, Charles C Thomas Publisher, LTD., provided copies of the books to the reviewers. The author - Dr. Anthony Chan is a well-qualified Professional Engineer, a Chartered Engineer, and a Certified Clinical Engineer. He holds a Ph.D. in Biomedical Engineering and a Certificate in Health Services Management. During his career, he has presented and published in both domestic and international congresses, on safety, risk management and technology management. In the Preface section of the book, the author writes that "This book focuses on applications, functions and principles of medical devices... and uses specific designs and constructions to illustrate the concepts where appropriate."

The primary function of this book is to describe the basic working principles of medical devices used for diagnostic and therapeutic in the healthcare area, though imaging equipment is not included. For a better understanding of the equipment working principles, the author presents a brief but sufficient description of the physiologic parameters and transducers used for the measurements of these parameters for each of the devices described in the book. Some mathematical concepts are introduced to help the understanding of the capturing and processing system used by these devices.

In addition to the Preface, the book is organized into four parts consisting of 38 chapters, four appendices, an interesting set of review questions, and an index for a

total of 901 pages. Part I – Presents a miscellaneous set of basic concepts about; how to classify medical devices, biopotentials, physiological signals, safety, biocompatibility, human factors, and several other subjects. In fact, the author’s intention is to lay the foundation and prepare the reader for what is going to be presented in the following chapters of the book. It also includes an introductory explanation of the mathematical concepts related to error measurements, signal processing, and analysis. Such concepts can help the reader to have a better general understanding of the scientific instrumentation foundation involved in medical devices.

Part II – Presents a wide variety of transducers used by medical devices. It is divided into eight chapters dedicated to explaining several specific types of transducers. Each chapter presents a quite didactic explanation of the operating principles of: pressure and force transducers; temperature transducers; position and motion transducers; flow transducers; optical transducers; electrochemical transducers; and biopotential electrodes. Each chapter provides an educative concept about transducers that are not only used in medicine but in a wide range of measuring instruments used from maritime exploration to kitchen devices.

Part III – Has three chapters that bring the concept of building blocks of medical devices and explain the basics and most common electronic circuit used to capture and process the electrical signals sensed by the transducer and the associated instrumentation amplifier. This part also discusses issues related to electrical shock hazards, including macro and micro shocks, grounded and isolated power systems, and methods to reduce electrical hazards.

Part IV – Presents a total of 24 medical devices, generally explaining their applications, basic building blocks, different applications for the device, and common

problems and hazards. It is not an extensive but sufficient description for the reader to understand the device well. An added feature is that in addition, each device has a specific description of issues that helps the reader to better understand its working principles. This section also presents a dedicated set of bibliographic references for each piece of equipment. Like previous sections of the book, most of the references noted material up to 2016 from when the 2nd edition was published. As the author writes in the Preface “...medical devices have a life span of about 5 to 7 years.” which suggests that more recent references will add to the readers’ knowledge.

The book also contains four appendices where the first presents a primer on Fourier analysis, the second an overview of Telemetry development, the third is about medical gas supply systems, and the fourth offers an explanation of the concepts of surgical asepsis and device infection control.

Complementing the book, the author elaborated with a list of review questions, one set for each of the chapters previously presented. In general, it is a very useful foundation of design and principles of devices that are used within and outside the healthcare environment and is useful for the training of clinical and biomedical engineers. Some important technological areas, such as digital health or mechanical ventilation are omitted. COVID-19 pandemic instrumentation like CPAP and oxygen concentrators are limited or missing.

We like the structure of the book content and note that the book delivers fair depth and scope well-suited for academic programs. However, the book could be strengthened by offering more recent references than those already included in the 2nd Edition, and more recent applications of pandemic-related devices.

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Application of Molecular Sieve Oxygen Generation Mini-plant under Harsh Environment

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ABSTRACT

Pressure Swing Adsorption (PSA) oxygen generation mini-plant is widely used in all various hospitals for its fast, convenient, and cost-effective features. However, considering the landscape of global markets, the PSA medical oxygen generation mini-plant design basis varies from location to location. Therefore, it forces the manufacturer to design and build the PSA oxygen generation mini-plant more flexibly to enable its compatibility in different extreme ambient conditions (temperature, humidity, pressure, cleanliness) of installation location. For the sake of these concerns, this paper employs the concept of modularity as an approach to PSA medical-grade oxygen generation mini-plant design and application and elaborates 10 key components for 4 modules of PSA medical-grade oxygen generation mini-plant, namely (a) air compressor module; (b) PSA module; (c) oxygen compressor module; (d) smart control module. Under this modularized design approach, this paper investigates the technical features and the design criticality of modular and key components in fulfilling the expected performance, finally achieving and maintaining the overall performance of PSA oxygen generation mini-plant with the selected modules which may be installed worldwide. This paper helps to highlight the variability of PSA oxygen generation mini-plants in harsh environments in four dimensions (temperature, humidity, pressure, cleanliness) and briefs the methodology of the phase gate model for modular approach in oxygen generation mini-plant. It contributes to the literature on this important subject in the modularized design method, adsorption technology, air separation process, etc.

Keywords – *PSA Oxygen Generation Mini-plant; Harsh Environment; Modularized Design; Process Design; medical-grade oxygen* .

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INTRODUCTION

Oxygen for industrial purposes is generated through several techniques such as cryogenic air separation units, and membrane-based or adsorption technology. Therefore, it is vital for industrial production, environmental management of food & and beverage, and healthcare. As of 2021, the global annual oxygen turnover has reached USD 46.24 billion and will steadily increase.¹

Since the first mention of oxygen therapy in the medical journal; *The Principles of Medicine* by Dr. William Osler in 1898, the rapid growth of medical oxygen is continuously driven by innovative technology and capital, today medical-grade oxygen is an indispensable part of medical care in hospital and at home, which the importance and

criticality of it have been demonstrated in the context of COVID-19.

Air separation by adsorption to produce oxygen for medical-grade applications represents one of several important commercialized adsorption processes: adsorptive air separation technologies, nitrogen-selective zeolite technologies, and intensification technologies. Furthermore, owing to the development of synthetic molecular sieves, the pressure swing adsorption (PSA) technology, thus the PSA oxygen generation mini-plant is widely used in all various hospitals for its fast, convenient, and cost-effective features.

In this paper, we have drawn the modularity concept and cascaded the PSA oxygen generation mini-plant into 4 modules. Next, 10 key components (units) are defined and elaborated with their respective functionality. Thirdly, we discuss how the module approach demonstrates flexibility to meet the various ambient conditions with its outstanding technical features. Lastly, we introduce the phase-gate review to ensure the module approach achieves the overall PSA oxygen generation mini-plant performance. This paper contributes to the literature on the modularized design method, adsorption technology, air separation process, etc.

DESIGN CONCEPT

Adsorption air separation technologies can generate oxygen from the ambient air in the range of several kilograms to hundreds of tons of Per Day Oxygen (TPDO, normally limited to 300 TPDO) at a purity of 93%±3%. Such oxygen purity levels are simply because the heavy component (nitrogen) accounts for ~78% of the feed air. Other elements, such as argon and moisture, must be pre-treated or integrated into the separation process. Therefore, it is understood that adsorption technology's basis is the adsorbent's variable absorptive capacity, depending on the consumption scale of hospitals and medical institutions and the characteristics of their oxygen therapy. Further, as a pressure swing cycle is tailored to the characteristics of the adsorbent, the final capacity very much relies on the temperature, pressure, and other ambient conditions such as humidity and cleanliness of the feed air.

To fulfill the customer's requirements flexibly while managing balance of quality and costs, a product management methodology is introduced to ensure a consistent product portfolio across all markets and drive the standardization and modularization of PSA oxygen generation mini-plants for medical applications. It combines standardization and modularization, such as standardized components designed to ensure exchangeability. Meanwhile, the whole mini-plant is organized by combining several fixed & adapted modules engineered on a project basis to improve its constructability, as it is usually pre-assembled and skid-mounted.

The concept of modularity

Modularity is very popular in design and manufacturing, and it is widely used in medical devices for its compatible assembly and flexible adaption to various applications. Modularity generally refers to breaking down complex product systems into simpler units called modules that may function independently. Specifically, modules are self-contained functional units that connect with other units, but do not rely on those other units for their own stable operation.²

The properties of modularity

The modular approach featured four defined key properties. When defined in terms of these properties, modularity is not an all-or-nothing feature of designs but can be described in degrees.³

1. **Partial decomposability.** It refers to the notion that a complex system may be partially divided into smaller meaningful functional units – modules.⁴ Depending upon the complexity of product systems and the necessity of product management, it can be divided from 3–5 modules to hundreds of modules with clear boundaries called battery limits.
2. **Proper functioning.** It signifies that the operation of each module in the design is expected to produce the intended result. This intended result is an integral part of the whole function of the designed complex system. For instance, the air compressor module generates the compressed air to feed gas into PSA module with the proper technical specifications range of pressure, temperature, and dew point.

3. **Standardized interface.** It denotes that modules within the design can connect or communicate with each other in a structured fashion. Interface management systematically controls all communications that support a process operation. In the most basic sense, this property is similar to the property of children's LEGO building blocks – pieces are designed so that one can plug into the next.
4. **Information hiding.** It is also known as “encapsulation” and refers to keeping the specific operation details within a module.⁵ For example, the smart control module aims to control the whole product system. But its control philosophy, logic, process parameter, and value are not disclosed to others unless specified.

SKETCH OF MOLECULAR SIEVE OXYGEN GENERATION MINI-PLANT

PSA oxygen generation mini-plant has been developed steadily over the last four decades since Praxair built the first small-scale prototype in 1985.⁶ which turned out from early progress driven primarily by large-scale industrial application. This development contributes to the on-site medical oxygen supply solution that prevails in hospital and other medical institutions. To fulfill the more flexibly designated function of the PSA oxygen generation mini-plant, the concept of modularity is applied and fixed modules and adapted modules were developed. Further, to make the modules more stable and minimize the cost, the components forming these modules are standardized, which could be sourced from off-the-shelf market or in-house manufactured.

Modules Definition

Considering the definition of modularity and the proper functioning above, we have described 4 modules of the PSA medical oxygen generation mini-plant, 3 of them are mechanical, and 1 module is instrumentation & control related. Their functionalities are introduced as follows:

1. **Air compressor module.** The system compresses atmospheric air by a screw-type air compressor to a required pressure and cools to ambient temperature through refrigerating drier. The condensed moisture is drained out automatically from the air receiver through an automatic drain valve. As a meaningful

functional unit, it has clean compressed dry air as feed gas at 7–8 bar, with air quality that optimally fits the oxygen generator.

2. **PSA module.** The compressed air at constant pressure is passed through filters set and then passed through twin tower PSA module packed with special grade Zeolite molecular sieves, where compressed air is separated to oxygen at the purity of 93%±3% and at a pressure range of 4.5–6 bar. In a few cases, it can be directly delivered to the downstream user.
3. **Oxygen compressor module.** The produced oxygen is filled in the oxygen buffer tank and then boosted by an oxygen compressor to higher pressure. It typically has two configurations: (i) it is boosted to 6–8 bar to achieve oxygen reservation, then delivered to the central pipeline system; (ii) it is additionally pressured to 150 bar for filling oxygen cylinders; however, this is not allowed in China.
4. **Smart control module.** The system has a 7” color touch screen control panel with an integrated oxygen monitor. The touch screen provides a normal user interface for the start-up system, monitors/controls the operation of the process valves, monitors signals coming from the pressure transducers, and provides an alarm system when conditions require it, as well as a fail-safe shutdown mode. This control panel also features diagnostic capabilities and remote monitoring of process parameters.

Standardized components

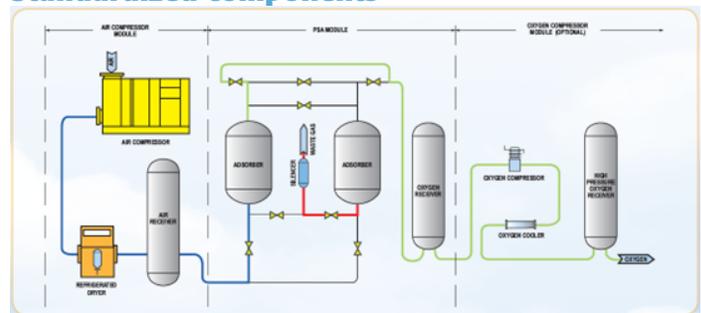


FIGURE 1. Typical PSA Medical Oxygen Generation Mini-plant

The total 10 key components are standardized in series:

- **(1-a) Feed air compressor system.** The mechanical compressor is the essential component in the

Generation mini-plant. It gives the compressed air at 7–8 bar for air separation. It typically consumes more than 90% of the generation mini-plant's power and generates most of the noise and vibration. It is either oil-free or oil-injected rotary screw type and air-cooled. It should have a built-in oil separator and air filter; its controls are suction throttle valve type with on-off line control and motor stopper start control. Normally, the advanced compressor should be provided with a soft start or variable speed drive and have a digital display indicating failure, LCD display, and records at least 24 hours of operational data.

- **(1-b) Air dryer.** This is a refrigerant-type capacity air dry with a dew point of $<+3^{\circ}\text{C}$ and pre-filters with automatic drains. The alternative is a desiccant type with auto-regenerating. It removes more than 90% of water in compressed air from the compressor to protect the molecular sieve and piping.
- **(1-c) Air receiver tank.** There is at least one set of air receiver tanks after the compressor. It is made of painted carbon steel with a capacity of at least 1000 L, depending on the compressor. It is equipped with a pressure gauge to indicate the vessel pressure, a safety valve, and a level-sensing auto drain valve.
- **(1-d) Filter system.** A three-stage air filter removes the compressed air's dust, oil, and other impurities. The micro and active carbon layers remove oil and dust up to $< 0.01 \text{ mg/m}^3$. The filtration level should comply with ISO Standard 8573-1:2010.1.4.1.
- **(2-a) PSA oxygen generator.** The duplexed tower PSA oxygen generator packed with special Zeolite molecular sieve is skid mounted. It produces $93\pm 3\%$ oxygen from compressed air with a capacity of $3 \text{ Nm}^3/\text{h}$ to $60 \text{ Nm}^3/\text{h}$ and usually not less than 4 bar outlet pressure.
- **(2-b) medical grade oxygen receiver tank.** The oxygen is separated through a PSA generator and received in an oxygen tank with less than 1000 L capacity with a bacterial/sterile filter. The oxygen receiver tank should be equipped with a pressure sensor. As aforesaid, the oxygen can be supplied to the central pipeline system.
- **(3-a) Oxygen booster.** The oxygen booster is configured for dynamic oxygen reservation. This has two primary purposes: backup to a short-time turndown case or adjusting the peak oxygen demand. In this scenario, a medical oxygen compressor with an after-cooler is required to boost the oxygen pressure back to 8 bar at a similar feed-in temperature. After that, the boosted oxygen is connected to the high-pressure oxygen receiver with a capacity of 1000–3000L.
- **(3-b) Cylinder filling station.** This component is optional and could be added at the client's request and as local regulations allow. The system comprises an oil-free oxygen-filling compressor at 150 bar pressure and a filling ramp for cylinders to be connected simultaneously. For filling the cylinder, wall-mounted racks shall be on the other side of the wall of the PSA mini-plant room.
- **(4-a) Measurement devices.** Several technical parameters are measured, such as the process's temperature, pressure, and flow rate. The measurement devices are installed in-field for easy checking. They are also transmitted to the centralized control system. Further, there is an integrated and continuous oxygen quality monitoring unit with the following alarm setting: Carbon monoxide (CO) @ 5 ppm, Carbon dioxide (CO₂) @ 300 ppm, water vapor (H₂O) @ 67 ppm, Oxygen (O₂) @ 90%.
- **(4-b) Smart control system.** With the installed sensor and transmitter of in-field measurement devices, the process data is automatically collected, recorded, and self-diagnosed under configured program embedded with the control philosophy and algorithm. Considering the tolerance of normal operation, alarm, and trip, as the three safety zones are pre-defined, the control system will be automatically triggered once the collected data is out of the normal operation range to protect against the potential damage of the PSA oxygen generation mini-plant. Consequently, the oxygen supplies will be shifted to other oxygen sources immediately.

MATRIX OF DESIGN BASIS COVERING HARSH ENVIRONMENT

The performance of the PSA oxygen generation mini-plant is determined by the adsorption and desorption process, which takes place in the duplexed adsorbers. The key variables for the adsorption and desorption process are multi-component thermodynamics and kinetics. Therefore, how to select and optimize those key variables are heavily linked to the physical properties of the adsorbent particles.⁶ Moreover, their operating environment is even more discrete when exporting them to the global market. Therefore, a design basis rooted in local operation conditions has to be seriously considered to capture these key variables.

Matrix of Design Basis

The landscape of China from the eastern coast to western Tibet is totally different, and the operating condition of PSA oxygen Generation mini-plant is remarkably changed. Assuming this PSA oxygen Generation mini-plant will be installed not only in China but also for global marketing, the full range of design basis has to be assured. The actual operating condition is very complicated, but in this paper, we focus on the four main factors: temperature, humidity, atmospheric pressure, and cleanliness. While optimizing the cost and balancing the design standardization, we define that the normal case shall cover 80% of application cases and extend to the extreme case in the remaining 20%. Ultimately the design basis is specified as follows in Table 1.

TABLE 1. Matrix of Design Basis

Ambient Condition	Temperature	Humidity	Pressure	Cleanliness
Normal	5–35 °C	40–80%	0.09–0.1 MPa	≤10 mg/m ³
Extreme high	55 °C	95%	(Not applicable)	400 mg/m ³

Ambient Temperature

In the normal design, the ambient temperature is in the range of 20°C±15°C. As the suctioned air as feed gas

is compressed, the temperature will be increased, and an air-cooled aftercooler is installed to ensure the discharged compressed air temperature is less than 10°C rising to the original ambient temperature. Further, the air dryer will continue to cool down to the pre-defined temperature before entering the PSA module. This cooling-down will generate cold, dry air for the temperature and minimize feed-gas moisture.

There are two sources for the extremely high ambient temperature. One is the high ambient temperature originating from hot summer land, a common understanding. However, another source actually comes from the air compressor. The heat radiation leads to heat accumulation, thus, high temperature. Therefore, ventilating fan and pipe duct shall be connected to the compressor's terminal to remove discharged hot air to minimize the negative compact on the ambient temperature of feed gas. In addition, an air conditioner shall be added for the area with the highest ambient temperature over 35°C.

However, heat preservation is required in cold areas in winter to maintain indoor temperatures above 5°C. Therefore, the discharged air of high temperature could somehow be utilized to warm the feed gas to meet the minimum requirement of 5°C. Therefore, in case of the gap to the normal range of 5–35°C is still extant after all heat balance and recycle measures, then a heater as an auxiliary facility shall be added and switched on in case the indoor temperature of the mini-plant house is lower than 5°C.

Ambient Humidity

In the normal design, the relative air humidity ranges from 60±20%. The air that leaves a compressor reaches 100% humidity as the air is compressed and has a higher temperature. Unfortunately, the compressed air also contains limited oil (unless you use an oil-free compressor) and solid particles. Together, they form an abrasive, often acidic, oily sludge. Without air treatment, this murky mix will enter the PSA module, harming the molecular sieve adsorbents, corroding pipework, damaging pneumatic tools, and potentially compromising oxygen products.

The air treatment typically includes three parts. Firstly, the condensate shall be drained out by the steam

traps. Although an automatic trap is usually mounted, in some cases, a manual trap also makes sense, depending on the amount of condensate. In addition, a humidity sensor is recommended to install to capture the failure of condensation prevention. Secondly, as a partial air dryer, the saturated air with 100% humidity is cooled down to dewpoint; thus, the moisture in the compressed air is removed.

As aforesaid, there are two types of air dryers. One is a refrigerant type with a pressure dewpoint of $<3^{\circ}\text{C}$ (100% relative humidity at 20°C), and another is a desiccant type with auto regenerating. In the normal case, both are suitable. However, if the ambient humidity is high, the refrigerant type is strongly recommended to ensure its higher reliability. Further, to meet the high humidity, the sufficient design margin of the air dryer shall be considered. For instance, 130–150% of the calculated capacity shall be configured.

Atmosphere Pressure

When addressing the pressure, it refers to the plateau area where the atmospheric pressure is less than 0.1 MPa. In the normal design, the mini-plant is assumed to be installed at an elevation no more than 1000 meters, which equals its atmosphere pressure in the range of 0.09–0.1 MPa. Therefore, when the atmospheric pressure decreases by 0.01MPa, the compression ratio of the air compressor will increase by 6~8%, and the compression energy consumption will increase accordingly. In addition, the reduction of atmospheric pressure will reduce the displacement of the air compressor, and the corresponding oxygen production will also be reduced.

To maintain the feed-air to the PSA module at the optimum pressure, the logical thinking is to enlarge the compressor's power to compensate for the insufficient pressure from the atmosphere. Adjustment to the atmospheric pressure by selecting the suitable compressor model is possible, while it should keep in mind that each compressor has a maximum compression ratio that cannot be exceeded. Further, for the compressor and its auxiliary equipment, in practice, it will have a significant impact on power consumption and air consumption. Meanwhile, changes due to altitude will also affect the rated power provided by the motor and internal combustion engine.

External Cleanliness

Cleanliness is very crucial for the oxygen industry. There is a significant issue regarding internal surface cleanliness resulting from machine and equipment, process-compatible coatings, and, more important, the grave consequence of molecular sieve pulverization. This is a profound issue that can be addressed in another special edition. In this paper, we only concentrate on external cleanliness, which is affected by the external environment, such as the oil, grease, particles, and liquid moisture in the feed air.

Therefore, it is heavily linked to two portions: (1) the inlet self-protected dust filter by the compressor. It is designed to remove dust and other physical impurities from the ambient air before it is further compressed in the air compressor; (2) the three-level filtration system for compressed air. Untreated compressed air can be contaminated by dust, water, and oil. This makes filtration a crucial component in the air compressor module. Depending on the external cleanliness, a series of filtration solutions are needed to protect the air-proceeded equipment and the final oxygen products. For instance, wrapped media for wet particles, pleated media for solid particles, macro-structured activated carbon for oil vapors, cyclone for moisture, etc.

DISCUSSION

The adsorption and desorption processes within the duplexed adsorbers are affected by pressure and pressure drop, heat and mass transfer, temperature gradients, and airflow velocity of the feed gas. These elements jointly determine the dense packing of the adsorbents and their fluidization for achieving optimum oxygen production. Taken individually, many of these elements may seem to be conceptually straightforward. However, integrating them to achieve a high-performance process concerning high oxygen purity, high oxygen productivity, and low power consumption at a competitive cost is not trivial.

Modular approach

The modular approach is widely used for complex product systems, including process plants. However, how to define the modular boundaries, the input and output

of the modules, and their coordination interface become more important.

Before applying and executing a project, a phase gate review is recommended to ensure the standardized components are properly selected and maintained in due time. Specifically, the phase aligns with the project's time frame, and the gate has a strictly defined project quality. For example, for successfully applying modules for PSA oxygen generation mini-plant, we recommend splitting them into the following phases: conceptual design, basic engineering, and detailed engineering. For the gate review, the gate requirement is specified in advance in Table 2.

TABLE 2. Phase Gate Review for Modular Approach in Oxygen Generation Mini-Plant

Phase	Gate	Typical Gate Requirement
Conceptual Design	CD	<ul style="list-style-type: none"> • Process topology defined • Utility consumption estimated • Process and environmental safety concepts prepared • Process flow diagram released for basic engineering
Basic Engineering	BE	<ul style="list-style-type: none"> • P&ID released for mini-plant design • Plot plan completed • Mechanical datasheet/inquiry spec completed • Mechanical tie-in data, installation dimension, and weights fixed • Basic requirements for operation and automation completed
Detailed Engineering	DE	<ul style="list-style-type: none"> • P&ID released for construction and commissioning • Electrical and instrumentation materials ordered • Equipment foundation completed • Isometrics drawing completed • Factory acceptance test (FAT) for key equipment completed

Temperature

Ambient temperature is a key parameter influencing the performance of oxygen generation mini-plant. The ambient temperature will have three impacts on the mini-plant's performance, finally determining its uptime

in the harshest conditions and its build-up cost. Firstly, each compressor has an ideal operational range, reflecting the operation temperature, pressure, and flow rate. Thus, the model selection shall be fixed during the conceptual design, and the deviation from the optimal operating temperature will decrease the compressor efficiency. When the ambient temperature rises, the discharge flowrate of the air compressor will decrease, which means that the shaft power will increase. The record shows that the shaft power increases by about 1% for every 3°C increment in ambient temperature.

Secondly, increasing the ambient temperature will also increase the exhaust temperature of the air compressor, which requires more refrigeration capacity to compensate for the cooling loss, ultimately leading to increased energy consumption. Furthermore, the higher ambient temperature will also decrease the efficiency of the air dryer by 10% for every 5°C and leads to a higher dew point of compressed air, which will have a grave consequence of molecular sieve pulverization. Therefore, the high ambient temperature needs more heat exchange by the pre-cooler or aftercooler of the air compressor. Therefore, it is calculated and additionally configured. Alternatively, a higher-capacity of air dryer is also possible.

Thirdly, the low ambient temperature will decrease adsorption efficiency and oxygen purity in northern winters, especially in extremely low-temperature conditions. Further, in the winterization, the electrical and instrumentation parts, including in-field measurement devices, could be blocked or malfunction, and the safety of the mini-plant could be destroyed.

In summary, besides the process engineering calculation and modules matching as a basis, additional measures should be tailored to the local conditions of hot/cold are assumed. For instance, the air conditioner, ventilating fan and/or electric heater shall be installed indoors to reduce ambient temperature deviation. In addition, of course, the manual assistance to keep the door of the mini-plant house full-open, half-open, and full-close (if still possible to guarantee its safety) is helpful to maintain the normal range of 5–35°C and save power.

Humidity

As aforesaid, the murky mix caused by high humidity could harm the downstream units by grinding, corrosion, and polluting the process air. Secondly, it also could influence electric insulation seriously. Thirdly, it will increase power consumption, leading to a high-pressure drop resulting from a block by water vapor or moisture. Last but not least, high humidity will increase the operating load of the air filter at the compressor inlet and increase the replacement cycle.

Although the air that leaves a compressor reaches 100% humidity, the remaining humidity in compressed air turns into water as the air cools while it moves through the system. Because water causes corrosion and damage, proper drains function must be installed, whether automatic, electronic, or manual, to keep downstream equipment working optimally.

One of the most important issues is that the compressor shall be equipped with an aftercooler. It cools the air, turning up to 70% of the humidity into water, which is immediately drained. However, production facilities with extremely high ambient temperatures might need additional cooling, meaning double capacity or add-on aftercoolers in parallel, preventing excess moisture from entering the downstream equipment.

Pressure

When addressing the pressure, it often refers to the plateau area. There are two related two issues. One is the atmospheric pressure in a plain area or plateau area. In the plateau area, lots of atmosphere pressure-related factors shall be considered. For instance, is a specific mass flow or volume flow required? Can the compression ratio, absolute pressure, or gauge pressure be measured? Is the temperature of compressed air significant? But of course, the most crucial factor is that the suction pressure of feed air varies with the altitude. For example, a compressor with a compression ratio of 8.0 at sea level will increase to 11.1 at 3000 meters above sea level.

Furthermore, the atmospheric pressure also depends on the weather. For a specific place, seasonal temperature changes can also affect the pressure value by up to 5%. By the way, high altitude locations always lead to low atmospheric pressure and temperature, which shall be considered in advance. For the details, please refers to the section on “temperature.”

Another issue is the process pressure inside the mini-plant, precisely the working pressure of the adsorption and desorption process, which is jointly determined by atmosphere pressure, compressed air, and the pressure drop in the process. There are two main adsorption technologies for air separation by adsorption: PSA and Temperature Swing Adsorption (TSA). PSA methods require electricity to be supplied to the compressor or vacuum pump, while the TSA method involves heating the adsorption bed during the regeneration stage. Here is just a short discussion on PSA pressure setting. For Pressure ratio (PH/PL) is determined from the pressures at the end of the feed step (PH) and at the end of the desorption step (PL). These end pressures establish the boundaries for the N₂ and O₂ working capacities. Selecting PH, PL and PH/PL is a compromise between O₂ recovery and energy consumption, all within the constraints of the available compression equipment.⁷

Cleanliness

Filtration is essential, so the diversified filter types offer a range of purity grades to meet the specific requirements for removing the smallest contaminants, including bacteria and viruses. However, three negative impacts shall be considered when selecting the suitable solution for every application: the pressure drop, the contamination, and the cost of spare parts for filter elements.

In the heavy industrial zone, the inlet filter has to be reinforced, which leads to a pressure drop rising and increases the motor's load; otherwise, too many impurities in the air will increase the purification load of the molecular sieve adsorber and filters. If the purified air fails to meet the expectation, it will also affect the production efficiency of the PSA system and the production quality of oxygen.

CONCLUSION

This paper introduces the PSA oxygen generation mini-plant, a small-scale complex product system widely used in various hospitals, which was neglected in innovation. It addresses how to design and build the PSA oxygen generation mini-plant more flexibly to enable its compatibility in different extreme ambient conditions (temperature, humidity, pressure, cleanliness) of installation location.

Specifically, this paper employs the concept of modularity and elaborates 10 key components for 4 modules of PSA medical oxygen generation mini-plant, namely (a) air compressor module; (b) PSA module; (c) oxygen compressor module; (d) smart control module. Under this modularized design approach, this paper further investigates the technical features and the design criticality of modular and key components in fulfilling the expected performance, finally achieving and maintaining the overall performance of PSA oxygen generation mini-plant with the selected module installed worldwide.

This paper helps to illuminate the variability of PSA oxygen generation mini-plants in a harsh environment in four dimensions (temperature, humidity, pressure, cleanliness) and briefs the methodology of the phase gate model for modular approach in oxygen generation mini-plant. Furthermore, it contributes to the literature on modular design methods, adsorption technology, air separation process, etc.

RECOMMENDATIONS

PSA oxygen Generation mini-plant has been widely used in all-levels of hospitals and medical institutions. To overcome the harsh environment, a new product development process has been established and optimized

via S/M/P (standardization/modularization/platform) approaches to ensure product portfolio management and successful application with the selective serialized & standardized components.

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Analysis of 2022 Chinese Clinical Engineering Body of Knowledge and Body of Practice Survey

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ABSTRACT

Background and purpose: Clinical engineers (CEs) face greater demands for their professional knowledge as healthcare technology, especially life support equipment, including ventilators and artificial heart-lung machines, becomes increasingly important and complex. However, there are significant differences in clinical engineering majors around the world, and independent research on the body of knowledge and practice in clinical engineering is lacking in China.

Materials and methods: This study is an initial investigation into the body of knowledge and body of practice in the field of clinical engineering in China, conducted through a questionnaire-based survey. The aim of the survey is to collect important data from Chinese CEs.

Results: The investigators' background highlights that Chinese CEs are predominantly young, highly educated, and have limited work experience. Ongoing education and training will be needed to keep up with technological advancements. However, the future of clinical engineering in China looks positive. The survey of knowledge and work activities in the clinical engineering industry in China indicates that the main focus is maintaining the normal operation of hospitals. After that, according to the future development trend of the hospital, new knowledge and practical activities are continuously expanded.

Conclusions: Although the survey provides insight into the knowledge and activities that are most relevant to clinical engineering in China, further research is necessary to establish a reliable body of knowledge and practice.

Keywords – *Chinese Clinical Engineering, Body of Knowledge, Body of Practice, Clinical Engineering Survey.*

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INTRODUCTION

Clinical engineering is a multidisciplinary field that combines knowledge from several disciplines such as engineering, medicine, and computer science. The work of CEs involves the application of technology to improve patient care, safety, and outcomes in a healthcare setting. Their work is highly practical and requires continuous

learning and experience to keep up with the rapidly evolving technology and medical practices. As a result, the body of knowledge and practice in clinical engineering has quickly grown over the years.

However, this growth in knowledge has led to challenges in education and personnel training. On the one

hand, the content taught in schools may not meet the knowledge needs of actual work, and different colleges and universities have different majors and curriculum settings, resulting in differences in knowledge structure and stock.¹ Conversely, due to differences in working environments, medical treatment focus, and existing hospital technology, CEs' knowledge and experience may gradually differ. These differences and deficiencies in knowledge and practical experience are common in the industry and pose a bottleneck for industry development and personnel training. Therefore, it is necessary to establish a correct knowledge framework in clinical engineering.

Recently, the Global Clinical Engineering Alliance (GCEA) and IFMBE-CED jointly conducted a clinical engineering survey. This time, it is important to understand the type of knowledge that CEs need to develop their work (Body of Knowledge) and identify the activities that CEs carry out globally (Body of Practice). The ultimate goal is to define a set of disciplines to help any teaching unit revise and develop its academic program to train CEs. In the past, similar studies have been conducted from a global perspective² However, this article only focuses on China, and aims to gain a preliminary understanding of the knowledge and practice system in clinical engineering through large-scale surveys.

The remainder of this paper is organized as follows. The research materials and methods are described in Section II. The third section is the research results, and then the fourth section analyzes according to the research results. The fifth section is the conclusion.

MATERIALS AND METHODS

The purpose of this questionnaire is to collect different relevant types of information from respondents to better understand the current knowledge system and practice system in the field of clinical engineering. The questionnaire is divided into four parts, each focusing on a specific aspect of the respondent's background and work experience.

The first part, titled "Basic Information," requests the respondent's name, gender, location, age, and contact information. This section is important for establishing

basic demographic information about the respondents and their location.

The second part, titled "Occupational Background," is designed to gather information about the educational and work backgrounds of the respondents. In this section, respondents are asked to provide information on their degrees, professional fields, working years, nature of work, and whether there is a clinical engineering (CE) registration and certification process in China. This section will help to provide a clearer picture of the educational and professional backgrounds of CEs in China.

The third part, titled "Knowledge," is focused on identifying the importance of 40 different knowledge areas in the respondents' work. Respondents are asked to evaluate the level of importance of each area according to their own situation, rating them as minor, moderate, high, or not important. This section will provide insight into the specific areas of knowledge that CEs find most relevant to their work.

The fourth part, titled "Work Activities," lists 8 categories of work activities that CEs commonly engage in, such as health technology management, service delivery management, and information technology/digital health. Respondents are asked to evaluate the percentage of time they spend on each category and provide choices for supplementary descriptions of other categories. This section will help to identify the specific work activities that CEs in China engage in and the relative amounts of time they devote to each one.

It is worth mentioning that this questionnaire utilizes an online questionnaire to collect data, benefiting from various advantages. The online format facilitates quick and easy questionnaire distribution to many potential respondents, increasing response rates. The online format eliminates the need for manual data entry, thereby reducing the potential for errors and enabling more efficient data analysis. Additionally, the online questionnaire allows for the inclusion of skip patterns and branching logic to ensure that each respondent only answers questions relevant to their specific background and experience. Therefore, the online questionnaire is a practical and effective method to collect knowledge and work activity data of CEs in this study.

RESULTS

Basic Information

The survey received strong support from CEs in 21 provinces across China, with 178 valid responses received. Among them, 67 were from Zhejiang, 21 from Shanghai, 17 from Sichuan, and none of the other provinces reached 10 (Figure 1).

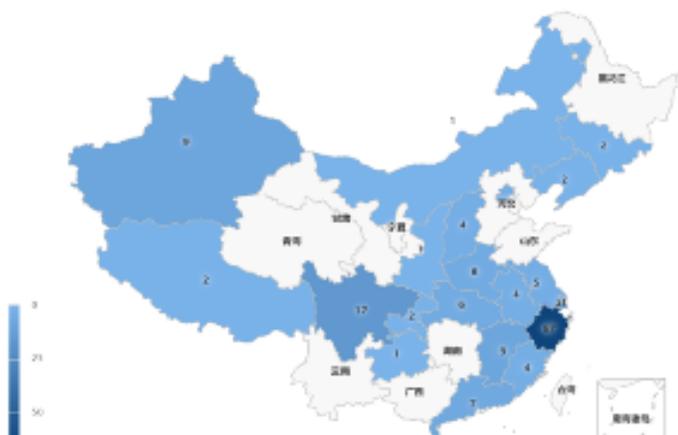


FIGURE 1. Geographical distribution of respondents.

The age structure of the respondents is an important factor in assessing the long-term development potential of CEs. As shown in Figure 2, 32.58% of the respondents are aged 20 to 30, 28.65% are aged 31 to 40, 23.03% are aged 41 to 50, and 15.73% are aged 51 to 60. Of the respondents, 60% are under 40, indicating that young and middle-aged people have become the backbone of China's clinical engineering talent pool.

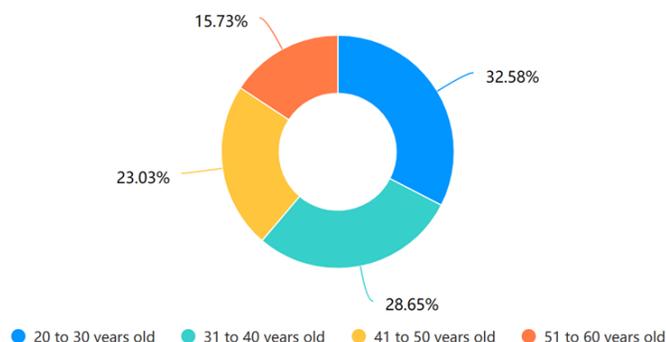


FIGURE 2. Age distribution of respondents.

Among the 178 respondents, it is worth noting that women accounted for only 27% (Figure 3). Encouraging more women to join the clinical engineering talent team is a long way to go.

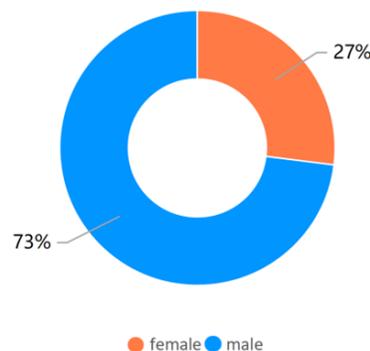


FIGURE 3. Gender distribution of respondents.

Occupational Background

The working years of CEs are an important factor in determining their level of professionalism, knowledge, and experience. In this survey, the distribution of respondents based on their working years is quite diverse. More specifically, 23.03% of the respondents have 1 to 3 years of work experience, indicating many early-career CEs in the workforce. 10.11% have 3 to 5 years of work experience, while 14.61% have 5 to 10 years of work experience. These respondents can be considered to be in the mid-career stage and are likely to have more experience and expertise in the field.

Moreover, the survey results reveal that there are also many CEs with extensive work experience. Specifically, 17.42% have 10 to 15 years of work experience, 10.11% have 15 to 20 years of work experience, and 24.72% have more than 20 years of work experience. This indicates that a significant number of senior CEs have accumulated a wealth of experience and knowledge throughout their careers. Overall, the diverse distribution of working years among respondents in this survey suggests that the clinical engineering field has both experienced and novice professionals.

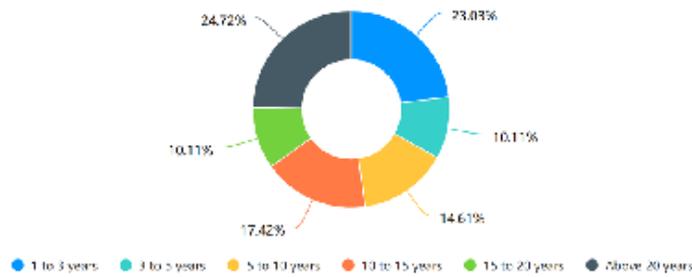


FIGURE 4. Working years distribution of respondents.

Older age is associated with more work experience (Figure 5), which seems to align with the objective law, but the trend of older practitioners with more work experience means that opportunities for professional development in clinical engineering are limited.

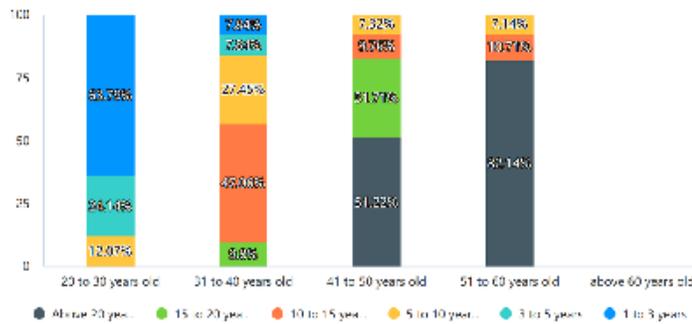


FIGURE 5. Working years of respondents in different age groups.

With the continuous and rapid progress of medical technology and the increasing integration of modern medical equipment into hospitals, the responsibilities of medical engineering departments in China have evolved from focusing on the maintenance of a single piece of medical equipment in the 20th century to covering a series of tasks such as preventive maintenance of medical equipment, regular repair and maintenance, quality control, metrological testing, technical evaluation, clinical evaluation, innovation, and improvement. This has led to an increase in the number of practitioners, and the level of education of personnel is gradually increasing to meet the needs of the role.³

The survey also included questions about the educational backgrounds of the respondents. The results showed that the majority of the respondents had an undergraduate degree in an engineering area (46.07%), and a significant number of them had a Master's degree in engineering area (28.65%). However, there were also respondents with educational backgrounds in non-engineering areas, such as undergraduate degrees in other areas (9.55%), Master's degrees in other areas (6.74%), and PhDs in both engineering and non-engineering areas (3.93% and 2.25%, respectively). There was also one respondent who had a degree in another area not covered by the survey options.

Figure 6 compares the educational background of respondents from the China Clinical Engineering Survey in 2021 and 2022. The results show a clear trend towards higher levels of education among CEs.

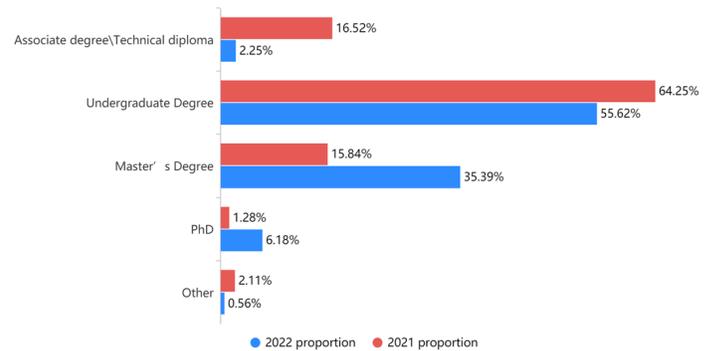


FIGURE 6. Educational background distribution of respondents in 2021 and 2022.

When asked about the main nature of their current position, above-average respondents chose Clinical/Biomedical Engineer (58.99%), followed by Healthcare Technology Managers (12.36%), Medical Equipment Planners (6.74%), Technologists (5.06%), Technicians (10.67%), Professors/Educators/Researchers (1.12%), Consultants (1.12%), and Others (3.93%). However, this question reveals an interesting finding: Chinese CEs focus more on healthcare technology planning, assessment, management, analysis, education, and support (Table 1).

Finally, the survey led to a consensus among CEs in China that there is a registration and certification process in place for CEs in the country.

TABLE 1. Occupational Nature of Respondents

Options	Count	Percentage
Clinical/Biomedical Engineer	105	58.99%
Healthcare Technology Manager	22	12.36%
Medical equipment planner	12	6.74%
Technologist	9	5.06%
Technician	19	10.67%
Professor/Educator/Researcher	2	1.12%
Consultant	2	1.12%
Other	7	3.93%

Knowledge

The knowledge domains were classified based on clinical engineering background knowledge. Respondents were asked to rate the importance of 40 items related to their daily duties and responsibilities, using a 4-point scale: 1 for not important, 2 for minor important, 3 for moderate important, and 4 for high important. The average score for each item was calculated, and the detailed results of the investigation are presented in Table 2.

TABLE 2. The Importance of Each Background Knowledge

Category\Options	Not Importance	Minor Importance	Moderate Importance	High Importance	Average
Medical Device Regulation	3	4	42	129	3.67
Maintenance Management	2	6	53	117	3.6
Quality Management	1	7	63	107	3.55
Computers, Networking, Information Technology	1	12	61	104	3.51
Data Management	2	10	66	100	3.48
Risk Management	2	16	56	104	3.47
Electronics (theory, design, analysis, etc.)	5	17	59	97	3.39
Facilities Management	1	22	64	91	3.38
Surgical Instruments & Devices	4	23	59	92	3.34
Medical Device Innovation	4	17	74	83	3.33
Interoperability of Devices and/or Systems	5	17	72	84	3.32
Procurement Strategies	5	18	72	83	3.31
Engineering Asset Management	2	24	74	78	3.28
Project Management	5	20	77	76	3.26
Respiratory Equipment	4	33	54	87	3.26
Hospital Engineering	7	23	67	81	3.25
Digital Health	4	23	81	70	3.22
Medical Imaging	0	35	73	70	3.2
Health Technology Assessment	7	25	73	73	3.19
Leadership or Executive Skills Coaching	9	25	74	70	3.15
Systems Engineering	5	32	76	65	3.13

Category\Options	Not Importance	Minor Importance	Moderate Importance	High Importance	Average
Patient Safety User/Patient Training	14	33	56	75	3.08
Health Facility Planning and Design	9	37	65	67	3.07
Statistics	3	43	71	61	3.07
Consumables	9	39	72	58	3.01
Management (area/s other than those listed)	13	27	83	55	3.01
Sterilization	10	42	65	61	2.99
Physiological Monitoring	17	40	57	64	2.94
Telemedicine / Telehealth	13	40	72	53	2.93
Hemodialysis	19	43	54	62	2.89
Presentation Skills	10	48	75	45	2.87
Airborne Infection Control	16	47	61	54	2.86
Clinical Laboratory	14	53	57	54	2.85
Human Factors Engineering	19	47	56	56	2.84
Simulation and Modelling	21	51	60	46	2.74
Home care/Virtual care (remote patient monitoring)	23	46	67	42	2.72
Accounting and Finance	15	61	65	37	2.7
Radiation Oncology	28	58	45	47	2.62
Neonatal and/or Pediatric Care	33	52	45	48	2.61
Anesthesia	35	62	35	46	2.52

TABLE 3. Overall Time Spent in Each Group of Activities

Activity\Percentage	0	1~25	26~50	51~90	91~100
Health Technology Management	2.81%	23.03%	29.78%	30.34%	14.04%
Service Delivery Management	5.62%	16.85%	22.47%	32.58%	22.47%
Development, Testing, Evaluation and Modification of Products	16.29%	38.76%	26.4%	12.36%	6.18%
Information Technology / Digital Health	9.55%	39.33%	24.16%	18.54%	8.43%
Education of Others	8.99%	39.89%	29.21%	16.85%	5.06%
Facilities Management / Infrastructure	8.99%	25.28%	29.21%	27.53%	8.99%
Risk Management / Security	0.56%	27.53%	28.09%	29.78%	14.04%
General Management	0.56%	17.98%	29.21%	37.08%	15.17%

Work Activities

Table 3 displays respondents' estimated percentage of time in eight job categories. These categories include health technology management, service delivery management, development, testing, evaluation and modification of products, information technology/digital health, education of others, facilities management/infrastructure, risk management/security, and general management. Besides these predefined categories, respondents were also allowed to provide information about other job categories they worked in. Table 3 data is a valuable resource for gaining insight into the work activities of CEs. This information can inform workforce development and training programs in the field, ultimately leading to better-prepared clinical engineering professionals.

DISCUSSION

Although the survey had a broad geographic scope, with respondents from multiple provinces in China, the fact that a large proportion of the responses (67 out of 178) came from a single province, Zhejiang, could potentially introduce bias to the data. Given that Zhejiang is a relatively affluent province and is home to many well-known medical device manufacturers, the experiences and knowledge of CEs in this region may not fully represent the wider population of CEs in China. Therefore, it is important to interpret the survey results with caution and avoid overgeneralizing based on the experiences of CEs in Zhejiang alone.

The survey results indicate that the clinical engineering community in China is relatively young, with limited work experience. However, it is encouraging to note that practitioners with more than 20 years of experience are still active in similar numbers as young practitioners. This balance between new and experienced professionals bodes well for the future of clinical engineering in China, with promising human resource reserves and team-building prospects for the younger generation.

The survey results also indicate that the vast majority of respondents, 97.75%, held at least an undergraduate degree, with many pursuing engineering-related studies.

This finding highlights Chinese clinical engineering practitioners' solid professional knowledge base. It is worth noting that this trend of increasing education among domestic CEs in China is not unique, as global survey results suggest that China is among the countries with the highest percentage of highly educated CEs. In fact, while 80% of CEs worldwide have a bachelor's degree or higher, the figure for China is 97%. However, the low representation of women in the field, accounting for only 27% of the total, is a cause for concern. Efforts to encourage more women to pursue careers in clinical engineering must be made.

In addition to the issue of job diversity, there is also a concern about limited opportunities for professional development within clinical engineering, especially for older practitioners with more experience. China has a well-established registration and certification process for CEs, indicating the profession's maturity. However, in situations with limited avenues for professional development or lateral transitions, experienced practitioners may face the challenge of stagnation, potentially hindering their ability to bring novel ideas and unique perspectives to their work. To address this issue, it is crucial to promote continuing education and training opportunities for CEs. Establishing a body of knowledge (BoK) and a body of practice (BoP) in Clinical Engineering can also facilitate their continuing professional development, allowing them to expand their knowledge and expertise and stay up-to-date with the latest developments in the field. Providing opportunities for continuing education and interdisciplinary collaboration can help experienced practitioners maintain their effectiveness and innovation, ultimately leading to a more dynamic and effective clinical engineering profession.

The issue of the main nature of work in clinical engineering sheds light on the various roles that practitioners play in the healthcare industry. In China, most CEs identify as clinical/biomedical engineers, focusing on planning, evaluation, management, analysis, education, and medical technology support. The position also includes functions such as healthcare technology managers, medical equipment planners, clinical engineering technologist, clinical engineering/biomedical equipment technician and others. Practitioners must possess diverse skills and knowledge to effectively carry out their responsibilities. Additionally,

many respondents were identified as healthcare technology managers and medical equipment planners. As time progresses, the work of CEs is no longer limited to the maintenance and repair of medical equipment. By combining their understanding of clinical needs, they can effectively provide hospitals with beneficial and appropriate configurations, management, and medical equipment planning.⁴ The diversity of reported positions also reflects the wide range of expertise required in clinical engineering, from technical proficiency to leadership and management skills.

Regarding the importance of knowledge, three parts can be roughly divided. Medical device regulation, maintenance management, quality management, data management, risk management, facilities management, and implementation methods such as computers, networking, and information technology rank highly in the clinical engineering industry. Among them, medical device regulations are considered to be the most important as a factual basis. This highlights the significance of regulatory compliance and the proper management of medical devices in clinical engineering. Clinical engineering work in China is mainly focused on managing and maintaining hospital operations, which is also reflected in the main nature of the work of CEs. Today's medical activities development in China greatly depends on medical devices' safety, reliability, and stability. CEs effectively ensure the normal operation of medical devices through evaluation, maintenance, quality control, measurement, etc., to ensure the normal development of medical activities.⁵ China promulgated the "Regulations on the Supervision and Administration of Medical Devices" on January 4, 2000.⁶ After two revisions, the latest version was implemented on June 1, 2021. It shows that medical devices must follow risk management principles, whole process control, scientific supervision, and social governance. This is a guide for all CEs in China.

The important knowledge areas that follow are some of the more specialized and precise subdivisions of day-to-day management work, such as surgical instruments & devices, procurement strategies, engineering asset management, project management, hospital engineering, statistics and health technology assessment, etc. Mastery of these areas can help bridge the knowledge gap for Chinese CEs, allowing them to ensure high-quality, safe,

and efficient healthcare operations. Knowledge of surgical instruments and equipment is crucial for ensuring the safety and success of medical procedures, while a procurement strategy is necessary to obtain the necessary resources while maximizing the budget. Engineering asset management involves the management of complex systems, requiring expertise in monitoring, maintaining, and optimizing equipment. Project management is critical to coordinating resources, managing timelines, and communicating effectively with stakeholders. Moreover, hospital engineering encompasses various technical disciplines, including electrical, mechanical, and structural engineering. Effective CEs must be able to design, maintain, and optimize complex systems to ensure healthcare facilities' safe and efficient operation is another essential knowledge area for CEs. A solid understanding of statistical analysis is crucial for evaluating the performance of healthcare systems, identifying areas for improvement, and measuring the impact of interventions. Health technology assessment (HTA) is an emerging field that is becoming increasingly important in healthcare. It systematically evaluates health technologies' safety, efficacy, cost-effectiveness, and social impact, including medical devices and equipment. HTA provides valuable information for healthcare decision-makers, helping them make informed decisions about which technologies to invest in and how to allocate resources effectively.

Finally, the knowledge categories in the lower part share a common feature: they overlap with the expertise of other occupations in the hospital. For example, sterilization is generally responsible for nurses, anesthesia is generally for anesthesiologists, and accounting and finance are generally responsible for professional accountants.

This rule also continues in the survey results of time spent on practical activities. Activities related to the clinical engineer's primary task—ensuring clinical applications for the medical device business (e.g., service delivery management, general management)—are more time-consuming and therefore ranked high.⁷ Conversely, less relevant activities (such as education of others, development, testing, evaluation and modification of products) take up less time and therefore ranked lower. This shows that Chinese CEs may be more inclined to the direction of traditional clinical engineer functions. However, CEs

play a bridge role in developing medical device products. They are integrators of medical technology, guardians of equipment safety, evaluators of instrument applications, and communicators between hospital construction and industrial development. To promote the further development of China's clinical engineering field, it is necessary to attach importance to industry-university-research-medical cooperation and knowledge sharing, and incorporate it into the strategic career development plan.

CONCLUSION

Under the new requirements of hospital-refined management and modern medical technology, the development of clinical engineering in China is facing new challenges. Strengthening the construction of the BoK and the BoP is an important measure for adapting to environmental changes and improving comprehensive strength. This survey may not cover the scope of all clinical engineering personnel and may not fully reflect the knowledge needed for clinical engineering in China, but the research results have predicted a set of knowledge required for clinical engineering in China.

The BoK and BoP in clinical engineering still require in-depth research, and determining key knowledge requires the consensus of numerous authoritative experts and stakeholders. Unless the BoK defined, relevant practices, research, and scholarly teaching information are collected, and consensus is reached, the clinical engineering knowledge system framework will be incomplete. It should be noted that the systemic nature of the knowledge system must be established based on verified evidence.

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Sustainable Procurement of Medical Devices in an International Context: Part 1 - Background and Definitions

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ABSTRACT

Background and Objectives: Sustainability is a working principle included in the United Nations (UN) procurement processes with the adoption of the Sustainable Development Goals (SDGs) in 2015. In the context of internationally funded projects in developing countries for procuring health-related goods during and following the COVID-19 pandemic, this article further investigates what sustainable procurement means when applied to purchasing medical devices (MDs), considering its impact on health services. It also proposes a reflection on the concepts of sustainability and quality assurance as guiding principles for technical teams during the process of MD procurement.

Material and Methods: This article aims to identify how sustainability can be implemented during the execution of a project based on the analysis of principles that guide procurement actions in the four UN agencies with the highest volume of MD procurement. The concept of sustainability is also explored from a macrosystemic point of view as the ratio between the impact of a procurement project on healthcare services and its investment. Its implications for population health and wealth is also discussed. Based on the experience of the authors in implementing purchasing processes of MDs, a framework for the specific technical activity is then proposed.

Results: In the UN system, sustainable procurement focuses on the social, economic, and environmental quality of the equipment and on the conditions of its production to guarantee that a sustainable good is procured. Not being enough, the focus should also be on the benefit of a procurement project, not as the possession of a new MD, but as the utility of the device: an instrument to provide healthcare services of the beneficiary country. Procuring sustainable goods should include planning their future use as an essential component for a sustainable positive impact on the health and wealth of the beneficiary population. Thus, the intended use of the procured devices should be defined, planned, and measured. In the proposed framework, sustainability is a ratio between an MD's social, economic, and environmental costs and the benefits of its use. When neglecting the essential factor of sustainable use of MDs, the risk of purchasing equipment that will not be properly and efficiently used is relevant. To guarantee the sustainable use of a MD, it is essential to assess the needs, the local conditions, and the conditions for its lifelong use. Further evolution of the concept of sustainability is developed towards the possibility of modulating the project's objective from procuring sustainable MDs to improving the sustainability of the health services by procuring MDs.

Conclusion: Sustainable procurement of MDs is a key factor in supporting the sustainable development of health services and health systems toward the SDGs. Post-pandemic investments to strengthen the resilience of health services in developing countries shall consider sustainable procurement, including the essential quality assurance process. This process, led by an expert clinical engineer, shall be centered on the future use of the equipment and not be limited to its quality as a material good.

Keywords – *Medical device procurement, sustainable procurement, needs assessment, health services in developing countries, quality assurance, sustainability.*

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INTRODUCTION

Sustainability principles have recently been included in the UN procurement processes.¹ Considering the opportunity to follow SDGs² and reduce health inequities by focusing on project implementation, this article investigates further what sustainable procurement means when purchasing MDs in a developing country and its impact on health services.

Quality in healthcare is a *comprehensive and multifaceted concept*, including technical competencies, effectiveness, efficiency, continuity, and safety. It is known that in developing countries, improving quality is not a luxury, and doing so often pays off.³

Therefore, It is essential and possible to place sustainability and quality assurance (QA) at the center of the biomedical engineer's efforts, aiming to improve quality healthcare services in developing countries.

Healthcare services save lives and increase the population's well-being, but at the same time, they have a relevant impact on the environment, social and economic aspects of the communities involved. If not correctly managed, this impact can weaken communities and threaten their ability to guarantee healthy lives for future generations.⁴

As the pandemic of COVID-19 progressed and the number of patients affected rose, the demand to procure materials and medical devices (MD) to deliver healthcare increased, especially in developing countries, which were more vulnerable to the pandemic due to a historical lack of investment in the health sector.⁵

In this context, the quality of the procurement process to ensure the sustainable purchase of MDs in developing countries becomes a key factor that goes beyond the technical characteristics of the device.

More than ever, the procurement of MDs needs to have a durable and positive effect on health services to improve patient care while reducing their environmental, social, and economic impacts according to the SDGs.⁶

This article presents the experience of the authors during the COVID-19 pandemic when the requests for MDs for developing countries exploded. Following this

increase, in 2021, UNOPS has become the second largest health procurement agency within the UN for MDs and supply, with USD 500 million in purchases, after UNICEF, the number one procuring Agency.

APPLICATION FRAMEWORK AND METHODS

The application framework can be depicted as an international procurement process where a *funding source* is donating or loaning money to a *beneficiary*, typically a public institution of a developing country, and the procurement is carried out by an *implementing agency*.

In developing countries, the knowledge asymmetry between private suppliers and public purchasers is more evident: "*Public procurers perceive it hard to know what the available market offerings are resulting in the problem of finding the best available solution. They also lack enough insight into the operations, making it hard to understand the need of which the procurement is meant to fulfill. In extension this problem makes it hard to mediate the need to the market.*"⁷

The rise of new technologies in the global market increases this knowledge gap, limiting the effort of public procurers toward a more sustainable procurement. It is essential to have public procurement institutions with enough technical capacities to challenge the market to reduce the dependence on information from manufacturers or suppliers that can be biased to their own advantage. To be able to take evidence-based decisions and choose only the innovative technologies that represent a real advantage, and finally to orient the market development toward sustainable innovations that are in the interest of developing countries. For these reasons, international implementing agencies are also responsible for bringing technical knowledge to strengthen local technical capacities.

This article focuses on the procurement of MDs, with particular attention on medical equipment that requires specific installation and safety measures. It also analyzes the main UN procuring agencies perspectives on sustainability and where the focus should be placed.

Consequently, this framework's target beneficiary of the procurement process will be part of secondary and tertiary care-level infrastructures. Expert in MDs, the

technical lead of the project should be a biomedical or clinical engineer leading the technical part of the procurement process; thus, they are institutionally in charge of ensuring the quality of the purchase.

Within the described framework, the procurement of MDs is a project limited in time, with a specific, well-defined schedule, budget, and expected quality. The Project Manager (PM) and their team will pursue these three dimensions simultaneously.⁸ If the PM is not an expert in MDs, they will pursue a schedule and a budget while relying on the technical lead to ensure the quality/scope.

Firstly, this framework will explore the meaning of 'sustainable' and its definition in the context of a procurement project of MDs. Secondly, what sustainable procurement means from the technical perspective of the project within the agency will be investigated. Finally, a discussion on quality and sustainability and their similarities and differences in the procurement of MDs will be made.

A MACRO APPROACH TO SUSTAINABLE MDS PROCUREMENT IN DEVELOPING COUNTRIES

The health of a population is positively correlated with economic development.⁹ A healthier population is more active and productive, thus increasing the development process of a country. In return, the development of a country increases its capacity to offer better health services to its population. If the third sustainable development goal 'Good-health and well-being'¹⁰ and universal health coverage, are to be achieved, countries must invest at least 5% of their GDP.¹¹ Focused investment is needed and funding agencies can play a key role in their strengthening.¹² Health capital expenditures and assets maintenance and management have been historically underfinanced. The pandemic pointed out this fragility and lack of resilience of health systems. As a result, in 2020, governments' increased health care expenditure to address the additional medical needs was observed.¹³

A procurement project of MDs represents the injection of funds into a developing country's health services, aiming to improve the population's health and contribute to the country's sustainable economic development. Implementing an investment project in the health sector is part of a virtuous circle: direct investments or loans coming from

present or future taxes are transformed into infrastructure and technologies that improve the population's health. The healthier a population is, the better the economy.

However, healthcare financial resources being limited, the high-quality (sustainable) or low-quality (unsustainable) of an MD procurement project is thus a critical factor that will impact the health services performance and thus, the population's health. This means that the work of the technical leads in MD procurement projects has a potential impact on the lives of millions of people.

Therefore it is possible to define sustainability as a critical 'gain factor' (Figure 1), which depends on how the project is implemented. A high-quality project will have a highly positive factor so that the investment will produce results that will exceed the loan reimbursement, thus increasing health services resilience.

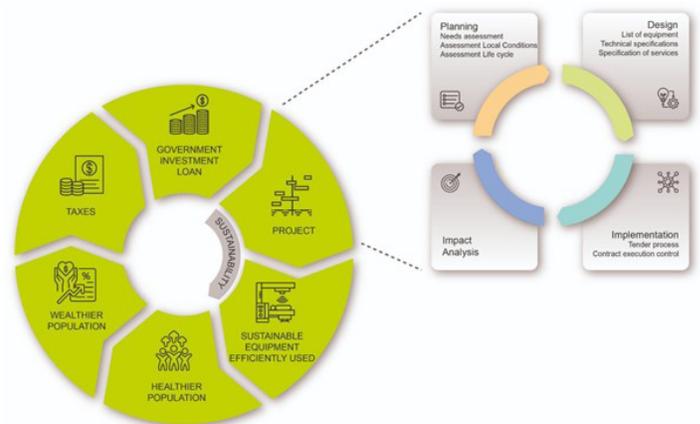


FIGURE 1. The virtuous circle of investments in health technology. The procurement project's sustainability is a critical factor in achieving the intended impact of a healthier population.

This factor is what makes a project sustainable for the convenience of the beneficiary country's population. In light of this top-down definition of 'sustainability' it is possible to define the sustainability of a project with the ratio between the impact of the project on the SDGs and the amount of the investment. From this macro perspective, QA and sustainability assurance are synonymous, depending on the project's impact.

When the impact of the project is reduced, null, or worse, negative (when for example, there are high costs to maintain brand-new medical technologies that are seldom

used), what will remain for the population is a debt that will be paid by their own taxes (Figure 2).

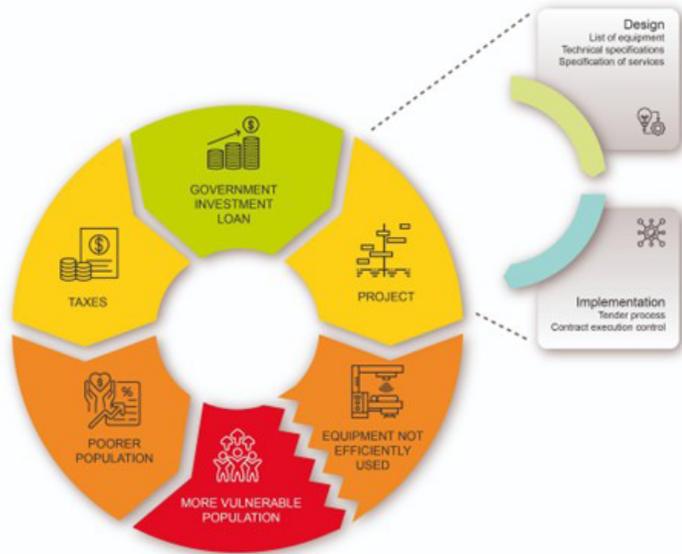


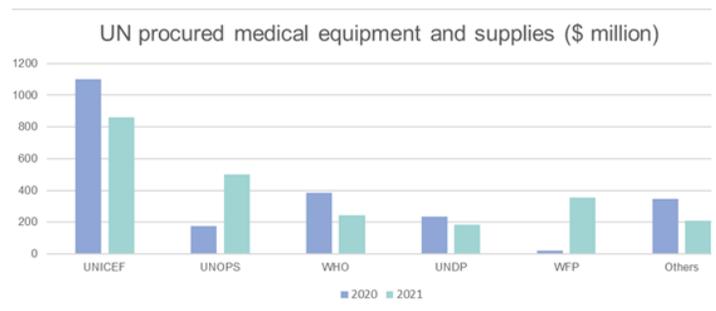
FIGURE 2. Disruption of the virtuous circle of investments in health technology: when quality Assurance/sustainability of the procurement project is lacking, sustainable growth of the population’s health and wealth associated with the project are not guaranteed and often negatively affect the population.

The population subsequently receives fewer benefits, and the economy doesn’t grow as expected based on social determinants of health studies. The lower the income, the worse the health.¹⁴ Therefore, an MD procurement project always impacts the wealth and the health of the population it aims to help. This impact depends on its sustainability.

Being aware of its impact during the project’s planning, design and implementation will improve its sustainability, in fact: *“...Economic growth and increased health spending alone are not enough to scale-up healthcare coverage and achieve better health outcomes. These must be combined with accountability of results, transparent management of public funds, and multisectoral efforts with community involvement at implementation level.”*¹⁵

PRINCIPLES AND DEFINITIONS OF SUSTAINABILITY APPLIED BY THE UNITED NATIONS AGENCIES

In 2015, the United Nations (UN) adopted the SDGs to end poverty and hunger, ensure prosperity for all and protect the environment by 2030.¹⁶ These goals and their targets, especially the third one ‘Good-health and well-being’,¹⁷ serve as a foundation to the MDs sustainable procurement strategies of the UN agencies working in the healthcare sector. UN procurement of medical equipment and supplies amount has grown from \$640 million (average 2013-2019) to \$2.26 and \$2.35 billion in 2020 and 2021.¹⁸ A group of these agencies, the UN Sustainable Procurement in the Health Sector (SPHS), whose objective is to contribute to more sustainable health services and greener economies through sustainable procurement in the health sector, has an estimated annual purchasing volume of \$5 billion in health products which represents the largest market share in the health sector.¹⁹ Therefore, UN agencies are committed to lead by example and may also influence manufacturers and suppliers in the healthcare market toward more sustainable products concerning the SDGs.²⁰ Graph 1 presents the five UN agencies that purchased the most medical equipment in the 2020-21 biennium.



GRAPH 1. Amount of medical equipment purchased by UN agencies in 2020 and 2021 in \$ million. WFP procures mainly food and clinical nutrition supplies that are out of the scope of this article.²¹

UN Agencies sustainable procurement approach

The sustainable procurement of MDs approach is slightly different depending on the specific mandate of each agency. However, the policies of WHO,²² UNICEF,²³ UNDP²⁴ and UNOPS²⁵ all have in common three dimensions

of sustainability: economic, environmental and social which are applicable throughout the life cycle of the MD. Table 1 summarizes the sustainable procurement principles of the four mentioned UN agencies working in the healthcare sector, and details the elements considered for a sustainable purchase. According to the UN agencies' policies, these three dimensions of sustainable procurement must be considered in all phases of the implementation project (program design, budgeting, implementation, and monitoring). The key to a successful project is to plan procurement collaboratively with the relevant stakeholders in the early phases of the project.²⁶

The definitions of sustainable procurement of the UN agencies include three dimensions: an environmental

aspect which focuses on the quality of the MD purchased - its carbon footprint - a social aspect which focuses on the quality of the manufacturing conditions of the MD - the condition of the labor force for its production - and an economic aspect which focuses on the quality of the financial resources allocation - its life cycle cost.

All the UN definitions of sustainability are centered on the quality of the device and the quality of its production and transportation. However, delivering a quality device to a beneficiary is insufficient to ensure sustainability. A sustainable device directly becomes unsustainable if not used because its environmental, social, and economic costs are compared with no benefits as discussed in the following paragraphs.

TABLE 1. Summary of the sustainable procurement principles of WHO,²² UNICEF,²³ UNDP,²⁷ and UNOPS.²⁵

	Economic	Social	Environmental
WHO	Entire life cycle cost. Local communities and small and medium enterprises (SMEs). Promoting sustainability throughout the supply chain.	Human rights and labour issues. Inclusions of persons with disabilities. Gender equality and women's empowerment. Social health and well being.	Prevention of pollution to air, land and water. Sustainable resource use. Climate change mitigation and adaptation Protection of the environment, biodiversity and restoration of natural habitats
UNICEF	Best value for money (price, quality, availability, functionality and innovation). Life cycle costing. Total cost of ownership. Economic development. Employment. Good Governance.	Human development. Education, Social inclusion. Human-labour rights. Poverty and inequality reduction. Security. Promotion of small and medium enterprises (SMEs).	Preservation of natural resources, ecosystems and biodiversity. Reduction of ecological footprint. Reduction of greenhouse gas emissions. Waste management.
UNDP	Costs of products over their entire life cycle (Acquisition, maintenance, operations and end-of-life management costs including waste disposal)	Recognizing equality and diversity. Observing core labour standards. Ensuring fair working conditions. Increasing employment and skills. Developing local communities and their physical infrastructure.	Natural resource use and water scarcity. Emissions. Climate change. Biodiversity.
UNOPS	Local Micro, Medium, Small Enterprises (MSMEs). Total Cost of Ownership (TCO). Long term cost efficiencies.	Local development and resilience. Protection of human rights. Improved labour conditions. Gender equality disability inclusion.	Reduced carbon emissions. Materials to be used in production. Packaging.

UNICEF explicitly includes a “*Definition of Need - Planning supplies with programme specifications*” at the beginning of the procurement process and an “*End-user Utilization - Fit for purpose Impact*” at the end to measure the impact of the purchase.²⁶ Nonetheless, this does not directly link the use of the goods with their sustainability and the design of their requirements.

SUSTAINABILITY LEVELS IN THE IMPLEMENTATION OF A MD PROCUREMENT PROJECT

As discussed previously, the sustainability principles depend on the project results and impact on the health services and can be summarized into different levels. The technical lead can pursue these levels according to their experience, awareness of sustainability principles, and role in the dialogue with the PM and the project stakeholders. It will also be linked to the policy and regulations of the purchasing agency. Local regulations have to be considered as well.

Basic sustainability level: procurement of a sustainable device

This level is the first level of sustainability to achieve and as depicted previously, most of the procurement policies within the UN system are focused on this level to purchase goods produced sustainably. However, owning a sustainable MD does not guarantee *per-se* a benefit for the health services and the population.

Moreover, an environmentally friendly MD purchased at a low price and with high ethical standards that are not used at all, or not appropriately, or scarcely used during all its expected lifetime harms the environment since its environmental cost cannot be balanced with an adequate health and economic benefit. And therefore, it represents a low-quality unsustainable purchase that will damage the financial wealth and thus, the health of the population it intends to benefit.

Intermediate sustainability level: procurement centered on the sustainable use of an MD

Reflecting on the procurement processes during the COVID-19 pandemic, the authors present *three pillars* that guarantee sustainable use of the procured device and thus contribute to sustainable procurement.

The lessons learned during the assessment of several hospitals in various developing countries show a significant percentage of medical equipment (estimated by the authors to up to 20%) that is not working or not efficiently used. It has been reported that about 40% of donated MDs in developing countries are out of service.²⁸ The main reasons for this situation are: the lack of patients and healthcare resources resulting from a weak needs assessment; inadequate installation of the equipment; absence of funds for consumables, maintenance, and spare parts; lack of experience and training of technicians and healthcare staff; delays in approvals/permissions as per local regulations.

Pictures like the ones shown in Figures 3 and 4 are quite common in developing countries where a significant amount of MDs is not used with high environmental, social, and economic costs.

Effective procurement is based on getting the correct goods to meet the functional needs of the beneficiary.



FIGURE 3. Photos of unused MDs in three different hospitals, the first in the Caribbean, the second in Central Asia and the third in Central America.



FIGURE 4. Pictures of stored new laboratory equipment. The boxes on the pictures were never opened several months after their delivery. The third picture shows equipment waiting for years to be completely installed.

That is to say that the planned use of the equipment has to provide planned benefits to the population. In fact, the entire procurement process is based on a needs assessment as its essential starting point. When a procurement process has been carried out transparently, efficiently, and coherently with the objectives, the reliability of the needs assessment is still to be confirmed to get quality results.²⁹

To guarantee that the purchased MDs will be correctly used, the project's technical lead should investigate its intended use by discussing the pretended use of the MD with the beneficiary. Thus, the first pillar of sustainability should be: the needs assessment where the following aspects shall be investigated:

1. The demand - design of the list of MDs to be procured: is there an evidence-based health need that justifies the proposed MD?
2. The intended use - design of the technological level: when the intended use is clarified, it is possible to choose the appropriate technological level of the MD and its accessories.
3. The expected quality/durability - design of technical specifications: by balancing the available budget with the expected quality, the technical characteristics of the goods to be purchased can be designed.

Therefore, an **adequate MD** will result from a procurement process that begins with a needs assessment strongly correlated to the population's health needs through a constructive technical dialogue involving the beneficiary and the clinical end-user.

The needs assessment and the preparation of the equipment list is usually a process carried out before the project starts to estimate the project budget and formalize the agreements between the beneficiary, the donor, and the implementing agency. Nevertheless, it is recommended that this preliminary needs assessment is validated and strengthened by a deeper analysis at the project's start, because the conditions may have changed, and the preliminary needs analysis is usually too quick and does not consider the intended use and the expected durability/quality.

The second pillar of sustainability is the **assessment of existing conditions**.

It is essential to focus on the context where the goods will be used. To this extent, the focus shall be on: (1) the sustainable and safe delivery of the equipment from the fabrication site to the installation site; (2) the infrastructure that will receive the MDs and the design of the interface of the equipment within the existing environment; (3) the interaction of the equipment with other equipment or technologies; and (4) the capacities of the human resources that will use and maintain the MDs.

The result of the assessment of existing conditions is an **adequate delivery and installation plan**.

The third pillar of sustainability is the **assessment of the lifelong use conditions** of the MD. As mentioned before, it is not enough to purchase an adequate MD and install it; a sustainable purchase should also include assessing its useful life conditions. To this extent, the focus shall be on: (1) The adjustment of the equipment's life span based on the project's conditions; (2) The warranty and post-warranty services; (3) The existence of organizational conditions such as trained resources for sustainable use and maintenance of the equipment; (4) The existence of funds for maintenance and consumables; and (5) The existence of a plan for disposal of the equipment.

The result of the assessment of the conditions during the life expectancy of the MDs is an **adequate lifelong use plan**.

Advanced sustainability level: purchasing an MD with a sustainable impact on the health service

When implementing an MD project, it is possible to broaden the framework approach to the national health service level by considering a targeted population and the entire national system of secondary and tertiary care infrastructure. In this broader vision, it is possible to achieve a wider needs analysis during the planning and implementation of a project to adjust the list of the equipment and their characteristics.

Some international procurement processes can be designed to target the population of an entire country so that the needs assessment of the project is focused on the national healthcare services. In contrast, others are limited to infrastructures of specific regions or sites such as the equipment of a new health infrastructure. In

an ideal international procurement project, the technical lead can include considerations on the impact of the purchase of MDs on the entire national health service. In this case, it is recommended for the technical lead to open a dialogue with the National Ministry of Health counterpart and request access to consolidated and updated health statistical data. This represents a challenge since during the implementation of a procurement project, the pressure to comply with the schedule and the budget may limit these kinds of actions and considerations.

Higher sustainability level: Purchasing MDs to increase the sustainability of the health service

The final level of sustainability definition includes the case when an MDs procurement project's objective is to increase the health service's sustainability. Since we are focusing on secondary and tertiary care, this means a more efficient and environmentally friendly way to provide care to patients through innovative technology. Targeting the improvement of health services quality through advancing technical competencies, effectiveness, efficiency, continuity, and safety can be the primary objective of an MDs procurement project.³⁰

New technologies and innovation in the health processes following their introduction in the health service is a major theoretical subject that includes health technology assessment (which is not the focus of this paper). Nevertheless, at least one specific aspect of introducing new technologies is worth underlying: the integration of medical equipment with information technology (IT) systems.³¹ This interface is an aspect that deserves to be further discussed since it has several well-known clinical benefits and improves workflow and efficiency.

IT systems produce a large amount of data that can be used for future needs assessment. Therefore, as a valuable side effect, the digitization of health services in developing countries will bring the decision-makers the data needed for evidence-based strategic investment decisions.

Projects that want to strengthen the sustainability of health services through medical technology procurement cannot be considered pure MDs procurement since other soft components such as "change management" are essential for their successful implementation, which usually

is spread over several years and requires a joint effort of the beneficiaries with the implementing agencies.

CONCLUSION

There are different definitions of sustainability in MD procurement within the UN system. The definitions used by the four main agencies in health procurement (UNICEF, UNOPS, WHO, and UNDP) are centered on environmental, social and economic sustainability, in the sense of the environmentally friendly quality of the MD, the socially acceptable conditions of its production and its economic impact on local communities.

Nevertheless, the attention to the long-term use of a MD is essential to its sustainability and will be achieved by considering aspects related to environmental, social, and economic development in addition to its impact on health services.

Selecting equipment that meets the beneficiary needs, the human resources capacities, and the local infrastructure conditions while considering its lifelong use brings to the health services much more benefits and is more sustainable than focusing only on the quality of the equipment itself. The technical lead in a procurement project is responsible for introducing and strengthening the analysis of the needs, the local conditions, and the conditions that can guarantee optimal use of the equipment during its lifespan. These analyses are the foundation that will guarantee a sustainable and efficient design of the equipment list, the technical specifications, the installation and training requirements, and the post-sales services, all in line with local conditions and capacities. No solution fits all. Each MD procurement project should be tailored to the local situation and the project's framework.

In an internationally funded project, the technical lead working for the implementation agency must establish a technical dialogue with the beneficiary to understand local needs and peculiarities and propose tailored solutions based on international sustainable standards adapted to the context. This technical dialogue is also a key factor for knowledge transfer and will strengthen the local technical capacities to plan new projects.

Once the needs assessment is completed, the project's objective will be defined; therefore, all the effort during the implementation phase should be spent on keeping coherence with the specified objective. Once the project is completed, measuring the impact of the MD purchase on health services by determining how much of the project's aim has been achieved will provide lessons learned to guide future purchasing projects. Examples of "outcomes performance indicators include cost effectiveness, compliance level, and client satisfaction and service leadership."³²

Considering a project's critical factor (correlation between the invested amount of money and the impact on the healthcare system) means investigating the needs, planning the objectives, and quantifying the outcome. Therefore, evaluating the project's sustainability as the gain produced by its implementation is possible. A critical factor with a positive impact can be achieved by ensuring that the project's objectives are built on the available country's evidence data to reach a planned outcome that can be measured at the end of the project. This implies a deep technical dialogue with the local beneficiary and will enrich the beneficiary's technical capabilities and the knowledge of the implementing agency about the local situation.

The SDGs can therefore be achieved by maintaining a strict coherence between any project's objective (or intended outcome) and the activities during its implementation. Careful planning addressing sustainability issues before the execution of the project is a fundamental recommendation. Still, in practice it often conflicts with the schedule and pressure to implement the project within a specific timeframe linked to the loan and political conditions.

On the other hand, investments in capacity building, health technology management and infrastructure could significantly improve existing medical equipment efficacy in a sustainable way, saving the costs of production and shipping of new equipment.³³ according to UNDP, *"in order to preserve a healthy environment and human well-being, there is a recognized need to move away from overconsumption, waste and ecological harm"*³⁴ which is especially true and applicable in the context of MD sustainable procurement.

CONFLICT OF INTEREST

The authors declare no conflict of interest regarding the publication of this paper.

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