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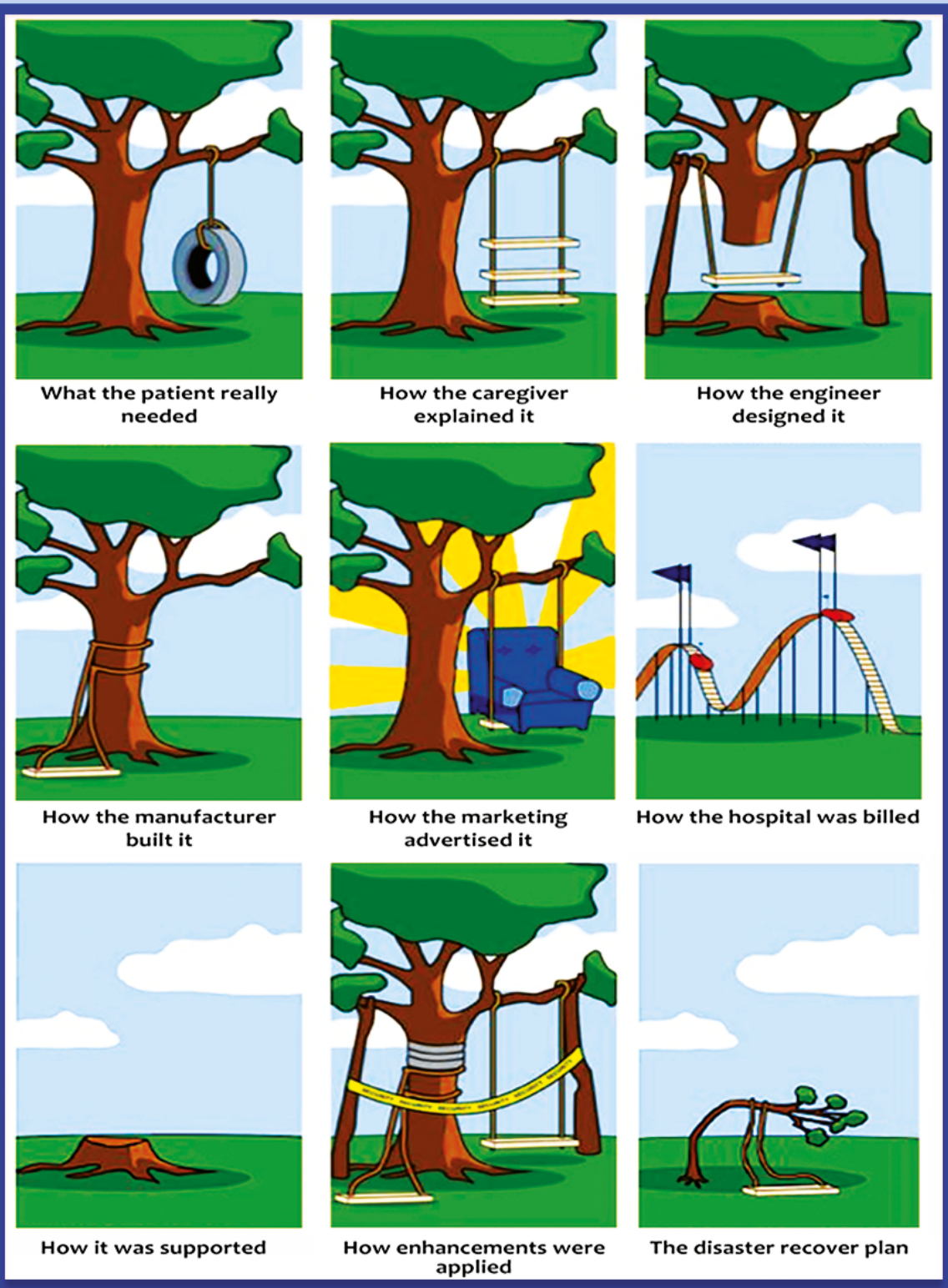

Editor's Corner

A Public-Private Medical Technology Model – India Case Study

The medical device development landscape has changed significantly post COVID. The pandemic has put the medical technology sector in top gear, pushing industries to innovate, develop, and manufacture products quickly. Countries like India have witnessed tremendous growth in the health technology sector, fueled by an exponential rise in government health allocation each year. One of the most significant efforts towards furthering medical device development has been the establishment of the Andhra Pradesh Medical Technology Zone (AMTZ).

AMTZ is India's first and one of the world's largest medical technology manufacturing cluster with over 100 companies working on research, development, and production of life-saving medical devices. It is India's premier medical technology park with Common Manufacturing Facilities & Common Scientific Facilities, including specialized laboratories, warehousing, and testing centers. The Center for Electromagnetic Compatibility and Safety Testing, Center for Biomaterial Testing, Center for 3-D Printing, Centers for Lasers, MRI Super Conducting Magnets, Gamma Irradiation Centre, Mold & Machining Centre, among many others, have played a key role in accelerating product development. This cluster of scientific facilities, access to raw materials, critical component supply chain within the zone, trained human resources, and ready-to-use infrastructure makes AMTZ the engine of growth for medical technology globally.

In the nation's battle against the pandemic, AMTZ contributed by producing over 100 ventilators, 500 oxygen concentrators, and 1 million RT PCR kits every day. In addition, many innovations from AMTZ, such as mobile container hospitals, mobile RTPCR vehicles, and mobile oxygen plants, were sent to even the most remote parts of the country. Built-in a record time of 342 days, AMTZ showcases modern India as a leader in the global medical technology stage.

AMTZ works to reduce the cost of manufacturing up to 40%, simplify the end-to-end operations, and reduce import dependency, which is presently around 75%. Furthermore, it believes in creating and operating an ecosystem that boosts innovations and supports affordable manufacturing scale-up, allowing technology accessible to every citizen globally.

The Kalam Institute of Health Technology (KIHT) at AMTZ has recently been designated as India's first WHO collaborating Centre (WHO-CC) for innovations. The WHO-CC will work directly with WHO headquarters to further health innovations and innovative technologies towards rapid development and global deployment.

Another essential element to success is the availability of a workforce that can be readily integrated into industrial design, development, and manufacturing. AMTZ understands that as India's medical sector experiences unprecedented growth, there is a strong demand for a dynamic, skilled, and capable workforce and a need for a new paradigm in training and development. Fortunately, the interdisciplinary nature of medical technology allows engineering professionals from the conventional domains of mechanical, electrical & electronics, instrumentation, and computer science, to specialize as biomedical engineers and fill the enormous vacuum domestically and globally.

Currently, the demand for a master's level program in India for Medical Technology far outweighs the limited options available. Recognizing this shortage, AMTZ is partnering with Skill-Lync to launch the country's first "Executive PG Program in Medical Technology." This will be a one-of-a-kind program that will offer students a flexible pedagogy, integrating online and offline learning through solid industry collaboration.

During the first 6 months, students will be offered 9 fundamental courses in a self-paced online environment in the Skill-Lync platform. Then, for the next 6 months, students will be engaged in taking coursework related to a specialization of their choice while undergoing hands-on training at the various medical device manufacturing facilities in AMTZ. This will provide the students with first-hand exposure to product design, development, and manufacturing while studying.

During the final lap of the program, the students will take a certification exam and get skill-certified by Indian Biomedical Skill Council (IBSC). The IBSC is yet another notable initiative of AMTZ established jointly with the Association of Indian Medical Manufacturers of Medical Devices (AiMeD), under the support of the Quality Council of India (QCI), to provide a certification system for biomedical engineers in the country who serve as the backbone of the healthcare services. Furthermore, it aims at strengthening the Biomedical Skill Sector in the country and, with this objective, develop job roles supported by the National Skill Development Agency (NSDA) under the Ministry of Skill Development & Entrepreneurship (MSDE).

The current VUCA environment requires continuous adaptation and assessment of learning paradigms to cater to industry requirements. Therefore, AMTZ strongly feels that this new foray into online learning combined with practical industry exposure will help create the ideal workforce.

We all know too well how much loss of life, suffering, ending family's livelihood and disrupted bread earnings routine this Pandemic caused. However, this necessitated forward-thinking, innovation, and capturing of unique new public-private collaborations that were not achievable previously. I focused on this India case study, but other initiatives hopefully are taking place around the world. I am looking forward to hearing from you about your local situation and will be happy to respond to comments and questions relating to our successful model.

The Author wishes to place on record, with sincere gratitude, the support received from Yadin David, Tom Judd, and a very large family of global clinical engineering leaders.

Together we are making it better!

Dr. Jitendra Sharma

CONTENTS

Book Review

Cybersecurity for Connected Medical Devices
Arnab Ray
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This book review is about the Elsevier Academic Press newly published ***Cybersecurity for Connected Medical Devices*** by author Arnab Ray, Ph.D. In addition to the Preface, the book contains nine chapters, an Afterword, and an Index for a total of 332 pages. This book contains a bevy of information that could overwhelm on first reading, but helpfully, from Chapter 2 onwards, every chapter serves up a summary and key takeaways that consolidate the key messages. Arnab Ray is a computer scientist with a background in critical software development and cybersecurity design of medical devices that provides a cybersecurity developer's perspective throughout this book.

Whilst the key audience is manufacturers of medical devices who are responsible for designing a cyber secure product, clinical engineers with an interest in cybersecurity should find this book a handy supplement to make sense of the fast-evolving landscape. They will gain a broad understanding of basic cybersecurity principles, which can help influence integration choices in a healthcare delivery organization (HDO). Often medical device manufacturers (MDM) have not given enough consideration to the challenges of incorporating and maintaining a medical device in an HDO IT network. Importantly, Arnab recognizes that cybersecurity is a shared responsibility between the manufacturers and healthcare providers, but does not propose an effective mechanism for defining and sharing such responsibility.

The introduction provides context to support the assertion that the cybersecurity of medical devices is a growing concern. It cites some high-profile examples of cyber-attacks on medical devices in a controlled environment to provide proof of concept. While there are no reports of cybersecurity incidents in a real-life context it warns, that since most devices do not log cyber-related issues, a cyber incident could be incorrectly diagnosed as equipment malfunction. It would have been useful to highlight tools available to HDOs such as intrusion detection, dynamic network segmentation, and malware prevention systems and to examine how they impact medical devices' performance.

With the increasing integration of connected medical devices, with varying levels of endpoint security, to information systems, there are more opportunities for cybercriminals to gain illegal access to confidential information and disrupt wider operations within a healthcare

delivery organization. This chapter helpfully discusses the development of national cybersecurity policies in the U.S. with some acknowledgment of similar policies in the E.U. Acknowledgement of the widely accepted challenge of designing a cyber secure product without introducing unintended negative consequences on usability and patient safety, highlights the limitations in designing a cyber secure product. Medical device manufacturers (MDM) are encouraged to consider risk-based controls, which conflicts with the recommendation of a controls-based approach, mentioned in Chapter 4. The introduction concludes with cybersecurity lifecycle challenges, and a suggestion for the development of a manufacturer's business model, that makes cybersecurity a distinct structural part of the business.

A helpful analogy of a home, bank vault, and a precious asset is referred to throughout Chapter 2, Basic Cybersecurity Concepts, which effectively convey the fundamental concepts and challenges of cybersecurity and risk management. The key concepts of vulnerability and threats are articulated in simple, easy-to-understand terms. As the cybersecurity landscape evolves around the globe, terminology develops meanings that can seem rather vague, and often mean different things to different people, which might be a little disconcerting to a novice. The author approaches this conundrum by adopting certain definitions from authoritative sources and using them consistently throughout the book. As a result, the reader has a stable foundation from which to explore and understand the core principles.

The medical device's information security objectives are described as availability, integrity, and confidentiality in order of priority. However, one could argue that integrity has a higher priority since an altered record is more likely to go unnoticed, potentially causing widespread harm before it is detected, whereas the unavailability of information is obvious and should result in the implementation of contingency plans. This chapter clearly describes five categories of controls used to reduce the likelihood of an attack being successful. One of the categories, cryptography, is explored in detail with a study of the major cryptographic techniques used to establish secure communications between the sender and the intended receiver. The level of detail given is appropriate for one who is new to this discipline and is informative enough to help a designer make decisions about the most appropriate method to implement.

Standards and regulations, which aim to ensure manufacturers build safe medical devices, are developing to include cybersecurity requirements. The increasing focus on cybersecurity is the subject of Chapter 3, Regulatory Overview and includes a summary of the current US and EU regulatory frameworks. It is recognized that a robust quality management system (QMS) is necessary for manufacturers if they are to meet the standards expected by the regulatory authorities. This chapter discusses key manufacturing quality standards, suggesting cybersecurity is not yet fully formed in them, and in fact lags behind some standards that HDOs have had access to for some time. Manufacturers struggling to adapt are offered useful guidance on how to achieve a cyber aware QMS with a suggested 5 step process for introducing regulatory requirements into an existing system.

In Chapter 4, The Product Cybersecurity Organisation, the author suggests that with few tools available to quantify cybersecurity impact it is difficult for MDM's decision-makers to be convinced of the benefits of investing. One could argue that making the case for investing is not difficult because of many well-known instances where damage has occurred from cyber-attacks on IT systems – the connected medical device is another type of IT system prone to the same attacks therefore, much is already known about exploitable system weaknesses. The author prefers a controls-based framework as opposed to a risk-based framework for building a cyber secure product. I believe that both frameworks have a place in design and there will always be an element of risk-based design due to the costs in terms of build and device performance. Recommendations for addressing

organizational shortfalls are made by offering key building blocks to achieving a product cybersecurity organization.

Cybersecurity risk management is a complex field and the author clearly wanted to give more attention to this area therefore it occupies Chapters 5 and 6. Chapter 5 predominantly addresses risk assessment and looks at threat modeling from system and subsystem levels. To help demonstrate a systemic threat and vulnerability modeling approach, an infusion pump with network connectivity is specified, and used as an example. This provides a convenient vehicle to explain the transferrable process for assessing cybersecurity risk. There is a lack of threat modeling tools specific to medical devices but there are modeling tools for IT systems that can be adapted. The author demonstrates this by using Microsoft's STRIDE framework to identify system threats and complete a threat model.

Chapter 6, Cybersecurity Risk Management-II, builds on the previous chapter with an illustration of a complete system cybersecurity risk model. The main theme of this chapter is the response to an identified risk. The infusion pump example specified in Chapter 5, again proves useful but this time to explore system threats and the corresponding responses or controls. The MDM cybersecurity designer is walked through high-level examples of threat articulation, responses, and undertaking a risk-benefit analysis.

It is recommended that technical controls are traceable to regulations and standards. Chapter 7, Cybersecurity Design Engineering, takes a look at these controls identifying them as master controls, and with examples, key factors for building cyber-secure medical devices are considered. A brief look at the limiting factors in the hardware and battery-operated devices clearly demonstrates the challenge of incorporating effective cybersecurity controls without degrading performance. It would have been useful to provide examples from other safety-conscious industries such as aviation or nuclear power, which are at an advanced stage of maturity.

Chapter 8 delves deeper into five more capabilities of an MDM that were defined in Chapter 4. Each capability is clearly described, providing industry insights with recommended best practices.

The final chapter, Chapter 9, Product Security Governance and Regulatory Compliance explores two more capabilities that an MDM should demonstrate. This chapter describes the governance elements required to satisfy regulations, which are fundamentally supported by a QMS. The advice given here is simple and clear - MDM's need to continually refresh their resources and processes, and be transparent about the product's cybersecurity posture.

Although this book is aimed at medical device manufacturers (MDM), I feel it is suited to anyone with an interest in medical device cybersecurity, including those working in healthcare delivery organizations. A lot of ground is covered mostly from a regulatory and compliance challenges angle; as a result, it only provides an overview, which the author concedes. However, the reader will find this book a useful springboard, from which to develop a greater understanding of a fast-evolving domain. This book successfully provides a framework for MDMs to design a cybersecurity-focused organization.

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Comparison of Automatic Sleep Stage Classification Methods for Clinical Use

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ABSTRACT

Sleep stage scoring is necessary for diagnosing several sleep disorders. However, it is an intensive and repetitive task and a vital automation candidate. This work seeks to evaluate different kinds of Machine Learning based classification algorithms available in the scientific literature to determine which one fits better the clinical practice requirements. The comparison is made with a predefined experimental design, using electroencephalography, electrooculography, and electromyography signals from the polysomnographic records of the Sleep-EDFx dataset. The comparison considers the accuracy and speed of algorithms based on Linear Discriminate Analysis, Support Vector Machines, Random Forests, and Artificial Neural Networks. The latter group includes the Deep Neural Networks DeapFeatureNet, based on Convolutional Neural Networks, and DeepSleepNet, additionally based on Recurrent Neural Networks. It is determined that several of the tested algorithms boast high accuracy levels (85%). From them, DeepSleepNet is chosen as the fittest due to its considerable advantage in execution time. Nevertheless, the final result should always be reviewed by the experts.

Keywords – *polysomnography, sleep stage scoring, machine learning, deep learning, signal processing.*

INTRODUCTION

Sleep stage scoring is necessary for diagnosing several sleep disorders, including insomnia, sleep apnea, narcolepsy, and hypersomnia. According to the American Academy of Sleep Medicine (AASM), this operation entails the division of a polysomnographic record (PSG) in consecutive 30-second windows, called epochs. Each epoch has to be classified as wakefulness (W), REM sleep (R), or one of three non-REM sleep stages: N1, N2, or N3. * Additionally, AASM defines the rules that have to be followed to perform the scoring based on the visual examination of each epoch of the PSG record.

A PSG record shows the behavior throughout the time of various electrophysiological signals. The three most important signals are (1) electrical activity in the cerebral

cortex, measured using electroencephalography (EEG); (2) in the face muscles, using electromyography (EMG); and (3) the eye movements, using electrooculography (EOG). It may also include the cardiac activity or electrocardiogram (ECG), the respiratory activity, and the body movements. The scoring rules rely on identifying various patterns in the signals, including the Alpha, Beta, Theta, and Delta Activity, K complexes, Spindles, REM, and SEM.** Table 1 summarizes some of these patterns.

TABLE 1. Common Patterns in Polysomnographic Signals

Pattern	Stage	Signal	Frequency	Morphology
Alpha Activity	W, N1	EEG	8 - 13 Hz	
Beta Activity	W, N1, R	EEG	14 - 30 Hz	
Theta Activity	NREM, R	EEG	4 - 8 Hz	
Delta Activity	N3, R	EEG	0.5 - 4 Hz	
Spindle	N2, N3	EEG	12 - 14 Hz	
K Complex	N2, N3	EEG	0.5 - 1.5 Hz	Biphasic high amplitude peak
Slow waves	N3	EEG	0.5 - 2 Hz	High amplitude waves

EEG = electroencephalography.

The PSG records may last for 8 hours, so the number of epochs is close to a thousand. Therefore, the scoring process is intensive, repetitive, and prone to errors. The scientific literature describes many algorithms that allow the automation of the process by using various Machine Learning techniques. However, the low inter-scorer agreement level,[1,2] among other limitations, has limited the accuracy of the algorithms and, hence, the reach of the automation process.

For instance, Fraiwan et al. [3] use the Continuous Wavelet Transform of the EEG signals as features and a Linear Discriminant Analysis (LDA) based classifier. As a result, they reach an 84% accuracy level with the MIT-BIH[4,5] dataset records. Susmakova & Krakovska[6] also use an LDA-based classifier, but their algorithm extracts a wider variety of features from different signals. Furthermore, they prove the importance of the information contained within the EOG and EMG signals to discriminate some of the stages.

Koley & Dey[7] evaluate the performance of a Support Vector Machine (SVM) based classifier with different combinations of features. Their algorithm has an 89% accuracy on their own dataset, close to the inter-scorer agreement level. Aboalayon et al.[8] also use an SVM classifier, reaching a 92.5% accuracy on records from the Sleep-EDF[5,9] dataset.

Set et al. [10] compare the performance of different classifiers, including Decision Trees (DT), Random Forests (RF), SVM, and Artificial Neural Networks (ANN). Moreover, they employ various feature extraction techniques, counting the Discrete Wavelet Transform (DWT). As a result, they determine that the RF obtains the best results, reaching a 97% accuracy with their own records. Finally, Aboalayon et al.[11] compare the DT, SVM, ANN, K-Nearest Neighbors, Naive Bayes (NB), and LDA classifiers. In their work, the DT classifier obtained the best results with a 93% accuracy on records from the Sleep-EDF dataset.

Finally, the Deep Learning techniques also have gained a foothold in sleep stage scoring. For example, Zhang et al.[12] propose using a Recurrent Neural Network (RNN) as a classifier but using conventional feature extraction methods. Their algorithm reaches 80.25% accuracy on the SHHS5 dataset records. Alternatively, Yildirim et al.[13] present a Convolution Neural Network-based algorithm that uses convolutional layers for feature extraction, with a 91% accuracy on Sleep-EDF records. Additionally, Supratak et al.[14] use a Convolutional Neural Networks (CNN) combined with an RNN, reaching an 82% accuracy on the same records.

The goal of this work is to select a sleep stage scoring algorithm to facilitate the work of the experts. Furthermore, the algorithm should be included in a software system

for the clinical analysis of polysomnographic records. Therefore, the selection should be based on the accuracy of the predictions and consider execution time and the general availability of the input data. With that in mind, the performance of several algorithms from the scientific literature will be compared using the same records and in similar conditions.

MATERIALS

The work uses PSG records from the Sleep Cassette dataset belonging to Sleep-EDFx.[5,9] The dataset has 153 subjects between 25 and 101 years old and was scored by several experts following the Rechtschaffen and Kales (R & K)[15] rules. The records include two EEG and one EOG signal, samples at 100 Hz, and one EMG signal at 1 Hz. Both EOG and EMG signals are considered in this work, but only the Fpz-Cz channel is used from the EEG signals. That way, all the implemented algorithms depend only on the minimum parameters of any PSG record.[1]

The dataset is split into two parts of approximately the same number of records. The first half contains the subjects with identifications 00 through 38 and is reserved for training the scoring algorithms. The second one, with subjects 40 through 82, is used to evaluate and compare the performance of said algorithms.

METHODS

The analyzed algorithms' execution time can be split into three main phases: Data preprocessing, feature extraction, and classification. The preprocessing and feature extraction phases are implemented in the Python and C# programming languages. For the classification, the work additionally employs the Weka software system[16,17] from the University of Waikato, New Zealand.

Preprocessing

The goal of the preprocessing phase is to prepare the data for the feature extraction phase. To achieve it, all signals are uniformly sampled at 100 Hz, and no digital filtering is applied beyond what is already included in the dataset: 0.5 to 100 Hz range for EEG and EOG and 0.7 to 16 Hz, for EMG. The records are segmented in 30-second windows that match the epochs that will be classified later. Also, the third and fourth non-REM sleep stages from R & K are combined into one Slow Wave Sleep or N3 stage[1,7] to fit better the AASM stages. Additionally, the unknown or invalid sleep stages are excluded from consideration.

The wake stages before the first and posterior to the last sleep stages are also excluded from the training dataset records. The latter operation reduces the disparities in the amounts of epochs classified with each sleep stage. Besides, more importantly, for the RNN classifiers, it does not affect the continuity of a record's epochs.

Feature Extraction

The feature extraction phase obtains descriptive values that reflect the information inside the relevant signals for the classification process. The values or features used in this work are obtained by analyzing the signals in each epoch in the time domain, frequency domain, time-frequency domain, and other nonlinear means.

Descriptive Statistics

These features are obtained by computing descriptive statistics from the signal's samples. The Mean, Variance, Kurtosis, Skewness, and 75th Percentile have been employed in this work.

Entropy

Entropy is a measure of the irregularity of a signal in the time domain.[18] Equation 1 shows the formula proposed by Shannon for this measure:

where p(x_i) is the probability of a signal sample having the value x_i.

$$ShEn = -\sum_{i=1}^{N} p(x_i)\log p(x_i) \quad (1)$$

Other estimation methods, including the Approximate Entropy, are displayed in equation 2.

$$ApEn(r,m) = \phi_r^m - \phi_r^{m+1} \quad (2)$$

The values of ϕ can be obtained using an algorithm that represents the signal in the phase domain $X_i=\{x_i, x_{(i+1)}, ..., x_{(i+(m-1))}\}$ and calculates the distance between those patterns using the L1 norm. Then,

$$\phi_r^m = \frac{1}{M}\sum_{i=1}^{M} \log \frac{N_r^m(i)}{M} \quad M = N - m + 1 \qquad (3)$$

where N_r^m is the amount of X_j patterns that satisfy $\|X_i - X_j\|_1 \leq r$.

In this work, the pattern length (m) is 2 and r is the standard deviation of the signal in the epoch, multiplied by 0.1, as estimated in.[18]

Largest Lyapunov Exponent

The Largest Lyapunov Exponent (LLE) indicates how unpredictable a signal is. It has been demonstrated that it can help discriminate the N1 and N2 stages.[7] The algorithm proposed by[19] allows estimating LLE by calculating the distances between the most similar trajectories, which are also distant in the time domain. Equation 4 describes this distance,

$$d_j(0) = \min_k \| X_j - X_k \|, \quad |i - j| > \tau \qquad (4)$$

where τ is the threshold in time domain and $X_i = \{x_i, x_{(i+J)}, \ldots, x_{(i+(m-1)J)}\}$ is a trajectory in phase domain. Once the distances have been calculated, the LLE can be obtained using linear regression with equation 5.

$$y(i) = \sum_{j=1}^{M} \frac{\log d_j(i)}{T_s M} \quad M = N - (m-1)J \qquad (5)$$

In our work we use the values 10 and 7 for m and J, respectively, while τ is the mean period of the signal (MNF^{-1}).

Fractal Dimension

The fractal dimension estimates the fractional dimensions of the geometric shape of a signal in the time domain.[18] This measure is especially useful for recognizing the N3 stage.[7]

The Higuchi algorithm calculates the fractal dimension as the slope of the mean squares fit of the values of log(L(k)) against log(1/k) for k between 1 and k_{max}. The values of L(k) are calculated using the equation 6:

$$L(k) = \sum_{m=1}^{k} L_m(k) \qquad (6)$$

where $L_m(k)$ is the mean length of the sequence

$$x_m^k = (x_m, x_{m+k}, x_{m+2k}, \ldots, x_{m+N_m^k k}),\ N_m^k = \lfloor (N-m)/k \rfloor k$$

calculated with equation 7:

$$L_m(k) = \frac{(N-1)\sum_{i=1}^{N_m^k} x_{m+i\,k} - x_{m+(i-1)\,k}}{N_m^k\, k} \qquad (7)$$

In this work we use the value 40 for k_{max}, that was estimated in.[18]

Discrete Fourier Transform

The Fast Fourier Transform (FFT) algorithm efficiently estimates the frequency spectrum. The spectrum can be used to obtain the mean frequency of the signal, the spectral entropy, and the relative spectral density of the relevant frequency bands (Table 1).

The mean frequency can be calculated using equation 8:

$$MNF = \sum_{i=1}^{M} f_i\ P_i \qquad (8)$$

where M in the amount of frequency bins, f_i are the frequency values and P is the normalized spectral frequency ($\sum P_i = 1$).[20] Similarly, the spectral entropy of a frequency band can be obtained from equation 9:

$$SpEn = -\sum_{i=f_l}^{f_h} \frac{P_i \log P_i}{\log N_f} \qquad (9)$$

where f_l and f_h are the minimum and maximum frequencies, respectively and N_f is the amount of frequency bins in the range $[f_l, f_h]$.[18]

High Order Spectra

The High Order Spectra analysis can extract features related to third-order statistics of a signal.[21] Before calculating the features, the Bispectrum has to be estimated using equation 10,

$$B(f_1, f_2) = \sum_{i=1}^{W} \frac{X_i(f_1)X_i(f_2)X_i(f_1 + f_2)}{W} \quad (10)$$

where X_i is the Short-Time Fourier Transform (STFT) of the signal on the i-th window and W is the number of windows. The STFT in a vicinity of x_i is the FFT of the product of the signal and a window function centered on x_i. [22] In our work, we use 2 seconds long Haan windows, with 1 second (50%) of overlap between consecutive windows. The Bispectrum is symmetric in both axes, so its domain of interest is defined in the expression 11.

$$\Omega = \{(f_1, f_2) | \ f_1 \geq 0 \ , f_1 \geq f_2 \ , f_1 + f_2 \leq 0.5\} \quad (11)$$

Once the Bispectrum is calculated, it is possible to calculate its mean amplitude, the Normalized Bispectral Entropy (equation 12), its logarithmic sum (equation 13) and its mean frequency (equation 14):

$$BiEn = -\sum_{n=1}^{N} p_n \log p_n$$
$$p_n = \frac{|B(f_1, f_2)|}{\sum_{\Omega} |B(f_1, f_2)|} \quad (12)$$

$$H_1 = \sum_{\Omega} \log |B(f_1, f_2)| \quad (13)$$

$$WCOB_1 = \frac{\sum_{\Omega} f_1 \ B(f_1, f_2)}{\sum_{\Omega} B(f_1, f_2)} \quad (14)$$

Wavelet Transform

The Wavelet Transforms translate a signal into the time-frequency domain. The transformation approximates the signal inside a time window by a Wavelet base (ψ) using different time scales.[22] The scale factors are inversely proportional to the frequency of the Wavelet base, as stated in equation 15,

$$\omega = \frac{f_\psi}{a \, T_s} \quad (15)$$

where T_s is the sampling period and f_ψ is the mean frequency of the Wavelet base (3).

The DWT decomposes the signal in two coefficient vectors with N/2 values, satisfying

$$a_1 = H_\psi \, x \qquad d_1 = G_\psi \, x \quad (16)$$

where H_ψ and G_ψ are dual filters with sub-sampling, related to the Wavelet base.[22] The a_1 vector contains an approximation of the original signal in the frequency range [0,1/4 f_s], while d_1 is a detail vector in the frequency range [1/4 f_s,1/2 f_s], where f_s is the sampling frequency.[10] The DWT can be computed again from vector a_1, in order to obtain the vectors a_2 and d_2 with frequency ranges [0,1/8 f_s] and [1/8 f_s,1/4 f_s], respectively. Thus, successively, the signal can be decomposed in L levels, after which the vectors d_1,d_2,...,d_L,a_L belong to different frequency bands.

The entropy of each relevant frequency band (Table 1) along the epoch in question can be calculated from the transform. We use the Daubechies function (*db1*) as the Wavelet base for the EOG signals and the reverse biorthogonal function (*rbio3.3*) for the EEG signals. Given the 100 Hz sampling frequency of the signals, once they are decomposed into 5 levels, the frequencies of the coefficient vectors approximately match the frequency bands in Table 1.

Classification

The classification phase is responsible for assigning a sleep stage to each epoch contingent on the features extracted from it. In our work, we use classifiers based on Linear Discriminate Analysis,[3] SVMs,[23] RF,[23,24] ANN, and NB.[23]

Several kinds of Neural Networks have been analyzed, including Multilayer Perceptrons (MLP),[10,25] CNN, and RNN. Specifically, we have tested the networks *DeepFeatureNet* (DFN) and *DeepSleepNet* (DSN),[14] implemented on Python using Tensorflow. The former is a CNN, while the latter is a hybrid network combining a CNN and an RNN. Both algorithms use CNN for feature extraction, so they do not require the methods described in section *Feature Extraction*.

The implementation proposed for a single signal has been expanded to process the EOG, EMG, and EEG signals.[14] This was achieved by taking advantage of the capacity of CNN layers to process several input channels

and by increasing the size of the filters proportionally to the number of channels. The DFN network has been trained with 75 epochs, while DSN has required 25 more in fine-tuning. The source code is available at https://github.com/ALabrada/deepsleepnet.

For the remaining classifiers, it has been used the implementations available in Weka, using their respective default parameters.

Evaluation

The performance of each algorithm has been analyzed, considering the accuracy (Acc) and Cohen's *kappa* coefficient. Additionally, the classification performance of the individual stages is considered using the Precision (PR) and Recall (RE) metrics.

RESULTS

The classification algorithms have been trained with the first half of the PSG records of the Sleep Cassette dataset. The set has 76 records that belong to 39 different subjects with identifiers 00 through 38. Table 2 shows the distribution of the stages assigned by the experts to the 74354 epochs that have been used from those records.

The 10-fold cross-validation technique has been used to estimate the hyper-parameters of the models and the validation error. Table 3 shows the estimated errors.

The trained classifiers have been tested using the second half of the *Sleep Cassette* dataset, and the results have been compared. The set has 77 records that belong to 39 subjects with identifiers 40 through 82. A total of 68.8% of the 208349 epochs belong to the wake stage.

TABLE 2. Sleep Stage Distribution of the Analyzed Epochs

Stage	Training		Testing (partial)		Testing (full)	
	Count	Percent	Count	Percent	Count	Percent
W	14884	20.0	33410	33.9	143265	68.8
N1	7536	10.1	14013	14.2	14013	6.7
N2	30143	40.5	33906	34.4	33906	16.3
N3	7954	10.7	5104	5.2	5104	2.4
R	13837	18.6	12062	12.2	12062	5.8
Total	74354	100.0	98495	100.0	208349	100.0

TABLE 3. Validation Error using the Training Records

Type	Acc	Kappa	PR					RE				
			W	N1	N2	N3	R	W	N1	N2	N3	R
LDA	77.29	0.6882	0.902	0.438	0.775	0.817	0.785	0.804	0.398	0.869	0.843	0.695
NB	64.79	0.5324	0.748	0.320	0.738	0.507	0.659	0.689	0.249	0.668	0.925	0.619
RF	83.09	0.7674	0.868	0.623	0.830	0.896	0.822	0.904	0.365	0.906	0.863	0.825
SVM	79.49	0.7155	0.858	0.501	0.788	0.872	0.787	0.867	0.286	0.894	0.848	0.745
MLP	80.60	0.7334	0.883	0.515	0.808	0.867	0.790	0.874	0.342	0.885	0.838	0.794
DFN	74.27	0.6630	0.969	0.287	0.883	0.652	0.822	0.789	0.692	0.721	0.912	0.658
DSN	78.10	0.7055	0.906	0.326	0.854	0.756	0.911	0.901	0.427	0.812	0.726	0.817
AVG	76.80	0.6865	0.876	0.430	0.811	0.767	0.797	0.833	0.394	0.822	0.851	0.736

Following the procedure that has been described in section *Preprocessing*, the disparity between stages can be decreased by reducing this quantity to the 33.9%. Table 4 shows a performance comparison between the algorithms using only the selected epochs, while Table 5 shows the same comparison, but with all the epochs.

Finally, Table 6 compares the execution time of the algorithms while classifying the whole test dataset. The execution time of the algorithms that use classifiers implemented in Weka is further split into the feature extraction and classification phases. The data has been collected in a personal computer with an Intel Core i5-4570 processor (CPU), 16 GB of DDR3-1600 memory (RAM), and executed in Microsoft .NET Framework.

DISCUSSION

The results show that the test error is less than the validation error when using the full records, but it is greater when using the selected subset of the epochs. This apparent discrepancy can be explained due to the previously mentioned high proportion of epochs classified with wake stages. Every one of the analyzed algorithms obtains relatively high precision and recall results classifying this stage.

In contrast, all algorithms attain poor precision and recall results that classify the N1 stage in absolute and relative terms. This behavior is consistent with other studies from the scientific literature,[24] especially those using the Sleep-EDFx dataset.[13,14,26–28]

TABLE 4. Performance Comparison of the Classifiers using the Partial Test Dataset

Type	Acc	Kappa	PR					RE				
			W	N1	N2	N3	R	W	N1	N2	N3	R
LDA	69.43	0.5776	0.911	0.385	0.664	0.465	0.723	0.759	0.279	0.840	0.752	0.563
NB	55.09	0.4109	0.841	0.329	0.594	0.241	0.555	0.604	0.231	0.582	0.954	0.515
RF	73.98	0.6335	0.858	0.504	0.692	0.637	0.737	0.853	0.183	0.887	0.756	0.652
SVM	72.93	0.6213	0.866	0.433	0.697	0.591	0.718	0.842	0.215	0.863	0.774	0.619
MLP	71.22	0.6009	0.817	0.399	0.724	0.558	0.682	0.856	0.244	0.784	0.770	0.634
DFN	67.78	0.5670	0.968	0.303	0.743	0.517	0.898	0.697	0.640	0.734	0.776	0.454
DSN	73.88	0.6308	0.864	0.347	0.772	0.812	0.959	0.894	0.419	0.744	0.553	0.675
AVG	69.19	0.5774	0.875	0.386	0.698	0.546	0.753	0.786	0.316	0.776	0.762	0.587

TABLE 5. Performance Comparison of the Classifiers using the Full Test Dataset

Type	Acc	Kappa	PR					RE				
			W	N1	N2	N3	R	W	N1	N2	N3	R
LDA	83.45	0.6804	0.981	0.340	0.644	0.429	0.655	0.913	0.279	0.840	0.752	0.563
NB	69.02	0.4682	0.966	0.222	0.504	0.197	0.380	0.766	0.231	0.582	0.954	0.515
RF	86.43	0.7263	0.966	0.466	0.666	0.622	0.711	0.947	0.183	0.887	0.756	0.652
SVM	85.73	0.7147	0.969	0.382	0.679	0.563	0.675	0.942	0.215	0.863	0.774	0.619
MLP	85.10	0.699	0.955	0.347	0.709	0.532	0.666	0.947	0.244	0.784	0.770	0.634
DFN	80.14	0.6366	0.991	0.270	0.687	0.415	0.879	0.862	0.579	0.774	0.772	0.432
DSN	85.30	0.6973	0.953	0.318	0.773	0.812	0.967	0.970	0.537	0.688	0.442	0.474
AVG	82.17	0.6604	0.969	0.335	0.666	0.510	0.705	0.908	0.324	0.774	0.746	0.556

The DFN and DSN algorithms reach around 20% higher recall measures for this stage, but its influence is mitigated by lower values in other stages. The low classification accuracy of the N1 stage can affect the result of the sleep quality analysis,[29] which makes the algorithms unsuitable for standalone usage and, thus, require the intervention of the experts.

From the first five algorithms, the ones using more conventional strategies, the RF-based classifier obtains the best results. This confirms the conclusions that were reached by previous studies.[10,30] Furthermore, SVM, MLP, and LDA also obtain satisfactory results according to both performance metrics.

From the two last algorithms based on Deep Learning, DSN reaches superior results in all metrics other than DFN. However, during validation, our implementation of DSN is 4% lower in accuracy and 6% lower in Kappa score than the one reported by Supratak et al.[14] with the same dataset, but using different hyper-parameters and half of the PSG records. Regarding the traditional algorithms, the accuracy of DSN classifying the test dataset is equivalent to the accuracy of RF within 1%.

Considering that several of the algorithms reach similar accuracy levels, their execution times are used as tie-breakers. The results in Table 6 prove that, from the analyzed algorithms, the ones based on Deep Learning require a significantly lower amount of time to identify the sleep stages of a PSG record.

TABLE 6. Comparison of the Execution Time of the Algorithms

Type	Time			
	Extraction	Classification	Total	Average per record
LDA	54758.69 s	6.08 s	54764.77 s	711.23 s
NB	54758.69 s	5.07 s	54763.76 s	711.22 s
RF	54758.69 s	10.97 s	54769.66 s	711.29 s
SVM	54758.69 s	1.41 s	54760.10 s	711.17 s
MLP	54758.69 s	2.64 s	54761.33 s	711.19 s
DFN	-	-	766.55 s	9.66 s
DSN	-	-	1695.68 s	22.02 s

CONCLUSIONS

As part of our work, we have compared the performance of a wide range of sleep stage scoring algorithms available in the scientific literature to find the one that better matches clinical use requirements. With that in mind, accuracy and speed are used as the selection criteria for the comparison. The results prove that the RF, SVM, MLP, and DSN algorithms reach the greater accuracy levels while classifying, exceeding 85% in this metric and 0.69 in Cohen's *kappa*. Moreover, from them, DSN is significantly faster, requiring less than 30 seconds to score a record's epochs on average. The combination of both criteria determines that DSN is the most appropriate sleep stage scoring algorithms for the context of the clinical practice, from the set of candidates taken into consideration. Nevertheless, the algorithms are much less accurate in classifying the N1 stage, so the experts should review the sleep stage scoring performed by DSN.

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Application of the AHP Method in Prioritizing the Criteria for the Selection of Calibration Services Provider

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ABSTRACT

SChoosing the best instruments, measurement techniques and the most qualified service provider is of paramount importance for an equipment calibration service. For the definition of the most qualified company, selection criteria and weights related to the criteria will be used. Thus, the main objective of this work is to choose the best service provider, that is, the most qualified to perform the calibration services of medical and hospital equipment, considering the listed criteria. The method used was AHP (Analytic Hierarchy Process). It makes it possible to prioritize, give weight and validate the consistency of the evaluation criteria (considering the importance and relevance). As a result, the validation of the criteria weights was obtained. The company that obtained the best score was the company hired for the service.

Keywords – *Medical equipment, Calibration, Selection service provider, AHP method.*

INTRODUCTION

The calibration of equipment, that is, the comparison of biomedical/physiological quantities measured or provided by biomedical equipment, compared to a standard, provide each equipment's errors. An internal team can calibrate biomedical equipment, provided qualified, with defined calibration procedures, appropriate instruments, traceability, etc. When calibration is performed by a third-party service provider, it is appropriate to perform a calibration process, with defined criteria.[1] Enable the validation of the consistency of weights and measurements of the selection criteria. Contribute in such a way that the best qualified company performs the calibration services of the equipment. Maximizing patient safety. One of the known methods is the AHP (Analytic Hierarchy Process) Method,[2] which makes it possible to prioritize, give weight and validate the consistency of the evaluation criteria (considering the importance and relevance).[3] SCB Associates[4] proposes a model to validate the consistency of the weights assigned to each requirement evaluated. It is possible to use a scale with paired views of evaluation parameters to assess the degree of importance.[5] The main objective of this work is to choose the best service provider company, that is, the most qualified to perform medical-hospital equipment calibration services. Considering that the selection criteria and their weights will serve as a reference to choosing the company that obtains the best score, the specific objectives are: to prioritize, give weight and validate the consistency of the evaluation criteria (considering the importance and relevance) for the selection of service providers of calibration of medical- hospital equipment.

METHOD

The method used was the AHP,[2] which allows prioritizing the evaluation criteria (considering the importance and relevance). The model provided by SCB Associates,[4] to validate the consistency of the weights assigned to each requirement evaluated. The following (Fig. 1) demonstrates the fundamental scale, with nine classifications of importance used in this model.

The initial weights for each criterion were defined by a specialized clinical engineering group composed of professionals with training of various academic levels and professional experiences of up to 25 years in the area.

Analytic Hierarchy Template: n=	14	Criteria

Fundamental Scale (Row v Column)	
Extremely less important	1/9
	1/8
Very strongly less important	1/7
	1/6
Strongly less important	1/5
	1/4
Moderately less important	1/3
	1/2
Equal Importance	**1**
	2
Moderately more important	3
	4
Strongly more important	5
	6
Very strongly more important	7
	8
Extremely more important	9

FIGURE 1. The schematic diagram of dental units.

With expertise in calibration laboratory and calibration services. Quality national and international certifications. As well as knowledge of norms related to the subject. A spreadsheet was sent with the 14 evaluation criteria for each service provider who participated in the selection to obtain the answers.

RESULTS

The matrix (Figure 2) below demonstrates the degree of importance given, according to a fundamental scale (as shown in Figure 1), in the paired comparations of 14 evaluation parameters.

The consistency index achieved with the method was 7% (Figure 3), indicating a good weight distribution.[6]

Then, considering the response of the service providers to the selection criteria, the specialized group of clinical engineering, listed the notes to each of the companies (Figure 4) so that it was possible to obtain the answer of which service provider was the best to perform the calibration of medical equipment.[7]

Calibration Selection Criteria

Pairwise Comparison Matrix

	1	2	3	4	5	6	7	8	9	10	11	12	13	14	Requirement 15
1	1	1	1/5	1/5	1/6	1/9	1/3	1/4	1/9	1/5	1/2	1/2	1/3	1/3	1
2	1	1	1/2	1/2	1/2	1/4	1/3	1/4	1/7	1/5	2	2	1/2	2	1
3	5	2	1	1	1/2	1/4	2	1	1/9	1/3	1	1	1	1	1
4	5	2	1	1	1	1/4	1	1	1/9	1	2	2	2	2	1
5	6	2	2	1	1	1/4	2	1	1/9	1	2	2	2	2	1
6	9	4	4	4	4	1	8	8	1/2	8	8	8	8	8	1
7	3	3	1/2	1	1/2	1/8	1	1/2	1/9	1/4	1	1	1	1	1
8	4	4	1	1	1	1/8	2	1	1/9	1/4	1	1	1	1	1
9	9	7	9	9	9	2	9	9	1	9	9	9	9	9	1
10	5	5	3	1	1	1/8	4	4	1/9	1	3	3	3	3	1
11	2	1/2	1	1/2	1/2	1/8	1	1	1/9	1/3	1	1	1	1	1
12	2	1/2	1	1/2	1/2	1/8	1	1	1/9	1/3	1	1	1	1	1
13	3	2	1	1/2	1/2	1/8	1	1	1/9	1/3	1	1	1	1	1
14	3	1/2	1	1/2	1/2	1/8	1	1	1/9	1/3	1	1	1	1	1
Req	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1

FIGURE 2. Model provided by SCB Associates.[4]

	AHP		Consistency check
1	0.015	1.5%	Consistency OK
2	0.031	3.1%	7%
3	0.041	4.1%	
4	0.051	5.1%	
5	0.057	5.7%	
6	0.215	21.5%	
7	0.034	3.4%	
8	0.043	4.3%	
9	0.311	31.1%	
10	0.083	8.3%	
11	0.028	2.8%	
12	0.028	2.8%	
13	0.033	3.3%	
14	0.030	3.0%	
15	0.000	0.0%	

FIGURE 3. Consistency index achieved with the method.

Weights		Supplier A	Supplier B	Supplier C	Supplier D
100,0%	Criteria	67%	70%	83%	91%
1,5%	1 - ID: ENABLE ART	10,0	10,0	7,5	10,0
3,1%	2 - COMMITMENT:	10,0	10,0	10,0	10,0
4,1%	3 - KNOW HOW:	7,5	10,0	6,0	7,5
5,1%	4 - QUALIFICATION:	5,0	5,0	10,0	10,0
5,7%	5 - RASTREABILITY:	8,0	8,0	8,0	8,0
21,5%	6 - UNCERTAINTY CALCULATION:	3,5	6,5	8,3	10,0
3,4%	7 - METHODS, PROCEDURES AND REVIEW	10,0	10,0	10,0	10,0
4,3%	8 - SCOPE OF CALIBRATION SERVICE AND ELECTRICAL SAFETY	10,0	10,0	9,4	10,0
31,1%	9 - BEST MEASUREMENT CAPABILITY	8,1	7,8	6,5	8,4
8,3%	10 - ACCREDITATION	0,0	0,0	9,0	10,0
2,8%	11 - FLEXIBILITY	10,0	5,0	10,0	10,0
2,8%	12 - SERVICE BONUSES	10,0	10,0	5,0	10,0
3,3%	13 - TIME CALIBRATION	10,0	2,5	10,0	2,5
3,0%	14 - LOGISTICS	10,0	10,0	10,0	10,0

FIGURE 4. Supplier's notes for each criterion.

DISCUSSION

It is important to highlight that it is necessary to evaluate and select the calibration service providers of biomedical equipment. The AHP methodology for the listed evaluation criteria was shown to be consistent. However, there can always be points to be improved and new versions to be proposed and tested, from this model. Or considering other models.

CONCLUSION

The AHP methodology proved to be adherent and assisted in the selection protocol of a calibration service provider. That is, it helped validate the weights of the criteria listed to evaluate the quality of the provider. Thus, it contributed to hiring the most qualified company to perform the calibration services of biomedical equipment, considering the criteria listed. The application of this method improved the evaluation process and choice of the provider, impartially increasing confidence and comprehensiveness. Considering that the equipment park is dynamic, each year changes with new approaches and technologies. Given the above, it can be observed that the implemented proposition of improving this selection process was successfully achieved.

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COVID-19, a blessing in disguise: the experience of a Nigerian radiotherapy engineer

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ABSTRACT

The health technology sector of low- and middle-income countries (LMICs) is bedeviled by performance failures that make it a significant obstacle to effective patient healthcare interventions. The predominant factors behind the sector's poor performance have been identified as (a) inadequately trained technical personnel and (b) the unserviceable condition of medical equipment.

Past studies show that after adequate training, there is an increase in the proficiency of in-hospital biomedical engineers, but the studies have been limited to the maintenance job description of the engineers. We present a case study of the successful installation of sophisticated medical equipment by an in-hospital engineer to demonstrate that comprehensive training can also develop the installation expertise of local engineers. The installation, which is usually accomplished by the equipment manufacturer, was delegated to the trained in-hospital engineer due to the COVID-19 pandemic.

Furthermore, the bulk of medical equipment in LMICs is imported, which has led to an over-dependence of their health sectors on non-indigenous technology to the detriment of local alternatives and know-how. The World Health Organization estimates that 7 out of 10 sophisticated medical equipment imported by LMICs are unserviceable due to the issue of compatibility and adaptability with the setting. Previous research focuses on equipment subsidy, frugal innovation, and health technology management to better adapt foreign equipment to the environment. Still, this paper explores the option of indigenous technology and expertise to provide in-country development of suitable and sustainable medical equipment.

Keywords – *COVID-19, medical equipment, engineer, LMIC, training, installation, local production.*

INTRODUCTION

As the world's nations grappled with the COVID-19 pandemic, several unprecedented measures were adopted to limit the spread of the disease. Social distancing, quarantines, flight restrictions, lockdowns, and other routine-disrupting changes were imposed by governments at all levels.

On the 21st of March 2020, Nigeria went into lockdown, and restrictions were introduced on travel by land and air.[1] This, however, had only a partial impact on hospital activities because health workers, as essential service providers, were exempted from the restrictions. Doctors, nurses, and other hospital personnel kept working to provide medical care and manage the increasing patient volume due to coronavirus. Treatment of the disease required many types of lifesaving medical equipment, especially in intensive care units; therefore, more than ever, clinical engineers were needed to ensure the uninterrupted operation of medical devices.[2]

The job function of clinical engineers includes equipment maintenance, acceptance testing, user training and education, clinical research and development, quality assurance, and productivity assessment.[3] It is important to note that clinical engineering began in the late 1960s to address patient-safety concerns as increasing numbers of medical devices deployed in teaching hospitals. Not long after that, a preponderance of electrical safety failures brought the maintenance job description of in-house engineers to the fore.[4]

Clinical engineers develop their maintenance and troubleshooting skills through a combination of a hands-on learning experience, in-service training, and short courses designed to equip them with the skills to handle a wide range of medical devices. However, when hospitals acquire new or sophisticated technology with maintenance requirements beyond the engineer's general skills, maintenance contracts are signed, or equipment-specific training is sought. Hospitals typically opt for maintenance contracts with the original equipment manufacturers (OEMs) or their agents in high-income countries. On the other hand, hospitals in low- and middle-income countries (LMICs) opt for training because of the long distance between them and the OEMs.[5]

Unfortunately, the equipment-specific training is adequate on most occasions, and the hospitals are forced to resort to high-priced maintenance programs that still involve the OEMs or their third-party agents.[3,6] The local engineers are authorized to carry out only run-of-the-mill repairs while the heavy-duty maintenance is performed by the OEMs, usually after long waiting periods with a likelihood of poor treatment outcomes for the patient.[7]

Delay in cancer treatment leads to increased patient distress, increased risk of local recurrence, and reduced patient survival over time.[8,9] In LMICs, where delayed treatment is common, it can be attributed to late presentation in patients, inadequate radiation therapy facilities, insufficient trained manpower, and machine downtime.[10,11] Therefore, the goal of the in-house engineer is to minimize downtime so that patients can avail themselves of the already limited therapy units.

A previous paper has shown that with adequate training, in-house radiotherapy engineers (RE) could develop improvisation skills to reduce machine downtime in a Nigerian radiotherapy center.[12] This paper is a case study that shows that in-house RE can go beyond the usual maintenance tasks to installing sophisticated equipment that preserves OEMs and their agents with comprehensive training. However, it is worthy of note that the case study could not have arisen but for the advent of COVID-19.

A SUCCESS STORY

Before the COVID-19 lockdown, High Dose Rate (HDR) brachytherapy equipment was set for installation in four radiotherapy centers across Nigeria. The equipment, a 25-channel Saginova HDR After loader Brachytherapy system (Figure 1) manufactured by Eckert & Ziegler BEBIG GmbH Germany, had been shipped in, and engineers from the company were scheduled to follow for the installation work when the pandemic struck, and a restriction was placed on traveling.

As travel restrictions lingered, the situation became worse because, at the time, the country had only one functional brachytherapy center for its growing number of oncology patients. Moreover, the delay grew costlier with each passing day as the cancer cases worsened from lack of treatment and the radioactive decay of the expensive Co-60 sources.[13,14] It was therefore imperative to find a quick solution.

FIGURE 1. A 25-channel Saginova HDR afterloader brachytherapy unit installed by the local engineer.

The equipment manufacturer reached out to an RE in the Radiation Oncology Department, University College Hospital Ibadan (UCH), who had undergone training at their company factory (Figure 2). The training was sponsored by UCH after installing the same brachytherapy equipment in the hospital by the manufacturer in 2019.

The training

The five-day course gave the trained technical specialists level A and level A+ proficiencies. For example, the level A certification authorized them to carry out standard maintenance and basic interventions on the equipment as advised by the manufacturer, while the level A+ certification authorized them to load and unload radioactive sources.

Each trainee was provided with a full-color illustrated manual containing step-by-step information on how to unpack the equipment, install it, test it while inactive, load the Co-60 source, test it while active, and adjust the equipment settings. It also included schematic and circuit diagrams and layout diagrams of the standard control and treatment rooms. The teaching method employed was hands-on learning, where trainees first observed the instructors and then practiced the lessons. Common real-life faults were simulated, and the trainees were instructed on how to solve them.

Each training module ended with a Q and A and a quiz to test for mastery of the module. The trained and authorized engineers were then awarded certificates of training.

The installation

The RE successfully installed the equipment, loaded the Co-60 source, and conducted acceptance testing in the four radiotherapy centers (Figure 3). Barring the occasional logistic problems, the installation was uneventful and did not lead to problems the German engineers would not have encountered, such as broken cables and a damaged SafeLogic compact arising from inadequate packaging.

FIGURE 2. The radiotherapy engineer at the training facility in Germany.

The OEM provided remote guidance throughout the installation process, and the equipment was installed and handed over to the centers in good time. The RE also worked with the resident medical physicists to ensure that all technical parameters of the equipment were within acceptable limits.

The trainee becomes a trainer.

Before embarking on the training, the goal of the RE was to be reasonably proficient in maintaining the equipment in his center and other centers in the country that may require his service. In addition, having witnessed the long waiting periods that LMIC hospitals are subjected to when working with OEMs and agents, he planned to become an alternative service engineer with the least response time. This desire was made known to the trainers, and they provided as much instruction as possible within the limited training period.

However, the engineer's goal was flawed because it took up to two days to arrive at some centers, and if he were their service engineer, the equipment would be out

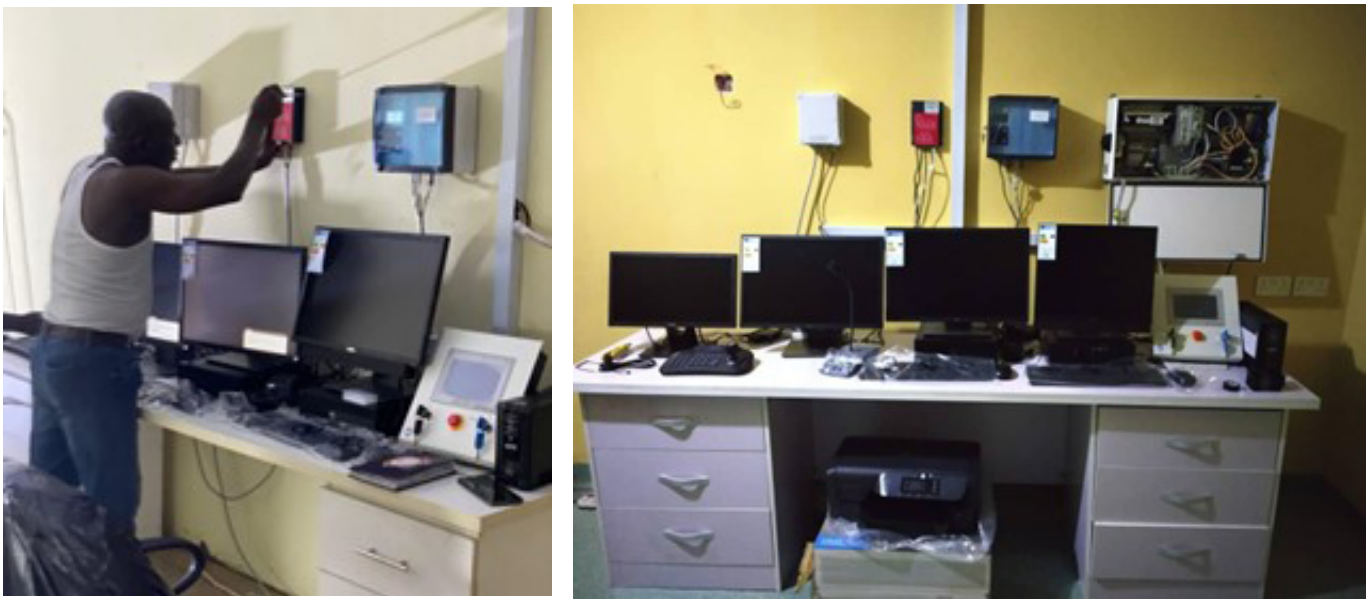

FIGURE 3. Setting up a treatment console (left). A fully installed treatment console (right).

of order for that long. Consequently, he rethought his plan and decided to train the centers' in-house engineers as much as possible so that they could independently maintain their equipment.

One center sponsored their engineer to join in installing the equipment of another center after participating in the installation at his center. The aim was to use the opportunity to further hone the expertise of their engineer.

BENEFITS ENJOYED FROM THE SUCCESSFUL INSTALLATION

Asides from the obvious benefits of timely brachytherapy treatment for cancer patients and obtaining value from the expensive Co-60 source, installing the equipment by a local RE had significant economic benefits for the hospitals. The two-way airfares for OEM engineers were eliminated, and the per diem was considerably reduced, saving the government some foreign exchange earnings. In addition, the experience boosted morale and increased the technical skills of the RE and his colleagues. It also gave him the expertise for guiding the prepurchase and procurement planning process of medical equipment in his department.

Finally, the trip to other radiotherapy centers helped develop a strong collaborative relationship between the RE and the in-house engineers of the centers.

LOOKING AHEAD

The healthcare needs in LMICs are tremendous, as is the quantity of medical equipment required to meet them. However, the bulk of medical equipment in these regions is imported or supplied by foreign donors. For example, a survey of 1,242 equipment in ten Indonesian hospitals revealed that only 4.2% were manufactured in that country.[15] The figures for Nigeria show the country is dependent on importation for about 99% of its medical equipment needs, and the small local production in the country is limited to simple devices like syringes. Regrettably, the impact of the country's $170m medical equipment market on patient care is still underwhelming as large numbers of imported medical equipment are unusable.[16]

Up to 70% of sophisticated medical equipment imported into LMICs is nonfunctional because of a mismatch between the equipment design and the setting where they are used. These "off-the-shelf" products fail to meet the environmental profile needs of LMICs already suffering from an unstable power supply, lack of clean water, an abundance of dust, and a hot and humid climate.[17] Even when the equipment is stripped down, they are still not explicitly designed to meet the 4 As for preventing equipment mismatch to a market: availability, accessibility, appropriateness, and affordability.[18]

In view of the above, LMICs should begin exploring the local production of low-resource medical equipment, starting with non-complex ones. Such equipment would be designed with the environmental profile in mind and consider practitioner/end-user input to meet the appropriateness factors. It would be made from locally available raw materials and stripped of nonessential features to solve availability and affordability problems.[19] However, this option remains only an aspiration until the many barriers facing local production are surmounted.

One of the principals but unintended barriers is the influx of donated foreign medical equipment. Low cost or donated medical equipment leads to aid dependency in LMICs and a stifling of the country's development.[20] Another barrier is the absence of an atmosphere conducive to R&D and innovation in LMICs.[18] R&D is funded mainly by industries in high-income countries, but in LMICs it is publicly funded through academic institutions. However, in Nigeria, for example, the better part of the time and activity of universities is devoted to teaching and assessing students, while research work is a secondary activity. Reasons like poor funding, insufficient research personnel, extraneousness of research focus on societal needs, and a delink between the academia and productive sectors have been attributed to the situation.[21]

To reverse this trend, the government needs to reappraise its allocations to the education sector, where the 2021 expenditure on salaries and overhead is 429% of the capital budget of the Federal Ministry of Education.[22] It also needs to double the funding for the Federal Ministry of Health to meet its 2011 Abuja Declaration of committing at least 15% of the annual budget to the health sector.[23] The two ministries and the Federal Ministry of Science and Technology must also work together to midwife the all-important collaboration among academic institutes, medical practitioners, and industries to kick off the production of domestically-designed medical equipment from locally-sourced raw materials for use in the nation's hospitals.

Other challenges that must be addressed before local production can begin in LMICs include establishing a regulatory framework for health technology assessment, harmonization of device classification, standardization for product safety and quality, and creating an enabling business environment. [23]

In-house hospital engineers can also contribute their quota to the local production of medical equipment in LMICs through additive manufacturing. A few hospitals have pioneered 3D printing laboratories for the fabrication of person-specific needs that are not on the market. These so-called hospital factories use additive manufacturing to make products like individualized prosthesis for patients and anatomo-functional models used for surgical planning and patient education.[24] Other areas where 3-D medical printing is used include the production of microfluidic devices for laboratory test, meal assistance devices for spinal cord injury patients, immobilization devices for radiotherapy and fixation plates implanted by orthopaedics surgeons.[25-27] Hospitals in LMICs can equip their biomedical engineering departments with 3-D printing labs to fabricate some of these personalized medical products.

The essence of locating the laboratory in the hospital is to foster collaboration between medical practitioners, patients (end users), and the engineers from the designing to production stages. While setting up the lab may be initially cost-intensive, hospitals can recoup their investments with a good business model, and patients can get apropos service at a fraction of the cost of getting it from OEMs.

CONCLUSION

Achieving adequate health technology in LMICs is long and fraught with many difficulties. Progress in the sector has come in fits and starts and has barely made a dent in providing healthcare facilities with the resources they need to provide patients with the care they need. But with a strategic plan to develop the local 'man and machine' and an unflinching determination to commit time and financial resources to the plan, LMICs too can begin the journey towards self-sufficiency in their practice of medicine.

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The Growing Role of Clinical Engineering: Merging Technology at the Point of Care

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Keywords – *healthcare, technology, clinical engineering, patient care, health systems, global collaboration, nursing, policy*

Fiza Shaukat is a native of Pakistan living in the United States. As a biomedical engineer, she was eager to improve her country's medical devices and digital health strategies. She approached us in 2018 seeking expertise in clinical engineering, which focuses on the point-of-care intersection between the use of health technology and the expertise needed for optimal support and resource management.

Pakistan, like many countries, has faced myriad systemic challenges, which were amplified by the covid-19 pandemic; these challenges include a fragmented delivery system and a lack of interoperability between medical devices, electronic health records, and other recent health technologies. We worked with Fiza on a health technology asset management method. Later, during the pandemic, we pointed her and her in-country colleague

Tazeen Bukhari to the covid-19 inventory tool, offered by the World Health Organization (WHO), to assess national gaps in the availability of medical devices and oxygen; the information was used to inform the Pakistani Ministry of Health's plan for confronting the pandemic.

Meanwhile, Fiza faced the premature loss of her grandmother due to cardiac complications—she had not received care in a timely manner because patient data and test results could not be shared quickly between providers. Fiza took initiative so that her loss would not be repeated for other families. She brought a technical solution to the point of care, using clinical engineering and emerging health information technologies.[1]

As clinical engineers (CEs), we have encountered variations of Fiza's story in several countries. Clinical engineers support and advance patient care outcomes by applying engineering, life sciences, and managerial skills to optimize healthcare technology during its life cycle deployments. They are sought for their systems thinking expertise, to conduct an independent validation of healthcare products, identify support requirements, and ensure that medical device users' needs are met and that products are accessible and ready for patients. They assess and manage the use of health technologies, which WHO defines as "the application of organized knowledge and skills in the form of (medical) devices, medicines, vaccines, procedures, and systems developed to solve a health problem and improve quality of care and/or life," including both traditional medical devices and emerging digital health tools.[2]

To illustrate the range of CE contributions, we offer two examples.[3] The first is in device innovation. In remote desert-like regions of Western and South Australia treatment for trauma victims requires long-distance and space-limited transportation. The patients are often in shock and require a blood/fluid transfusion. But these fluids are kept at a very low temperature, and rapid infusion of cold fluids can worsen a patient's condition or even induce hypothermia. Two clinical engineers developed a fluid/blood warmer that does not require electrical power but uses the latent heat principle to warm intravenous fluids at accident sites, overcoming the lack of suitable portable fluid warmers that are not dependent on main electrical or battery power.

The second example involves risk reduction and safety of medical devices at the point of care. A clinical engineer and his team in Mexico's National Center of Health Technology Excellence investigated national management of medical equipment in public hospitals. They concluded that, among the country's 32 states, health technology management was effectively coordinated by trained CE practitioners.[4]

Clinical engineers are trained to identify challenges and opportunities to improve healthcare delivery through the adoption of effective and safe technological solutions. For example, "alarm fatigue" can be eliminated in ICUs with smart medical device alarms that triage the urgency of attention needed, distinguishing life-threatening events from those less urgent. And remote care for patients isolated due to infection concerns can reduce the time and cumbersome logistics involved for care providers to monitor and tend to their patients.

Clinical engineers recognize the need for both systems expertise in healthcare partnerships and the development and implementation of national policies to reduce fragmentation and inefficiencies in healthcare delivery.[5] The case for such expertise and partnerships has been made in classic consensus reports of the National Academy of Medicine—To Err Is Human: Building a Safer Health System (2000), Crossing the Quality Chasm: A New Health System for the 21st Century (2001)—and in a joint publication with the NAE, Building a Better Delivery System: A New Engineering/Health Care Partnership (2005). The latter report notably described "opportunities and challenges to using systems engineering, information technologies, and other tools to advance a twenty-first century system capable of delivering safe, effective, timely, patient-centered, efficient, equitable health care" (p. vii).

We are encouraged to see recent evidence of engineering partnership improving healthcare delivery, in the May 2021 NAE Perspective, *ERs Rise to the Covid-19 Challenge: Teamwork between Engineers and Healthcare Providers Cuts ER Waiting Time*, and in a Johns Hopkins University January 2020 article, Enter the Surgineer. But the vision, alas, is yet to be fully realized.

Since 2020 the US healthcare delivery sector has lost over 300,000 workers,[6] exacerbating a staffing shortage that existed before the pandemic. Nurses are among the most impacted group.[7]

A new approach that includes shared interprofessional training can help alleviate the situation by training clinical engineers for engagement at the point of care. We envision broader systems responsibilities for all care delivery team members, to overcome the segmented and increasingly specialized healthcare workforce and thus ensure higher quality and safety through a new collaborative approach.

THE INTERSECTION OF TECHNOLOGY AND HEALTHCARE DELIVERY

Clinical engineers have the expertise to facilitate a systems approach to health, where technological tools are needed to measure health system inputs and outputs. Tools for monitoring and reporting clinical parameters and laboratory results enhance the identification of early trends in large populations and can support better health and wellness.

The use of health technologies must be strategically guided, with coordination of local, national, and international resources, optimal resource management, policies that guide technology-related outcomes,[8] and plans for life cycle stages. To that end, a healthcare model is needed that integrates the delivery of care to improve both care outcomes and patient experience.[9] Such integration requires adequate knowledge of the technology life cycle, from innovation to application; academic programs that keep up with changes to point-of-care technologies; and participation in technological innovations such as robotics, artificial intelligence, and implantables.

Clinical engineers have a foundational role in this integration, with their unique knowledge related to the management of health technology systems and validation at the point of care. In coordination with clinicians and other stakeholders, CEs are demonstrating the benefits of their inclusion as equal members of the healthcare delivery team, particularly during the global pandemic, at both the point of care and population health levels.[10]

GLOBAL NEED

As the sales of global medical products are predicted to reach $658 billion by 2028,[11] it is clear that, for optimal return on investment and sustainability, the implementation of such products should be managed and supported by trained professionals such as clinical engineers.

During the first 2 years of the covid-19 pandemic, WHO's World Health Assembly focused on the need for intensive care ventilators (2020) and medical oxygen (2021).[12] WHO has specifically recognized clinical engineers for optimally managing assets such as medical devices, personal protective equipment, oxygen, and digital health tools, particularly in low-resource settings.[13]

Two CE organizations, the International Federation of Medical and Biological Engineering Chemical Engineering Division (IFMBE CED) and the Global Clinical Engineering Alliance (GCEA), grew tremendously during the pandemic with a surge in the need for their members' expertise. In partnership with WHO, these organizations are now connected to colleagues in nearly 200 countries, sharing best practices and solutions to complex challenges.

The next step is to build the right systems capabilities for improving global healthcare delivery.

A CALL FOR ACTION

For clinical engineering to transition from localized point of care to population health, certain systems competencies must be in place:

1. Education of the workforce to create greater collaboration and resiliency. Collaborative interdisciplinary educational training[14] will ensure the 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. National health technology policy to address priority national challenges. Pandemic-related impacts necessitated rapid implementation of national health technology policy in many countries.[15] 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 policy.

3. National and international alliances and partnerships to share expertise and lessons learned. Such alliances 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 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 point of care and in regional and global populations.

As healthcare delivery systems around the world increasingly depend on technology for access to the best care, the expertise of clinical engineers in the use and management of this technology is critical for achieving best outcomes. For both point-of-care and population health, a systems approach can improve the delivery of health services through education, workforce collaboration, policy development, and partnerships. Clinical engineers are indispensable partners in achieving this mission. Just as Fiza was driven to overcome challenges, the approach described here shows a pathway to achieve the outcomes we all need.

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