Review Article

Efforts to establish indigenous technology for healthcare in a low resource country – Bangladesh experience

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Abstract

The astounding developments in healthcare technology is not available to about 84% of the global population in the low-medium income countries (LMIC). Good meaning medical equipment donation programmes from the high income countries (HIC) have made very little impact, most devices failing to give the desired service and increasing e-waste. The author, with his four decade-long experience feels that people in the LMICs with higher education in science and technology should be motivated and trained in the design and manufacture of medical devices, and they should also take the responsibility for commercial manufacture and distribution of the developed products. With this realisation early in life, he initiated similar efforts in his home country Bangladesh about four decades back against many challenges and obstacles. This produced some success stories and this paper lists some of the devices developed and distributed by groups under his leadership. The author argues that the existing industries in the LMICs are based on fully foreign technology, and do not have the capability or preparedness to take up commercial manufacture of indigenously developed technology based products. He has come up with the design of a 'Micro-eco-system' for the LMICs which involve the leadership of a single technology innovator or a single group of innovators to organise R&D and commercial manufacture, both. An LMIC may have hundreds or thousands of the above 'Micro-ecosystem' to create an overall eco-system, which may be the solution eventually leading to a more equitable world, with each and every person of the globe having access to developments in science and technology in healthcare.

Keywords: Healthcare technology, Global Health, Healthcare in LMIC, Research based entrepreneurship.

INTRODUCTION

Quality of healthcare is very much dependent on the use of modern technology, in the form of medical devices. Although the world has seen astounding developments in technology for healthcare in the recent times, the benefit to about 84% of the global population, living in the so called 'Low and Medium Income Countries (LMIC)' [1,2: percentage derived from numbers appropriate for 2018], remains very limited till today, particularly to the common people in the lower economic ladder in these countries and to those living in the rural areas [3,4]. Modern devices, however, do have a presence in the LMICs, but because of multiple factors, the benefits to the large population spread throughout the country is not satisfactory. For example in Bangladesh, the Government has established about 607 hospitals (2016 figure) [5] out of

which 421 are Upazilla Health Complexes (UHC) with 30 to 50 beds (Upazilla is a sub-district administrative unit) aiming to serve about 300,000 of the rural population each [6]. In addition, the number of registered private hospitals and clinics are about 5,023 [5], but most of them are established in urban areas. In terms of providing all of the following five basic diagnostic tests - haemoglobin, blood glucose, urine protein, urine glucose, and urine pregnancy - only 16% of the public facilities (district and sub-district facilities) offer all these, according to Bangladesh Health Facility Survey Report of 2014 [4]. About one-third of private hospitals and NGO facilities provide these five basic laboratory tests. In terms of X-ray machines, 73% of district hospitals in the public sector, 60% of district hospitals in the private sector and 20% of the UHCs have a functional one. Again, considering the presence of a functional ultrasound machine, the figures are: over 60% of district hospitals in the public sector, about 67% of private hospitals, 16% of NGO facilities and 4% of the UHCs. It needs to be noted that UHCs cater to the majority of the population (63%) living in the rural areas [7] who have a very low access, even to minimum of equipment that are necessary for day to day healthcare services. Similar situations are expected to be encountered in other LMICs. One should ponder, a vital medical device like the X-ray machine was invented in 1895, more than one hundred years ago [8], and still a majority of the global population are deprived of its benefits.

Through his long experience of working in Bangladesh the author feels that one of the major factors behind this unfortunate scenario is that modern electro-medical devices are almost universally imported from High Income Countries (HIC), either procured through purchase or through donations, and not made locally. Because of warm and humid weather and extreme abnormalities of power line voltage in the LMICs, such equipment get out of order within a few years, even within months of installation [9]. The technology of the modern equipment are such that these are very difficult to repair in the LMICs. Again most of the modern equipment use microcontroller embedded electronics which need programming codes to repair, but these are kept secret by manufacturers. Therefore, most modern medical devices cannot be repaired even if knowledgeable manpower is available and the phrase 'for one time use' are frequently used to characterise such foreign equipment. For very highly priced equipment like CT scanners and MRIs it may be feasible to cover the high costs of repair by foreign engineers coming to LMICs, and these are typically used with satisfaction, but for moderately priced equipment like Ultrasound scanners, X-ray machines, ECG equipment, or anything of lower price, the above modality is not feasible, but these constitute most of the healthcare equipment that the people need. A country like India, which is placed among the top 10 countries of the world with the highest industrial outputs [10], imports about 70% of its medical devices from abroad [11]. In a slightly different scenario, almost 80% supply of medical devices in some countries in the lower ladder, or, Low Income Countries (LIC), come as donations from HICs [12] but 40% to 70% of these are out of service [13-15].

The author has been very active in the area of access to medical equipment and appropriate consumer technology by the indigenous population in Bangladesh since 1978, and he has worked at various levels and capacities, being a university teacher and researcher, an appropriate technology innovator and inventor, an entrepreneur, a lobbyist (to reshape Government policies), member of various relevant Government committees, founder and member of relevant manufacturing trade bodies and founder of research institutes and

manufacturing companies in the private sector. He took this daunting task with just one single aim, the common people of his country should get benefit of scientific and technological expertise that he has acquired. Through this long and varied journey he has gained deep insight into many of the situations with regards to technology eco-system in the LMICs that come from a first-hand experience, and are unique. Therefore, some of the opinions expressed in this paper stem from his own experience and analysis, which may not have been published and lack a reference. However, the author takes full responsibility of such information and opinions.

In the Bangladesh market, there is a visible absence of indigenous technology based products, not to mention medical devices. This unfortunate scenario has a complex mix of factors ranging from anthropology, history of the colonial era and social, political & economic policies adopted in the post-colonial era. Most people trying to do something different either back away after facing a few obstacles, or join the bandwagon of importers or traders. Specifically, some policies obstructing indigenous technology based industries may be traced to the erroneous political and economic policies of the past which took the 'Trickle Down' theory as the basis. Although proved ineffective [16,17] the beneficiaries of such systems happen to influence the present day policies of the LMICs, benefiting only a few, and the legacy continues. In fact the thought processes have become so blunt that nobody cannot think beyond this, even though everyone feels that something is not going right. Therefore, even if someone strives to promote products based on indigenous technology, which obviously has to start small, the powerful importers and traders, beneficiaries of the previous systems, would block such efforts through influencing Government policies whenever they feel that such activities may go against their own interests. The large and medium industries that exist in Bangladesh are all based on foreign technology, through 'turn-key projects' and initiated with huge funds, only possible for the already rich people who can borrow from public savings kept in banks. On the small industry side, there are a few thousand units making mostly mechanical spares and parts for vehicles and machineries and some electrical ones making accessories for use in mains power line equipment [18]. The entrepreneurs are basically technicians, either with some technical education or learning the trade through apprenticeship. Besides, the mechanical units are not 'industries' in the strict sense, these are basically 'workshops' taking orders, they do not have a 'product', ready to offer to the market. Again, the absence of highly educated segment of the population in this area is clearly discernible.

On a different scenario, most of the good meaning efforts from the HICs have been directed to medical equipment donation programmes, which have proven to be of not much use as mentioned above. Eventually these devices will be dumped prematurely [13], contributing to increased global e-waste. Again, there are attempts by researchers in the HICs to design low cost medical devices for the LMIC's, which has been questioned in terms of quality and safety and utility [19]. The author feels that another negative side of such attempts is that the innovators and developers from the HICs are not exactly familiar with the real life conditions and requirements that are relevant to the target LMICs. Even if some of them are originally from the LMICs, they had their professional lives in the HICs mostly, so they have basically the same alienation from the real life situation. This often makes the outcome unsuitable for the target application. Besides, the original problem remains, these will use technologies that

are not familiar to people in the LMICs; spares, components and expertise may not be readily available if a need for repair arises.

'Giving a fish to a man feeds him for a day, but teaching him how to fish feed him for a lifetime' is an ancient saying and the author also feels that the solution lies in this. The design, development and manufacture of the essential medical devices has to be carried out in the LMICs by their own knowledgeable and skilled manpower [20-23], and this has to be done gradually, starting from non-invasive diagnostic devices first, that have less hazards than invasive ones. Under this strategy, one can easily check the locally made diagnostic devices for quality against medical devices from reputed global manufacturers existing in the country. Assistive devices and those related to public health may also be taken up. Once a group of skilled manpower is developed, and their products come to the service of the local people, they will gain much needed expertise, experience and self-confidence, to take up more complex devices and therapeutic ones eventually. This will also eliminate other negative mind-set against locally made devices that the society and the Government suffers from, and as the local medical devices flourish, the benefits will be delivered even to the marginalised population in the country.

It is well-known that for any technology innovation with a potential for commercialisation, this has to go through a process of industrial design, field trial and modification of the technology based on the feedback, commercial prospecting, process development for commercial manufacture and trial marketing. Only then it can be taken up for full scale commercial manufacture. This is the whole eco-system from innovation to commercial manufacture. Most of the HICs went through the first industrial revolution a few centuries back [24] when the technology innovators turned themselves into entrepreneurs to commercialise the innovated products. Through this process, networks of subcontracting industries and supply chain grew and some of these manufacturers became the giants in business and created all the facilities and environment for the above activities needed for manufacture. They can now absorb new technologies by other innovators too, converting it to a product on their own.

On the other hand in LMICs like Bangladesh, the industrial revolution never happened, and the above mentioned eco-system does not exist in reality, even today. Most of these countries were colonies of the HICs in the past [25, 26] and their technological innovation capabilities, manufacture and commercialisation could not develop in a natural way, and were in fact, suppressed. In the colonial India, local products were heavily taxed while imported items from Britain were made tax free [27, 28]. From these courses of events it may be envisaged that these policies gave rise to a rich group of importers who represented foreign manufacturers. After India, Pakistan, and later, Bangladesh became independent, the rich importers could easily influence the tax policies of the Government in a very subtle way, so that local indigenous technology based industries could not flourish in the way that should be desired [29, 30].

Coming to the issue of medical devices, these need the involvement of manpower having higher education, in the tertiary level. Unfortunately, in Bangladesh and many LMICs, the highly educated human resource in science and technology is hardly of use to the country's people. Having PhDs in advanced topics in the HICs, a great majority of them stay back in the HICs.

Those who come back, carry the conception that research only means working on topics that they had done for their degrees in the HICs; publishing papers in high impact international journals become their only goal. Therefore, local problems remain ignored by the knowledgeable people in science & technology, which also goes for the case of medical devices. While the situation in the LMICs offers substantial avenues for innovation, most of the local scientists think that they would not be able to publish in international journals and not get desired upgrades in their career if they tackled a local problem. Besides they tend to consider such problems as 'too mundane'. These scientists would spend millions of dollars of public funds to set up high end laboratory facilities for research, just for publishing papers, not at all for contributing something directly benefiting the local population. Again, the published papers would hardly make a dent in the global arena since much improved work in similar topics usually come from the HICs. Thus all the financial resources and talented manpower of the country are wasted. This mind-set is prevalent among scientists in most of the LMICs. As mentioned before, even India, which is a top industrial nation in the world [10] imports about 70% of medical devices [11]. It is the author's personal observation that industrialisation in India was achieved through technicians, moderately educated people in technology, not through the highly educated group. Since indigenous medical device industry require leadership from the highly educated manpower, this did not flourish in India even.

In Bangladesh, people often ask, 'why does not the large industries give money to the universities as they do in the HICs?' The author's answer to the above question is that most of the large and medium industries in Bangladesh are set up by people who can borrow large amounts of money from banks for setting up industries based on fully imported technology, as 'turn-key projects', also mentioned before. These industries only use local 'cheap' labour, and in some cases, local raw materials for some fixed range of products. Most of the industrial processes are based on proprietary technology which do not need any input from the local scientists and technologists. Nor the local experts can design and develop products that can be produced through such industries. A large technology gap, developing through centuries, have created an unsurmountable barrier. Except for installation, operation, maintenance and testing, these industries do not require local technical manpower. They do not need outcome of local research either. Therefore, it is only natural that these industries do not pay money to the universities. From first hand personal level discourses with people asking such questions, some of whom were top scientific minds of the country, the author had learned that they had thought industries pay universities for philanthropy in the HICs. They did not have the idea that in the HICs the industries and universities have a mutual interest for such interaction, it is not philanthropy; the industry needs new technology for which it comes to the university, and the university needs funds to continue research activities. If this is the situation with top level scientists, one can understand what may be expected from policymakers of the country, who mostly do not have backgrounds in science.

On the above backdrop, it is also natural that these industries based on completely foreign technology cannot take up the manufacture of any new technology based product from the indigenous innovators, not in the least, medical devices.

Therefore, the only solution to utilise local technological ingenuity lies in 'Start-up Industries' initiated by the technology innovators themselves. However, in Bangladesh and most LMICs, the challenges are huge in implementing such solutions because of a complex web of factors mentioned before. Through his four decade long effort in the country, the author has seen many young technology enthusiasts setting up small manufacturing units, based on their own technological innovations. As long as they remain small, they make good progress, but as soon as they create a market that becomes visible, some unseen forces come into play and eventually the entrepreneur either quits or turns into an importer or a trader. The author also came to know a handful of people who tried to establish technology based manufacturing facilities in Bangladesh, after obtaining higher degrees and job experience from the HICs, but almost all eventually gave up and went back to the HICs. Therefore, the LMICs, losing their most talented people, never come out of the perennial failures and frustrations. The Bangladesh Government is trying hard to promote technology based start-ups of late, but again, except a few ICT based ones in the service sector, none in the hardware sector could flourish. On the other hand, the hardware based innovative small industry is very much essential to enhance the quality of life of the common people.

However, things have to change, and the initiation should be through efforts to bring confidence among the people that it is possible for local scientists and engineers to design, develop and commercially manufacture technology based products including medical devices, following the age old saying, 'seeing is believing', and the author's journey through the last four decades has been dedicated to this end. Unnerved by repeated failures, he has been finding out avenues to bend around obstacles as they come along the way, and has been able to garner the support of a host of talented young scientists and engineers together with whom the author is trying to pave the way for the future generation, hoping for a change to come, and some rays of hope have started to shine already.

Through this personal endeavour the author eventually found out that an industrial infrastructure that is needed to take innovations to manufacture does not exist in Bangladesh, and therefore, a technology innovator has to take care of this part as well, at least at this point in time. Otherwise, all research outcomes will rot in the laboratory, which happened to almost all researches done in this part of the world. Eventually, when some of these R&D based industries will grow big, they will be able to accommodate innovation by others, and will have the facilities, capabilities and the mind-set to take a new technology to maturity, to an industrially successful product, as that which exists at present in the HICs.

The following sections briefly illustrates a few of the medical devices that the group under the author's leadership have developed and taken to implementation or production level by their own efforts, also to illustrate the salient features of innovations that makes these devices appropriate. Most of these have been described in details in the original publications which have been referred to. The descriptions below will also show how indigenous development of an existing product may lead to new knowledge and innovation benefitting the whole world as well, which would not be possible had the original technology of a device were not developed locally. This will also reveal the challenges of developing and implementing medical devices in an LMIC like Bangladesh. Of course the situation may not be the same in all LMICs, but an

idea may be obtained from these observations. Some other devices made by the author's group will be mentioned very briefly later, to give a snapshot of the spectrum.

DEVICES DEVELOPED BY THE AUTHOR'S GROUP IN BANGLADESH

i. PC based EMG/EP equipment

EMG/EP stands for Electro Myo-Gram/ Evoked Potential. Using this equipment most neurological measurements are made, including nerve conduction, audio and visual evoked potentials. With the help of UK scientists, the author developed this microcomputer based EMG/EP equipment in 1988 [31] as shown in Figure 1 using which all the above measurements could be made.

Why was this item chosen? The EMG/EP equipment is quite a sophisticated electronic item requiring computer interfacing and measurement of minute bioelectrical signals, of the order of microvolts to millivolts in amplitude, which again are associated with much larger 50Hz mains borne noise. The author realised that if he can learn and master such a technology, it will



Fig 1 (left): The first EMG/EP (with integrated ECG) equipment made by the author in 1988 with the help of British scientists. The components are shown through arrows. The main amplifier with an integral nerve stimulator is linked to a BBC computer and external floppy disk drive. The high-low voltage protector developed by the author's team gives protection up to 440V on a 220V line which is very important to the equipment's survival. The commercial light flash driver is used for visual evoked potential studies.

be possible for him later to tackle most of the technology related to other electro-medical devices. He mainly chose electrical and electronic devices because most mechanical devices need expertise and facilities that may not be available in Bangladesh. On the other hand, electronic devices are easier to develop in Bangladesh, using components that are widely available, and he himself already had some expertise in designing electronic equipment and products. He also targeted microcomputer based instrumentation as microcomputers are widely

available at a reasonably low cost. So combining these expertise would extend the author's group a capability to produce modern electro-medical devices of various sort.

Coming back to the developed EMG/EP equipment, the main amplifier was designed to make it versatile, through switched gain and filter options. Of course, for audio and visual evoked responses some additional hardware units were required. Minor modifications in software allowed single channel measurements of EMG, ECG and EEG. For nerve conduction measurements, a nerve stimulator was built into the same cabinet as the amplifier. The Preamplifier connecting electrodes on the patient was taken out on an extension cord to minimise noise interference from the mains ac line. All necessary safety features like electrical isolation of patient were made to follow relevant British safety regulations. This is possibly the first computer controlled device made by anyone in Bangladesh and the author used it to provide clinical nerve conduction service in Bangladesh, which was another first in the country. For this the software was appropriately developed so that clinicians could use it with ease. Here, the point of user friendliness comes, which depends much on the culture and mind-set of the local people, where the author utilised feedback from users as the device was tested in the field, on real life patients.

The microcomputer initially used was a British BBC computer, very popular at that time with the availability of a great amount of information for developers including data acquisition and interfacing circuitry. The software was written in BBC BASIC language. The data acquisition system was chosen at 8 bit since this gives adequate resolution (about 1% for full sized signals

with dual polarity) for most clinical applications in the field conditions. This decision helped to keep the cost and complexity low. Most similar imported equipment would use 16 bit data acquisition system, which is definitely better, but increases the cost and complexity. Signal averaging facility was also incorporated through software and computer interfacing to eliminate noise from very low evoked potentials [32]. This equipment developed by the author's group used off the shelf ICs for the electronic circuitry and the circuit assembly was done on prototyping Veroboards. Fig. 2 shows the inside of a second unit which the author's group made indigenously later in Bangladesh.



Fig.2: Inside of a second unit of EMG/EP equipment which the author's group made indigenously later in Bangladesh.

Again, in Bangladesh, occasionally extreme high or low power line voltages are experienced (300V to 400V on one end on 220 Volt line, and voltages lower than 150V on the other end), which are not merely transients, but sustained till the line problem is resolved. All electrical devices are destroyed in a moment in the case of a high voltage. Such abnormalities are unheard of in the HICs and therefore, no solution to this problem was available. Although such

occurrences are not frequent, one occurrence is enough to cause premature failure of many equipment, stopping service and causing immense financial loss. The cause for such abnormal voltage occurrence is the opening of the neutral line in a 4-wire, 3 phase power distribution system [33], which is usually the result of poor junctions at distribution points. Such poor junctions are not infrequent in a society where technology consciousness is very little and power line workers appear to have a casual view of accidents. Again moderate high and low voltages may occur due to heavy unbalance of loads in the 3 phases, and where the neutral line is made of a thinner gauge wire than required to save costs. The voltage dropped in the neutral wire adds or subtracts appropriately to produce the high and low voltages in the three different phase to neutral lines. The author, had earlier designed and commercialised a high and low voltage protection device [34] which was added to the EMG/EP device as a standard fixture. Possibly because of this, the medical device survived a long period of daily use over 23 years. It went out of order only a few times within this period, which were repaired by the author's group at the circuit level, requiring changing an IC or mending a torn cable, etc., at virtually no cost. This was possible since the author's group knew all the minute details of their own design, and had the background knowledge in the fields of physics, electronics, computer and information technology and a minimum of the required knowledge of related medical aspects. Besides, they selected and laid out all electronic components in such a way that warm and humid weather does not cause malfunctions.

However, while used in Bangladesh, the BBC computers started to malfunction within a short time. It was found that the computer did not have adequate ventilation inside and the circuitry became hot. It worked well in the cold climates (most of the HICs have cold climate), but failed here in Bangladesh. The author's group made some cut outs and holes in the cabinet and arranged blower fans which kept the computers going. However, as the BBC computer was going out of the market, the author's group decided to convert the equipment for a more popular IBM PC or its clones, available at low cost. This was around the 1990s. For this, the challenge was in getting a data acquisition board at low cost. One commercial Analogue to Digital conversion circuit board was procured through an importer at a cost of about USD 200. This was one of the cheapest at that time; any standard ones would cost in excess of USD 1000. The



Fig.3. EMG/EP equipment based on a IBM comaptible PC. Photo shows its use in nerve conduction investigation.

ADC board worked for a few days only and then went out of order. It was not possible to fix it locally and had to be dumped. Then the author decided to design one at home using basic ADC and analogue multiplexer ICs (as the design intended to use multiple inputs sometimes). This was designed based on the 8 bit ISA bus connecting port [35] of the PC for interfacing. Without a logic analyser at hand (which were expensive at that time) it was quite a challenge in testing out if the data were being acquired properly through the designated pins. Here again, ingenious

ways were found out developing some codes in the software to test if the interfacing circuitry worked or not by measuring minute variations in the average dc voltages at digital output pins of the ADC. The software was developed by a young researcher in C++ language with guidance from the author. This system worked for many years. In course of time, the ISA bus became obsolete and Enhanced Parallel Ports (EPP) [36] came, allowing parallel data entry through external printer port. The interface circuitry and relevant software were redesigned accordingly. Again, the EPP became obsolete eventually, and USB ports [37] came in. The author's group of young researchers learned the necessary technology and converted the interfacing appropriately, which arrangement continues till today. The device running on an IBM PC is shown in Figure 3. It needs to be mentioned that in order to make a probe for nerve stimulation, a commercially available 2 pin mains power plug was used, an improvisation, which simplified the design problem.

The user interface and the design of the outputs for screen display and printed reports were made keeping the Bangladeshi doctors' technical skills and mind-set in purview. Thus these did not exactly follow those of the standard commercial equipment available from the HICs. Later the author received personal comments from senior doctors, who said that the outputs of this local equipment were easier for them to understand and interpret, compared to those of the imported ones. The user interface makes a big impact in the successful use of a device, and local design and development definitely can take better care of this aspect. Top neurologists and orthopaedic surgeons of the country were sending their patients regularly to the author for routine testing of nerve conduction and were highly satisfied with the results and the reports, given by the author himself.

Anyone would think that successful development of such an equipment will be heralded with enthusiasm in the country where there is dearth of modern medical devices. There was no other similar equipment of its kind in any hospital at that time (1988) in Bangladesh and patients had to go abroad to get these tests done. Requests were made to the Government to procure locally made equipment like this for the medical colleges having neurology as a speciality. However, the effort did not produce any tangible outcome. Failing this, the prototype was installed at private facilities of supportive neurologists or of orthopaedic surgeons in Bangladesh at different times to give routine clinical service, which continued till a few years back, in spite of the fact that a number of hospitals had procured similar foreign equipment in the recent times.

An innovation for the world, possible since the device was made locally

The device was used for a research on diabetic patients in a premier diabetic hospital and research centre in Bangladesh [38] in the early 1990s by the author's group. There they found out that some patients who had severe weaknesses in limbs, showed normal NCV, measured in the conventional way. In NCV measurement, stimulation is given to a point of the nerve pathway using surface electrodes and the resulting evoked responses are measured from another point of the same nerve or from a supplied muscle, again using surface electrodes. The author's group concentrated on the latter which involved motor nerve fibres in a nerve trunk, and were working with median nerve of the hand in the beginning. The nerve was stimulated at the wrist and evoked EMG was collected from the Thenar muscle, at the base of the thumb.

The following description will refer to this particular nerve and the site of measurement, although NCV are obtained from other peripheral nerves too.

The author argued that to obtain conventional NCV measurement, one measures the time to the onset of the evoked EMG response from the instant of the respective pulsed electrical stimulation of the nerve at the wrist, and that this timing corresponds to the fastest nerve fibre within the nerve trunk. The contribution of the slower nerve fibres occur at the later parts of the evoked EMG response. Possibly in these cases the neuropathy had affected the slower nerve, not the fastest ones, and therefore, the neuropathy could not be identified through this procedure. The procedure may be likened to the time measured in athletics using a single stopwatch; it is stopped when the fastest runner cuts the tape. This procedure does not give any information on the timings of the slower runners. Therefore, the author was looking for a simple-to-measure clinical technique to obtain the distribution of conduction velocity (DCV) of nerve fibres in a nerve trunk, which could be the ultimate in diagnosis. However, except for a complex laboratory technique [39], no reliable method was available for clinical measurements, although people have been trying to obtain DCV for a long time. This put forth a challenge, and after years of research with various techniques the author came up with the idea of a new nerve parameter which he named, 'Distribution of F-Latency (DFL)' that can be obtained clinically with ease through multiple (30 to 40 times) stimulations, from which an approximate DCV may be obtained through simply a mirror image [40]. Of course an accurate DCV may be obtained through somewhat more involved mathematical analyses, but for most clinical purpose, the above is adequate. This interrelationship was possible through arguments based on physics, physiology and statistics and provided a solution to a much sought after parameter.

While pursuing the work further, the author's students observed that the patterns of DFL changes for patients with cervical spondylosis [41]. The author tried to explain this phenomena again based on anatomy, physiology and statistics [42] which led to an early detection tool for such cervical neuropathy [43-45]. Doctors at Singapore General hospital also collaborated in this study. Figure 4 shows four patterns of DFL obtained from the median nerve of different subjects [42]. The one with a single peak represents normalcy while all the other three patterns, with a broad peak, double peak and triple peak – represent the presence of cervical neuropathy due to compression of the spinal cord (myelopathy) or compression of exiting nerve trunks from the vertebra (radiculopathy) or both. Such abnormalities were detected even before a person felt neck pains. Therefore, further deterioration could be prevented through such early detection.

Similar neurological problems also occur causing low back pain, due to compression of nerves in the Lumbo-sacral region. The author's group also detected such problems taking DFL from the Tibial nerve or from the Common Peroneal Nerve, not yet published. Therefore, these techniques will be invaluable in the management of neck and back pain, to identify if these are due to muscular problem or due to compression of nerves. At present, MRI is needed to diagnose such disorders with confidence, but MRI is very expensive and is not available to the majority of the population in the LMICs. The author's group found 75 to 80% agreement between prediction of cervical neuropathy using DFL and MRI investigation through a double



Fig.4: Typical DFL from median nerve of different subjects showing single peak, broad peak, double peak and triple peak from different subjects. Only the single peak represent normalcy. All the other three indicate the presence of either cervical myelopathy or radiculopathy or both.

blind study [45]. Although evoked EMG/EP equipment made in the HICs are very expensive, the author's group can make a PC or a smartphone based device to give only the essential NCV and DFL measurements at a fraction of the cost. Therefore, this new technique of detection of cervical or lumbo-sacral compression neuropathy will contribute significantly for management of neck pain or back pain globally, particularly in the LMICs where MRI is not so accessible and affordable.

These innovations, whose benefit goes to the whole world and adds to the global knowledge, was possible since the medical device was made locally. When the idea came for such a procedure, the hardware and software were modified by the author's group easily within a short time. This would not be possible, and that in Bangladesh, had the initial NCV work been carried out using an imported standard equipment which usually have fixed sets of procedures.

Commercialisation challenges and prospects

As can be seen from the timeline, this device was made first in 1988, and still now it has not been procured by hospitals, either in the public sector or in the private sector. Only one unit, at the cost of the author's group, was installed at several private hospitals at different times using which routine nerve conduction tests were provided to patients, again managed by the author's group. The earnings from carrying out investigations on patients were shared. This shows the magnitude of obstacle that any developer of locally made devices would face. Imported EMG/EP equipment are very expensive, so only a few hospitals have this device in Bangladesh. Pricewise, the local device looks attractive, but there are complex factors that prevents these hospitals from procuring the local device although the diagnostic outputs from the local device was accepted by top neurologists of the country for their treatment procedures, with satisfaction.

ii. Iontophoresis equipment for treatment of excessive sweating

The second device under discussion is an Iontophoresis Equipment for treatment of excessive sweating, a condition whose medical name is Hyperhidrosis. Excessive sweating of palms, soles, armpits, etc., causes severe embarrassment in social mixing and difficulty in certain types of activity, particularly in writing and typing.

One of the techniques for a remedy to this problem is tap water iontophoresis, which has been under intense research since the 1950s [46-48]. The author's team, with the support of a local dermatologist, designed, developed and tested a device locally based on this principle in the mid-1990s and has been selling the device in a limited way for pilot trial, under a brand name 'Anti-Sweat', directly to patients for home use [49]. This activity was kept to a minimum, just to maintain enough sales to keep the activity going, and to see the long term efficacy and sustainability of the device. Many Anti-Sweat devices have been sold since then, allowing the patients to lead an almost normal life.

In the protocol practiced by the author's group, passing a constant electric current in a daily session of about 2|0 minutes in each hand, the affected person gets normal sweating in about two weeks. This treatment is not permanent and subsequent maintenance treatment sessions for only a few days each, at intervals of about four to six weeks, allows a sufferer to lead a normal life. The mechanism of the iontophoresis treatment is not well understood, but it has proven success statistically by a significant amount; almost 90% sufferers get better and can lead a near normal life [50].

The device made by the author's team uses two aluminium electrodes in two segmented sections of a tray, topped by two folded wet towels, kept separated, as shown in Figure 5. Simple tap water is used to wet the towels. A person places a hand on both the wet towels and uses the other hand to control the



Fig.5: Iontophoresis equipment for treatment of Hyperhydrosis (excessive sweating of palms and soles)

strength of the energising current. This allows firstly, a customised control of power and secondly, limits the current to a localised region within one hand, which does not pass through other parts of the body, nor through the heart. Some devices available in the world market uses

two hands immersed in water in two metallic trays. The strength control has to be done by a second person which sometimes can make it unbearable for the patient. Besides, it cannot be used by persons with a pacemaker as the current crosses the heart. Therefore, the design developed by the author's team has distinct advantages.

Commercialisation prospects and challenges

Two other effective treatment modalities are around, one involves neurosurgery [51], not performed in Bangladesh, and the cost and the hazards may naturally be guessed. Another involves pushing Botox (extremely diluted form of Botulinum toxin, an extremely powerful poison) injections at intervals of 4 to 6 months [52]. It is a painful procedure, requiring several injections around the affected region in one session and needs a very specially trained doctor to administer. Again, this is offered by only a handful of facilities in Bangladesh, and the cost that one has to bear for one session only is much more than the price of the Iontophoresis device being distributed by the author's group. Although earlier studies estimated about 3% of the population to have Hyperhidrosis, recent studies show it to be much greater, 5% or more [53]. Therefore, Iontophoresis has a potentially big market.

The present price of 'Anti-Seat', made by the author's group is within the reach of the common people. Thousands have been sold direct to customers, as mentioned before, but only a handful of this device has been purchased by Dermatologists giving service to patients at their chambers. One of the main reasons for such low penetration to dermatologists is that many of them are still unaware or unsure of this modality of treatment and they only prescribe medications or ointments to patients, who keep on coming to the doctors repeatedly, without much benefit. Although iontophoresis technique for the treatment of hyperhidrosis has been around for about six decades, such alternative medical modalities are very slow in getting accepted by the medical professionals. On the other hand, patients are buying this device directly since they are suffering, and they need a solution. However, if the marketing drive could be increased to convince the doctors then the device would sell more, delivering benefit to more people.

iii. Telemedicine system

The third 'device' under discussion here is a Telemedicine system. It is strictly not a device, but is a combination of a software product and many specialised hardware devices. Therefore, the author deems it fit to discuss it in the present paper on medical devices. Telemedicine simply means '*medicine at a distance*'. Through modern computer and Internet technology, it can provide consultation of a qualified doctor located anywhere in the world to patients in any other location. Most current telemedicine systems available from the HICs focus on tertiary care, providing consultation of specialist doctors, general doctors being available at the patient-end [54]. On the other hand in the LMICs, doctors do not want to live in villages. So majority of the population living in rural areas of the LMICs (about 63% in Bangladesh [7]) consult quacks or drug sellers, leading to maltreatment, even death or disability [55]. Misuse of steroids and antibiotics are also rampant, the latter now a global scare. Early intervention, at primary or secondary stage, giving consultation of a qualified doctor, can save patients from a lot of

complications later and reduce the demand on tertiary care. Therefore, telemedicine is possibly the only solution for the rural areas of LMICs.



Fig 6: Devices to go with an indigenous telemedicine system, developed by the author's group in Bangladesh, (a) digital webcam on flexible stand, (b) improvised electronic stethoscope, (c) electrical impedance device for lung ventilation and respiration rate measurement, (d) tele-palpation device (under development), (e) PC based ECG equipment, (f) palm wearable electrode for measurement of lung ventilation and respiration rates in infants or babies without making them cry (which changes respiration rate), (g) a kiosk for telemedicine, (h) internet connected ECG data acquisition and (i) simultaneous ECG display at a distant location.

How a telemedicine system is designed and how it is implemented is important for its success, and the system should give particular attention to the culture, education, economic status and availability of doctors in the target region. Therefore, a system from the economically advanced country may somehow work for the economically solvent and educated city population in Bangladesh but may not work for the rural population. Therefore, the author's group designed the whole telemedicine system from scratch locally, which involved developing software and some integrated diagnostic devices, which also demanded innovations in the modality of application in the rural areas [56-58]. Figure 6 shows some of the hardware developed, or under development for this purpose which includes an improvised electronic stethoscope and a 12 lead digital online ECG equipment, designed by the author's group from scratch. An electrical impedance based localised lungs ventilation monitor and a tele-palpation device are under development.

The author's group also implemented the telemedicine service in rural Bangladesh under the name, 'Dhaka University Telemedicine Programme (DUTP)' after taking necessary permission from various authorities. This has been deployed through an entrepreneur based model, targeting self-sustainability in the long run. In this system a trained operator at a rural

telemedicine centre registers a new patient giving an ID, takes basic physical data like height, weight, temperature, blood pressure, etc., using commercial devices and types in the data to the system input. Such devices are available at low cost in the market and is feasible to get a replacement by the operator if one breaks down. For old patients, the unique ID gives access to all registration information and previous health records. The doctor (mostly a general practitioner) is chosen from a pool who are available at any moment. They can provide this service from anywhere in the country, in fact from anywhere in the world, where there is internet. The doctors do not have to come to a call centre. When a request is received, a responding doctor gets all the previous health records, if desired, and talks to the patient and the operator through video conference. In this system, the doctor finds out details about the ailment through talking to the patient directly, not depending on intermediate information collected by a paramedic. Such modality, chosen by some telemedicine systems to save doctor's time, may mislead the doctor at times. Besides, the patient is also relieved of the annoyance of responding to similar questions more than once. If the doctor wants, the operator sends stethoscope sounds and ECG data instantly to the remote doctor. The ECG will in turn be sent to a cardiologist through email. Based on the report received the general doctor will advise the patient whether to see a specialist cardiologist or not. Then the doctor generates a prescription using a software aided facility and uploads to the cloud server. Data bases of locally available medicines and typical symptoms and advices help the doctor in preparing the prescription in a short time. The operator downloads the prescription instantly and gives a printed copy to the patient. Figure 7 shows a rural patient with a printed prescription received through this system. This eliminates possibility of error which may occur when one is given through mobile phones or video conference only. Besides, the doctors can prescribe any drug depending on their specialty, not being limited to over-the-counter drugs only, if permitted by local regulating bodies. Thus the system developed by the author's group is an improved telemedicine than that using video conferencing only. It is being planned to introduce commercially available low cost imported ultrasound scanners, otoscopes, etc., to provide more diagnostic facilities, later to be replaced by locally developed devices when ready.

The author's group also developed a mobile smartphone based solution. Roving Operators can provide telemedicine service to rural people straight from their homes. This has proved very useful to women, babies, elderly and the disabled. Figure 8 shows a village woman consulting a city based doctor through a smartphone held in her front by one of two roving telemedicine operators, visiting village homes following a schedule.

The administrator can monitor all the activity from the web through a secure password. This also provides necessary data for further analysis, which may be useful for improving the system and for policymaking decisions. DUTP so far (till December, 2021), provided more than 33,000 patient consultations in Bangladesh amassing a vast amount of data and experience. The stored data also offers much scope for future research. During the Covid pandemic, DUTP also provided a free telephone based consultation service with obviously limited scope. From April 2020 to June 2021, when it was closed, about 5,000 patients availed of this service. DUTP received several national and international awards in the last few years [59-62]. Through continuous R&D, the scopes of acquired data and analaysis are being expanded and it is now planned to spread this telemedicine system to other LRCs.



Fig 7: A village woman with a prescription obtained through Dhaka University Telemedicine Programme.



Fig 8: A village woman getting doctor's tele consultation organized through roving telemedicine operators under Dhaka University Telemedicine Programme.

Telemedicne appears to br the panacea for the health problems of the people in the LMICs, particularly in the rural areas, for the poor, and for the people living in hard to reach areas. The last scenario is applicable even for the HICs. The author's group is ready to transfer their technology to any group working in the LMICs.

iv. Solar water Pasteuriser, a Public health device

This section describes a simple and low-tech innovative device that is very important for public health and the author feels this should be discussed in this article as a preventive device. It is a very low cost 'Solar Water Pasteurisation' device for providing safe drinking water in rural areas.

It is well known that drinking water poses a big problem in the rural areas of almost all LMICs and the main source of contamination are waterborne pathogens causing diarrhoeal diseases. Boiling water could be a solution, but used on a large scale would contribute to environmental issues. Besides, in situations like floods, for people in the city slums and those under forced displacements in large numbers, fuel becomes a scarcity.

The solar water Pasteuriser is based on the information that all diarrhoeal germs in water are destroyed if water is maintained at 60° C for half an hour (Pasteurisation). The time required reduces significantly at higher temperatures, only 15 seconds at 70° C [63]. The contraption developed by the author's group uses a commonly available bamboo tray painted black inside which is placed on a thick hay bed (Figure 9). Water to be treated is taken in a large transparent polythene bag so that the depth of water is no more than 2cm, and it is laid flat on the tray, removing any air bubbles trapped inside. Two transparent polythene sheets are then laid on top with some sort of separator inside to maintain two air layers in between. Finally a few pieces of weights are used surrounding the tray to keep the polythene sheets taut. It



Fig 9: Solar water Pasteuriser using blackened bamboo tray on a thick bed of hay, water in transparent polythene bag and covered by two polythene sheets with air gap in between. This makes a flat plat collector that utilizes 'Green House Effect'. Heated water harvested in the bag.



Fig 10: Enhanced model of solar water Pasteuriser using packing foam (polystyrene foam), black cloth as a base, water in transparent polythene bag and covered by two polythene sheets wrapped around a frame of PVC pipe (left). Residents of an urban slum using these devices as a normal routine (right).

essentially m akes a solar flat plate water heater, u tilising 'Green House Effect' [64-67]. In clear sunshine in Bangladesh, an exposur e of one and a half to two hours is enough to raise water temperature to more than 70°C, enough for Pasteurisation. Higher temperatures were obtained on summer days. Water samples treated in this way were subj ected to microbiological tests and all the results indicated destruction of harmful pathogens, immediately after the tests and after six months of storage [68]. In this device, the water layer is also exposed to UV, and pathogens were found to be destroyed even at a lower temperature of 50°C, maintained for about an hour, while these were not destroyed for water heated in a water bath to the same temperature. A 75 cm diameter bamboo tray will Pasteurise about 5 litres of water. Doing it twice a day, one can get 10 litres of safe drinking water, enough for an average family of 5. Altogether, the cost is about US \$2 and the device will last many days of use, if used with care. One NGO disseminated this technology to river gypsies (who live on boats) in a part of Bangladesh around 2002. Initially a few of the gypsy leaders were trained in the technology. Subsequently 70% families of the community started using these devices reporting improved health [69]. This publication also indicates an interesting finding. The users were also given an option of using transparent PET bottles (SODIS) promoted by a Swiss group [70], in which UV plays the major active role (not so much rise in temperature) and one has to keep the bottle for about six hours in clear sunshine. It was found that the gypsy families eventually opted for the solar Pasteuriser as developed by the author's group. The author feels that in the Pasteuriser, one can get a feedback of the temperature simply by

touching the outside of the water bag, while in SODIS, this feedback is not there, and the presence of UV is not easily monitored.

The author's group also made an enhanced model using polystyrene foam, black cloth or plastic lining and a framed transparent cover for easy and quick handling as shown in Figure 10 (left). This was particularly targeted to poor people living in urban slums. They get piped water but it is usually contaminated. The device was made on a folding table so that it can be stored in a crammed up dwelling. In this model, 10 litres of water could be heated to about 90°C in 2 hours. Doing it twice, this device can support 2 families. Slum people used the device regularly and the right hand picture in Figure 10 shows a view taken on an unannounced visit to the area. A small survey also showed that children suffered less from diarrhoea in families where they used this device [71]. Again, after some months the whole slum was razed down and the people moved to unknown places and no follow up was possible.

However, all the above efforts make it clear that the solar ware Pasteuriser developed by the author's group has immense potential.

Dissemination

Although these devices can be made part of an entrepreneurial programme, the target of the author's group is to empower people through knowledge dissemination so that they can make their own devices using easily available raw materials from the local market. Thus they would not have to depend on others or on the supply of special items from outside. That this is possible is exemplified by the above mentioned example of the river gypsies.

Regarding large scale deployment of this successful design, again, complex psycho-social factors come into play. The initial bamboo tray device was developed towards the end of the 1980s. The author talked to the local branch of an international aid agency, they appointed a person for it. Soon after he was transferred to another country and the initiative stopped there. The author taught the technique to a local NGO who later organised the dissemination programme among the river gypsies as mentioned before. However, the NGO had funds only for a few years, after which they did not keep any track of this activity, and the author had to obtain the information from other sources, who worked in that programme. He also came to know that the Government dug some tube wells for this gypsy community, now settled, and they stopped using the solar device as tube-wells offer a much simpler source. However, for many situations where tube wells are not available or appropriate, the solar Pasteurisation device may be a life saver.

The author wrote detailed illustrated articles in national newspapers, organised several press conferences at different times requesting relevant agencies to take up this technology, saying that it would be taught to their workers totally free of cost, but nothing happened. In 2011, the author got a small fund from UNESCO for its dissemination and published an illustrated coloured booklet describing the process of making the devices in detail [72]. The education minister was present at the book launching ceremony, highly placed bureaucrats of the disaster and relevant ministries were invited some of whom were present, however, no follow up occurred. The author sent copies of the booklet to all the heads of the 64 districts and 420 sub-

districts, Vice Chancellors of all the Universities and to Principals of a few hundred degree colleges by registered post; not a single response, nor even an acknowledgement was received.

This shows the general apathy of the people who are responsible to provide service to people. Unless these programmes come with large funds from international donor agencies direct to the Government or an NGO, nobody appears to be interested. The author did receive small grants from the Ministry of Science of the Government for development of the technology, but there was no scope in these grants for large scale deployment of the devices, which would need considerably larger amounts of funds. Therefore, a simple technology, which could be a life saver in many occasions, not only in Bangladesh, but throughout the world, still lie unexploited. It appears that unless the author's group take up an initiative to disseminate the technology on their own initiative and efforts, this technology will not reach the people.

v. PC based ECG for Standalone use or for Telemedicine

This is a 12 lead single channel diagnostic ECG machine, acquiring data for one lead at a time through a PC. It records 4 second data for each lead and sends it over internet to a remote PC if these are set up with the appropriate software and internet link (Figure 11). At the end of taking all 12 lead data, these are combined into a single page data tracing, as for conventional



Fig 11: PC based 12 lead ECG device, developed from scratch by author's group. May be used as a stand-alone device or for telemedicine, instantly transferring data over internet.

ones (Figure 12). During acquisition of data, these can also be transferred over internet for a remote doctor to see the traces as they are being acquired. Although some people may prefer a 12 channel one giving all the data needed in a few seconds, this single channel device has several advantages. Firstly, it collects 48 seconds of data (=12 x 4 sec) which has a greater chance of demonstrating any arrhythmia, if present. Secondly, for telemedicine in rural areas of low and medium income countries (LMIC) the ECG is acquired by a trained operator, not an expert doctor. If there is noise or other problem in one particular lead, the doctor monitoring



Fig 12: Combined 12 lead ECG data, saved as a pdf file for viewing by a cardiologist. This file may be sent using email, WhatsApp or any other suitable means.

the data from a remote centre can ask the operator to retake that lead only, there is no need to repeat all the 12 leads, and this can be done immediately while the patient is still connected. Thirdly, since all the data are acquired through a multiplexer and go through a single electronic amplifier, all the 12 leads have a proportional relationship even if the amplifier loses calibration somewhat. On the other hand, a 12 channel device has 12 separate amplifiers and if one or two lose calibration, this may wrongly lead to an interpretation of a clinical condition.

This ECG device was designed and developed by the author's group fully from scratch [73, 74] and received a certification in 2014 from Directorate General of Health of the Government. This device was distributed to a few of the telemedicine operators under the Telemedicine programme of the author's group who has been using it for years without any problem. Since heart problems have become the main killer in many countries including Bangladesh, a wide distribution of such PC based ECG devices sending data over internet will be a necessity. There is also a possibility to create a new market of home users, those who are economically well off and have PCs at home, to use this device to send ECG data together with blood pressure and other measurements to the family physician periodically. In view of the increase of heart problems, this might pave the way for prevention.

vi. PC based Dynamic Pedograph for foot pressure imaging:

This device could prevent toe or leg amputation of a large number of diabetic patients who develop foot ulcers and gangrenes due to high pressure under their feet, but which they cannot recognise due to nerve degeneration [75]. The design of the author's group [76, 77] is an improvisation of an optical technique developed in Sheffield, UK [78], through the use of locally available materials and tools (Figure 13). The cost is a fraction of that of similar imported equipment. Selected grabs of some video frames show the pressure distribution for a



Fig 13: Top surface of the Dynamic Pedograph made by the author's group. The marked region (the black region within the red marked tape) is the sensitive area and a patient walks with a foot onto this to give a scanned image.



Fig 14: selected frame grabs of the video display of foot pressure for a normal foot (top) and for a person with high pressure points (indicated by colours going towards red)

normal foot and one with high pressure regions (indicated by colours going towards red) in Figure 14.

The first device was developed and delivered in 2011 on request of a doctor from a neighbouring country who was present in a lecture given by the author at an internationally reputed diabetic centre in Bangladesh. Later, when doctors found out that it is working satisfactorily in the neighbouring country, they were ready to accept it and four units have been

installed subsequently in the country. Three more units have been sold to the neighbouring countries. Doctors at present are not aware nor are not very concerned about prevention of foot ulcers and gangrenes in diabetic patients. They are happy going about traditional practices of providing medications or surgery. Therefore, it will need motivational efforts when the demand for this device will increase.

vii. Bioelectrical Impedance, Focused Impedance Method (FIM)

The author's group is also working on Bioelectrical impedance in which one of the innovations of the author's group has drawn international attention and will be described briefly.



Fig 15: A mother holds a palm-worn four electrode FIM probe (fifth electrode for ground, eliminated later) on her child to get the tidal breathing waveform from which necessary lung ventilation information including breathing rate can be obtained. The interesting part is that the child did not cry during the procedure, which would have jeopardised the whole effort since crying changes breathing rate [93]

All body tissues have electrical properties, therefore, bioelectrical impedance have a potential in physiological study and diagnosis. Electrical currents normally spread out within the body and small regions of interest cannot be targeted. Here, one of the author's innovations named, 'Focused Impedance Method (FIM)' provides a solution [79, 80]. Using FIM the author's group are trying to focus organs both at shallow depths and at greater depths [81]. They are also working on applications of these techniques for lung ventilation studies and detection of pneumonia, particularly in infants and children, gastric emptying studies, particularly on unconscious patients in intensive care units of hospitals [82-85]. Another application for which this group is trying to use FIM is non-invasive breast tumour characterisation, whether malignant or benign [86]. Many PhD and Masters level thesis work has been carried out in Bangladesh under the author's supervision. Some groups in Norway, Korea and Switzerland have also published work on FIM [87-90]. The author also wrote book chapters on FIM, on invitation [91, 92]. Figure 15 shows a mother holding a palm-worn FIM electrode probe on her

child's chest which gave the tidal breathing wave patterns shown on the right [93]. Figure 16 shows an electrical impedance system developed by the author's group in use in a hospital to monitor gastric emptying for an unconscious patient in a hospital [94].



Fig 16. An electrical impedance system developed by the author's group in use in a hospital to monitor gastric emptying for an unconscious patient in a hospital [94].

vii. Pain relief using PEMF

PEMF stands for Pulsed Electromagnetic Field, and this nomenclature specifically relates to very low intensity fields with peak magnetic fields of the order of a few mT or less [95]. Research on the application of PEMF for bone healing in cases of non-union and delayed union was initiated in Bangladesh by a group of physicists including the author himself at the University of Dhaka in late 1978, in collaboration with a team of orthopaedic surgeons. Using an indigenous device designed and developed by the author, more than 80% success was

achieved in a clinical trial carried on 16 patients with non-unions and delayed unions, carried out over a period of two years [96]. Figure 17 shows a portable bone healing PEMF device made by the author in the 1980s. Later the method was also applied on rats for fresh fractures and induced non-unions, in collaboration with histopathologists. Both provided positive evidence [97, 98].

Although this work was not continued at that time further due to various reasons, a renewed interest grew recently in the author's group in view of global activity on the application of



Fig 17. A portable PEMF device for bone healing made by the author in the 1980s.

PEMF in pain relief in many of which their earlier paper was cited. Furthermore, it was found that no hazardous side effects were reported in about 50 years of research using PEMF and that most commercial systems in the developed countries were being sold as wellness devices for over the counter sales. Based on the earlier experience, the author's group designed appropriate versions of the PEMF device for pain relief at neck, back and knees and were immensely successful. This led to a mass distribution by BIBEAT Limited, an ownerless company for public good and founded by the author; more about it is given later. Figure 18 shows the device with fixations for pain at neck, back and knee.



Figure 18. PEMF device of the author's group with fixations for pain at neck, back and knee.

viii. Covid19 inspired devices:

a) Negative Pressure Isolation Canopy-on bed (NPIC)

In order to prevent healthcare workers in a Covid Hospital a multi-institutional team led by the author designed and developed a Negative Pressure Isolation Canopy-on bed (NPIC) completely from scratch, based on their original design, and that during the Covid pandemic when most of the supply shops were closed and import of components were restricted because of flight cancellations. Innovators in some countries developed a 'negative pressure hood' [99] or a 'negative pressure half canopy - on bed' [100] based on ideas borrowed from earlier designs of negative pressure rooms, but the design of a full bed canopy was the first of its kind in the world. It also provided facilities to open segments of the canopy for health workers to handle the patient and a hinged frame to allow inclination of the head-side of the bed. Furthermore, all other designs used only a High Efficiency Particulate Air Filter (HEPA), using its H-14 type which blocks more than 99.995% of particles of 0.2 micrometer diameter [101]. This would also block viruses which are of similar size and definitely bacteria, which are much larger. The one developed by the author's group had both a H-14 HEPA filter and UVC (254nm wavelength) lamps. UVC is well established to inactivate viruses akin to Covid19 and also to destroy other bacteria and fungi [102]. This double acting protection was also a world's first. Figure 19 shows four of such canopies installed at Bangabandhu Sheikh Mujib Medical University (BSMMU), the premier medical institution in Bangladesh [103].

b) Positive Pressure Isolation Canopy – on bed (PPIC)

Inspired by the success with the NPIC the author's team at Dhaka University and BiBEAT Limited designed and developed a Positive Pressure Isolation Canopy – on bed (PPIC) to



Figure 19. Negative Pressure Isolation Canopies, designed and developed by the author's group, installed at BSMMU, Dhaka



Figure 20. Positive Pressure Isolation Canopy, designed and developed by the author's group, installed at SHNIBPS, Dhaka

prevent Hospital acquired infection of patients. This was a completely new device and the first of this kind in the world. Of course there are positive pressure surgical rooms and rooms with laminar flow of air, a PPIC on bed is a completely new concept. One of such unit was installed at Sheikh Hasina National Institute for Burns and Plastic Surgery (SHNIBPS), Dhaka and shown in Figure 20 [104]. Initial reports of the benefit to burn patient looks encouraging.

c) Powered Air purifying Respirator (PAPR)

In order to provide protection to doctors and health workers in a Covid unit, particularly when they perform interventional procedures on Covid patients, the author's group at Dhaka University and BiBEAT Limited designed and developed a Powered Air purifying Respirator (PAPR) from scratch. Such devices are available in the world market, particularly useful to miners working in dusty environments, these are not readily available in the local market of Bangladesh. Figure 21 shows the PAPR developed by the author's group at Dhaka University and BiBEAT Limited. It uses an H-14 type HEPA filter and is powered by rechargeable batteries. The unit is worn on a belt while safe and purified air is pumped to a hood which the



Figure 21. PAPR designed and developed by the author's group

user wears covering the whole head. Four units have been readied for use at Dhaka Infectious Diseases Hospital (DIDH) of the Bangladesh Government.

AN ECO SYSTEM FOR TECHNOLOGY FOR LMICS

(i) Example of a triangular ecosystem, all led by the author as the technology innovator

The above descriptions give an idea of the attempted efforts by the author's group in Bangladesh which could provide a basis for thinking for medical device policies in the LMICs.

Facing the immense challenges over the last four decades, the author personally spearheaded the whole eco-system ranging from innovation to commercial manufacture and marketing, and which has been able to overcome some of the obstacles to bring some positive changes in the country. Of course these evolved from the experience gathered from attempts with different approaches, as some succeeded and some failed, due to conditions existing in Bangladesh. He co-founded each of the organs of the eco-system, not necessarily in sequence, but as answer to challenges faced at certain times. In this eco-system, decision making was in the hands of the team of innovating scientists and engineers under the author's leadership although the organisations employ persons with business and marketing expertise as appropriate. *In the present world order, scientists and engineers do not lead all the three organisations in this eco-system, which makes the difference.* In the prevalent scenario, manufacture and distribution goes to business groups with the main motivation of earning

profits. Since the business experts do not have command over the technology, they emphasise on having patents and keeping the technologies secret, which, the author feels, eventually led to a huge technology gap between nations of the world, leading to an unacceptable disparity and human suffering. He feels that if the leadership in commercial manufacture comes from the technology innovators themselves, things will not be so bad since they will have the confidence to innovate new solutions and improve old ones to remain in a leadership position. They would not get scared or frightened if others copied their technology. In fact, they would feel pleased that their innovations are getting widespread acceptance and more people will be getting the benefits of their innovations through this mechanism. Actually, this is the process through which early human civilisation spread, and if followed, will eventually lead to a greater world equity.

The evolution of the eco-system by the author is briefly described below. He initially worked at the Department of Physics where he carried out research work since 1978. He soon realised that all outcomes will remain without any use within the four walls of the laboratory unless these are commercially manufactured and distributed, and that he has to take the initiatives all by himself, since his efforts to hand over these responsibilities to others had failed at different times. Therefore, he had to find way outs, taking along groups of young enthusiastic science and engineering graduates, who contributed to the realisation of his visions; owning the visions themselves too. The organisations that the author founded, which eventually make the full eco-system, are briefly described below. These are not in sequence of founding time, but follow a functional sequence.

- 1. Department of Biomedical Physics & Technology, University of Dhaka (BMPT) [105]: It was established in 2008 with the author as its founding Chairperson. It started with only PhD research, then opened Masters courses all having a strong component of research. Starting with PhD only was rather against the norms existing in the university and the author had to argue against oppositions at different bodies of administration of the university to get it through. This department under his leadership allowed the author to realise his visions on the kind and type of research that were directly related to the needs of the local people.
- 2. An Institute under Relevant Science & Technology Society (RSTS) [106]: RSTS was registered in 1996 under the Societies Act in Bangladesh. The author had realised long back that the existing university system will limit furtherance of the outcomes of the research and their implementation, and with this vision he had founded RSTS even before BMPT. Under RSTS he initiated 'Bangladesh Institute for Biomedical Engineering & Appropriate Technology (Bi-BEAT)' through which the group carried out industrial design and generated some income through limited pilot sales of some of the devices that came out of the R&D.
- **3. BiBEAT Limited** [107]: It was established in 2013 in order to go out for a proper commercial manufacture and marketing of the products developed at BMPT and Bi-BEAT. BiBEAT Limited was registered in Bangladesh as a 'Company Limited by Guarantee', an ownerless non-shareholding company where nobody can take the profits. It is essentially a social enterprise and the purpose of getting it registered this way was to

stimulate dedication and passion among all the team members joining at different times, so that they can share the philosophy and the prime motivation of the company, delivering the benefits of technology to the deprived people of the globe. Profits should be targeted as a means of achieving sustainability, not the prime motivation. The author feels that a philosophy for life is essential to develop and build any durable infrastructure, whether for research or business, and this was expected to bring out the goodness and dedication of its members, which is already showing positive signs. The registration of BiBEAT Limited was made this way so that when it can earn enough, it will also fund R&D at institutes under RSTS and at the University department. Eventually it may also fund other organisations in Bangladesh or in other LMICs to promote the objective.

The activities of RSTS and BiBEAT Ltd. were maintained at a low key so far because of practical considerations, but the team is now working their path to gain a stronger foothold, with more time from the author since his retirement from the university, although the University is maintaining a link by appointing him as an Honorary Professor.



Figure 22. The proposed triangular Micro-eco system, all under the leadership of a technology innovator, or a group of innovators, for success of dissemination of technology in LMICs.

(ii) Micro-eco-system and Global dissemination

The main common objective of all the three institutions mentioned above is development and application of innovative, appropriate and low cost technologies necessary for improved health, in order to take the benefits of modern technology to the common people of the LMICs, home to about 84% of the global population. Better healthcare will lead to a better quality of life and alleviation of poverty as well.

Having evolved the triangular eco-system under the leadership of a technology innovator through BMPT, an institute under RSTS and BiBEAT Ltd., it was felt that this model needs to be placed before the world, particularly the LMICs, so that they can initiate similar eco-systems under individual or group led innovator-leaders. The university is not a must in this

eco-system, but from practical considerations, highly qualified innovators need the support of public institutions of research initially, with their innovations and capacities developed through public funds. So it could be a publicly funded research organisation as well. Here, we may rename such an eco-system under a single leadership (or under a single team of closely working innovators) as a 'Micro-eco-system'. There can be hundreds of such Microeco-systems in different areas of technology in a single country, to enhance the quality of life of the common people. Thus a collection of all these myriads of micro-eco-systems could lead to a full eco-system for an LMIC with the objective of utilising technology for the enhancement of the quality of life.

The concept of a Micro-eco-system ranging from research to commercial manufacture and marketing organised under a single group of technological leadership does not normally happen in the present day HICs, although it was the practice in the early phase of the industrial revolutions, which most people have forgotten. Therefore the LMICs will not follow this model unless campaigns are made internationally. For this reason, the author wants to initiate something like an 'International Centre for Technology Equalisation (ICTEq)', which will try to promote this idea of innovator led Micro-eco-system throughout the LMICs and will allow scientists and engineers with a similar viewpoint to come together from all over the world, whether from the HICs or the LMICs, and contribute to furtherance of the objectives. It is felt that a tremendous amount of goodwill exists across the globe, and if a right model coupled with sincere and dedicated efforts can be established, there will be cooperation from many quarters. With time, the eco-system may diversify to technologies other than healthcare, technologies that are needed to improve the quality of life of the common people and ICTEq can be a catalyst in joining hands between different groups and different nations.

(iii) Ensuring quality of the developed medical devices, regulation or alternatives?

In Bangladesh, there are no facilities to formally test, calibrate and certify medical devices. The terms of reference the Directorate General of Drug Administration (DGDA) of Bangladesh was extended to include medical devices recently (in 2015) [108], but DGDA does not yet have the capacity to test any medical device properly. Its activity with respect of medical devices is mainly limited to giving registration only or sending them to Contract Research Organisations (CRO) for clinical trial, which evolved in the aftermath of the Covid pandemic, but no CROs exist who can properly evaluate the technological aspects of a medical device. In many case, the innovator is possibly the only person in the country having the requisite knowledge and experience and also may be having the only laboratory having appliances to test the particular medical device.

The author's history of developing medical device goes far back to 1978 before DGDA included medical devices in its agenda. Besides, there was virtually none else in Bangladesh with the required expertise to test the devices that he was developing. Therefore, for each of the devices the author had to learn the requisites through personal study of books and scientific literatures and running experiments in the laboratory. However, for the PC based EMG/EP equipment, he developed the main unit with the help of expert scientists in Sheffield University, UK while on short visits between 1985 and 1988 under an academic link sponsored by an organisation of the British Government. With their help he got the equipment

tested and calibrated at Sheffield University so that it satisfies British Safety specifications. Through this procedure he was able to acquire knowledge and skill to test such devices and to understand the safety issues of medical devices. The EMG/EP equipment (which also includes facilities for measuring EEG and brain evoked responses) is one of the most sophisticated electro-medical equipment, and learning about it prepared the author for testing almost any electro-medical device. For the Iontophoresis equipment developed in 1990s, a dermatologist, who requested for this device, was involved throughout its development and the author designed and developed the device based on his own acquired knowledge of biomedical engineering. For the solar water Pasteuriser, the treated water quality was thoroughly assessed by co-researchers in the Department of Microbiology of the University of Dhaka. For the Dynamic Pedograph developed in 2010, a diabetic foot care specialist from a neighbouring country was involved in the development (in fact he requested for this device) who assessed its clinical performance, while the technical performances were tested by the author's team at the University acquiring the expertise through studying scientific literatures. Again, designers of a shoe industry were taught to make custom made shoes with special insoles made based on the pressure image obtained using the Pedograph.

However all of the above assessments remained informal, although some of these items were published in journals or presented in conferences. For the PC based ECG equipment the author had formally applied to the Director General of Health Services (DGHS) of the Bangladesh Government in 2013 for getting the clinical quality tested. DGHS appointed the head of a cardiology department of the prime Medical College in the country, who, after testing the device against the foreign devices that they were using, gave a certificate of satisfactory clinical performance. The author in turn has trained the young members of his team in carrying out all the necessary tests and calibration, as and when a device is developed, transferring his knowledge and experience as far as possible. Therefore, the author is giving utmost importance to knowledge on the medical devices being developed and keeping the criterion of assessing the quality of the devices at a high level. Besides, he always gets the involvement of relevant medical doctors with the highest expertise available in Bangladesh. Furthermore, if any confusion arises, he consults experts in UK with whom he has developed strong links at personal level as well.

At this point, one important question needs to be discussed, how to ensure the quality of the medical devices developed and taken to commercial production through the Micro-ecosystem in any LMIC where there may not be a second person other than the innovator to test such devices? Besides, even if there is a Government body to test and regulate the quality of medical devices, sooner or later, some of the officers there will turn corrupt who will pass low quality devices in exchange for bribes. Usually, a dedicated scientist or engineer developing medical devices would not like to pay the 'bribes' asked for, and obviously their good quality equipment will not get the 'pass'. So the end result will be that people will be forced to get services of sub-standard devices, whether locally made or imported. Therefore, the regulatory system developed in the HICs will not work in the LMICs. Here the million dollar question is, 'is it the conventional system from the HICs that we want to preserve which could not give good solutions in the LMICs over the past half century, or is it the end result of providing quality services of medical devices to the people that we should be going after?' A rational thinking will definitely go for the second option.

A proposal was put forward in a WHO forum by the author in 2013 towards this alternative option [109]. Its essence is a written and signed self-declaration by a manufacturer or importer, certified by a notary public or a legal body, which states that the devices being put to the market satisfy the quality and safety features desired of such devices. They also need to declare that they have manpower with requisite educational qualifications who understand and have expertise for the specific tests, and also that they have the requisite test equipment. Here, the author suggests that WHO prepares specifications giving minimum quality and safety specifications of all the major medical devices commonly used, which is to be ratified by each of the LMICs to give these a legal validation in each individual country. Now if any individual or institution suspects that the marketed products do not satisfy the minimum quality and safety requirements, they may get these tested from a university or a reputed scientific organisation. If the suspicion comes out true, they may file a case with the existing judicial system, who may get more devices of the company tested by reputed organisations, even by foreign experts if needed. Based on the outcome of the tests, the court may warn the offending company for minor digressions with an order to correct the error and submit the products for further testing. For major digressions, the court may order the company to stop production till they come up with a consistent quality device.

In a recent presentation in a global forum [110], the author, together with two co-authors from Canada and Peru presented a new alternative for a regulatory body. This they called a 'Quality Assurance Board (QAB)' instead of a regulatory body. The QAB will not act as a 'gate-keeper' like the regulatory bodies, rather it will act like a 'parent' facilitating product innovators to attain the necessary standards through bringing in support of scientific and technical experts from home or abroad, if necessary. This will naturally encourage talented individuals in putting their efforts in developing and manufacturing most of the medical devices that the people of the respective country needs. The QAB will also take up programmes to create awareness among the medical device users in the country so that the devices, whether locally made or imported, maintain good quality including calibration and will organise special educational and training programmes to achieve such goals.

The author feels that such a system may give effectively a better outcome in the LMICs than pursuing a regulatory environment existing in the HICs.

DISCUSSION

This paper summarises the efforts carried out in a single lifetime under the author's leadership in a low resource country like Bangladesh. He had to work against many odds which include backward looking mind-set, inferiority complex, lack of self-confidence, most of it created due to the historical past and which will take a long time to change. There may be a question, why bring in these issues in a science journal? To answer this question, we need to ask, 'what is the main objective in pursuing the scientific and technological research and activities? The answer would be obviously, 'to enhance the quality of life of the human beings, together with creating a harmonious universe'. The global convention as in existence now limits the scientists and technologists to development only, the outcome is handed over to business groups for commercial distribution, which in many cases lead to 'exploitation' of the human beings. As indicated in the body of the paper that this may apparently be working in the high income countries (HIC) but has completely failed in the low and medium income countries (LMIC). Therefore, the scientists and technologists have to take charge of their innovations, to take charge of the whole process of R&D, manufacture and distribution in an LMIC. Unless this is done all the efforts put into R&D will simply be wasted. Therefore, the author, through the experience gathered over a lifetime feels very strongly that an applied science journal as this one should also present challenges and solutions in the whole process of reaching the people through industrial design and entrepreneurship.

The author feels that human civilisation owes itself to technology; igniting and controlling fire was the technology that laid the foundation of human civilisation. Therefore, improvement of the quality of life of the whole of the human race depends on the availability of technology right to the weakest person. Those of us, who had the opportunity to get the knowledge and expertise of technology has a lot of responsibility in taking the world forward. Attitudes abound within the society in the LMICs against indigenous technology innovation and their application, which is no different in Bangladesh. Sometimes the obstacles appears almost unsurmountable. Taking detours and engaging in diplomatic ways, the author could steer his ways through somehow. This has given him unique understanding and in-depth understanding of the social, political and economic undercurrents influencing the technological backwardness in the LMICs.

There are people who hold the view that LMICs should not try to develop and make medical devices as they may not do it correctly and endanger people's lives. This thinking arises because most existing small industries in the LMICs are spearheaded by technicians with little education and inadequate knowledge. As mentioned above, medical device industry needs the involvement of people with high level science and technology education, which already exists in almost all LMICs. As mentioned above, these people do not take up entrepreneurship in technology manufacture, rather they are more interested in going abroad or to work with the sole aim of publishing papers in high impact journals. This is a problem of social appreciation and views, a cultural problem, which needs to be changed. In fact hosts of youths have been working alongside the author in his continuous struggle as mentioned above, and many had to argue hard with their parents who wanted them to go abroad or take up more secure and career oriented jobs elsewhere. These young people were attracted by the philosophy of the author that each of us has only one life, we want it to be meaningful, and this can only happen if we do something for others rather than looking after career building and seeking avenues for self-interests only. Unfortunately, the whole world is presently under the grip of a self-destructive course where self-interest and extreme competition with the motivation to push others behind are heralded as the cornerstones for progress. We need to reverse it urgently. Unless we take all people of the globe along to a better life together, nobody can live in peace. The Nobel Laureate Bengali poet, Rabindranath Thakur (Tagore) had said about a hundred years back (translation by the author), 'You will have to equal in humility and disgrace to those, whomsoever you have disgraced'.

The author has a point on the cost of medical devices, why they can be much cheaper if developed in an LMIC, without sacrificing quality. Actually, much of the cost of a medical device produced in an HIC goes in the cost of R&D, in obtaining patents and in satisfying other regulatory requirements. Again, due to high competition, companies in HICs add unnecessary precision and gimmicks to devices which are not that essential for clinical purposes. Since these items are produced in low volumes and are continuously upgraded through R&D, these high costs come into the pricing. Again, much of the R&D cost goes into the expert manpower in the HICs; the manpower cost with a comparable expertise would be many times less in an LMIC. Besides, other expenses related to research and development would be also low in an LMIC. Furthermore, one does not need to go for patents, because most of these devices already exist in the world, what is needed is mostly appropriate redesigning and going into manufacture. Of course innovations would definitely come along the way, which will benefit not only the LMICs but the whole world.

Many global laboratories in the HICs have realised of late that the LMICs need a slightly different type of technology, and they are trying their best to design such devices at low cost. However, one must acknowledge that the HIC scientists do not have a clear idea of the situation existing in an LMIC and often such devices end up nowhere. The author feels that rather than developing low cost medical devices targeting the LMICs working in an HIC, experts from the HICs may make a much better contribution if they taught and trained highly qualified manpower in the LMICs, either going to the target LMICs, or bringing some capable individuals to the HIC, or both. The author's group has been benefited immensely through such an academic exchange programme with UK universities under a British ODA sponsorship during 1983-1992 that has eventually led to adequate local capabilities that have been described to some extent in this article.

For designing and developing medical devices in the LMICs, what one needs is qualified manpower with the highest education. The author feels that such knowledgeable manpower already exists in almost all LMICs of the world who have been taught under various science and engineering courses in the universities, who can be easily trained in designing and developing medical devices appropriate to their own circumstances. At present they cannot do it since their curriculum does not have the approach needed for designing of devices. Rather they are taught why and how these work, how to install, maintain and repair the devices. Designing devices from scratch needs a little twist in the curriculums and appropriate teachers, which is lacking at present. The proposed centre, International Centre for Technology Equalisation (ICTEq), in fact wants to intervene here, to organise such interchanges between scientists and engineers in both HICs and LMICs with the above aim. ICTEq can also try to promote and spread the idea of the Micro-eco-system under technology innovators in the LMICs, and lobbying with the respective Governments to change the relevant national policies appropriately. If the highly educated and science and engineering manpower in the universities and research organisations in the LMICs can become entrepreneurs contributing to the proposed micro-eco-system, the desired changes will come eventually.

Regarding the 'self-declaration' as opposed to authoritative regulation to ensure the quality of medical devices may occur as impractical to some who are habituated in a system of regulation

as practised in the present day HICs. However, living in an LMIC the author has seen how the authoritative system turns an honest person to become corrupt, even for people who were very honest and promised to remain so early in their life. The author feels that it is because of many complex factors nurtured over millenniums through political, social and economic systems that promotes self-interest and extreme competition, rather than bringing out the self-sacrifice and empathy which is also present in every human soul.

To emphasise the value of trust even under the present day regime of 'mistrust', the author would like to cite the following real life example. Although Bangladesh is ranked 146th among 180 countries of the world in terms of corruption index by the Transparency International in 2020 [111] a recent experiment by the Anti-Corruption Commission of the Government in setting up 'Integrity Stores' in schools where books and stationaries are kept marked with the price tags with a cash box at one corner, without a human attendant (nor any camera either!), proved highly successful [112]. The author also has a direct experience to share. He initiated an enterprise based on one of his innovations in 1993. Starting with meagre resources, he led this business to a highly successful one earning profits, where he practiced his philosophy of 'trust', without any policing. In order to expand the activities further in 1998 the author made a joint venture with a reputed and large NGO which took charge of the management taking 51% of the shares. Obviously the management switched to one with 'mistrust'. Within two years the company suffered heavy losses and corruption engulfed the company and it was decided to close it down. On the insistence of the author the board gave him the charge of the company with a challenge to bring it to break-even in 6 months. The author took the challenge side by side of his duties at the university, not full time. However, from day one, the author promised to forget all the past if the deputies pledged honesty from that point on, when everyone opened up and disclosed how they became corrupt because of the corrupt practices of the previous head of management. Under the author's management based on 'trust' the company was making operating profits in two months. At the board meeting after 6 months some of the members remarked that the author has achieved a 'miracle'. The miracle in fact lay in the culture of mutual trust and going into the root of a fault, not blaming an individual, without any policing. Therefore, the author feels highly confident that a system based on 'selfdeclaration' as suggested for ensuring quality of products would work, and will give a much better outcome than that obtained using an authoritative regulation as practiced in the HICs.

Therefore, this 'Micro-eco-system' led by technology innovators, and that based on trust, could be a starting point for all LMICs under the present scenario, which could lead the whole world to a new phase not only in respect of medical devices, but in respect of an 'international equalisation of technology', which has the promise of taking the whole of the global population together to real progress.

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