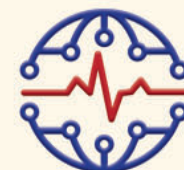


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Editor's Corner

Who owns the right to repair?

I recently participated in an effort led by members of the health technology management community in North America about what is becoming to be known as “the right to repair” movement. This is not just a healthcare equipment issue but rather its origin is from outside the healthcare industry and spread throughout many industries including information technology (computers), consumer electronics (phones), agricultural products, appliances, automotive and more. The debate is about the principal question: Why do consumers not have the right to access parts, tools, or guides (service manuals) for the equipment that they own? Holding back information or placing replacement parts as inaccessible to consumers/owners or an independent equipment service providers takes away the owner’s property rights. The right to repair coalition maintains programs aimed to change that by raising awareness including within the healthcare technology management field. The coalition’s website post a quotation, under their medical technology tab¹, that “In some developing countries, up to 50% of the medical equipment is unusable at any given time. In some hospitals, up to 80% of their medical equipment is inoperative ...” World Health Organization. To access service information, you and many others are probably familiar with, and perhaps even used, the Frank’s Hospital workshop site² to find needed information not otherwise provided for repairing your medical equipment.

This coalition’s website posts Frank’s story as follows: “Frank Weithoener is a well-regarded biomedical repair technician in Tanzania. He identifies five major barriers to medical device repair in developing countries:

1. No spare parts for repairs and maintenance
2. No technical manuals
3. Poorly trained biomedical technicians
4. No technical support from the manufacturers

5. Lack of awareness of the advantages of preventive maintenance

Since manufacturers weren’t supporting the repair of their products, Frank decided to do it himself. He runs a website², dedicated to training technicians. Unfortunately, Weyer, General Electric, and other manufacturers regularly send him legal threats and take-down notices demanding that he stop teaching people to repair life-critical medical equipment.” The US FDA issued a report on the topic in May 2018³ summarizing, in part, that “the objective evidence indicates that many OEMs and third party entities provide high quality, safe, and effective servicing of medical devices” and that “The continued availability of third party entities to service and repair medical devices is critical to the functioning of the U.S. healthcare system.” However, this did not address the questionable access to manuals and spare parts. Others, including an Apple Inc. co-founder, Steve Wozniak, stated during an interview with one of the supporters of this movement in part⁴ “if you know what you’re doing and you’re doing certain steps that other solved...why stop the self-repair community?” Even politicians engage with this debate, like US Senator Mr. Ron Wyden and US Representative Y. D. Clarke who together introduced a bill in the Senate of the US titled “Critical Medical Infrastructure Right-to-Repair Act of 2020”⁵ attempting to alleviate medical equipment repairs during COVID-19 crisis.

However, as medical equipment is used at times in life critical conditions, we must ask the question: who is competent to service such important technology. This led me to search for an answer to the question what is a competent clinical engineer? I visited variety of sources and came across an article *A day in the life of a clinical engineer system supervisor*⁶ where “this sophisticated technology requires constant assessment, management and maintenance to deliver on that promise” points to the public expectations that the equipment will improve

providers' ability to manage their patient's conditions and raise their care outcomes.

During my search I used terms such as how to become an engineer where the Quora website that states its mission is "to share and grow the world's knowledge", showed as a response one of the titles that asked: Can anyone become an engineer, or do you have to be born into it with natural skills?⁷. An interesting angle that I wonder if it suggests that it is possible that engineers' DNA set us apart? Hopefully, they are not serious about that. Another source adds the suggestion that soft and interprofessional skills must be part of clinical engineering education program^{8,9}. So, while I believe in the principal of right to repair, I also strongly recommend that clinical engineers should seek demonstration of their competency through credentialing program. In a recent article *Is Clinical Engineering an occupation or profession?*¹⁰, where I am included as one on the list of international authors, it states in part: "Clinical engineers also need to recognize, like other professions that when establishing defined requirements to enter the professional practice, there needs to be consensus about and adopting clinical engineering practice criteria. This includes domain boundaries, establishing a minimum qualifications criterion for entering clinical engineering practice in healthcare, a commitment for compliance with life-long continuing education, adherence to ethical behavior, service stewardship to their communities, and rules for self-governing. Adoption of these cannons will gain wider recognition and elevate the professional standing they desire."

Did you experience any of the obstacles when looking for service manuals or access to replacement parts or software keys to equipment apps? Would you agree with me that, since we are concerned with patients' lives, the Right to Repair movement should modify their poster to reflect that it's argument should be about the Right to Repair by Competent Workers. Let me know your opinion.

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Together we are making it better!



Dr. Yadin David

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The Status of Medical Devices and their Utilization in 9 Tertiary Hospitals and 5 Research Institutions in Uganda

By Robert Tamale Ssekitoleko¹, Beryl Ngabirano Arinda¹, Solomon Oshabahebwa¹, Lucy Kevin Namuli¹, Julius Mugaga¹, Catherine Namayega¹, Emmanuel Einyat Opolot, Jackline Baluka, Charles Ibingira², Ian Guyton Munabi², Moses Lutakome Joloba³

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ABSTRACT

Backgrounds and Objective: Advancements in technology have led to great strides in research and innovation that have improved healthcare provision around the world. However, the majority of the technology available is underutilized in Sub-Saharan Africa. In addition, the ever-increasing sophistication and cost of medical equipment means that access and proper use is limited in low- and middle-income countries (LMICs). There is, however, a general paucity of well-documented evidence for the utilization of medical equipment in LMICs. Therefore, this study evaluates the current availability and utilization of medical equipment in tertiary hospitals and research facilities in Uganda and provides baseline information to clinical/biomedical engineers, innovators, managers, and policymakers.

Material and Methods: The study evaluated the equipment currently used in 9 purposively selected public tertiary hospitals and 5 research laboratories representing different regions of Uganda. Data were collected by personnel specialized in biomedical engineering utilizing a mixed-method approach that involved inventory taking and surveys directed to the health workers in the designated health facilities.

Results: The hospitals contributed 1995 (85%) pieces of medical equipment while the research laboratories contributed 343 (15%) pieces amounting to 2338 pieces of equipment involved in the study. On average, 34% of the medical equipment in the health facilities was faulty, and 85.6% lacked manuals.

Discussion and conclusion: Although innovative solutions and donated equipment address the immediate and long-term goals of resource-constrained settings, our study demonstrated several issues around existing medical devices, and these need immediate attention.

Keywords – *Medical Devices, Biomedical Engineering, Healthcare Technology, Clinical Engineering, Appropriate Healthcare Technologies, Health Technology Management.*

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INTRODUCTION

Advancements in technology have led to great strides in innovations and research, resulting in a general improvement in healthcare provision, greatly impacting diagnostics, monitoring, and therapy. Medical device technology has played a key role in preventing, diagnosing, treating, and rehabilitating many diseases and contributes to complex research and innovations such as understanding the entire human genome.¹⁻³ Many innovative devices have been applied to the early diagnosis of complicated diseases, including non-communicable diseases such as cancer, and management of chronic illnesses such as diabetes and HIV/AIDS. They have also been utilized to invent and track many drug regimens for most deadly diseases such as tuberculosis and HIV.⁴⁻⁷ Access and effective use of healthcare technologies leads to improved quality of healthcare provision to most of the population worldwide.^{8,9} It is therefore essential to have functional equipment. This is particularly urgent in Sub-Saharan Africa,¹⁰⁻¹³ a region with 24% of the world disease burden, 1% of the global financial resources and 3% of the human resource capacity.¹⁴ Lack of functional equipment has a devastating effect on the quality of healthcare provision and research in resource-poor settings and affects the overall healthcare system.^{10,15}

Many medical technologies have been made available to improve healthcare services in hospitals and research laboratories in Sub-Saharan Africa.¹⁶ Application of these technologies in service delivery ensures improved work efficiency and enhanced quality, leading to cost-effective medical care for patients.⁹ However, the availability of medical equipment does not necessarily translate to improve health service delivery in health facilities in low resource countries.¹⁷ Indeed, health institutions worldwide are still struggling with managing quality healthcare delivery in resource-constrained conditions.¹⁸ Most Sub-Saharan countries hugely depend on medical equipment donations to facilitate healthcare and research technology needs.¹⁹ In fact, nearly 80% of medical devices available in healthcare facilities in developing countries are donated or funded by international donors or foreign governments.²⁰ Most of these devices are poorly maintained, under-utilized, and or out of service due to various reasons such as inaccessibility to spare parts, accessories, and consumables.²¹ In addition, the high rate of dysfunctional equipment is

attributed to the rising costs of medical devices, lack of reliable power and water, lack of public infrastructure such as air-conditioned rooms, and inadequate planning.^{16,22} Perry and Malkin²³ report that 38.3% of medical equipment in developing countries is non-functional because of the lack of trained professionals able to execute the needed repairs or maintenance, mainly biomedical engineering technicians (BMET) or biomedical engineers.²³

Several approaches were been taken to spur innovations in contextually appropriate healthcare technologies to respond to the challenges outlined above. Funding mainly came from international donors and philanthropists.²⁴ However, with the recent cessation or reduction of this funding due to shifting priorities such as the recent COVID-19 pandemic, most of these innovations have been abandoned due to the absence of sustainability plans. This has led to a setback in this field with actual progress showing little clinical efficiency.^{25,26} Apart from limited funding, WHO highlights other barriers that hinder the effective adoption of innovative solutions in low- and middle-income countries: inadequately trained support staff to manage the novel equipment, shortage of technical expertise, and designs not being suitable for the African setting.²⁷

Steps have been taken to avert the challenges in medical equipment management, including designing novel medical equipment suitable for sub-Saharan Africa setting,^{28,29} developing policies on donations and equipment procurement,³⁰ and training biomedical engineers locally to enhance technical support.³¹ There is little evidence published on how these efforts have improved medical equipment access to the people in most need.

Therefore, this paper aimed to evaluate the current availability, status, and utilization of medical equipment in tertiary hospitals and research facilities in Uganda.

METHODOLOGY

Study design and setting

This was a cross-sectional study that utilized a mixed-method approach that involved inventory taking and surveys. The study evaluated the equipment in current use in 9 purposively selected public tertiary healthcare facilities and five research laboratories to represent different regions of Uganda in January 2017. The research

laboratories included three research-based institutions, that is, the microbiology laboratory at Makerere University College of Health Sciences (central region), the microbiology and molecular biology laboratories at Gulu University (Northern Region), and Mbarara University of Science and Technology (MUST) clinical and research laboratory (Western Region) and two independent research laboratories; Uganda Virus Research Institute (UVRI) and Infectious Disease Institute (IDI). Each of these laboratories serves as a reference laboratory receiving samples from neighboring hospitals for clinical diagnosis support and analyzing samples for research and academic purposes. Figure 1 below shows the spread of the facilities surveyed. The healthcare facilities selected serve about 21% of Uganda’s Population, translating to about 7.9 million people as of 2017 Uganda population census estimates.

Data collection and analysis

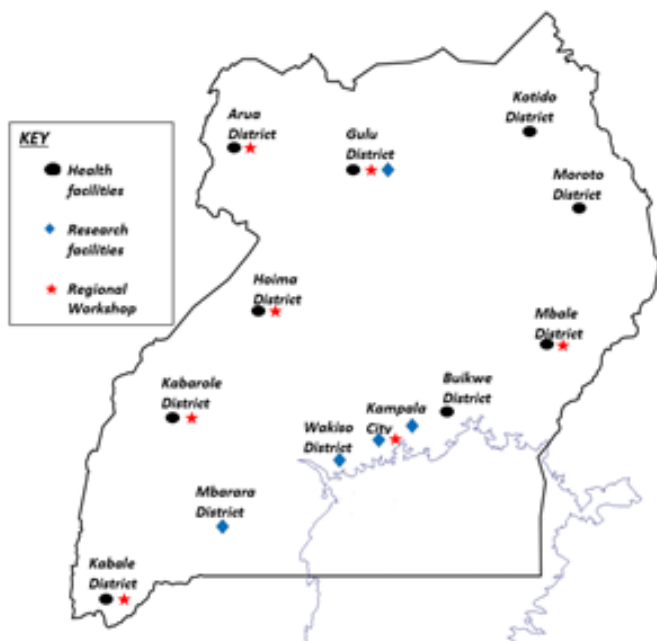


FIGURE 1. A map of Uganda showing the different locations of the study sites and nearby regional Biomedical Engineering workshops.

All data collectors had a bachelor’s degree in biomedical engineering and were given uniform data collection tools and were trained to conduct interviews and collect inventory. Data on the collection inventory was aimed at generating information on the working condition of the

various devices currently available in the study facilities. The inventory assessment included all medical equipment available at the study site when conducting the study and excluded furniture, instruments, drugs, computers, computer accessories, and disposable tools and instruments. The equipment details collected in the inventory included the medical equipment name, type, model, equipment number, serial number, functionality, manufacturer, year of manufacturer, and location. The condition of the medical equipment was recorded using an A to F scale recommended by the Uganda Ministry of Health³² and the non-functional equipment in categories B, C, D, E, and F were further categorized as shown in Table 1.

The data were analyzed using STATA version 14.0. Discrete variables were summarized by their means and

TABLE 1. Key to the A-F Scale of Medical Equipment Conditions Used To Assess Medical Equipment in this Study

Category	Interpretation
A	Equipment in good working condition and in use
B	Equipment in good working condition but not in use
C	Equipment in use but need repair
D	Equipment in use but needs replacement
E	Equipment out of use but repairable
F	Equipment out of use, to be disposed of

standard deviations, whereas categorical variables were presented as frequencies and percentages. Logistic regression was used to compare the functionality of equipment between groups, and results were reported with odds ratios. All differences with a p-value less than 0.05 were considered statistically significant.

Ethical consideration

Ethical approval was obtained from Makerere University School of Biomedical Sciences Institutional Review Board and the Uganda National Council of Science and Technology (UNCST; # SS 4166). Informed consent was obtained from all participants before enrolment into the study. Confidentiality was assured through de-identification of the data.

RESULTS

This study included 2338 pieces of medical equipment categorized in 255 medical equipment types, of which the hospitals contributed 85% (1995). Table 2 shows the characteristics of the facilities included in the study. The out-patient department attendance per day characterized the study, number of admissions per day, population served, number of biomedical engineers and technicians (BMETs), number of pieces of medical equipment found, the percentage of medical equipment classified as non-functional, the number of pieces of equipment without

manuals, and the number of manufacturers supplying the hospital with medical equipment. A total of 12 biomedical engineers and technicians (BMETs) were identified to be working in the hospitals studied, out of which only 3 had a bachelor's degree while the 9 were diploma holders. In the hospitals where the availability of manuals was recorded, more than 50% of the medical equipment had no manuals. On the other hand, the IDI research laboratory had manuals for all their equipment. The number of manufacturers was also relatively high, with the highest recorded being 120 manufacturers supplying a single hospital served by 2 BMETs.

TABLE 2. Characteristics of the Hospitals and Research Laboratories Included in the Study

Health Facility	Location (Region in Uganda)	OPD attendance per day	Admissions per day	Population served	No. of BMETs employed	No. of pieces of equipment included (% of equipment non-functional *)	% of equipment without manuals	No. of manufacturers recorded
Regional Referral Hospitals (RRH)								
Arua RRH	North Western	443	65	3.5 million	1	200 (50%)	91%	78
Fortportal RHH	Western	254	70		2	240 (4%)		
Hoima RHH	Western	413	65	3 million	2	53 (26%)	77%	31
Kabale RHH	South Western	178	33	2 million	2	510 (30%)		
Mbale RHH	Eastern	210	135		1	347 (36%)		
Mbarara RHH	South Western	468	85	4 million	2	392 (52%)	53%	120
Moroto RHH	North Eastern	160	20	1.5 million	1	138 (52%)		74
General hospitals								
Kotido Hospital	North Eastern	77	15		0	59 (54%)	75%	29
Health centre IV								
Kawolo hospital	Central Region	217	30	1.2 million	1	56 (50%)	68%	25
Research laboratories								
MUST	Western					24 (29%)		14
UVRI	Central					153 (29%)		
Makerere Univ.	Central					23 (22%)		11
Gulu Univ.	Northern					114 (10%)	41%	57
IDI	Central					29 (7%)	0%	20

*All medical EQUIPMENT IN CONDITIONS B, C, D, E, F WERE CLASSIFIED AS NON-FUNCTIONAL.

Table 2 shows the percentage of non-functional equipment was 4 to 54% with an average of 37%, while the research laboratories had a better performance with the non-functional equipment ranging from 7 to 29% with a mean of 20%. According to the A-F scale, further breakdown of the equipment categories (see Table 1) revealed that the non-functional medical equipment was spread out in categories B, C, and E, as shown in Table 3. Out of 2338 pieces of equipment, 157 were identified in category B, 296 in category C, and 193 identified in category E. The top reasons identified for equipment in category B were lack of user training and lack of consumables. On the other hand, the equipment in categories C and E was usually there because of a lack of spare parts, testing equipment to identify faulty equipment, and technical knowledge on performing repairs.

The medical equipment manufacturers were recorded at 6 of the health facilities and 4 of the research facilities. The number of manufacturers supplying the facilities ranged from 11 to 120, with an average of 46. This number varied with the number of pieces of medical equipment at each facility (Figure 2).

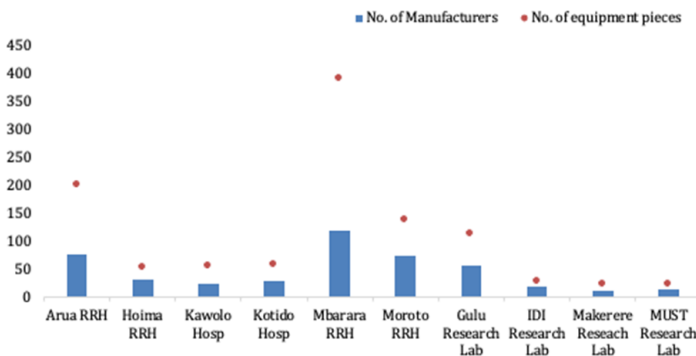


FIGURE 2. Bar graph showing variation in the number of equipment manufacturers supplying 6 of the 9 healthcare facilities and 4 of the 5 research facilities included in this study. The number corresponding to the highest point of each bar is the number of pieces of equipment in each facility and the number represented by the dot above each bar is the number of equipment pieces in that facility.

According to the study, 358 (15%) pieces of equipment were donated and the facilities bought 195 (8%) pieces of equipment. The remaining 77% of the equipment was classified as unknown because the interviewees could not ascertain whether they were donated or bought. The study also assessed the availability of user and technical

manuals for the equipment and revealed that 345 (14.4%) pieces of equipment had manuals, whereas 2055 (85%) pieces of equipment had no manuals available (Table 2). Thus, 80% of the donated equipment had no manuals, whereas 86% of the equipment purchased had manuals.

Table 3 also shows the distribution of some of the equipment types identified in the six equipment categories. This table shows that a high number of oxygen concentrators and pipettes were found in category C. This was because the facilities did not have working oxygen sensors to determine the concentration of oxygen concentrators and lacked a clear basis for their use. Similarly, the pipettes were never or rarely calibrated. Many glucometers were not used despite being in good working conditions (category B) because of a lack of strips, while a large number of infant incubators and nebulizers in the same category were mainly due to lack of user training.

The non-functional equipment (categories B, C, D, E, and F) was further categorized according to the host departments, and analysis revealed that dental and sterilization departments had the highest percentage of non-functional equipment. In contrast, the laboratory equipment in both laboratories within the hospitals and research laboratories had a significantly lower percentage of non-functional equipment than the mean. Indeed, when all pieces of laboratory equipment were excluded from analysis, the average percentage of non-functional

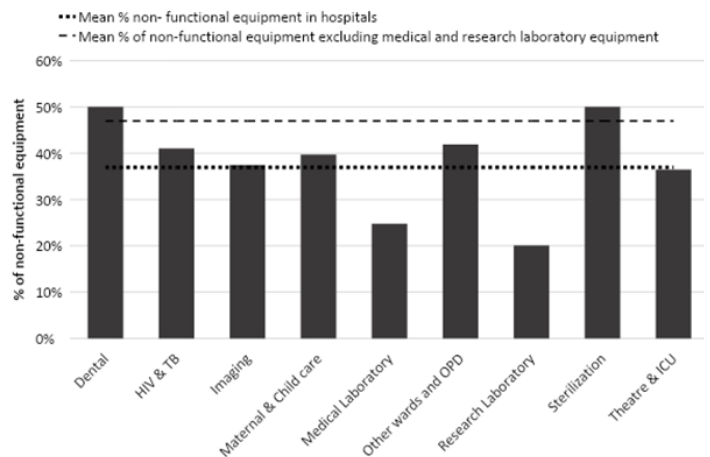


FIGURE 3. Percentage of non-functional equipment categorized according to the department, the mean percentage of non-functional equipment and then mean percentage of the non-functional equipment excluding medical and research laboratory equipment.

TABLE 3. The Condition of Medical Equipment in the Hospitals, Health Facilities, and Top Medical Equipment Types Are Broken Down Into Each of the Six Categories in the A-F scale

	Equipment condition categories						Total # of pieces of equipment
	A	B	C	D	E	F	
Total	66%	7%	13%	1%	8%	6%	2,338
Hospitals	63%	7%	13%	1%	9%	6%	1995
Research laboratories	80%	3%	11%	0%	4%	2%	339
Medical Equipment Types							
Refrigerator	77%	1%	5%	2%	4%	10%	135
Weighing Scale	58%	5%	9%	2%	18%	9%	126
Patient Monitor	66%	9%	12%	0%	11%	2%	117
Suction Machine	48%	5%	9%	0%	15%	24%	105
Autoclave	53%	8%	19%	1%	8%	10%	98
Microscope	76%	7%	8%	1%	6%	3%	90
Centrifuge	76%	1%	4%	1%	1%	17%	78
BP Machine	69%	9%	10%	0%	6%	5%	77
Oxygen Concentrator	67%	4%	21%	0%	3%	5%	76
Operating Light	57%	3%	10%	13%	11%	6%	63
Examination lamp	59%	17%	7%	0%	9%	9%	46
Infant Incubator	65%	30%	4%	0%	0%	0%	46
Pipette	7%	0%	70%	0%	0%	23%	43
Freezer	74%	5%	5%	0%	13%	3%	39
Anesthesia Machine	62%	11%	14%	0%	8%	5%	37
Glucometer	43%	37%	10%	0%	10%	0%	30
Operating Table	83%	3%	7%	7%	0%	0%	30
Nebulizer	39%	25%	14%	0%	18%	4%	28
Vortex Mixer	88%	0%	8%	0%	0%	4%	24
Ultrasound Machine	43%	0%	13%	0%	30%	13%	23
Hematology analyzer	86%	0%	0%	0%	9%	5%	22
Ventilator	17%	11%	6%	0%	67%	0%	18

equipment in the other departments increased from 37 to 47%, as seen in Figure 3.

DISCUSSION

This study found that, on average, 37% of the medical equipment found both in the hospitals were not in use, needed repair, and was completely non-functional. These

results agree with a similar study done in Southwest Ethiopia in 2016 that reported that 32.1% of healthcare equipment was broken.^{10,23} In addition, Malkin in 2011 reported that, on average, 40% of medical equipment in resource-constrained countries is out of service.²³ Our studies showed that the percentage of non-functional

equipment in research laboratories was reduced to 20%. Strategies identified that led to this improvement included (1) the provision of technical and user manuals. The IDI research laboratories had manuals for all their medical equipment, whereas all the hospitals surveyed did not have manuals for more than 50% of their equipment, implying a lack of technical support in proper use, maintenance, and repair; and (2) the laboratory equipment in both hospitals and research laboratories were supplied with service contracts usually from a local distributor. The distributor is tasked with user training, regular preventive maintenance (usually on a 6-month basis), and corrective maintenance upon breakdown. In general, medical equipment in the other department was procured with hardly any plans for their service and maintenance during their life span; (3) Research laboratories usually have funds to support medical equipment maintenance and repair.

It was observed that 7% of medical equipment was in good condition but out of service. These results fall within the same range as another study conducted in Ethiopia, which found the frequency of equipment in good condition but not in use ranging from 3 to 21%, with a mean of 12%.¹⁰ An example we saw in our study was glucometers, which have a huge potential in the fight against diabetes by providing fast and affordable point-of-care blood glucose measurement in low-resource settings. While the devices are cheap, the glucometer strips are unaffordable for many patients in low-resource settings thus are never used. Other reasons for not putting functional equipment to use included not knowing how to use the equipment correctly, lack of installation space, and lack of required infrastructure and utilities.²¹

The results also show that 13% of the medical equipment identified in the health facilities was faulty but used on patients. For example, we found some oxygen concentrators in use but delivered oxygen concentrations as low as 45% compared to the recommended concentrations greater than 82%.³³ This was often due to a lack of the right tools or testing equipment for the equipment functionality. There were also cases where the users were aware that the equipment was faulty but used it due to a lack of alternative options. This was usually coupled with a lack of spare parts and technical personnel and insufficient funds to support corrective maintenance. The

use of faulty equipment on patients affected the overall outcomes in diagnosis and therapy.³⁴

FACTORS AFFECTING MEDICAL EQUIPMENT UTILIZATION

Medical equipment management

This study found that hospitals did not have manuals for 68% of their medical equipment. Logistic regression analysis showed that the lack of equipment manuals was statistically related to medical equipment being non-functional (p -value < 0.001). Without these guides, equipment maintenance becomes very difficult, especially in Uganda, where nearly all medical equipment is imported with limited contact with the manufacturers. A survey conducted by the ministry of health in 2015 supported these findings, which found that only 13.4% of the health facilities in Uganda had scheduled medical equipment maintenance and that only 37% of the health facilities in Uganda have a budget for routine maintenance and repair of medical equipment.³⁵ This failure to follow routine maintenance procedures results in the escalation of equipment faults. Therefore, collective efforts from medical equipment manufacturers, local distributors, health facilities, and the ministry of health are essential to provide the technical and user guides for medical equipment, put measures in place to provide technical support, source and avail funding for medical equipment management, and carry out routine user training and preventive maintenance.

Technical human resource

Our results show that in each of the hospitals included in the study, one or two BMETs, was responsible for maintaining and repairing the medical equipment at the health facility. When this workload is compared with the number of pieces of equipment identified and the number of manufactures supplying each hospital, on average, each BMET was charged with maintaining 167 pieces of equipment and from 51 variant manufacturers, each supplying a unique model of medical equipment. In addition, the BMETs in the regional referrals were expected to maintain the medical equipment in the lower-level health facilities. With little funding, lack of spare parts, manuals, and limited technical support from the manufacturers, these BMETs are indeed overwhelmed.

There have been considerable efforts to train BMETs locally; as of March 2021, seven teaching institutions train

biomedical engineers and technicians at various levels. Makerere University, which pioneered bachelor's training for Biomedical Engineers in Uganda, has graduated 150 biomedical engineers at bachelor's level. However, the level of uptake by the Ministry of Health into the public health care system has been low. This is reported to be due to limited financial recourses. In addition, inadequate personnel available in health facilities to guide the procurement process, train users, and conduct routine maintenance and repair of medical equipment significantly contributes to medical equipment failure.^{31,36}

Administrative support

Administrative structures play a crucial role in medical equipment management. This can explain the variations observed in the percentage of non-functional equipment among the health facilities in this study. For example, most research laboratories have autonomous or semi-autonomous administrative structures and considerable donor funding that enable fast procurement of the required spare parts, consumables, and contracting skilled human resources to increase medical equipment utilization.³⁷ Public hospitals, on the other hand, are characterized by long bureaucracies in the procurement process and minimal funding to support medical equipment maintenance.³⁸ Some hospitals have, however, streamlined their procurement process to support infrastructural and resource utilization. The Biomedical Engineering workshop in one of the hospitals, for example, operates with a framework contract in which a comprehensive list of spare parts and consumables is submitted to procurement at the beginning of each financial year, and the items are purchased in a batch.³⁹ This, therefore, eases repairs of medical equipment that require spare parts previously identified and listed. Thus, practical approaches to abridge convoluted administrative procedures to enhance infrastructural and resource utilization are paramount to improving medical equipment utilization in health facilities in low-resource settings.

Procurement guidelines

Despite recommendations by WHO³⁰ and Ministry of Health⁴⁰ to regulate donated equipment, many hospitals in Uganda still accept medical equipment donations without following the guidelines to ensure that the equipment is fit for purpose and the setting.⁴¹ Additionally, there is still a lack of adequate procurement tools to assist hospital

administrators in the appraisal of new equipment before purchasing in low-resource settings.⁴² This primarily contributed to the observed 7% of medical equipment being purchased or donated but never put to use due to lack of installation space, lack of consumables, or incompatibility with existing infrastructure and resources in this study. Additionally, it seemed that hospitals were eager to acquire medical equipment at low initial costs without considering the lifetime / hidden costs of the medical equipment, such as cost of consumables, maintenance costs, and cost of required utilities, among others. It was observed that medical equipment suppliers commonly offer health facilities medical equipment at low or no cost but charge them highly to procure reagents and consumables over long periods. However, the equipment procured under this contract ends up unused as the hospitals and patients cannot afford the cost of reagents. Another example observed was sterilization equipment procured by the hospital, but it later realized that the equipment's electricity consumption was way above the hospital's budget, thus putting it out of use. These point to deficiencies in the procurement appraisal process and a lack of technical guidance during procurement.

Supporting infrastructure and resources

System-wide deficiencies in infrastructure and resources to support medical technologies in low-resource countries have been shown to affect the utilization of medical devices. The lack of clean water, stable electricity supply, space, and administrative structures also affects medical equipment utilization, especially in the lower level health facilities and facilities in hard-to-reach areas. For example, some of the equipment identified in the study was designed for use with a 110V power supply, and yet Uganda has a 240V power supply. Without a step-down transformer, this equipment will remain unused in category B for years. Another example is autoclaves designed to operate with distilled water, yet the hospitals struggle to get access to distilled water. These are thus used with ordinary tap water, which significantly reduces their lifespan. This is, therefore, vital to consider in the design of novel medical equipment or during the procurement process.

Innovations and implications

Novel approaches custom-made to suit low resource settings provide an alternative to the hugely dependent

on donated equipment. Development of these innovative inventions have been supported and financed by international donors and philanthropist.²⁵ However, the majority of the funding comes to an end, and the inventions are abandoned²⁶ while those that progress fails to translate to the African setting. The WHO highlighted that one significant barrier to the effective adoption of these inventions is that the design technology incorporated in these innovations does not suit the African setting.²⁸ This study showed that most unused equipment in category B was new technologies that could not be applied to the Ugandan setting. An example was the microscopes; contributing to the 7% equipment in category B were new microscopes in storage because of inadequately trained support staff to manage the novel equipment while other models applied sophisticated technologies that were not suitable for the Ugandan settings. These findings align with WHO findings on the reasons for hindrances to the effective adoption and utilization of innovations in low- and middle-income countries.²⁸ There is, therefore, a need for more emphasis on the context when designing new technologies for low- and middle-income countries.

CONCLUSION

Although innovative solutions and donated equipment address the immediate and long-term goals of resource-constrained settings, our study showed that most of this equipment does not translate to the African setting, with an average of 37% of the equipment in hospitals non-functional. Research laboratories have successfully reduced non-functional equipment to 20% by ensuring that medical equipment is supplied with manuals and technical assistance, negotiating service contracts with the distributors, and securing funding for medical equipment management. Other factors noted as affecting medical equipment utilization include medical equipment management, technical human resource, administrative support, procurement procedures, supporting infrastructure, and resources.

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analysis, and interpretation of the data or writing of the manuscript.

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Overview of Trending Medical Technologies

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ABSTRACT

Healthy population is regarded as the most valuable asset of any country. Unfortunately, the health challenges that hinder mankind's wellbeing are enormously increasing. Examples include but are not limited to: the diversity of emerging diseases afflicting the global population, the projected demographic growth of elderly people who need consistent monitoring, the deficiency in medical staff, the lower density of physicians, and the challenging geographical location of the population from healthcare providers. The mitigation of such health challenges calls for novel technologies to improve patient outcomes. In this article, seven emerging technologies, namely: Wearable Devices and Internet of Things, Artificial Intelligence, Blockchain Technology or Distributed Ledger Technology, Robotics Technology, Telehealth and Telemedicine, Big Data Technology and Nanomedicine have been highlighted. For each discussed technology, its historical background, development drivers, market status and trends, significance to healthcare, key player companies, and associated challenges have been presented. The information contained in this paper was collected from different journal articles, websites, reports, conference proceedings, and books. It was observed that though the technologies discussed in this article show growth at different rates, healthcare technology development and implementation are very promising in revolutionizing the health sector and improving the health of the population. Therefore, healthcare providers and countries are recommended to put in place Healthcare Technology Assessment Programs to help them collect data regarding the technology efficacy, relevance, safety, outcomes, and alternative technologies towards better planning for healthcare services improvement.

Keywords – *Wearable devices, Internet of Things, Blockchain, Telehealth and Telemedicine, Artificial Intelligence, Big Data, Nanomedicine, Market, Drivers, Challenges and Companies.*

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INTRODUCTION

The triumph of modern medicine is axed to the emerging technological innovations, and there is no doubt that the medical expenditures and life expectancy are variables driven by technological progress.¹⁻² Medical technology uses scientific knowledge to improve healthcare by new and improved equipment to make work easier, pleasant, quick, and productive.³ The management and treatment

of diseases have become largely dependent on innovation and discoveries in newer drugs, surgical techniques, diagnostic and therapeutic equipment.³ Medical doctors themselves are becoming more reliant on technology to diagnose and carry out treatments.⁴ The scope of medical technology is vast; it covers consumables (bandage, syringes, hearing aids, wheelchairs, etc.), implants (hips

and knees, stents, pacemakers, etc.), medical equipment (imaging machinery, dialysis equipment, etc.), and in-vitro diagnosis.⁵ Technological innovations are appreciated by the general population because they enable a 4P-model for medicine (predictive, preventive, personalized, and participatory).⁶

The factors that reinforce the market for medical technology include advances in science and engineering, patent protection, increasing prevalence of chronic diseases, aging population, emerging pathogens, financial incentives of technology companies, mass media reports, public demand driven by direct-to-consumer advertising, consumer awareness and advocacy, rising prices of physician and hospital services, off-label use of drugs and devices, malpractice avoidance, strong and growing economies.⁷⁻⁸ The maintainability of high quality of life in the aging population is probably the most significant underlying global which requires requiring technological mindset.⁹ For example, Japan has the longest life expectancy, and its aging population ratio is still increasing.

This has called for rising expenditures, giving concerns about the future inflation of health costs.¹⁰ In 2050, 16% (1.5 billion) of the world's population will be above 65 years old.¹¹ In China, 2.4 young people will have to support 7.9 old people in 2050.¹¹ The physical nature, purpose, and stage of diffusion constitute the three ways to describe a healthcare technology.⁷ According to the stage of diffusion, medical technologies classification is presented in Table 1.

TABLE 1. Classification of Medical Technologies According to the Stage of Diffusion⁷

Medical Technology Class	Explanation
Future	in a conceptual stage, anticipated, or in the earliest stages of development
Experimental	undergoing bench or laboratory testing using animals or other models
Investigational	undergoing initial clinical (i.e., in humans) evaluation for a particular condition or indication
Established	considered by clinicians to be a standard approach to a particular condition or indication and diffused into general use
Obsolete/ outmoded/ abandoned	Superseded by other technologies or demonstrated to be ineffective or harmful

Today the actual figures for medical technologies are not available, but it is estimated that 500,000 different types of medical devices are in service.¹² From 1960 to 2007, health care expenditure in OECD countries increased, on average, from 3.8–9.0% of GDP.¹

In 2020 it was forecast that the global market for medical technology would achieve a volume of 490 billion euros.¹¹ In 2025, global turnover for medical devices is estimated at approx. 615 billion dollars.¹¹

The main categories of healthcare technology include but are not limited to: drugs, biologics, devices/equipment and supplies, medical and surgical procedures, public health program, support systems, organization, and managerial systems. However, not all technologies fall neatly into the category, and certain hybrid technologies combine drugs and devices.⁷

In the past decade, the medical technology revenues have increased by 44.7% (USD 352.⁹ billion to USD 510.⁹ billion for 2011 and 2021, respectively), and the forecast is to reach USD 594.5 billion in 2024.¹³ In 2022, the strongest medical technologies segments will be in cardiology, imaging diagnostics, orthopedics, and surgery. These technologies will account for 50% of the market.¹¹ Although there are giant companies in medical technology, 95% of all medical technologies businesses are small and medium-sized companies (SME), with the majority having fewer than 50 employees.¹¹ As of 2020, Medtronic Inc. was the leading medical technology company with a revenue of 30.¹² billion USD.

It was seconded by Johnson&Johnson with total revenue of 23 billion USD. In a survey conducted about medical technology in Belgium,⁵ 106 companies participated, and the results are that 67.9% were active in medical devices-consumables, 15.1 % in In-vitro diagnosis, 12.7% in pharmaceutical products, 6.6% in para-pharmaceutical products, 43.4% in medical software, 40.6 % in implants and 45.3% in medical equipment and systems. Medical technologies are classified into preventive, screening, diagnosis, rehabilitation, palliation, and treatment types.⁷

The technological acceptance and use expansion vary from society cultures. The Technology Acceptance Model developed by Davis, Theory of Planned Behavior, and Unified Theory of Acceptance and Use of Technology 2 (UTAUT2) developed by Venkatesh showed that perceived usefulness, perceived ease of use, price value, and habit

are the key factors that determine the application and market expansion of a particular technology in a certain region.^{14,15} In addition to those factors, commercial-grade, durability, reliability, sustainability, technical support, disinfection, alarm management, network, and device security also advocate adopting a particular technology.^{16,17}

LITERATURE REVIEW

It is not easy to cover all details of the medical technologies available in a single paper due to their diversity. In this paper, the following trending technologies are looked at: Health Wearables and Internet of Things, Artificial Intelligence (AI), Blockchain Technology (BCT) or Distributed Ledger Technology (DLT), Robotics Technology, Nanomedical Technology, Telemedicine and Telehealth, Big Data

Health Wearables and Internet of Things

Environmental, psychological, behavioral, and physiological domains that adversely impact the quality of life are recognized by the World Health Organization.¹⁹ Wearables as medical technologies are becoming part of personal analytics, measuring physical status, recording physiological parameters, or informing schedules for medication.²⁰

The journey of wearables started with the invention of spectacles around the 13th century by English friar Roger Bacon.²¹ Growth in wearables was slow until the 20th century, when in 1907, the first portable camera was put on the market. Since then, the pace of developing new devices never ceased to increase until 2014, when android wearables were commercialized. The whole evolution of wearable technology is picturesquely presented in the chronological sequence in Figure 1.

From a monetary perspective, the market of wearable devices is anticipated to grow exponentially at a rate of 20% and is expected to reach 150 billion EUR by 2028, as presented in Figure 2.

In the third quarter of 2021, the Chinese market shipped 35.28 million units across the globe,²² and the

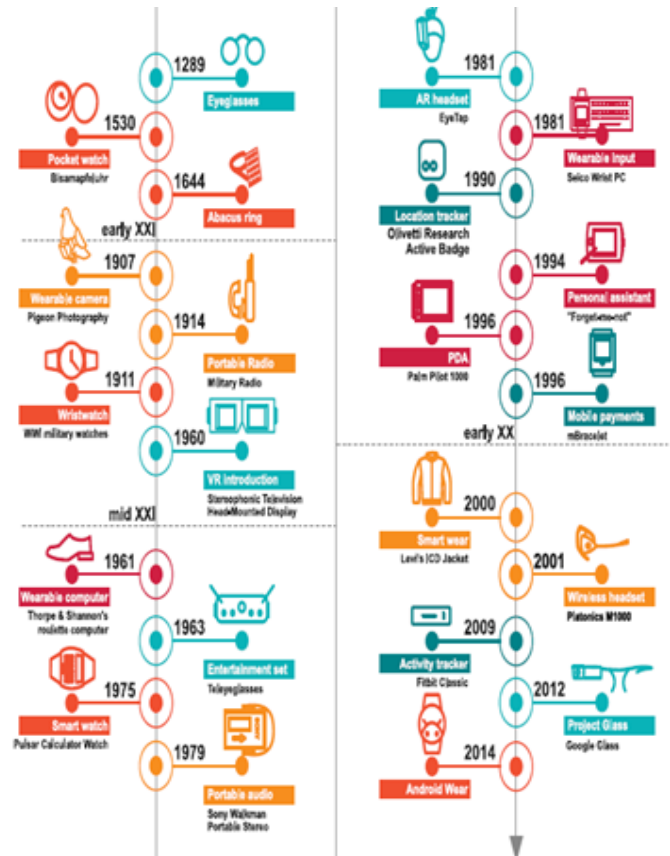


FIGURE 1. Evolutional milestones in wearable devices.²¹

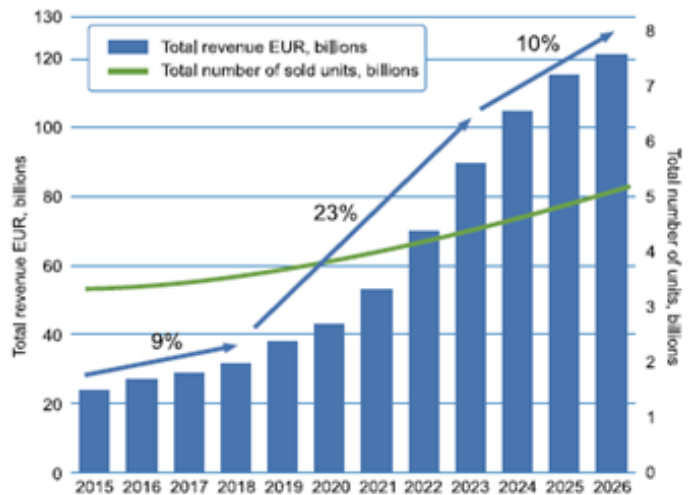


FIGURE 2. Wearable market growth forecast.²¹

market was dominated by Huawei.²³ From a technological point of view, wearables are self-contained devices with embedded sensors worn by the user to detect, diagnose, monitor, and communicate the health and performance data of the user.²⁴ Wearable technologies include smartwatches, wristbands, hearing aids, electronic/optical tattoos, head-mounted displays, subcutaneous sensors, Smart belts, electronic footwear (Smart shoes and socks), and Smart textiles (Smart pants, Smart shirts).^{20,25} Generally, wearables devices are composed of five components: sensors, connectivity, battery, interface, materials/algorithm.²⁵ From the design and manufacturing consideration, wearable devices contains microprocessors, interface including data communication, different types of sensors: inertial measurement units (gyroscopes, accelerometers, barometers, and magnetometers), optical sensors (complementary metal-oxide-semiconductor [CMOS]) sensors, spectrophotometers, cameras, temperature sensors, chemical probes, electrodes, microphones, shock detectors, strain gauges.²⁰

These days, when the world is dealing with COVID-19, vital-sign wearable solutions were implemented in different countries. Wearables can provide a key early-warning system about the likelihood of COVID-19 infection and its surveillance.²⁶ For example, in Singapore, ViSi mobile developed by Sotera was used as a wearable device on patients in mild illness to monitor heart bit rate, respiratory rate, body temperature, and oxygen saturation.¹⁶

Wearable devices find different application in biomedical and clinical services, as shown in Figure 3.

Apart from measuring vital signs, aggregate data taken from wearables can also contribute to the research by

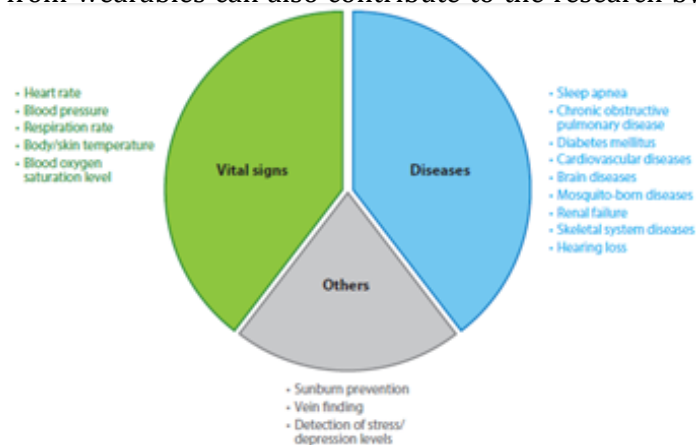


FIGURE 3. Some biomedical applications of medical wearables.²⁷

detecting general patterns and trends within a population, contributing to improved public health responses.²⁶ Wearables are positioned to different body parts depending on the parameter to be measured, as shown in Figure 4.

Wearable devices come into 4 main classes²⁵:

- **Lifestyle and fitness devices.** This includes fitness

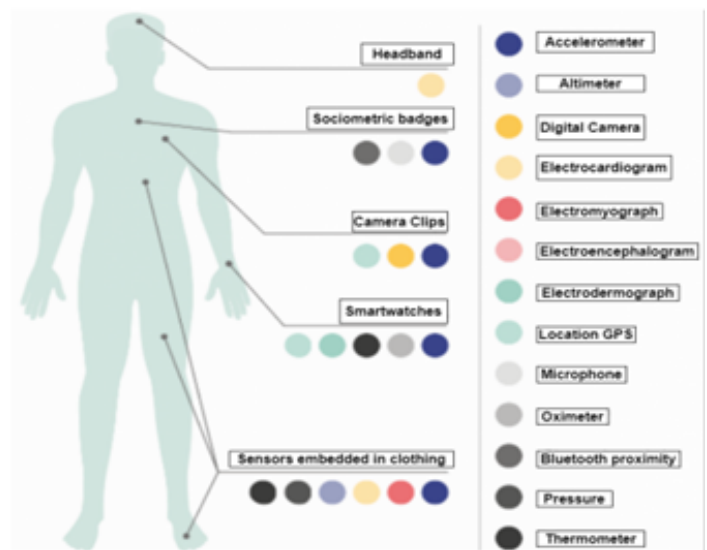


FIGURE 4. Wearables based on on-body location.²⁶

trackers, sport and activity trackers (e.g., Moov Now, Misfit Shine, Fitbit charge2).

- **Diagnostics and monitoring devices.** These non-invasive devices provide valuable health information (e.g., DexcomG4, Quardio Core).
- **Therapeutic devices.** These devices monitor disease states, track activity, store data, and deliver feedback therapy (e.g., Quell, Minimed530GInsulin Pump).

Injury prevention and rehabilitation devices. This includes body motion monitoring devices, wearable sensing garments, fall detection devices (e.g., Philips lifeline, sprouting baby monitor).

The International Electro-technical Committee Standardization Management Board Strategic Group10 distinguishes wearable technologies into near-body electronics, on-body electronics, in-body electronics, and electronic textiles.^{17,21} Wrist-worn and handheld wearables are the most widely adopted and market-filled niche covering Smart rings, wrist bands, smartwatches, and gesture control devices.²¹

Unlike conventional testing in a clinical setting, which may occur a few (or less) times a year, wearables offer continuous access to real-time physiological data.²⁸ In their use, wearable devices are applications of the Internet of things, a concept used by devices for sending and receiving data via the Internet.¹⁸ Embedded intelligence connectivity offers a unique opportunity for condition monitoring, localization, identification, personal contextual notifications, information display, and virtual assistance.²¹

The wearables data processing cycle follows 6 stages, as presented in Figure 5.

The wearable market is growing faster in patients with specific conditions like epilepsy, chronic obstructive pulmonary disease, asthma, heart arrhythmia, chronic pain, and breast cancer.¹⁷

Today, many wearable devices are commercially available, such as rings, headsets, sleep masks, wearable patches, arm straps, finger clips, chest straps, fitness bracelets, fitness bands, and flex garments. Specific products include Google Glasses, GOW Pack, LUMObac, Metria Wearable Sensor Technology, nECG Platform, Peeko Monitor, PER-Smobile, NuMetrex Heart Sensing Racer Tank, Re-Timer, SleepShirt, T. Jacket, 360 Kids Guardian, and Vega.^{15,24,29}

Significant growth in purchased wearable devices has been recorded in North America, Western Europe, and the



FIGURE 5. Wearables data processing cycle.²¹

Asia Pacific region, while in the rest of the world, the market growth is lower. Reports about the future of wearable technologies predict that the market volume will be 27.8 billion dollars in 2022 and 93.¹⁹ billion dollars in 2027.¹⁸

Some of the challenges of wearable devices include the feeling of constant surveillance, inefficient data analytics, lack of appropriate data labeling, insufficient computing capabilities, inefficient switching among resources in hybrid networks, lack of modern energy harvesting opportunities, low data resolution.²¹ The major market players in wearable medical technologies are: Apple, Fitbit,

TABLE 2. Wearable Wireless Technologies, Operating Frequency, and Range.²¹

	Communication Technology	Frequency Range	Range
Short-range	RFID	125–134 kHz, 13.56 MHz, 860–960 MHz	Up to 100 m
	NFC BLE (IEEE 802.15.1)	13.56 MHz	<0.2 m
		2.4–2.48 GHz	Up to 100 m
	Zigbee Zigbee (IEEE 802.15.4)	868–868.6 MHz, 902–928 MHz, 2.4–2.49 GHz	Up to 100 m
	Wi-Fi (IEEE 802.11a/b/g/n)	2.4–2.48 GHz,	20–250 m
		4.9–5.8 GHz	
	Wi-Fi 5 (IEEE 802.11ac)	4.9–5.8 GHz	Up to 70 m
	Wi-Fi 6 (IEEE 802.11ax)	1–6 GHz	Up to 120 m
	WiGig (IEEE 802.11ad/ay)	57–70 GHz	10–100 m
	VLC (IEEE 802.15.7)	400–800 THz	Up to 100 m
VLC (IEEE 802.15.7)	LTE frequency bands	Up to 15 km	
Long-range	LTE-M	LTE frequency bands	Up to 10 km
	LoRa	867–869 MHz	Up to 50 km
	Sigfox	868–878.6 MHz	Up to 50 km

Jawbone, Misfit, Mykronoz, Samsung, Garmin Ltd, Xiaomi Technology Co. Ltd, Qualcomm Technologies, Inc; Adidas Group, Sony Corporation, Lifesense Group.¹⁸ The details on many body-worn devices are presented in Figure 6.

Artificial Intelligence (AI)

AI is rapidly evolving in clinical practice in dealing

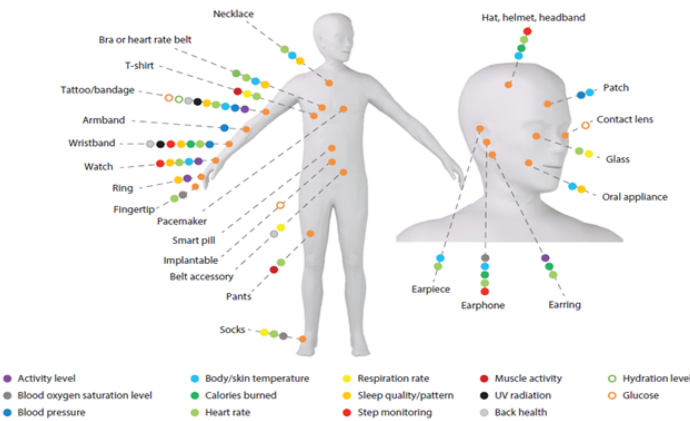


FIGURE 6. Wearable devices worn on various body parts and the parameters they can monitor.²⁷

with a significant amount of data provided by Smart wearables, Smartphones, and other monitoring systems in medical services.⁶ The concept of AI was first conceived in 1950 by Alan Turing in his book entitled Computers and Intelligence in what was called Turing test when he was trying to determine whether computers were capable of human intelligence. In 1956, John McCarthy described “Artificial Intelligence” as the science and engineering of making intelligent machines.³⁰ The systematic evolution of AI is presented in Figure 8. Today, AI is defined as using computers and technology to simulate intelligent behavior and critical thinking comparable to a human being or the science and engineering of making intelligent machines.³¹⁻³⁴

The evolution of AI is presented in Figure 3. AI is not one type of machine or robot but a series of approaches, methods, and technologies that display intelligent behavior by analyzing their environments and taking actions—with some degree of autonomy—to achieve specific targets that can improve health services.^{35,36} Studies about AI have exponentially increased from 826 in 2012 to 12563 in 2019.³⁷ By 2019, there were 279,145 AI patent applications in the US, with the global market expected to reach

190.61 billion dollars in 2025. AI can add about \$15.7 trillion to the world economy by 2030,³⁸ with China leading the global market in 2030 with a share of 26.1%.³⁹

These assertions are justified by the research article published by Chinese universities from 2015 to 2019, as seen in Figure 7.

With AI, patients will receive more rapid, accurate diagnoses and reduced adverse events. The top applications of AI include robot-assisted surgery, virtual nursing assistant,

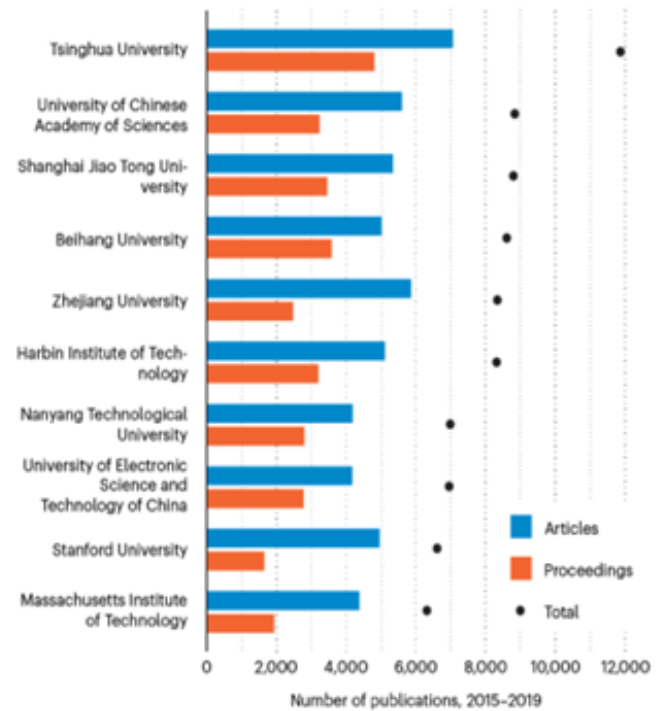


FIGURE 7. Top 10 institutions with the most AI-related publications (2015-2019).⁴⁰

administrative workflow assistance, fraud detection, dosage error reduction, clinical trial participant identification, preliminary diagnosis, automated image diagnosis, cybersecurity, health research, and drug discovery and development.⁴¹ AI also finds application in diagnosis and case identification and prognosis and prediction.

The AI umbrella encompasses the following subfields³⁰:

- **Machine learning (ML):** Machine learning involves training an algorithm to perform tasks by learning from patterns in data rather than performing an explicitly programmed job.⁴² Machine learning algorithms can automatically learn and improve from experience

without explicitly programming. The most common algorithms of ML are: **supervised learning** (used when we can precisely define the task we want the algorithm to learn based on data that we already have), **unsupervised learning** (It is like learning without a teacher. We have a group of patients with different sets of data, but we do not know their individual diagnoses. We build a model, then try to cluster patients based on similar attributes such as the symptoms they presented with, their lab markers or age and gender), **Reinforcement Learning** (this allows the algorithm to learn how to complete the tasks with a sequence of decisions by itself without being told how to do it).^{35,37}

- **Deep learning (DL):** It is a subset of ML with similar functions but with different capabilities.³⁷ This method of AI allows a machine to be fed with large quantities of raw data and to discover the representations necessary for detection or classification.⁴³ DL uses chips called graphics processing units to rapidly perform required calculations, a single card of which can potentially process hundreds of millions of images a day.⁴² DL mammography is used for breast cancer detection, in computed tomography (CT) for column cancer diagnosis, in chest radiographs, for the detection of pulmonary nodules.⁴¹

- **Natural language processing:** This branch of AI is concerned with the use of computational methods in understanding and interpreting human language.^{35,42}

Artificial Neural Networks (ANN) or Simulated Neural Networks (SNN): ANN are considered the heart of DL. ANN is technology based on a human neural network.⁴⁴ Examples of ANN include handwriting recognition, speech-to-text transcription, weather prediction, and facial recognition.⁴⁵ An SNN contains a node layer, one or more hidden layers, and an output layer. Each node, or artificial neuron, connects to another and has an associated weight and threshold. If the output of any individual node is above the specified threshold value, that node is activated, sending data to the next layer of the network.⁴⁶ ANN are used in economics, ecology, environment, biology. In medicine, the most widely used family is the multilayer perceptron (PMC) in therapeutic decisions to process data for anthropology.⁴⁷

- **Computer Vision (CV):** CV allows the building of artificial systems capable of retrieving any information from an image previously obtained. CV involves different stages, namely: image acquisition (image capture with a sensor and transformation of visual information into digital information), pre-processing (preparing the image for the next level handling), feature extraction (detection of some objects to be analyzed), segmentation (separation of images into cohesive regions), noise reduction and high-level processing.⁴⁸ Today, there are many practical applications where AI was successfully useful.

The key challenges of AI are their computing power, trust deficit, data privacy and security, data scarcity,³⁸ ethical regulations, high resource and research cost, short-

TABLE 3. Examples of Success of Artificial Intelligence.³⁷

Company	Application
Babylon Health	Software application for online consultation where the system gives medication based on the symptoms entered in the system
Sensely (developed Molly app)	A virtual nurse that was designed to have a smiling face coupled with a pleasant voice to assist patients with monitoring their health
Deep Genomics (developed Oncecompass Medicine app)	To match genetic mutations found in patients' tumor samples with ongoing clinical trials worldwide
IBM Watson	Software that provides evidence-based treatment options for oncologists
Atomwise	Uses supercomputers to root out treatments from a database of molecular structures

age of transparency, poor governance and accountability, notability of data annotation.⁴⁹

Globally, the AI companies are NVIDIA Corporation, Amazon.com, Inc., Meta Platforms, Inc., DeepMind, OpenAI, Affectiva, DataRobot, Ubiquity6 CloudMinds.^{50,51} To ensure appropriate utilization of AI, companies need to embrace techniques that help them achieve fairness, security, and explainability.⁴⁹

TABLE 4. Applications of Artificial Intelligence in Diagnosis and Prediction.⁴³

Diagnosis and case identification			Prognosis and prediction
Function	Clinical area	Applications	
Waveform analysis	Obstetrics	Intrapartum monitoring	Cardiovascular risk prediction, Prediction of breast cancer survival. Prediction of outcomes in colorectal cancer, Predicting of survival in non-small cell lung cancer. Prediction of hospitalization due to heart disease. Prediction of sepsis in the intensive care unit, emergency department, and hospital floor Prediction of treatment outcome in social anxiety. Prediction of psychiatric readmission from discharge summaries
	Neurology	Remote monitoring of gait	
Image processing	Pathology	Detection of lymph node metastases in breast cancer	
	Dermatology	Identification of benign and malignant tumors, identification of fungal infection, classification of skin cancer	
	Ophthalmology	Identification of diabetic retinopathy, grading of macular degeneration	
	Cardiology	Diagnosis of acute coronary syndrome, identification of heart failure status through remote patient monitoring	
Electronic health records analysis	Radiology	Mammography, diagnosis of pneumonia from chest x-ray	
	Identification of sepsis in the emergency department, Identification of breast cancer symptoms, Heart failure case identification, Identification of patient phenotype from analysis of intensive care unit data, identification of medical subdomains in clinical notes		

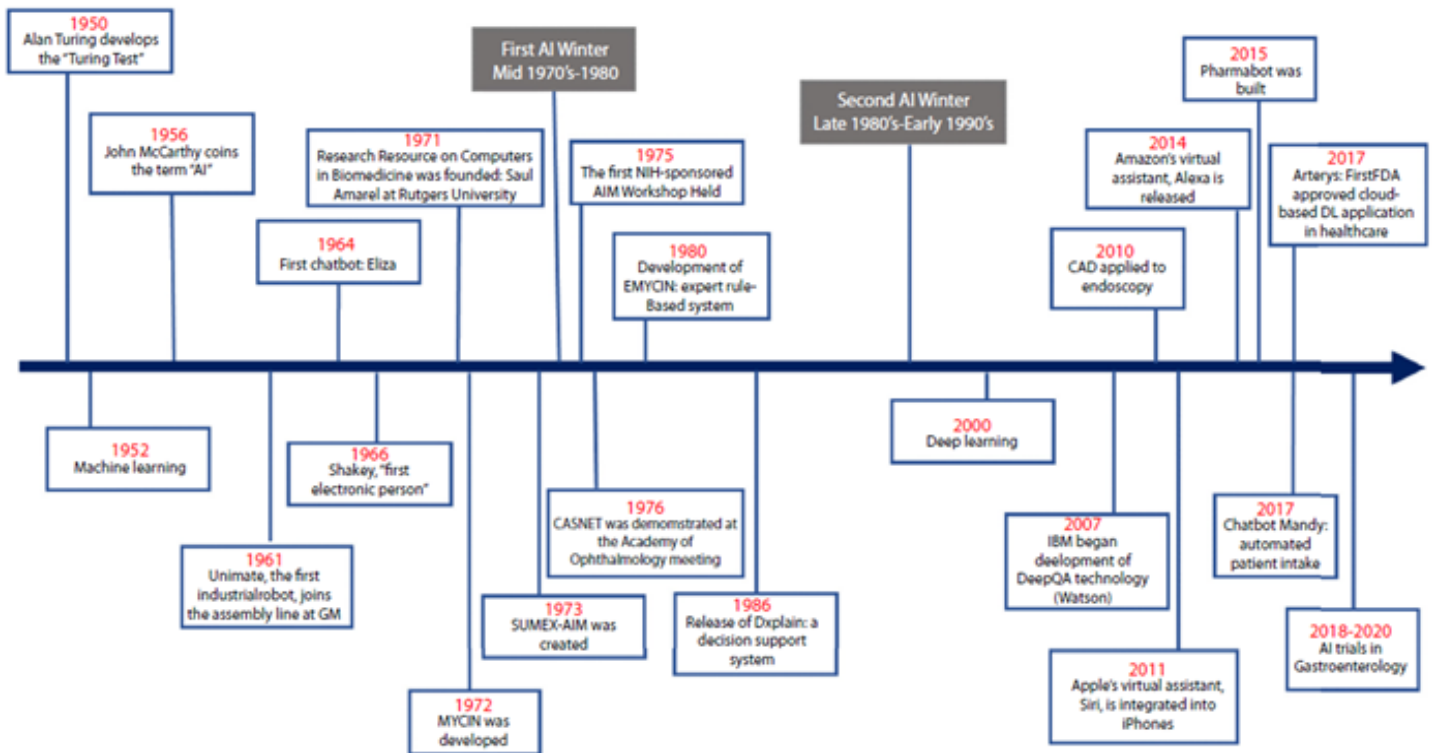


FIGURE 8. Historical evolution of artificial Intelligence.³⁰

BCT or DLT

Patients and healthcare practitioners are faced with the challenge of accessing, managing, integrating, and sharing health records securely.⁵² In many countries data are recorded on legacy papers and numerous disconnected electronic systems. In the US, 90% of physicians use unconnected computerized systems. Patients must recount their history multiple times, which may be done incompletely. Medical errors are estimated to be the third leading cause of death for Americans. In 2015, 140 million patient records were breached according to Protenus Breach Barometer Report.⁵³ The WHO estimates that many countries in Africa and parts of Asia and Latin America have areas where more than 30% of the medicines on sale can be counterfeit.⁵⁴

In 2018, the healthcare industry continued to be plagued by data breaches involving sensitive patient information. According to the Breach Barometer 2019 Report, more than 15 million patient records were breached in 2018. Such incidents allow blockchain vendors to launch new solutions.⁵⁴

To alleviate the associated adverse effects, an interconnected system is needed. In the UK, the NHS planned to interconnect all computerizing health network records by 2018; however, this target was delayed first to 2020 and again to 2023.⁵⁵ Nevertheless, during COVID-19, which is ravaging the globe, blockchain technology was used by two UK hospitals to keep tabs on the storage and supply of temperature-sensitive COVID-19 vaccines.⁵⁶

In March 2021, Moderna, a biotechnology and pharmaceutical company based in the United States, signed a new agreement with IBM to use blockchain technology to manage its COVID-19 vaccines. Additionally, 3M Pharmaceuticals, another American pharmaceutical giant, uses blockchain technology to curb counterfeit pharmaceuticals. Recently, it has started using blockchain technology to identify and stop counterfeit face masks.⁵⁷

BCT, though initially designed for the financial market, its inherent characteristics make it suitable for the health sector; insurance, pharmacy, IoT, food science, industries, e-voting, tourism, energy, and legal contract.⁵⁸⁻⁶⁰ BCT helps streamline business processes by establishing trust, accountability, and transparency.⁵⁸ In medical applications,

the ideal blockchain model would be scalable with high security and data privacy. In finance, bitcoin and Ethereum are examples of cryptocurrencies that use blockchain technology.⁶¹

In medical and clinical services, by using BCT, patients become the platform, owning and controlling access to their healthcare data. The data are stored in the private blockchain cloud, where they cannot be changed by anybody, including physicians and patients themselves internally and natively.

Because data is stored on a decentralized network, there is no single institution that can be robbed or hacked to obtain a large number of patient records. Data is encrypted in the blockchain and can only be decrypted with the patient's private key. Even if a malicious party infiltrates the network, there is no practical way to read patient data.^{62,63}

In terms of patients' full control of their health record history, there are three major aspects of privacy that need to be considered: (a) data ownership; (b) fine-grained access control; (c) data transparency, integrity, and auditability.⁵³

In healthcare services, the key enablers of blockchain are the need for patient data security, desire to reduce medical errors and mistakes, breakthroughs in genomics, drug traceability and safety, government partnerships, removal of unscrupulous attacks, reduction of cost in medical transactions, and improved confidentiality in healthcare business operations.⁶³

A blockchain is a ledger of transactions where an identical copy of the ledger is visible to all the members of a computer network. It is a digital healthcare system management from which authorized users, such as providers and patients, have access.⁶² BCT is a permanent record of online transactions distributed, shared, and maintained by multiple parties.

The first blockchain was developed by Satoshi Nakamoto in 2009. The technology brought breakthroughs until 2021 when Dubai hosts all government operations and record-keeping operations on blockchain as part of the Smart Dubai 2021 initiative.⁶⁴

The data-sharing practice is essential to enable clinical practitioners to transfer their patients' clinical data to the concerned authority for a quick follow-up.⁶⁰ BCT differs

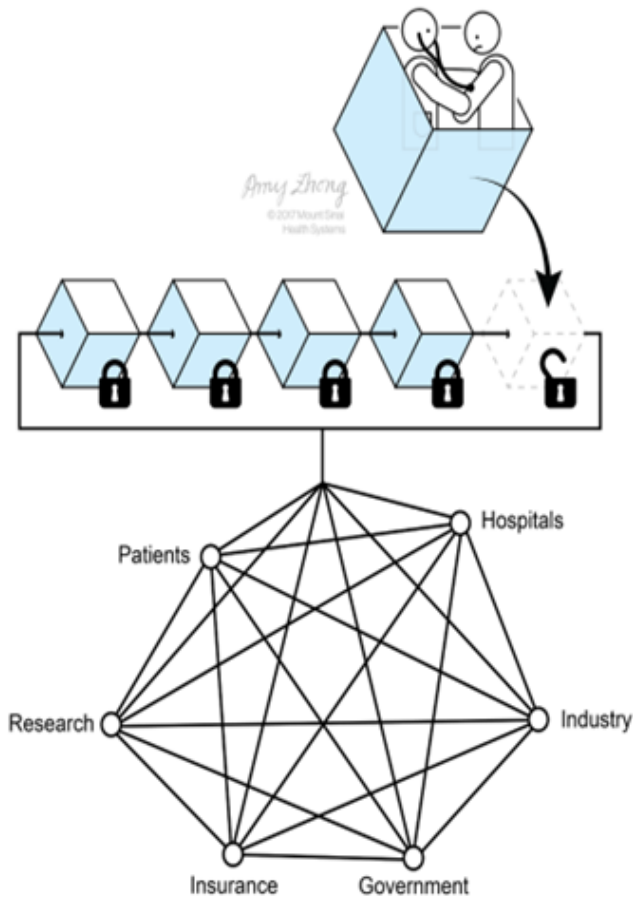


FIGURE 9. Theoretical schematic of blockchain technology in healthcare.⁵⁹

from a personal ledger in the number of security checks, whereby a blockchain makes many security checks.⁶¹ This technology is interpreted as blocks linked together to form a chain to offer patients and caregivers the ability to securely share the patient identity and healthcare information across platforms.

Today, the market for blockchain technology is very promising because it is forecast to save \$100 billion per year since 2025. The saving will be realized in a reduction in data-breaching related costs, operations costs, information technology (IT) costs, counterfeit-related fraud, and insurance fraud.⁵² In healthcare, the blockchain market in healthcare was valued at USD 2.12 billion in 2020 and is expected to reach USD 3.⁴⁹ billion by 2026 and USD 4.7 billion in 2027 with a CAGR of 8.7% during the forecast period, 2021–2026, with North America as the fastest-growing market.⁵⁴ Regarding research, the number of

scientific publications about blockchain technology shifted from 5 in 2016 to 64 in 2018. This was another indicator that this market was rapidly attracting researchers.⁶⁵ In its structure, the components of blockchain technology are listed below.

- **Blocks** are the base of a blockchain and contain records linked lists, chains, genesis blocks, and consensus protocol.⁶⁶ Blocks contain records of the past transactions and have segments reserved to save the data for future transactions. A block on a blockchain network consists of hash codes, root hash of merkle tree, and nonce.⁶¹
- **Chains** are blocks inside a blockchain network that are connected to each other. Multiple blocks that are joined together form a chain of blocks.
- **Nodes** contain the entire history of a blockchain network. Nodes are the devices that store these vast amounts of data. Computers, laptops, and big servers function as nodes. All the nodes in a blockchain network are linked together. Nodes verify the signatures, double-check the answer of the hash code after authenticating the details, and add a new block to the blockchain network. Nodes can stay both online and offline.⁶¹
- **Master nodes.** Selective blockchain networks have master nodes which are more capable than normal nodes.⁶¹
- **Peer-to-peer networks (P2P)** are networks designed for linking two nodes.

There are four types of blockchains:

- **Public blockchains** are permissionless blockchains that allow anyone to join. All nodes of the blockchain have equal rights to access the blockchain, create new blocks of data, and validate blocks of data.^{58,67}
- **Private or managed blockchains** are permissioned blockchains controlled by a single organization. In a private blockchain, the central authority determines who can be a node. The central authority also does not necessarily grant each node with equal rights to perform functions.⁶⁷
- **Consortium blockchains** are permissioned blockchains governed by a group of organizations, rather

than one entity. However, setting up consortiums can be a fraught process as it requires cooperation between several organizations presenting logistical challenges and potential antitrust risks.⁶⁷

- **Hybrid blockchains** are controlled by a single organization, but with a level of oversight performed by the public blockchain, which is required to perform specific transaction validations.⁶⁷

Some key players in the blockchain market are IBM Corporation, Microsoft Corporation, Gem, Patientory Inc., Guardtime Federal, Isolve, and Factom⁵⁷

Robotics Technology

Technological advancement has revolutionized how medical procedures take place, including surgical opera-

TABLE 5. Challenges of Blockchain Technology^{59,62,60}

Technology	Blockchain software is still in its infancy, continually being developed and refined
Integration	Must initially be co-existent with current technologies, must be integrated overtime
Cost	Adoption of new technologies will incur initial greater costs to institutions
Regulation	Government institutions have yet to settle regulatory concerns over blockchain technology
Culture	Adoption of the technology will require significant buy-in from the global community
Energy	Maintaining the blockchain requires a network of nodes, and resulting substantial computing power
Privacy	Emerging cyber security concerns must be addressed before individuals will entrust data to a public blockchain

tions. Credits go not only to the development of actuators, sensors, control systems, and materials but also to the growth of imaging systems for medical applications such as higher resolutions and magnetic imaging.⁷¹ Apart from the industrial robot (a word originating from the Czech word “robota” meaning compulsory labor) first developed 50 years ago, today’s medical and healthcare robots are used in tremendous clinical work.^{72, 73}

According to the Robotic Institute of America, a robot is a machine in the form of a human being that performs

the mechanical functions of a human being but lacks sensitivity. The first robot was developed by Leonardo Da Vinci in 1495, purposed at amusing royalty. It was followed the creation of the first operational robot by Joseph Marie Jacquard in 1801, in which an automated loom, controlled by punch cards, created a reproducible pattern woven into cloth.⁷³

In medicine, robotic systems were first introduced in the mid-80s, and today they make an impact in various medical disciplines, including general surgery, research, therapy, rehabilitation, neurosurgery, orthopedic surgery,⁷⁴ and medical transport (for example, TUG Robot able to carry around more than 400 kilograms of medication).⁷⁵

As per 2017, 20% of the world population experience difficulties with physical, cognitive, or sensory functioning mental and behavioral health, which can be solved with robotics technology application.⁷⁶ The very first mechanical robot to be used in surgery was the Puma 560 in 1985 for the precise positioning of the cannula for brain biopsies.⁷⁷

Statistics show that 1 in every 25 patients will contract hospital-acquired infection (HAIs) in the USA, and 1 in 9 will die.⁷⁵ That is why next-generation smart hospitals have robotics that can help reduce infections, viruses, and bacteria.⁷⁸ For example, Xenex Robot allows for fast and effective systematic disinfection of any space within a healthcare facility by destroying deadly microorganisms causing HAIs using special ultraviolet (UV) disinfection methodology.⁷⁵ Data from the USA show that surgery costs annually are estimated to be \$170 billion, with an estimated \$41 billion US spent on readmission due to complications. In Europe, over half (52%) of all surgeries were due to unexpected complications. Consequently, robotics can lower the readmission rate by up to 50%, resulting in a saving of \$10 billion annually.⁷⁹ The global landscape of robotics application in healthcare and well-being are presented in Table 7.

In their general design and construction, medical robots consist of a Central Processing Unit (the robot’s brain for coordinating all its activities) and Sensors (acting as the powerhouse of the robot feedback mechanism). These include light sensors, sound sensors, temperature sensors, contact sensors, proximity sensors, distance sensors,

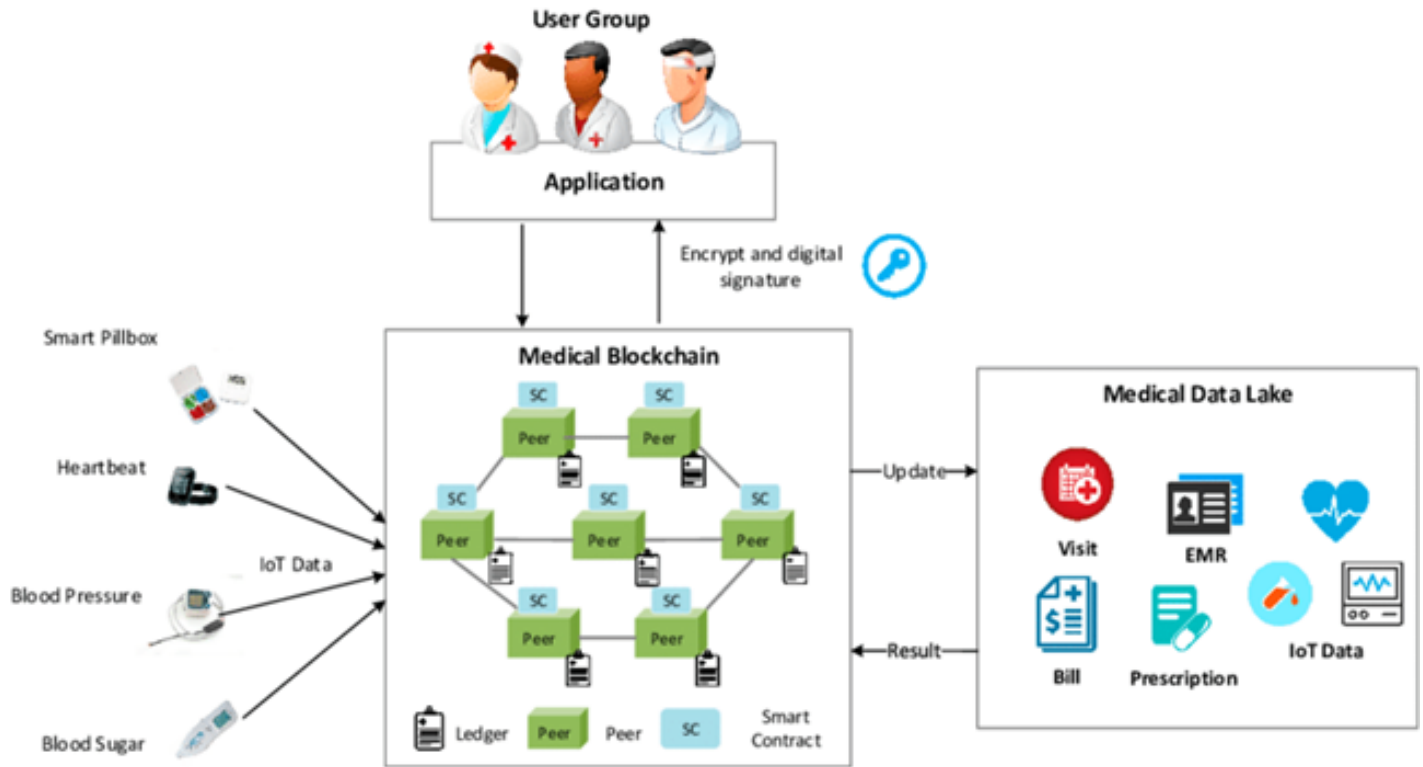


FIGURE 10. Blockchain structure in hospital applications.⁶⁸

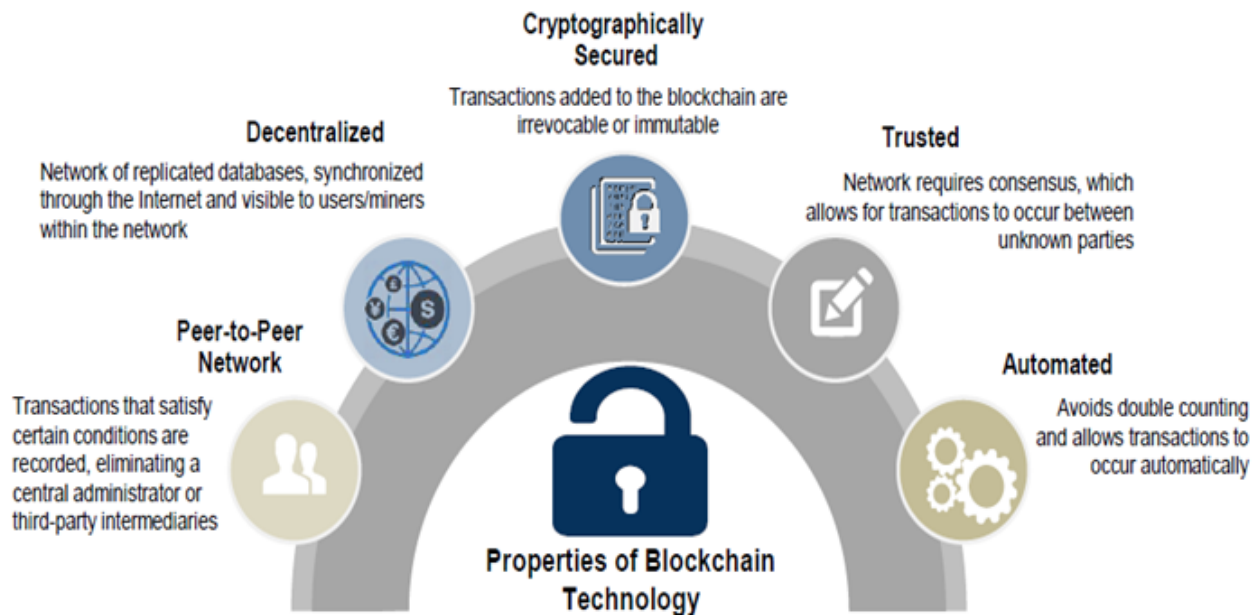


FIGURE 11. Properties of blockchain technology.⁶⁹

TABLE 6. Blockchain Potentials for Healthcare and Life Science^{52,59,70}

Category	Potential use	Key Benefits
Patients	Patient empowerment. Patients can keep track of their medical background. Patients can check their latest medical prescriptions, Patients can share their data securely across their providers	Increases patient trust. Improves patient access to trusted data. Facilitates better collaboration, Increases transparency. Improves and personalizes the patient experience. Increases efficiency and reduces operations costs, Enables patient access to their health records anywhere in the world. Enables patient access to their latest prescriptions
Regulation and compliance	Compliance tracking, Smart contract-based check	Establishes a trusted audit trail verifiable in real-time. Establishes a platform to enforce privacy regulations automatically. Enables monitoring of who has shared data and with whom, without revealing the data itself
Inter-company processes	Transfer of funds. Medical devices supply chain. Temperature-controlled supply chains, Services	Facilitates automated payments through smart contracts. Increases speed for payments. Provides full transparency of assets across the supply chain to the patient. Enables certified & private messaging between medical devices and service providers. Brings all transactions into a single platform
Administration and back offices	Revenue management	Improves efficiencies in tracking and tracing areas where leakage occurs. Reduces admin costs, Increases reliability and auditability. Speeds up financial transactions process
Pharmaceuticals	Verifies drug provenance. Creates an industry-wide, single source of aggregate information	Tracks and traces pharmaceuticals, Proof of authenticity for anti-counterfeiting techniques. Helps prevent the transport and sale of counterfeit products. Makes it is possible to detect the full spectrum of complications related to pharmaceutical treatment
Research and development	Securing clinical trials	Prevents theft of intellectual property. Enables users to authenticate any document and ensuring proof of the existence. Enables access to a huge anonymous and authenticated database of patients

pressure sensors, positioning sensors, etc.). Also included are Actuators (the robot's hydraulic, pneumatic, or electric muscles), End-Effectors (the tools that perform the actual work and interact with the environment or a workpiece), the Power Supply (energy required for robot operation), and the Program (for providing the logic that drives the robot behaviors and activities).⁸¹

Robotics applications in medicine involve different stakeholders, including primary stakeholders (direct robot user, clinicians, and caregivers), secondary stakeholders (robot makers, environmental service workers, health administrators), and tertiary stakeholders (policy makers, insurers, advocacy groups).⁷⁶ Among robotics applications, surgical robots have a high revenue growth market segment, are highly competitive with established

players, well-defined market entry routes, and a good product innovation pipeline.⁸⁰

In 2020, the leading global company in medical robotics was Intuitive Surgical, with a market cap of \$121 billion, 6335 robots in service,⁷⁸ with more than 1.2 million procedures performed globally, and with a growth of 18% per year.⁸⁰

Other companies in service include Boston Dynamics, Stryker, Accuracy, Vicarious Surgical, Medtronic, GE Healthcare, Myomo, Stereotaxis, Ottawa^{77,78} Neocis.Inc, Medtronics, Brainlab, Smith & Nephew plc, Corindus Vascular Robotics, Inc., Riverfield Co., Ltd, Auris Health, Inc., etc.⁸⁰

TABLE 7. Medical Robotics Market Potential Assessment Summary⁸⁰

Healthcare robotics		Technology Readiness level	Breadth of application	Current adoption	Growth potential
Medical robots	Surgical Robots				
	Diagnostics Robots				
Healthcare Service robots	Medication delivery and dispensing				
	Cleaning and disinfecting				
	Telepresence and remote monitoring				
	Autonomous vehicles				
Care robots	Personal assistant/ Companion robots				
	Assistive robots				

Predominantly R&D and prototype phase Several Commercial Products Technology Development	Low, Specific High, Multiple Breadth of Applications	Low, Pilots High, Commercial Current Adoption	Low High Growth Potential
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Between 2015-2020, China emerged as a leader for next-generation surgical robotic systems’ innovations with 237 (36.5%) patents published in this area from 2015 to 2020 (Figure 12).⁸⁰

The global medical robot market is expected to reach USD 12.7 billion by 2025 from an estimated USD 5.9 billion in 2020 at a CAGR of 16.5% during the forecast period. On the other hand, 82 medical robotics market is forecast to account for \$43.22 billion in 2028 with a

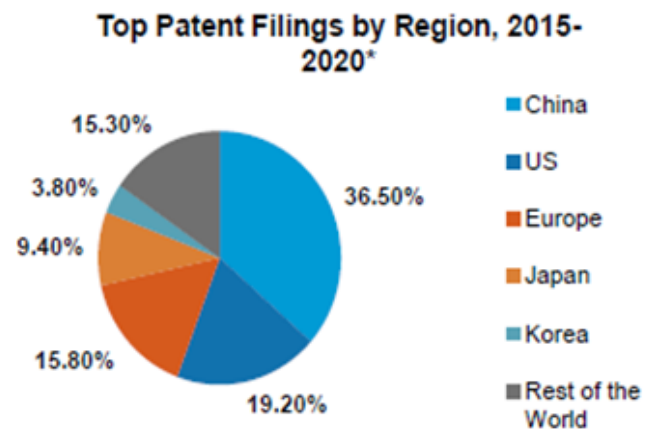


FIGURE 12. Medical robotics patent filings from 2015 to 2020.⁸⁰

compound annual growth rate of 22.3% from 2021 to 2022 (Figure 13).⁸²

The key drivers of medical robotics market evolution include demand for minimally invasive procedures for diagnosis, improved precision in diagnosis and treatment, technological advancement in AI, management of surge capacity during peak demand, and improvement of the

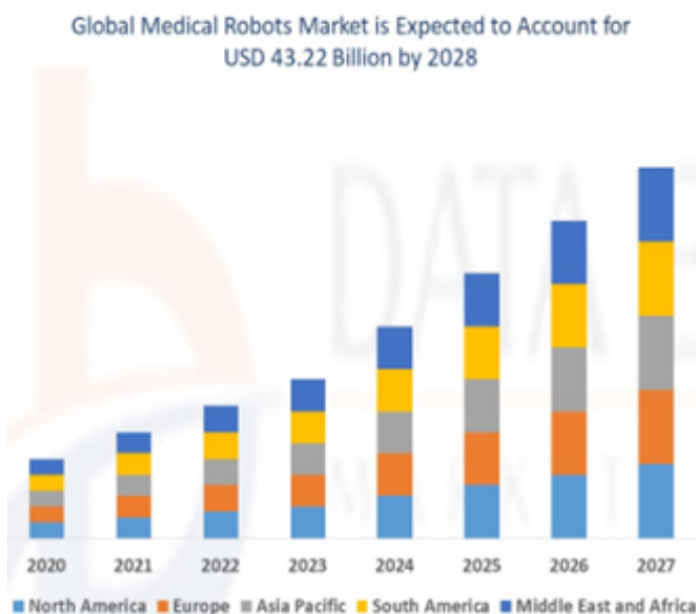


FIGURE 13. Market growth for medical robotics.⁸²

overall efficiency of logistics. Also, there is a desire to increase the automation of pharmacy operations, large population living with chronic illnesses, hospitals' will to maintain hygiene protocols and standards, especially as it directly impacts hospital accreditation, reduces manual labor, improves efficiency and cost savings for cleaning and disinfection. Increasing prevalence of stroke, multiple sclerosis, Parkinson's disease, cerebral palsy, Rise of the elderly population, and shortage of caregivers.⁸⁰

Nowadays, since 2019 when the whole world experienced the COVID-19 outbreak, robotics has been finding applications in undertaking human-like activities.⁸³ In Rwanda, robots were deployed to minimize contact time with confirmed cases and reduce the risk of contamination of health professionals in COVID-19 treatment centers. The 5 human-size robots are programmed to perform temperature screening, take vitals readings, deliver video messages, detect people not wearing masks, and then

instruct them to wear masks properly. One robot called Urumuli deployed at Kigali International Airport had the capacity of screening 50 to 150 people per minute and reporting abnormalities to officers on duty.⁸⁴

Later, on 9 February 2021, in partnership with the United Nations Development Programme, the government deployed another set of three THOR UVC robots to Nyarugenge District Hospital to strengthen the national response to COVID-19 pandemic.⁸⁵ Robots were also used to store patients' data during diagnosis and treatment, reduce the workload of healthcare providers, ease the diagnosis procedures, and assist the physicians and students in learning more about the new disease in a short time.⁸⁶

In South Korea, a self-driving robot with cameras and an LED screen was used to greet clients at the country's biggest mobile operator, check their temperatures, dispense hand sanitizers, and disinfect the floor. Other robots were used to disinfect 33 square meters in 10min using ultraviolet radiation. In addition, they could detect people's gatherings, advise them to disperse, and wear face masks.⁸⁷ In China, Wuhan City, where the pandemic was first detected, constructed a fully robot-staffed hospital where patients entering were screened by connected 5G thermometers to alert staff for feverish. In addition, Patients wore smart bracelets and rings that synced with Cloud Minds' AI platform so their vital signs, including temperature, heart rate, and blood oxygen levels, could be monitored. Doctors and nurses also wore the devices to catch any early signs of infection.⁸⁸ Regarding the future of medical robotics, up to 2013, Nanorobotics was still the largely hypothetical technology of creating machines or robots at or close to the scale of a nanometer.⁷³

Though the growth of the medical robotics industry is promising, it is humped by the following challenges: high establishment cost, fewer trained professionals to administer the tests, technical complexities leading to operational issues, the high running cost for disadvantaged people.⁸⁰

Nanomedical Technology

It is a technology for diagnosing, treating, and preventing disease and traumatic injury, relieving pain, preserving and improving human health using molecular tools and molecular knowledge of the human body.⁸⁹ Nanotechnology

classically refers to the matter in a size range of 1–100 nm but can be extended to include materials below 1 μm in size.⁹⁰ Nanomedicine is also defined as the application of nanobiotechnologies to medicine.^{91,92}

Though the concept of nanotechnology dates to 1959, the optimistic expectation of nanoparticles and nanoscale tools to improve the diagnosis and pharmacological treatment of several diseases was first established in 1990.⁹³ The basis of this new science derives from the development of an array of ultramicroscopic devices and the studies of cellular, molecular, and finally atom-sized structures in biology, chemistry, and physics in the 20th century. Nanotechnology is not in itself a single emerging scientific discipline, but rather a meeting of different traditional sciences linking physics, chemistry, biology, medicine, electronics, and IT.⁹⁴ Nanotechnology in medicine was recently focused on because there is a diversity of diseases originating from the alteration in biologic processes at the molecular level like mutated genes, misfolded proteins, and infections caused by viruses or bacteria (Figure 14).⁹⁵ The three main subsections of nanomedicine are: nanobiotechnology, nanotechnology, and nanobiomimetics.⁹⁶

Currently, in medicine, nanotechnology is used in antibacterial treatment, wound treatment, cardiovascular diseases, ophthalmology, cancer-fighting, cell repair, imaging, probing of DNA structure, tissue engineering, tumor detection, separation and purification of biological

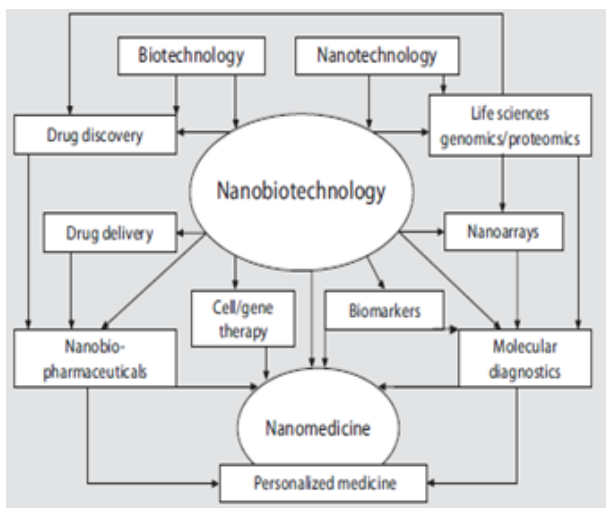


FIGURE 14. Relationship of nanobiotechnology to nanomedicine and other biotechnologies.⁹¹

molecules and cells, MRI contrast enhancement and phagokinetic studies, company directory and to deliver drugs, heat, light or other substances to specific types of cells (such as cancer cells).^{91,97} Its use in diagnostics is at the development stage. The use of nanoparticles will reduce damage to healthy cells in the body and contribute to the early detection of diseases.⁹¹ The global Nanomedicine market size is projected to reach USD 232 million by 2026, from USD 150 million in 2019, at a CAGR of 6.4% during 2021-2026.⁹⁸

The nanomedicine market segmentation by type includes:

- **Quantum dots (QD):** QD are semiconductor nanocrystals that have a reactive core (made of cadmium selenide CdSe, cadmium telluride [CdTe], indium phosphide [InP], or zinc selenide [ZnSe]), for controlling their optical properties. QD are used in medical real-time tissue imaging,⁹⁹ biological probes, for live cells labelling,¹⁰⁰ drug delivery vehicles, in vivo imaging, therapeutic delivery,¹⁰¹ blood cancer assay, and cancer detection and treatment, in vivo animal targeting, tracking different particles, forecasting of disease stage.¹⁰²
- **Nanoparticles:** A considerable fraction of the solid matter on earth can be found in the size range of colloids and nanoparticles, and in the last 2 decades, scientists have shown that colloids and nanoparticles are present everywhere in the environment.¹⁰³ NPs are categorized into three types: natural nanoparticles, incidental nanoparticles, and engineered nanoparticles (Figure 15).¹⁰⁴

From a chemical point of view, nanoparticles are classified into inorganic and organic types. Inorganic nanoparticles are used as antimicrobial agent against bacteria, fungi, parasites, and viruses.¹⁰⁴ Organic nanoparticles prepared from various materials, including polymers and lipids, have found exciting therapeutic delivery and imaging applications.¹⁰⁵

The choice of material impacts various properties, including drug encapsulation, immunogenicity, and targeting. At the same time, the design of nanoparticles, such as size, shape, flexibility, and compartmentalization, will also impact nanoparticle performance. These two attributes

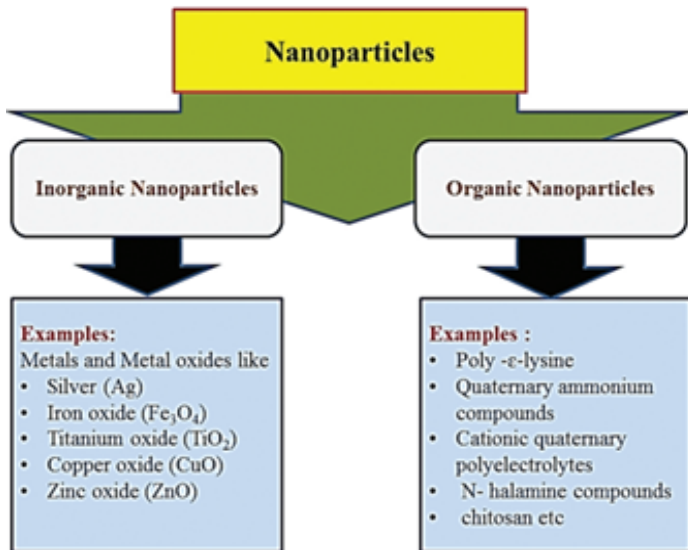


FIGURE 15. Types of nanoparticles.¹⁰⁴

(choice of material and nanoparticle design) collectively determine the therapeutic outcome (Figure 16).¹⁰⁵

Other applications of nanoparticles within medicine include tissue engineering, bio-micromechanical systems (bioMEMS), biosensors, anticancer drugs, microfluidics, and diagnostics.¹⁰⁶

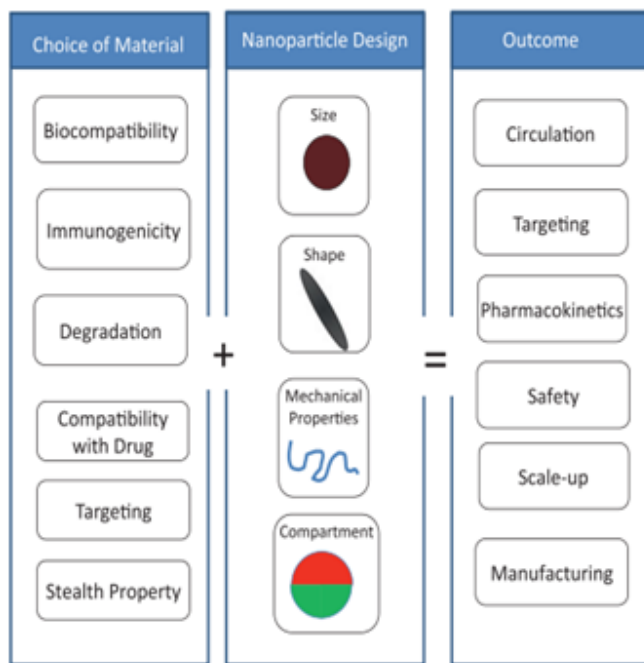


FIGURE 16. Design parameters for nanoparticles.¹⁰⁵

- Nanoshells:** The discovery of nanoshells was made by Professor Naomi J. Halas and her team at Rice University in 2003.¹⁰⁷ These are a special class of nanomaterials that consist of concentric particles.¹⁰⁸ A nanoshell is a type of nanoparticle with a dielectric (e.g., silica) core and a thin metal coating (usually gold).¹⁰⁹

Nanoparticles find a place in medicine because of their safety, biocompatibility, stability, bioavailability, optically tunable, and photo-luminescent ability as well as high ability to attach to many therapeutic materials. Nanoshells (and especially gold nanoshells) show promise application in biomedical imaging, target therapy, gene delivery, tissue welding, drug delivery systems, therapeutic applications in general, and cancer imaging and treatment (Figure 17).¹¹⁰

Gold nanoshells exhibit unique optical properties because their interaction with the electromagnetic field is greatly intensified by a phenomenon known as localized surface plasmon resonance. They are designed to

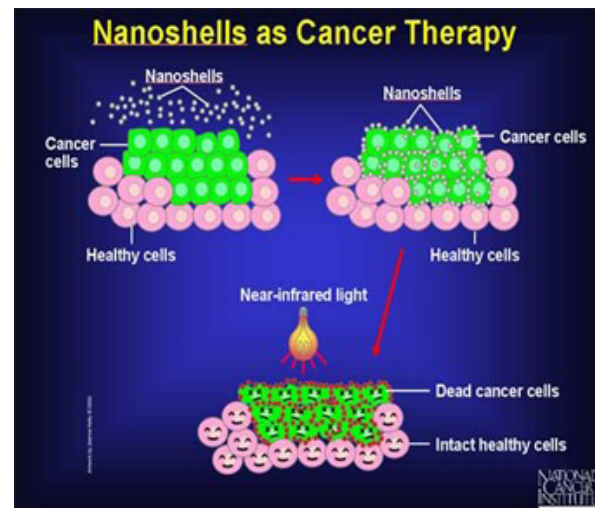


FIGURE 17. Use of nanoshells for cancer treatment (Source: National Cancer Institute).

absorb radiation at various frequencies absorb certain types of radiation. Once the nanoshells are attached to the cancerous cells, only laser light is needed to treat cancer. Near-infrared (NIR) light passes through the body and reaches the gold nanoshell. The tuned gold nanoshell receives the NIR light and converts the light energy into heat, killing the cancer cells.¹⁰⁷

- **Nanotubes:** Nanotubes, usually made in carbon (CNTs), consist of carbon atoms arranged in a series of condensed benzene rings rolled up into a tubular structure.¹¹¹ Carbon nanotubes (CNTs) are cylindrical molecules that consist of rolled-up sheets of single-layer carbon atoms (graphene). They can be single-walled (SWCNT) with a diameter of less than 1 nanometer (nm) or multi-walled (MWCNT), consisting of several concentrically interlinked nanotubes, with diameters reaching more than 100 nm. Their length can reach several micrometers or even millimeters (Figure 18).¹¹²

Their impressive structural, mechanical, and electronic properties are due to their small size and mass, incredible mechanical strength, and high electrical and thermal

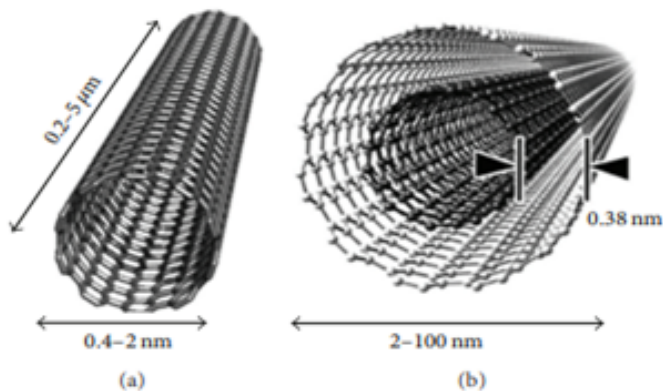


FIGURE 18. Conceptual diagrams of single-walled carbon nanotubes (a) and multiple-walled carbon nanotubes (b).¹¹¹

conductivity. In medicine, nanotubes are used in pharmaceuticals, drug delivery systems, gene delivery and therapy, tissue engineering, bio-imaging, biosensor applications, lab-on-chip devices, photo-thermal therapy, diagnostics, and high-performance composites for implants.^{113,114}

Although there are advantages of nanotubes (like biocompatibility, rigidity, mimicking of natural tissue nanofibers, stimulating the adhesion and proliferation of cells and ability to form strong 3-D architectures, high surface area, high photo-stability and absence of quenching, special optical, mechanical, and electronic properties),¹¹⁴ concerns related to their toxicity, biosafety, and biodegradation still remain.¹¹³ Examples of nanotechnology equipment in medicine include atom probes,

atomic absorption spectrometer, profilometers, raman microscopes, calorimeters, cryogenic probe stations, scratch testers, flow chemistry reactors, graphene, surface analyzers, Spectroscopic ellipsometer, wafer bonders, x-ray detectors, x-ray diffractometer, etc.¹⁰⁶

The challenges faced by nanotechnology include high manufacturing costs, technical challenges, raised skeptical opinions within the scientific community about the clinical relevance of nanomedicine.⁹³ The competitive landscape of the industry has also been examined along with the profiles of the key players who include Abbott Laboratories, Arrowhead Pharmaceuticals Inc., General Electric Company, Luminex Corporation, Merck & Co. Inc., Nanobiotix, Novartis AG, Pfizer Inc., Sanofi SA, Starpharma Holdings Limited.¹¹⁵

Telemedicine and Telehealth

The provision of primary healthcare has been challenging during the recent and current periods of COVID-19 due to overcrowding of medical services seekers to different health facilities.¹¹⁶ It is evident to many that COVID-19 accelerated the adoption of Telemedicine globally.¹¹⁷ Telemedicine uses electronic communications and information technologies to provide clinical services when participants are at different locations.^{118,119} Some writers prefer to use the term “telehealth” interchangeably with “telemedicine,” but Telehealth is broader because it also considers even non-clinical services. Telehealth refers to ‘the use of telecommunications and IT to provide access to health assessment, diagnosis, intervention, consultation, supervision and information across distance.’¹²⁰

Telemedicine is traced back many centuries, starting from ancient hieroglyphs and scrolls to share information about health-related events such as outbreaks or epidemics. This was followed by using smoke signals to warn nearby cities of sickness.¹²⁰ In contemporary times, Telemedicine through telephone and video technology has been used since the 1960s in the military and space sectors.¹²¹ Apart from military services, Telehealth was first used in 1972 when Murphy and Bird conducted 500 patient consultations via interactive television.¹²² Today, Telemedicine is applied in radiology, dermatology, surgical peer monitoring, medication management, mental health, diagnosis, patient monitoring, etc.¹²³

The drivers of Telemedicine include: enhancement of care coordination, patients and doctors are fascinated by the services offered by Telemedicine, society, and healthcare tendency to digital life (in OECD countries, nearly 65% of people aged 65 to 84 years are estimated to have more than one chronic condition, a prevalence that reaches 89% for those aged 85 and over), bridging of the rural gap, continuous innovation in the consumer technology market, projected shortages in the health professional workforce, growth of consumerism in health care cost-effectiveness, quick access to medical services,^{123,124} improved quality, medication management, changes in care models.^{125,126}

The services offered by Telemedicine include specialist referral services (assisting a general practitioner in rendering a Diagnosis), direct patient care (sharing audio, video, and medical data between a patient and a health professional for use in generating a diagnosis, treatment plan, prescription or advice), remote patient monitoring (devices to remotely collect and send data to a monitoring station for interpretation), medical education and mentoring, consumer medical and health information, patient support service (reminders to take medication, supervision, scheduling of appointments and similar applications which are not implicitly medical).¹¹⁸

There are four key elements needed for a successful telemedicine program.

1. Collaboration tools are devices that help patients to connect with healthcare service providers. They include smartphones, laptops, tablets, etc.¹²⁷
2. Medical peripherals are the diagnostic tools used in Telemedicine, such as otoscopes, ultrasound machines, or digital stethoscopes.¹²⁷
3. Workflow represents adequate software to manage the complete process of connecting patients to medical professionals and to integrate Telemedicine with their existing IT resources.¹²⁷
4. Cloud-based services: Cloud computing delivers different services through the Internet. These resources include tools and applications like data storage, servers, databases, networking, and software. When using cloud computing, the user is not required to be in a specific place to access it, allowing the user

to work remotely.¹²⁸ In Telemedicine, cloud-based services help user-friendly access to medical records for both clinicians and patients from anywhere they can access the Internet.¹²⁹

When the world experienced COVID-19 pandemic, social distancing measures were put in place to fight its sustainability. Moreover, the rapid global spread of COVID-19 has increased the volume of data generated from various sources.¹³⁰ The cloud technology had a major role in fighting the epidemic; it became a salvation for governments and organizations in numerous fields of life, education, health, industry, communication, remote surveillance, and more information (Figure 19).¹³¹

Generally, the lines of action of the telehealth program are based on three components, as presented in Figure 20.

From 2010 to 2017 the world experience growth in the use of Telemedicine, with three diseases dominating the growth rate. Those are diabetes, congestive heart

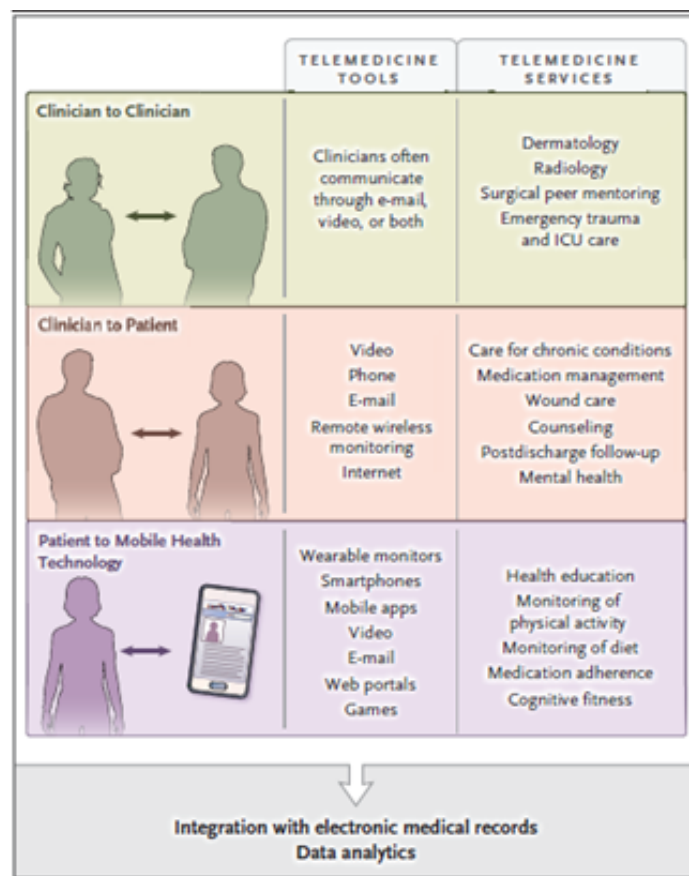


FIGURE 19. Use of Telemedicine by doctors and patient benefits.¹²³

failure (CHF), and chronic obstructive pulmonary disease (Figure 21).

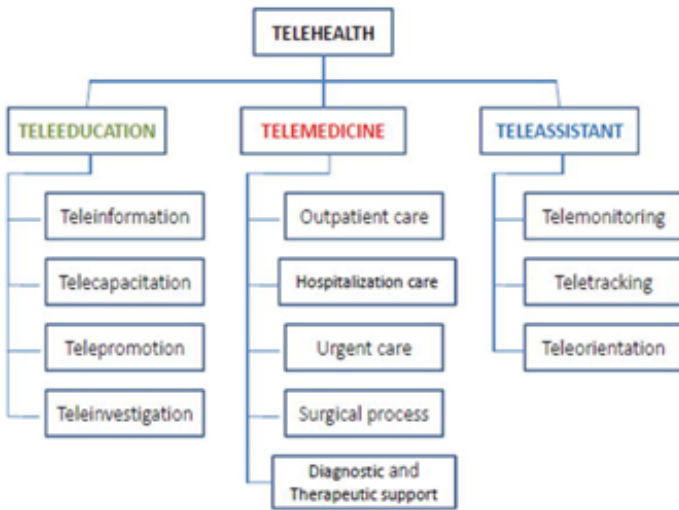


FIGURE 20. General lines of action of telehealth.¹³²

Since 2018, the quarterly investment in Telehealth has experienced peaks and bottoms, but when WHO officially declared COVID-19 as a pandemic on 13 March 2020, the investment in Telehealth has drastically increased compared to previous years, as presented in Figure 22.

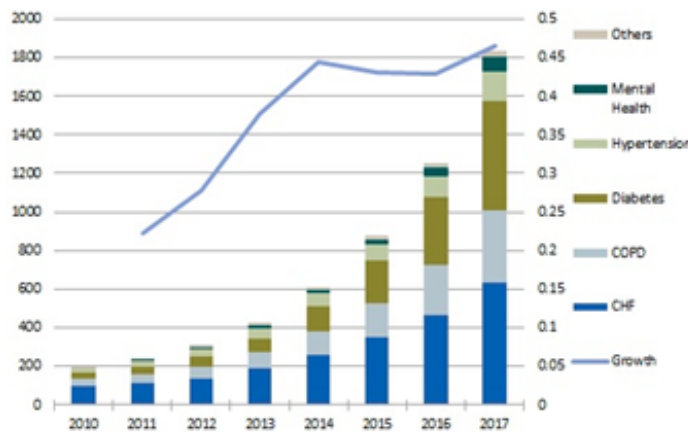


FIGURE 21. World Telehealth Patients (thousand) per disease.¹³³

Generally, the global telemedicine market was valued at \$50 billion in 2019, with forecast potential growth to increase to \$460 billion by 2030.¹³⁵

There are three types of Telemedicine:

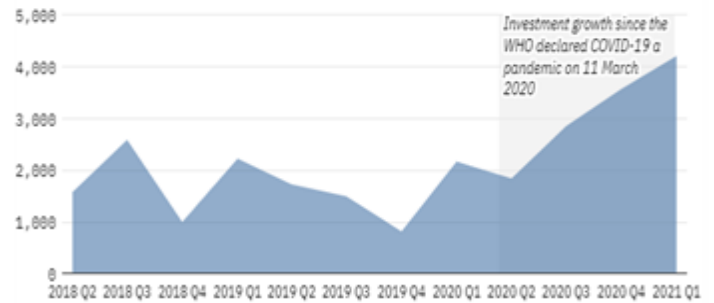


FIGURE 22. Quarterly global telehealth funding (2018-2021) in \$M.¹³⁴

- **Store and forward telemedicine or asynchronous Telemedicine.** In this type of Telemedicine, patient information such as medical images or bio-signals can be sent to the specialist as needed when it has been acquired from the patient.¹³⁶ It is regarded as the acquisition and storing of clinical information such as lab reports, data, images, sound, and videos that are then forwarded to (or retrieved by) another site for clinical evaluation.¹²²
- **Real-time video or synchronous Telemedicine.** In this type of Telemedicine, consultations use video conferencing to connect the patient with the physician. Patients from their homes can use smartphones, tablets, or computers to interact with physicians. This method enables the physician to conduct a medical consultation as they would in person.¹²²
- **Remote monitoring telemedicine.** This uses a range of technological devices to remotely monitor a patient's health and clinical signs. This is extensively used in the management of chronic diseases such as cardiovascular disease, diabetes mellitus, and asthma.¹³⁶

The key challenges hindering the growth of Telemedicine are system development costs, digital literacy, Digital Technology Acceptance, less accurate diagnosis for specific images transmitted with Telemedicine concerning the original images, aspects linked to security and confidentiality in the doctor-patient relationship through appropriate interfaces, and system implementation by the involvement of different parties.^{132,137}

Although Telemedicine has many challenges to overcome, there are also opportunities to sustain its development. They include gap service coverage (for example, in the USA, teleradiology predominates other services), urgent

service coverage (a case of a mobile telemedicine system for consulting acute stroke even remotely by employing a wireless LAN or a mobile phone network), and video-enabled multisite group chart rounds (model of medical education linked to clinical care).^{138,139}

Big Data

The healthcare landscape is saturated with a large, diversified amount of data. Big Data in healthcare is overwhelming because of its volume and the diversity of data types, and the speed at which it must be managed.¹⁴⁰ Those data could be an enabling resource for deriving insights for improving care delivery and reducing waste.¹⁴¹ Over more than a decade, as in other industries, the medical industry has experienced rapid digitization due to an increase in electronic medical records (EMR).¹⁴²

Driven by mandatory requirements and the potential to improve the quality of healthcare delivery and obtain the best healthcare services meanwhile reducing the costs, requires a significant diversified quantity of electronic health records to help in clinical decision support, disease surveillance, and population health management.^{140,143}

Big Data should be collected and used to ensure agreements between patients, healthcare service providers, and policy and research. Today, there is no common definition to explain what Big Data is. However, some researchers tried to formulate the meaning of Big Data. According to McKinsey the term “Big Data” refers to “datasets whose size is beyond the ability of typical database software tools to capture, store, manage, and analyze.”¹⁴⁴ Big data is unmanageable using traditional software. We need technically advanced applications and software to employ fast and cost-efficient high-end computational power to utilize it properly. The term Big Data is described by the following characteristics: value, volume, velocity, variety, veracity, and variability, denoted as the 6 “Vs”.¹⁴³

According to some studies have shown that 93% of healthcare organizations have experienced a data breach because personal data is extremely valuable and profitable on the black markets, and this pushed organizations to start using data analytics to help them prevent security threats by identifying changes in network traffic, or any other behavior that reflects a cyber-attack.¹⁴⁶

Big Data help to identify individual and community trends and develop better treatment plans or predict at-risk patients, forecast patient admissions trends and schedule the correct number of staff, drive innovation, compare chronic disease and population growth in neighborhoods, streamline insurance claims processes, easy detection of fraud and inventory tracking.¹⁴⁷ The global health data in 2013 only was estimated to be 153 Exabytes, with forecast potential growth to 2,314 Exabytes in 2020 alone.¹³⁵

Big Data analytics are divided into four categories:

- **Descriptive analytics.** This consists in decrying the current situation and reporting on it.
- **Diagnostic analytics** aim to explain why certain events occurred and what factors triggered them.
- **Predictive analytics.** This reflects the ability to predict future events; it also helps identify trends and determine probabilities of uncertain outcomes.
- **Prescriptive analytics.** This proposes suitable actions leading to optimal decision-making.¹⁴⁸

The global Big Data analytics in healthcare market size was valued at \$16.87 billion in 2017 and is projected to reach \$67.⁸² billion by 2025, growing at a CAGR of 19.1% from 2018 to 2025.¹⁴⁹

The nine stages that make analyzed data useful are shown in Figure 23. Big Data come from clinical practices and research, patient-generated data, medical claims, electronic healthcare records, social media, patient summaries, genomic and pharmaceutical data, clinical trials, Telemedicine, mobile apps, sensors, and information on wellbeing, behavior, and socio-economic indicators.^{142,144} Big Data are used in medical services to gain advantages as shown in Figure 24, and Big Data architecture for healthcare is presented in Figure 25.

The Big Data analysis ensures that the health facility manager sees a big picture of the hospital, the attendance, its nature, the costs incurred, etc., which will help run it smoothly. An example of a dynamic dashboard for patient care is shown in Figure 26.¹⁴⁶ The challenges facing Big Data technology are: segmentation of data in healthcare providers (clinical data, financial data, administrative data, patient data are not linked and shared), protection

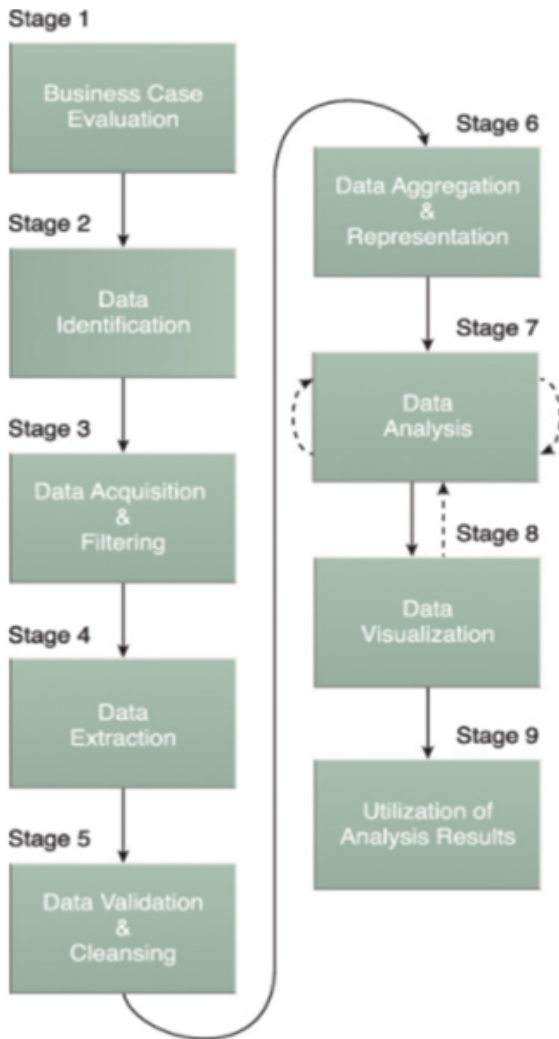


FIGURE 23. The nine stages of the Big Data analytics lifecycle.¹⁵⁰

of patient’s privacy,¹⁵¹ data capturing, cleaning and storage, stewarding and querying.^{152,153}

There are several challenges in adopting Big Data technology: data in many health care providers are often segmented or siloed, complicated use Big Data is complicated, long system response time.^{151,154} The key players in healthcare data analytics include IBM, Cerner, Health catalyst, McKesson, Oracle.¹⁵⁵

CONCLUSION

In conclusion, driven by needed increases in medical productivity, the growing prevalence of chronicling diseases, the increasing aging population, and the increasing



FIGURE 24. Application areas of Big Data technology in medicine.¹⁴⁶

emphasis by healthcare agencies towards early diagnosis and treatment, many countries and healthcare providers are struggling to scale-up technology level to provide adequate services to patients. In addition, physicians themselves believe in introducing new technologies to help them prevent, diagnose, treat, monitor, and care for patients.

Technology advancement has proven effective in providing access to information, facilitating remote care, improving efficiency by connecting the patients with physicians, cost-effective and time-saving solutions. Medical technologies encompass data centers, medical devices, software, drugs, IT services, public clouds, cyber-security, communication services, surgical procedures, and Internet of things.

The medical technology market is growing fast in Asia, with different and bulky products available on almost all global markets. As a result, the global market for medical devices only is projected to grow from USD 455.34 billion in 2021 to USD 657.98 billion in 2028.

The key challenges humping the development of medical technology are biomedical complexity, standardization, cybersecurity and data privacy, higher starting costs, and regulatory and environmental consideration.

The revolution of healthcare technology applications in medical services requires knowledge and skills in assessment, planning, procurement, inventory management, installation, and maintenance. Therefore, healthcare providers need to be watchful about Healthcare Technology

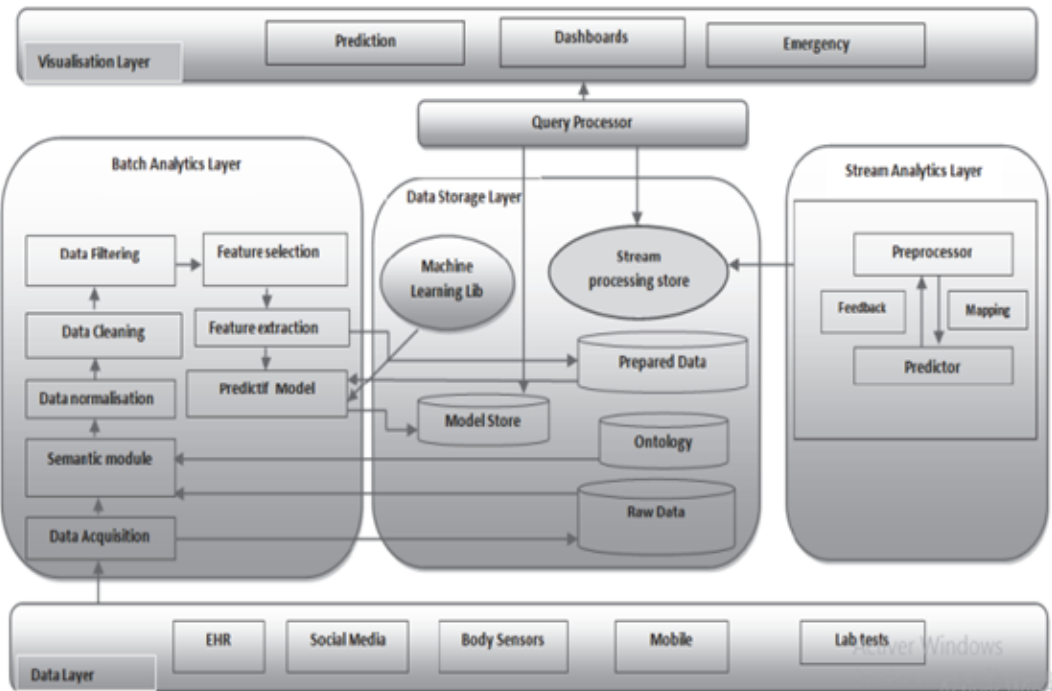


FIGURE 25. Big Data architecture for health system.¹⁴⁸

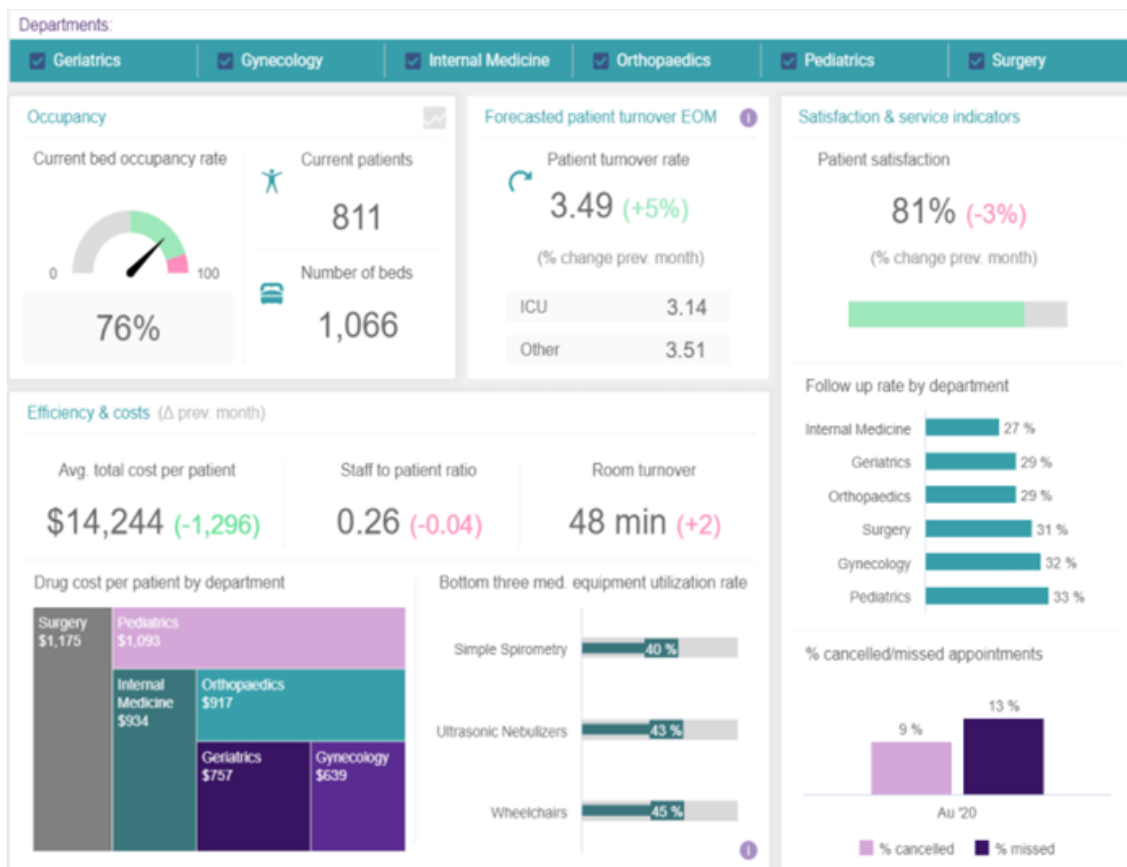


FIGURE 25. Big Data architecture for health system.¹⁴⁸

Assessment (HTA) to ensure evidence about safety, effectiveness, relevance, technology outcomes, and alternative technologies when running a particular technology. HTA is a multidisciplinary process that summarizes information about the medical, social, economic, and ethical issues related to using health technology systematically, transparent, unbiased, and robustly.

According to World Health Organization, only 70 countries worldwide have a National Agency or committee that provides HTA reports to the Ministry of Health, among which only 3 countries come from Africa (Benin, Mali and South Africa). Governments are therefore encouraged to adopt HTA programs because they provide information to support decisions about priorities in healthcare. Furthermore, HTA involves different parties, including patients' experience, caregivers, policymakers, physicians, HTA agencies, clinical engineering industry representatives, payers, pharma groups, and finance managers.

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Clinical Engineering Role in the Development of Emergency Use Medical Devices

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ABSTRACT

Clinical Engineering (CE) professionals have a crucial role in healthcare institutions during the pandemic caused by the COVID-19 disease, mainly by supporting the front line by allowing the proper and timely access to the medical equipment required to diagnose and treat patients affected. But another one of their roles, probably not so expected, has been their contributions to the development of emergency use medical devices, especially those for respiratory and oxygen therapy. Using the case of critical care use ventilators, and as presented during an IFMBE-CED webinar on the topic, this paper mentions the role of CE for the rapid response manufacturing of such vital care devices in three main aspects: development, regulation, and education. The results from such efforts have paid off by having safe and efficient support equipment while the shortage from commercial products has been receding, by establishing international guidelines for future innovators to take into consideration, and by leaving valuable knowledge in the form of educational and training videos for future generations to consult from.

Keywords – *Clinical engineering, medical devices, ventilators, pandemic.*

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INTRODUCTION

COVID-19 pandemic put healthcare and industry systems to the test, and it has been evident that healthcare professionals and workers were in the middle of it all. CEs were no exception, and their responsibilities doubled as they were required to look after the medical technology needs of front-line workers and the rest of the clinical services personnel. CEs did not hesitate when new challenges required their skilled efforts. For example, early in the pandemic expansion, there was a shortage of several types of medical devices needed for respiratory and oxygen therapy, and one, in particular, was the

most in-demand – ventilators for critical care units. As it became clear that the industry was struggling to cope with the shortage, several technical groups, including academia, professional organizations, and non-medical devices companies, started their own efforts to build locally produced ventilators. However, they soon realized that it was necessary to consult CE professionals with expertise in this vital equipment's use, technical specifications, safety considerations, and normative and regulatory concerns. This collaboration focused on three

main areas: contributions to the design and development of ventilators, health regulation considerations, and education and training.

Clinical Engineering Role in the Development of Medical Devices

Medical device design and development is no easy task, especially with equipment that operates using mechanical, electrical, electronic, and pneumatic components, such as vital support devices like ventilators. Many of the initial initiatives were non-invasive ventilation mechanisms that certainly couldn't comply with safety and performance standards, and that's where CEs entered the scene to help with the efforts. CEs contributed to the manufacturing of locally produced, emergency use ventilators with actions such including:

- Putting engineering knowledge and skills together with the development of the devices.
- Helping companies, academia, researchers, and investors to identify clinical needs and the right normative and tech specs for this type of device.
- Testing the prototypes and finished products through the proper metrology practices.

Clinical Engineering Role in Health Regulation

No matter how urgent the need for a medical device may be, the authorization process must be approved by a competent health regulatory authority because such a device needs to prove its safety and efficacy. In the pandemic, authorities understood that they had to offer fast-tracking processes without losing their objectives related to the emergency use authorizations. Once again, CEs stepped up as the connection between the regulatory process and unexperienced ventilators developers with some of the following interventions:

- Identifying international standards and normative and best practices to establish a local, applicable normative.
- Developing technical specifications for local production based on established specifications but adjusting as necessary for a proper response.
- Support WHO/PAHO efforts for worldwide use guidelines and other relevant technical documentation.

Clinical Engineering Role in Education

Because of their multidisciplinary approach, clinical engineers are well known as skilled trainers and educators, and this aptitude has helped share knowledge and experiences regarding the manufacturing, principles, operation, care, and safety topics for critical care use ventilators. In a world that was forced to social distancing, the use of web-based meeting platforms was rightly exploited for these purposes of education and training, something that clinical engineers used in the form of: (1) webinars on diverse topics related to patient ventilators, (2) training courses on manufacturing and standards applications, and (3) calls with other health professionals around the globe to exchange knowledge and experiences.

One prime example of the noble and vital role of knowledge sharing has been the efforts from IFMBE-CED, which right away began with organizing and offering relevant webinars, with helping hands from experts from all corners of the World and with a variety of topics regarding clinical engineering approach for the pandemic.

CONCLUSIONS

CE has been evolving almost at the same pace as medical devices increase in complexity, from participating in service and safety checks, going through integral management, and even collaborating with policymaking at a national health system level. These evolving skills now can cover research, innovation, and development of medical devices, and the pressing circumstances of the COVID pandemic just set the stage for clinical engineers worldwide to showcase such abilities. The challenge now is to write down the experiences in scientific papers and pass the knowledge to younger generations because the inertia to strengthen these skills shouldn't be subjected only to health emergencies. There is a lot of health technology yet to be discovered.

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Analysis and Solution of Dental Unit Failure

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ABSTRACT

Objective: To discuss and analyze the common causes of dental unit failures and summarize maintenance experiences.

Methods: The failures were studied through retrospective analysis in our dental clinic from January 2019 to December 2019. Causes for four common failures were analyzed deeply, and the corresponding improvement solution was implemented.

Results: These solutions reduced the failure rate for dental units and improved understanding of the importance of using and maintaining the equipment correctly.

Conclusion: Analysing and improving proper maintenance can save costs for the hospital and effectively enhance the management level of medical equipment maintenance.

Keywords – *dental unit, failure, solution, maintenance.*

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INTRODUCTION

With the improvement of people's living standards and the enhancement of oral health awareness, oral health has been paid more and more attention. The dental clinic of most domestic hospitals is often overcrowded, and the number of patients treated every day is much higher than in some foreign hospitals. The dental unit is a piece of essential medical equipment in the clinic. Since the establishment of Binjiang Hospital, 30 A-DEC dental units, including 4 A-DEC 500 units and 26 A-DEC 300

units, have been introduced and installed. With preventive maintenance and emergency repair by hospital engineers', they run stably. As we all know, dental units are generally composed of a dental chair, delivery system, cuspidor, and support center, dental light, etc. The schematic diagram is shown in Figure 1.

The structure of dental unit is complex and includes a waterway, electrical circuits, and gas circuits. During the

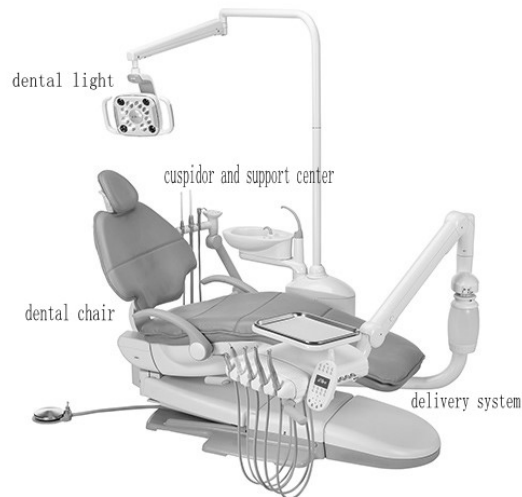


FIGURE 1. The schematic diagram of dental units.

installation of the dental units, dealers generally recommend that the hospital use an independent water storage tank with pure water or a treated centralized water supply as oral treatment water. The hospital should use oil-free and dry air, in which the pressure is not less than 80 psi to drive high-speed air-powered handpieces. Considering the actual diagnosis and treatment needs in China, most hospitals will choose a centralized water supply, and the water quality should meet the requirements of GB 5749-2006. After the dental units are installed, the hospital engineer will carefully check whether the functions of the equipment are normal and whether the accessories are consistent with the contract. However, many accessories may not be original but might be domestic accessories, so the service life cannot be accurately judged. During the use of the equipment, the manufacturer recommends preventive maintenance and regular replacement of some wearing parts. The hospital will also handle it according to the actual situation. To ensure the water quality of dental units, many domestic hospitals will regularly use sodium hypochlorite or other disinfectants to sanitize waterways. However, this solution will cause certain damage to the internal valve and pipeline of dental units and increase the failure rate, bringing some challenges to hospital engineers.¹

As a maintenance engineer, the author has been responsible for oral-related equipment maintenance work for many years and has accumulated rich experience in maintenance. In the following, the author summarized and analyzed the care of our hospital dental units by using

the A-dec brand as an example in recent years. From the engineers' point of view, the corresponding improvement measures were put forward to prevent and solve the common malfunctions for peer reference.

Fault statistics

According to the statistics, from January 2019 to December 2019, our hospital's dental unit received maintenance 780 times. Specific failure conditions are shown in Table 1 below. As can be seen from the table, the failure rate of dental units is relatively high in the waterways, electrical circuits, air circuits, and human factors. Particular failures include water pipe rupture, water valve failure, saliva ejector failure, and dental syringe accessories absence.²

METHODS

Cause Analysis and Solution of Four Common Failures

Replace worn parts and plug potential water leaks

The waterway is an essential part of the dental unit and provides the water supply during oral diagnosis and treatment. A water leakage problem is one of the most common malfunctions of the dental unit.

At the initial installation stage, the manufacturer equipped each unit with a water heater to heat the internal waterways. The structure of the heater was simple, the appearance of the heater was made of stainless steel, it was supplied by 24V power, and the material of the inlet and outlet water pipes was brittle. Therefore, it was common to see cracks that can lead to water leakage after 2-3 years of use. This phenomenon had a high failure rate. Engineers assessed the situation and determined that the water leakage problem was caused by unapproved material supplied by the manufacturer. So the engineer comprehensively checked all the pipes inside all the dental chairs, recorded the pipe diameter and length details, purchased approved water pipes, and replaced the water pipes at potential leakage risk one by one to prevent the occurrence. After monitoring over time, all dental units did not have a recurrence of the problem.

TABLE 1. Failure Statistical Table of Dental Units in 2019

Fault Classification	Fault Point	Fault Phenomenon	Fault Cause	Number of Cases	Proportion %	
Waterway	Delivery system	Handpiece drips water or no water	Handpiece failure	18	2.31	
			Water valve failure	38	4.87	
	Cuspidor and support center	Spittoon or gargle cup leakage water or no water	Heater leakage water	Water pipe rupture	19	2.43
			Solenoid valve failure	19	2.43	
				Circuit board failure	2	0.26
			Communication failure	21	2.69	
Cuspidor water contains air	Diaphragm rupture	22	2.82			
Circuit	Dental chair	Chair base can't move	Circuit board failure	2	0.25	
			Communication failure	13	1.67	
		Chair back can't move	Sensor failure	1	0.13	
	Delivery system	Handpieces failure	Panel error	Panel failure	22	2.82
			Pipeline rupture	32	4.10	
				Shelf valve loose	46	5.90
				Handpiece failure	15	1.92
				Circuit board failure	5	0.64
			Cuspidor and support center	No water	Solenoid valve failure	6
	Circuit board failure	4			0.51	
	Communication failure	15			1.92	
	Dental light	Cannot work	Bulb failure	12	1.54	
			Switch failure	3	0.38	
Gas Circuit	Delivery system	Handpiece failure	Handpiece lack of driving gas	5	0.64	
			Improper regulation	21	2.69	
			Handpiece failure	12	1.54	
			Water pipe rupture	31	3.97	
	Cuspidor and support center	No negative pressure	Small negative pressure	Saliva ejector failure	68	8.72
			Relay failure	5	0.64	
Human Causes	Delivery system	Plate tilt	Overuse	18	2.31	
			Handpiece failure	Incorrect setup	5	0.64
		Handpiece leakage water	Incorrect installation	7	0.90	
			Handpiece no Water	Panel incorrect setup	5	0.64
		Dental syringe leakage water	Water master switch off	12	1.54	
			Accessories absence	74	9.49	

Fault Classification	Fault Point	Fault Phenomenon	Fault Cause	Number of Cases	Proportion %
Human Causes	Dental chair	Armrest failure	External force	3	0.38
	Cuspidor and support center	Unreasonable Flush time	Incorrect setup	81	10.38
	Footswitch	Handpieces work automatically when lift	Footswitch failure	12	1.54
	Doctor's chair or assistant chair	The assistant chair sprang up	Hydraulic failure	59	7.56
		Back failure	Lack of parts	36	4.61

Improve the existing structure to ensure adequate disinfection and instrument integrity

The study showed that the water supply of the dental unit was seriously polluted due to multiple factors such as the suction effect of the treatment instruments and water stagnation, and regular disinfection of the water, which is vital in controlling nosocomial infections.³ Our hospital disinfects the water pipes of dental units every quarter. The Hospital Infection Management Department uses a 500 mg/L sodium hypochlorite solution to disinfect the lines. The medical staff in the department of stomatology discharge water on all the effluent parts of dental units one by one, and the continuous discharge time shall not be less than 10 minutes so that the disinfectant can flow out of each terminal effluent point, ensuring effective disinfection. However, the high concentration of this chlorine-containing disinfectant can corrode the internal structure of the dental unit, mainly the valve, rubber band, and diaphragm. Specifically, high-speed handpieces, low-speed handpieces, motors, and tooth cleaning machines hung on the valve after use will automatically leak water in varying degrees from spittoons and cup water spills.⁴ Looking back to 2019, this kind of failure frequently occurred about 3-5 days after each pipe disinfection, and several dental units leaked varying degrees.

Given this phenomenon, engineers searched for relevant information, consulted manufacturers, analyzed, and discussed the main reason for such failure. Specifically, the disinfectant had a particularly corrosive effect on the copper and rubber parts inside the dental unit. Specific damaged parts included water valve, solenoid valve assembly, diaphragm, etc. Considering the balance between disinfection effectiveness and the damage rate of the dental unit component, we proposed a preventive

strategy. After each disinfection, the nurse extended the discharge water time to 20 minutes on the day. Before starting the machine, the nurse discharged water for 10 minutes every morning for the next 5 days to remove the residual disinfectant in the pipeline and reduce the corrosion of the disinfectant on the dental unit parts. Because the discharge water at all the outlet points of the existing dental unit cannot be controlled with one key, and the discharge and disinfection time cannot be controlled, the medical staff need to discharge water manually, which undoubtedly increases the workload of medical staff.

For this reason, based on existing dental units, our engineers have added an automatic discharge water control device.⁵ This design has been authorized national utility model patent. The specific structure is shown in Figure 2 below.

The specific working process is as follows: firstly, select the knob above of the time relay to 10min, and then press

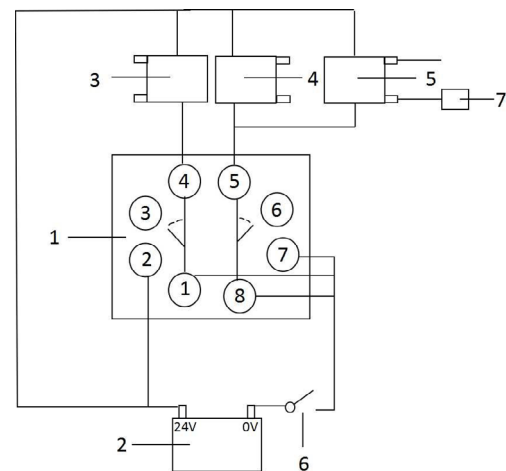


FIGURE 2. Structure drawing of automatic draw water control device.

the switch, the time relay starts the timing, the exhaust solenoid valve opens, the backup air of dental unit will open four water valves in the water and air control module, four handpieces will drain away water at the same time, the solenoid valve of cup water and spittoon water will open, and cup water and spittoon water will also drain away water at the same time. After the timing is over, Pin 1 and Pin 4 of the time relay will disconnect, Pin 1 and Pin 3 will pull, Pin 5 and Pin 8 will disconnect, and Pin 6 and Pin 8 will pull. The exhaust solenoid valve, cup water solenoid valve, and spittoon water solenoid valve will stop working, The water valves in the water and air control module are closed, and the handpieces will not drain away water. Cup water solenoid valve and spittoon water solenoid valve are closed, cup water and spittoon water will stop drain away water. The clinical use of the device can not only realize the one-button control discharge of water and effective disinfection at all outlet points of the dental unit, but control the time of water discharge and disinfection accurately. However, this will also reduce the workload of medical staff and improve the compliance of medical staff in daily waterway disinfection, which is of great significance to clinical diagnosis and treatment in the department of stomatology.

Do a good job of regular maintenance to reduce the occurrence of suction malfunction Attract tube

Oral suction has a high utilization rate in daily oral diagnosis and treatment, and the subsequent failure rate is relatively high. The suction tube absorbs a large amount of dental debris and blood in the patient's oral cavity every day, and the oral pollutants are discharged underground through a long and thin tube, which is prone to pipe obstruction or suction failure. The negative pressure pump in the center of the hospital generates suction, and the positioning valve on the dental unit controls the start and stop of the negative pressure. Then the doctor can attract the patient's mouth through the suction tube to remove the dirt in the mouth. The main fault phenomena in the use process are suction pipe obstruction resulting in reduced suction, pipe aging rupture resulting in insufficient suction, positioning valve failure resulting in no negative pressure. If the suction malfunctions, it will negatively impact the doctor. For this kind of problem, engineers analyzed: (1) the high frequency of use, and

(2) the lack of effective maintenance of the dental unit. Notably, medical staff only knew the use but did not know the regular maintenance for the suction tube.⁶ For this reason, the engineer actively communicated with the users of the equipment and formulated a routine maintenance items list for the dental chair according to the infection control guidelines recommended by the Centers for Disease Control and Prevention of the United States and the Australian Dental Association,⁷ as well as the manufacturer's maintenance manual. The guidelines were implemented in April 2020, and relevant records were made. The specific contents are shown in Table 2.

Strengthen medical education to prevent the loss of dental syringe accessories

Each dental unit in our hospital is equipped with a

TABLE 2. Routine Maintenance Items List of Dental Units in Dental Clinics

Project	Content	Maintenance Frequency
Suction tube	After use, draw clean water and rinse for 1 min	Once per person
	After treatment, detergent was attracted for 3 min	Once per day
	Clean suction tube solid strainer	Two times per week
Handpieces	Flush the pipeline for 2-3 min	Daily before use
	Flush waterway for 20-30 sec	Between each patient
Spittoon and mouthwash cup stand	Rinse and wipe	Between each patient

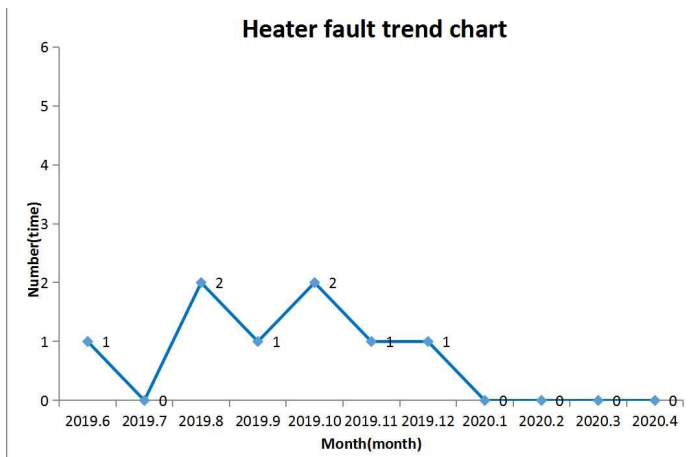
three-use spray gun for the doctor and a three-use spray gun for the assistant. Engineers often receive repair calls during daily use, such as leaking or unusable dental syringes. After careful observation of the use and malfunction of the three-use gun in the oral clinic, it was found that most malfunctions were caused by the absence of accessories. Engineers analyzed such problems mainly due to improper operation of medical staff and insufficient understanding of the spray gun structural components. Prevention measures could be taken from two aspects: First, strengthen the education and training of medical

staff. The engineer communicated with the director of the department using the equipment and organized training on daily use and other matters of attention with the dental unit. This ensures that the medical staff can understand the structure of the dental unit, be familiar with the structure of the three-use gun, master the daily disassembly and assembly, and put the three-use gun into the daily inventory list. The nurse at each position was responsible for checking the related accessories of each tooth chair and reported if anything was missing.⁸ Second, engineers should strengthen regular inspection and prepare relevant accessories as needed.

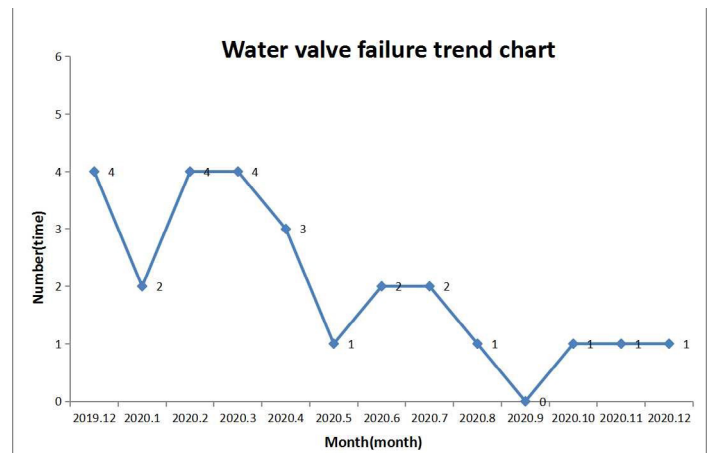
RESULTS

Since the beginning of 2020, engineers have purchased and replaced all the internal pipes of our dental units to

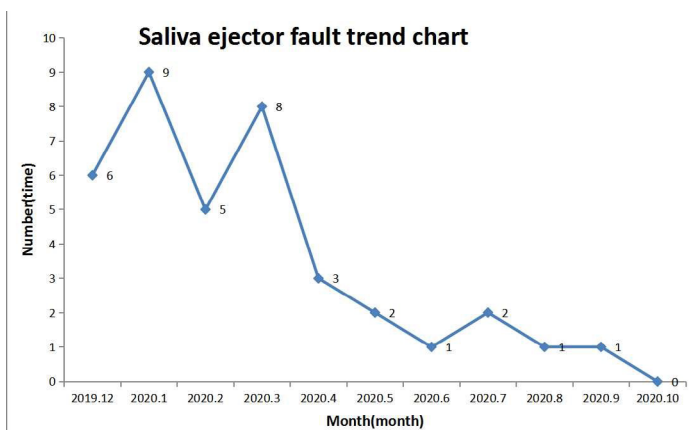
prevent water leakage from the heater. Figure 3 (a) shows the heater failure trend, and the number of failures is reduced to zero. After the dental unit pipes are disinfected, the failure rate of water valves are significantly reduced, and water valves replacement costs are saved through the installation of automatic discharge water control device and the implementation of relevant measures. Figure 3 (b) is the failure trend diagram of the water valve. Since the routine maintenance items list of the dental unit was implemented in April 2020, the saliva ejector's failure rate has decreased significantly. Figure 3 (c) shows the trend chart of the failure rate of the saliva ejector. In addition, since the management of the dental syringe was strengthened in May 2020, the failure rate of the dental syringe decreased significantly. Figure 3 (d) shows the failure trend of the dental syringe.



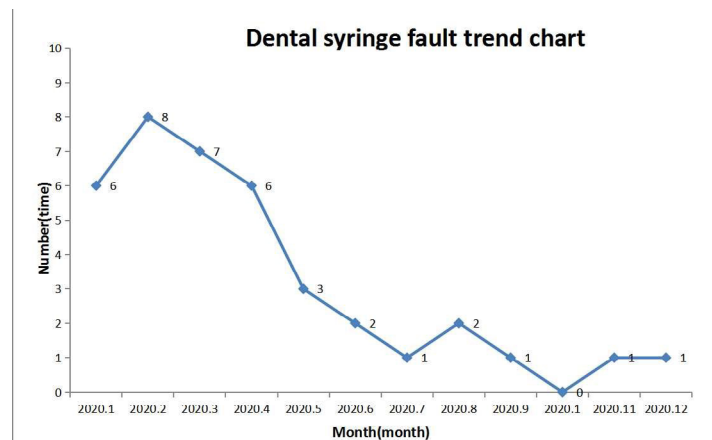
3(a). Heater fault trend chart



3(b). Water valve failure trend chart



3(c). Saliva ejector fault trend chart



3(d). Dental syringe fault trend chart

FIGURE 3. Chart showing the different kinds of fault trends before and after improvement measures.

Although the daily maintenance will increase a certain amount of work and maintenance time, it can effectively reduce the downtime of dental unit failure, reduce the number of repairs, reduce the repair expenditure, prolong the service life of the equipment, and improve the quality of clinical diagnosis and treatment. Comparison of items before and after maintenance are shown in Table 3. Among them, the average downtime was based on the time of failure to treat patients caused by each repair, and the average maintenance time was based on the time spent to complete the maintenance project. The average number of repairs was based on the number of repairs per dental unit in a year. The repair cost mainly includes replacing the water valve, saliva ejector, and position valve. The average repair expenditure was based on the repair expenditure per dental unit in one year.

TABLE 3. Comparison of Items Before and After Maintenance

Items	Before Maintenance	After Maintenance
Average downtime/ min	20±5	5±2
Average maintenance time/ min	3±1	30±3
Average number of repairs/time	26±1	5±1
Average repair expenditure/ ¥	353±3	13±3

DISCUSSION

In this paper, by sorting out the common failure cases of the dental unit and selecting several typical problems with a high failure rate, the causes of the failures are deeply analyzed, and the corrective measures are put forward.⁹ The reasons for each failure type are analyzed from different perspectives in these cases, such as failing to replace wearing parts in time, inadequate equipment maintenance, incorrect operation, etc. There is also the question of balancing the requirements of hospital disinfection with the damage of dental unit components. Finally, engineers put forward the improvement schemes from their own point of view. The practice has proved that our dental units are running well, and the failure rate of several typical malfunctions is obviously reduced.

CONCLUSIONS

Maintenance engineers not only need to deal with daily failures but also need to deeply analyze the causes of failures and how to prevent similar failures. Medical engineers and technicians should use their professional knowledge to make appropriate innovations and feasible improvements to the existing equipment to solve the current problems.¹⁰ In the context of the current advanced management of medical equipment, engineers should improve their maintenance concepts, transform their experience into practical maintenance practices, and use information technology and quality management methods to improve medical equipment maintenance.¹¹

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CONFLICT OF INTEREST

The authors declare that they have no conflict of interest.

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