

Exploring the process of deep integration of medical testing and clinical care

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Abstract. With the rapid development of science and technology and medical technology, the development of medical testing technology is on the fast track and is becoming increasingly integrated into clinical care. This phenomenon has revolutionized the medical profession, but at the same time, the pitfalls This paper examines the process of integrating medical testing and clinical care in depth, discusses the current state of This paper examines the process of integrating medical testing and clinical care in depth, discusses the current state of integration and makes recommendations accordingly.

Keywords: medical testing technology; clinical care research; Ispr.

1. Background

The testing industry was first established in Europe over two hundred years ago, mainly for the testing of goods in the maritime industry. With social progress and economic development, the requirements of society as a whole for living standards, product quality, safety conditions and environmental protection have increased, and the testing industry has gradually expanded its scope and spread out of Europe into the daily lives of countries around the world. With the good development our economy has achieved in recent years, the level of life security of our people has been steadily increased. This increase in life security has prompted an increased concern for their own health situation. The fast-paced work and the increasing pressure of life, enjoying the dividends of convenience brought by society, while people's health is threatened to a certain extent by overload, medical testing has come into being. The emergence and application of medical tests helps people to keep abreast of their health conditions and can provide accurate information and more time for the treatment of diseases, providing targeted treatment plans for the stages of the disease and safeguarding people's health.

The emergence of a new coronavirus (SARS-CoV-2) in early 2020 has shown us how indispensable medical testing technology can be in the detection and control of disease. Due to the highly infectious and lethal nature of SARS-CoV-2, testing for it using rapid, accurate and convenient diagnostic methods is key to detecting the source of infection, interrupting the chain of disease transmission and thus preventing and controlling outbreaks [1]. Several nucleic acid detection methods for SARS-CoV-2 are available, including polymerase chain reaction (PCR), loop-mediated isothermal amplification, and CRISPR/Cas systems [2-5]. However, all of these pathogen detection methods are time-consuming, inefficient and have low specificity for serum antibody detection [6]. Therefore, there is a greater clinical need for a shorter, more specific and more sensitive nucleic acid detection method.

In addition to this, medical testing is an important tool for assessing health conditions and monitoring the treatment process. Clinical medical testing technology has become one of the main research components in the current medical field. In the light of the reality of our large population base and therefore the relatively high demand for clinical medical testing technology, it is of profound significance to improve and develop clinical medical testing technology in China [7].

In this paper, we explore both medical testing and its integration into the clinical setting, and then present various aspects to predict future developments and make recommendations.

2. Overview of medical testing

Medical testing comprises two main components, medical testing equipment and medical testing technology, which work in harmony with each other to drive the medical industry forward.

2.1 Medical testing equipment

Medical testing equipment is a process in which people in the medical environment, in production, experimentation, research, use, maintenance and other areas, with the help of specialised relevant instruments and equipment, timely use of relevant medical testing equipment to obtain the measured (controlled object) of the work and to carry out real-time or non-real-time qualitative detection and measurement and the issuance of test reports. In the course of its use, medical testing equipment needs to be constantly tested and evaluated to ensure that it works properly and that the results of medical testing are optimised.

As the key carrier of medical testing, medical testing equipment involves a wide range of technical fields, industry span, professionalism and a wide variety, and is now increasingly used in the prevention, diagnosis, treatment, monitoring, rehabilitation and other medical and health fields. Common medical testing equipment in hospitals include blood cell analyser, urine analyser, biochemical analyser, haemorheometer, luminometer, enzyme immunoassay, plate washer, glycated haemoglobin meter, electrolyte analyser, biological safety cabinet, centrifuge, microscope, water purifier, UPS, autoclave, medical refrigerator, etc. Medical testing equipment plays a huge role in biomedical aspects from routine blood and urine testing to microscopic view of cell and tissue culture.

2.2 Examples of medical testing equipment and related technology over the ages

2.2.1 Blood cell analyser

Blood cell counting is the most routine test in the laboratory. The traditional manual method is to use different cell dilutions for each cell counted and then count them manually using a cell counting plate. This manual counting method is time consuming and laborious. Since the introduction of the first blood cell divider over 50 years, the performance of the blood cell analyser has been greatly improved, and has been achieved by multi-reference testing, automated testing.

2.2.2 PCR instrument

PCR, or Polymerase Chain Reaction, is a simple and effective method for the rapid amplification of specific DNA fragments, which has revolutionised genetic diagnostic techniques and has seen rapid development in clinical applications. With the advent of real-time fluorescence PCR, PCR technology has entered a new phase where it has evolved from the previous qualitative or semi-quantitative experiments to quantitative experiments where the results are analysed through the collection of fluorescent signals. In addition, the assay is monitored in real time by fluorescence and therefore avoids the influence of the reaction plateau period on the results.

2.2.3 High throughput detection instruments

In the mid to late 1990s, high-throughput testing technology represented by biochips emerged in the biomedical field and was described as one of the world's top 10 technological advances in 1998. Multiple tests that previously required multiple devices to complete were expected to be completed by a single chip. After the application value of biochip technology was discovered, the state and

relevant ministries and commissions invested a lot of human and material resources in the research of multiple application areas of biochips. A variety of protein detection chips and gene detection chips are currently being used in clinical applications [8].

Studies have been conducted to determine the diagnostic efficacy of tests for patients with COPD combined with community-acquired pneumonia by high-throughput detection gene chips, and have demonstrated greater validity than clinical tests [9].

2.2.4 Local Surface Plasmon Resonance (LSPR)

The localised surface plasmon resonance (LSPR) effect is an optical property unique to metallic nanoparticles. In recent years, with the rise and development of nanotechnology, metal nanoparticles have received much attention for their unique electromagnetic, optical and mechanical properties for applications in sensing platforms. With the rise of nanotechnology, biosensors based on the localised surface plasmon resonance effect generated by precious metal nanoparticles have become a hot topic for research and application in the field of detection sensing due to their high potential in the field of detection. With its sharp spectral absorption, scattering peaks, enhanced electromagnetic fields, tunable spectra in the visible range and high absorption coefficients, local surface plasmon resonance is emerging as an excellent new chromogenic substrate, playing an important role in photocatalysis, chip fabrication and biomedicine. At the same time the high spatial localisation of the local surface plasma gives it a more significant energy enhancement effect in the local space, so the LSPR biosensor has the advantages of small device size and low cost while retaining the characteristics of high sensitivity, high selectivity, real time and label free of SPR sensors.

According to existing studies, LSPR-related technologies have been applied to antigen-antibody detection systems, nucleic acid detection systems, and enzyme-related detection systems. For the antigen-antibody detection system, Vakili et al. used lipopolysaccharide (LPS) extracted from *Brucella* sheep and *Brucella* bovis as an antigen immobilised on the surface of AuNP to detect anti-*Brucella* antibodies in human serum with a positive predictive value of 100%; the LSPR-based detection strategy was able to distinguish between infected and uninfected individuals. Moreover, the LSPR assay was chosen for its high selectivity, sensitivity and reproducibility [10]. For nucleic acid detection systems, Li et al. constructed an AuNP-DNA probe to visualize point mutations in the K-ras gene of colon cancer [11], and Yoo et al. used a multi-focus AuNP array chip to achieve highly sensitive detection of BIGH3 point mutations in corneal dystrophy-associated genes [12]. And for an enzyme-related monitoring system, Martín-Barreiro et al. designed an LSPR sensor to detect L-phenylalanine concentration using the principle that L-amino acid oxidase catalyzes the oxidative deamination of L-phenylalanine to generate hydrogen peroxide [13].

And in response to the widespread epidemics of various emerging viruses around the world since 2003, which have caused substantial public safety and socioeconomic losses, such as the Zika virus (ZIKV) outbreak in 2014 and the ongoing SARS-CoV-2 epidemic [14,15]. Huang et al. developed an LSPR-based nano-plasma array sensing chip with a surface modified by SARS-CoV-2-specific antibodies, which can detect SARS-CoV-2 virus particles down to 370 vp/mL within 15 min, allowing for fast and effective detection of the virus [16].

The above illustrations demonstrate that LSPR-related technologies are also used to varying degrees in medical applications and can provide examples for future medical applications of LSPR.

2.3 Medical detection technology

Lymphocyte testing is a technique that uses medical testing equipment to analyse various secretions (blood, urine, faeces) from the human body, compare the results with normal levels and analyse changes in the balance of substances in the body (e.g. the level of white blood cells in the blood, the leukocyte). It is a more accurate and widely used technique to assist clinicians in making diagnoses. Medical laboratory technology is the study of basic knowledge and skills in chemistry, basic medicine, clinical testing and other aspects of clinical testing, health testing and pathology testing in primary health care institutions, blood stations and disease control centres.

In recent years microwave detection techniques have been widely used in medical device testing and consist of three main methods: radiographic detection, infiltration and eddy current detection. The cleaning of medical devices is a key focus of the inspection technology, the cleanliness of the cleaning directly affects the preservation and life of the medical device as well as the accuracy of the inspection, commonly used methods include visual inspection, occult blood test, residual protein monitoring method, etc.

With the development of medical testing technology, traditional testing methods can no longer meet the current requirements for accuracy, and the trend is to combine network information technology with medical testing technology. A mature network information management system provides real-time monitoring of medical equipment testing, effects, etc., and plays a more comprehensive and accurate role. At present, many medical testing institutions in China have introduced information technology systems to improve the effectiveness of testing and greatly promote the development of the medical device industry [17].

2.4 Current status of medical testing at home and abroad

At present, the development of domestic medical testing equipment is relatively late compared to developed countries, the level of technology is in the exploration stage, medical equipment products in the volume of more inclined to large and medium-sized, cost-effective, to ensure the quality of medical testing equipment, service life and service to a wide range of people need, the market share is higher. Self-service medical testing instruments are smaller in size, but the demand for technology is higher, and the range they can detect is less compared to large and medium volume devices but their accuracy and portability are substantially improved, so they have a lower share in the market. The current medical testing products in domestic hospitals contain: height, weight, body fat content, blood pressure, blood oxygen, blood sugar, electrocardiogram, bone density, uric acid, etc. The testing equipment is able to carry out health analysis based on the test results. In terms of health management, medical testing technology is associated with the internet, and through communication facilities such as personal computers or mobile phones connected to the testing equipment, personal health data and health analysis are obtained, while health testing, remote consultation and intelligent supervision are achieved through mobile phones. At present, the domestic medical testing market is equipped with infrared or ultrasonic sign measurement technology, blood oxygen non-invasive sensing measurement technology, infrared body temperature measurement technology, and the processing of information by the Internet of Things [18].

Foreign medical examination technology has a long history of development, in developed countries and regions in the higher economic conditions and technical level, has established a more mature set of digital medical system containing health - medical - insurance. In terms of medical check-ups it is even more important to make appointments in advance and to actively and regularly follow up on the physical condition of the person being examined, rather than waiting for the person to be passively tested, which facilitates the early detection of abnormal changes in the body and the intervention of treatment methods. In terms of medical testing products, there are many small home-based devices and some personal health monitoring products that track the user's condition in real time, while there are relatively few large and medium-sized medical testing products designed for welfare purposes [19].

In a vertical comparison of domestic and foreign medical testing, China started late but is developing at a faster pace and can catch up with many western countries in terms of medical testing; while foreign countries have the advantage of earlier development of medical standards, which promotes the continuous updating of medical testing technology, and the level of medical testing at home and abroad is now similar. In a side-by-side comparison, the US has the advantage of strong domestic demand, increasing internationalisation and a social environment that is conducive to innovation [20].

3. Medical testing and clinical integration

In the second half of the 17th century, the chemical detection of protein, bilirubin, etc. in urine represented the birth of "clinical chemistry". The invention of the first microscope by Levin Hooke ushered in the era of cytological and microbiological tests. The earliest medical tests were often performed by clinicians and did not yet form a separate discipline, all tests were simple and manual until 1887, when George Dock established the first dedicated clinical laboratory in history at the University Hospital in Philadelphia. This meant that medical testing officially became a separate discipline.

In the 1950s, Coulter's invention of the resistive resistance method microparticle technique for blood cell counting and Skeggs' invention of the single-channel and multi-channel continuous flow biochemistry analyser (manufactured by Technicon in the USA) marked the beginning of modern, automated laboratory medicine. In the modern era of widespread internet and rapid information development, there have been remarkable developments in the automation, informatisation and intelligence of testing equipment, the quality of practitioners and the philosophy and practice of quality management.

The start of laboratory medicine in China was later than that in Europe and the United States, and the first clinical biochemical testing courses were offered in the Department of Biochemistry of the Union Medical College in the 1920s; from the 1930s to the 1940s, medical testing laboratories were established in some hospitals in China; from the 1980s, semi-automatic and fully automatic testing equipment was introduced; around 2000, with the development of the national economy, the laboratory conditions and hardware equipment in the testing departments of large general hospitals and hardware equipment have been continuously improved, and have now basically reached or approached the level of medical testing departments in large foreign general hospitals [21].

In recent years, the medical and health care industry has received policy dividends, from the "Health China 2030" planning outline to the "General Office of the State Council on promoting the development of "Internet + medical health" and many other documents are providing support for the healthy development of the medical and health care industry. The "Medical and Health Industry 2022 The 2022 Action Plan for the Medical and Health Care Industry and the Implementation Opinions on Accelerating the Innovative Development of Medical Education in Shandong clearly point out that we should actively support the development of "new medical science" and the cultivation of "new medical science" talents, and vigorously promote the development of multiple disciplines within medical science as well as medical engineering, medical science and medical literature. In this context, medical testing equipment is the most important part of the medical education system. In this context, the integration of medical testing equipment and clinical care has ushered in an opportunity for deeper development.

China from the 1990s began to gradually independent research and development and production of medical testing equipment, and has made great strides in development. However, with the improvement of people's living standards, the demand for medical testing equipment is also increasing. According to statistics, the consumption ratio of medical equipment to drugs in China at this stage is about 1:10, indicating that there is a big gap between China and medical equipment at this stage, and the quantity of medical testing equipment cannot meet the needs of clinical care. Made in China 2025" also pointed out that the innovation ability and industrialization level of medical equipment should be improved, focusing on the development of imaging equipment, medical robots and other high-performance diagnosis and treatment equipment. At present, many of China's domestic medical testing equipment has also reached the international leading level, and the combination with clinical care is becoming closer and closer, but there is still the problem that the combination of production, learning and research is not close enough. At present, the enthusiasm of domestic clinicians to participate in the research and development of medical equipment is not high enough, while in foreign countries the enthusiasm of clinicians to participate in the research and development of medical products is very high. According to statistics, 45% of the new medical products launched by major pharmaceutical companies in the United States are jointly completed by clinical and

pharmaceutical companies [22]. It shows that the transformation chain of China's industry-university-research has not yet been formed, the results of research cannot well dovetail with clinical needs, and the products and technologies of enterprises cannot really meet the clinical care needs of hospitals at this stage. The reason for this is that, on the one hand, clinicians and enterprises or relevant institutions have not reached a long-term effective exchange and cooperation mechanism, and many clinical care needs have not been truly transformed into products by enterprises, and on the other hand, limited by China's industrial On the other hand, due to the level of industrial development in China, some fine equipment cannot be put into production or the effect cannot meet expectations, which hinders further technological innovation.

4. The impact and significance of combining medical testing with clinical care

In the area of medical testing equipment, as the integration with the clinic gradually deepens, more subdivided fields and their respective leading enterprises have emerged, such as Nanmicro Medical for endoscopic diagnostic and treatment instruments, Sanno Bio for blood glucose monitoring, and Lepu Medical for cardiovascular field. The more detailed division of labour in the field has on the one hand improved the efficiency of enterprises and reduced their labour time and conversion costs, while on the other hand, technological innovation in equipment has brought about a qualitative leap in clinical treatment, especially in departments that rely on changes in equipment and materials, and cutting-edge medical testing equipment is better able to meet the clinical needs of patients. At the same time, the integration of medical testing equipment and clinical care has further promoted the informatization and intelligence of medical equipment. The introduction of high-throughput clinical testing equipment, rapid bedside testing, molecular diagnostic equipment and automated microbiological testing systems has enabled medical testing to extend from medical institutions to patients' homes, forming a personalized, digital clinical treatment model centred on patients' needs and largely alleviating the This has largely alleviated the problem of "difficulty in accessing medical care".

The continuous refinement of medical testing levels can provide more accurate data for clinicians' diagnosis and treatment. A medical testing equipment management system based on artificial intelligence and 5G communication has been built in Shandong Province. This system can help solve problems such as communication delays between medical equipment and slow processing of data, effectively improving the efficiency and accuracy of doctors in diagnosing the causes of patients' diseases [23].

The concept of integration can be applied to the development of medical devices currently used in clinical practice, mainly through functional, spatial and equipment intensification. It is possible to make a single device with multiple functions and to achieve the purpose of intensive design of medical testing devices by accumulating and complementing related functions [24]. The size of a medical testing device can be reduced to allow for some reconfiguration and movement of different individuals within a range [25]. Or by forming several large parts of the instrumentation equipment for different purposes according to different spatial characteristics and functions. Efficiency is increased while costs are reduced [26].

The integration of medical testing equipment with clinical care will, on the one hand, promote the renewal of medical testing equipment in China and, on the other hand, better meet the requirements of clinical care. The integration of medical testing equipment with clinical care will enable testing equipment that is more relevant to the clinical needs of patients, making clinical testing more convenient and efficient, better meeting the growing needs of the people for a better life, and at the same time promoting the development of domestic medical testing equipment, thereby increasing the cost of medical institutions in terms of equipment and medical costs for patients, and promoting the benign development of the industry.

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