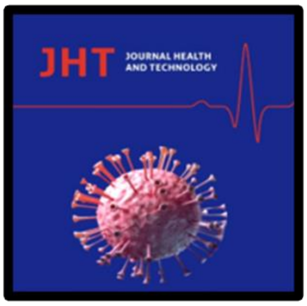

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THE TECHNOLOGICAL EVOLUTION OF FETAL MONITORING IN PREGNANCY CARE

A EVOLUÇÃO TECNOLÓGICA DO ACOMPANHAMENTO FETAL NA ASSISTÊNCIA À GRAVIDEZ

LA EVOLUCIÓN TECNOLÓGICA DEL SEGUIMIENTO FETAL EN LA ATENCIÓN DEL EMBARAZO

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ABSTRACT
The current context of medical activity demands from obstetricians a broad understanding of the scientific and technological advances. The objective of this article is to reveal the historical evolution of medical practices and technology in a particular field of health, namely the health of the fetus and the medical practices of its follow-up, in the face of the enormous technological advances that have occurred in the supply of cross-cutting technologies with potential use in this particular field. The methodology used was a non-systematic bibliographic review carried out in scientific journals in the medical field, and for the interpretation of the material collected, the approach of sectoral innovation system was adopted, which can be defined as a network of agents that interact in a specific technological field. The main results of the research show that over the centuries, with the advancement of technology, new equipment has been proposed to eliminate the limitations of interobserver interpretation, thus allowing new multicenter randomized studies. Furthermore, it has become clear that the health crisis caused by the Coronavirus limited, broke, and disrupted face-to-face care in all medical fields and served as a springboard for accelerating the use of electronic systems and artificial intelligence in medical care. And finally, it can be observed that the process of technological diffusion encounters several tensions between those who defend remote prenatal care and those who have aversion or distrust towards modernization, excessive medical conservatism, lack of regulation on the subject, and ethical issues that limit its advances.

KEYWORDS: Perinatal mortality. Fetal distress. Telemedicine. Medical technology.

RESUMO
O contexto atual da atividade médica exige dos obstetras uma ampla compreensão dos avanços científicos e tecnológicos. O objetivo deste artigo é revelar a evolução histórica das práticas médicas e da tecnologia em um determinado campo da saúde, a saber, a saúde do feto e as práticas médicas de seu acompanhamento, diante dos enormes avanços tecnológicos ocorridos no fornecimento de tecnologias transversais com potencial uso neste campo específico. A metodologia utilizada foi uma revisão bibliográfica não sistemática realizada em periódicos científicos da área médica e, para a

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interpretação do material coletado, adotou-se a abordagem do sistema setorial de inovação, que pode ser definido como uma rede de agentes que interagem em um campo tecnológico específico. Os principais resultados da pesquisa mostram que, ao longo dos séculos, com o avanço da tecnologia, novos equipamentos têm sido propostos para eliminar as limitações da interpretação inter observador, permitindo novos estudos randomizados multicêntricos. Além disso, ficou claro que a crise de saúde causada pelo Coronavírus limitou, quebrou e interrompeu o atendimento presencial em todos os campos médicos e serviu de trampolim para acelerar o uso de sistemas eletrônicos e inteligência artificial na assistência médica. E, por fim, observa-se que o processo de difusão tecnológica encontra diversas tensões entre as que defendem o pré-natal remoto e as que têm aversão ou desconfiança em relação à modernização, ao conservadorismo médico excessivo, à falta de regulação sobre o tema e a questões éticas que limitam seus avanços.

PALAVRAS-CHAVE: Mortalidade perinatal. Sofrimento fetal. Telemedicina. Tecnologia médica.

RESUMEN
El contexto actual de la actividad médica exige de los obstetras una amplia comprensión de los avances científicos y tecnológicos. El objetivo de este artículo es revelar la evolución histórica de las prácticas médicas y la tecnología en un campo particular de la salud, a saber, la salud del feto y las prácticas médicas de su seguimiento, frente a los enormes avances tecnológicos que se han producido en el suministro de tecnologías transversales con uso potencial en este campo en particular. La metodología utilizada fue una revisión bibliográfica no sistemática realizada en revistas científicas del campo médico, y para la interpretación del material recogido se adoptó el enfoque del sistema de innovación sectorial, que puede definirse como una red de agentes que interactúan en un campo tecnológico específico. Los principales resultados de la investigación muestran que a lo largo de los siglos, con el avance de la tecnología, se han propuesto nuevos equipos para eliminar las limitaciones de la interpretación interobservador, permitiendo así nuevos estudios aleatorios multicéntricos. Además, ha quedado claro que la crisis sanitaria causada por el Coronavirus limitó, rompió e interrumpió la atención presencial en todos los campos médicos y sirvió como trampolín para acelerar el uso de sistemas electrónicos e inteligencia artificial en la atención médica. Y finalmente, se puede observar que el proceso de difusión tecnológica encuentra varias tensiones entre quienes defienden la atención prenatal remota y quienes tienen aversión o desconfianza hacia la modernización, excesivo conservadurismo médico, falta de regulación sobre el tema y cuestiones éticas que limitan sus avances.

PALABRAS CLAVE: Mortalidad perinatal. Sufrimiento fetal. Telemedicina. Tecnología médica.

INTRODUCTION

The acceleration of paradigmatic changes since the end of World War II has provoked a process of transformation and constant innovation also in health. It is possible to observe a great evolution in medical therapies and in the emergence of techniques, instruments and diagnostic resources that are used today and that were not known seventy years ago or more. Each year, new knowledge and health products become available, driven by the waves of innovations made possible by the paradigms of information and communication technologies and biotechnology, which emerged in the 1970s.

However, the factors that influence the dynamics of incorporation of these new therapies and technologies, that is, their diffusion, are mainly influenced by the demand and supply of the technology. On the one hand, the advancement of scientific medical knowledge demands new technologies, and, on the other hand, the advance of technological knowledge allows the creation of devices that facilitate the practice of new medical therapies. Underlying these forces are the desire to provide wellness in health, and national and international biomedical research.

Although the diversity of evolution patterns and technological advances, as well as their incorporation in the health sector, is explained by innovations in products and services, their variety and different times of diffusion in medical practice are the result of different, and often conflicting, views of the actors and interests that operate within a specific technological field.

The objective of this article is to reveal the historical evolution of medical practices and technology in a particular field of health, namely the health of the fetus and the medical practices of its follow-up, in view of the enormous technological advances that have occurred in the offer of transversal technologies with the potential to be used in that particular field.

The article is structured in four sections, in addition to this Introduction and Conclusion. The first section presents the research methodology and the theoretical framework through which the bibliographic references collected were analyzed. The second section presents the first observations related to fetal health, as well as pioneering inventions. In the third section, the focus is on the emergence of new technologies driven by paradigmatic advances in information and communication technologies. Finally, in the fourth section, the results are discussed.

1 METODOLOGY

The methodology is exploratory and descriptive of a particular field of the health sector. The object of study is the evolution of medical practices and technologies used for the well-being of fetal health during the period of pregnancy, that is, the monitoring of fetal health.

The main research instrument was the non-systematic literature review carried out in scientific journals in the medical field. The search was conducted in the CAPES Periodical Database between April 8, 2021, and September 25, 2021.

For the interpretation of the material collected, the approach of sectoral innovation system was adopted, which can be defined as a network of agents that interact in a specific technological field – in this case, the health sector – has a particular institutional infrastructure with the objective of generating, disseminating, and using technology (MALERBA, 2002). Specifically in health, there is a great proximity between the agents who produce science and technology. These agents, in turn, are influenced by macro policies and their impact on public and private health institutional arrangements, funding and support institutions, physical infrastructure, current ethical and cultural norms, and an adequate regulatory framework. These are some of the factors that condition the supply and demand of health technology and its diffusion (HASENCLEVER et al., 2011) and that will be considered in the bibliographic references collected.

v.1, n.4, 2022

JOURNAL HEALTH AND TECHNOLOGY - JHT
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2 THE BEGINNINGS OF THE EVOLUTION OF FETAL HEALTH

The history of fetal well-being assessment begins in 1650, when Marsac, in France, reports to his friend Philippe LeGaust, hearing the fetal heartbeat when placing his ear under the abdomen of a pregnant woman. Apparently, the discovery was transmitted orally, as no written documents of his authorship have been preserved (STEER, 2014).

Only in 1818, François Mayor (1779-1854), a Swiss surgeon, reports the auscultation of intrauterine fetal heartbeats by immediate/direct auscultation, placing his ear under the abdomen of a pregnant woman (RIBEMONT-DESSAIGNES; LEPAGE, 1923).

In 1821, the French physician René Laënnec (1871-1826) invented the stethoscope, a device that consisted of a wooden tube with a trumpet-shaped end that made contact with the chest. The air-filled cavity transmitted sounds from the patient's body to the doctor's ear. Jacques-Alexandre Le Jumeau, Viscount of Kergaradec (1787-1877), Breton disciple of Laënnec, was the first to use the new invention in auscultation of the abdomen of pregnant women. He presented the results of his research to the Royal Academy of Medicine in Paris on December 26, 1821, under the title Memory on Auscultation Applied to the Study of Pregnancy.

Laënnec's success turned Paris into a stetoacoustic training center, however, despite the advance, acceptance of his ideas in France was delayed, due to aversion or distrust towards change/modernization (misonism) and excessive medical conservatism (SARAVÍ, 2014).

In 1876, Adolphe Pinard (Figure 1), a French obstetrician, invented a specific device based on the stethoscope created by Laënnec for the auscultation of pregnant women that bears his name, the Pinard stethoscope, and continues to be used for obstetric auscultation, almost 140 years after his invention (SARAVÍ, 2014).

Figure 1 - Photo of Adolphe Pinard's (1844-1934), French obstetrician born in Méry-sur-Seine

Source: Wikiwand, 2021.

Auscultation of fetal heart beats, in addition to monitoring fetal movements – *MOBILOGRAMA* (BRASIL, 2012), remained for more than a century as the primary form of fetal health assessment available to healthcare professionals.

Fetal movements have long been recognized as an important biological index to estimate the status of a fetus (MANNING; PLATT; SIPOS, 1980). Fetal movement counting is a method by which a woman quantifies the movements she feels to assess the condition of her baby. The aim is to try to reduce perinatal mortality by alerting caregivers when the baby may be compromised.

Fetal movement counting can allow the clinician to make appropriate interventions in a timely manner to improve outcomes. On the other hand, fetal movement counting can cause unnecessary anxiety to pregnant women or lead to unnecessary interventions (MANGESI; HOFMEYR; SMITH, 2007), being subjective and not suitable for long periods (HOFMEYR; NOVIKOVA, 2012).

However, despite being a simple method, which can be used by the mother without the need for a doctor or equipment, it has been abandoned in the practice of prenatal care and replaced by new apparently more efficient technologies, which use sophisticated devices and allow recording documentation, whether recording fetal movements, fetal heartbeats or their sum, giving the physician the impression of better control (PEREIRA, 1999).

Thus, throughout the 19th century, many new ways of monitoring the condition of fetal well-being emerged, such as cardiotocography (ALFIREVIC, 2006; GRIVELL, 2010; PATTISON, 2010). Cardiotocography is a method frequently used to assess fetal well-being, based on the analysis of graphic records of fetal heart rate and uterine tone/uterine contraction (NOMURA, 2009).

Resting cardiotocography before delivery is the most used modality in prenatal care because it is easy to apply and does not present additional risks to the health of the mother and the child. It is usually used from the 28th week of gestation, as it depends on the maturity of the fetal autonomic nervous system, which regulates the fetal heart rate. This maturity gradually increases with the advancement of pregnancy, improving the interpretation of the cardiotocographic tracing (NOMURA, 2009).

In an attempt to reduce false positives on cardiotocography (altered exam), fetal stimulation was introduced. This fetal stimulation can be vibroacoustic (sonic stimulus) or mechanical (movement of the cephalic pole), with the objective of changing the fetal sleep state to the waking state. Along with the technological evolution promoted by computers, in 1978, computerized cardiotocography, which is still little used in Brazilian obstetrics services, appears (NOMURA, 2009).

Another technological advance in the medical diagnostic field was the emergence of ultrasound. The research of the Austrian physician Karl Theodore Dussik (1908-1968), published in 1941, entitled *Über die möglichkeit hochfrequente mechanische schwingungen als diagnostisches hilfsmittel zu verwerten* (On the possibility of using high-frequency mechanical vibrations as a diagnostic tool), which provided the first technical information on the use of this technology for medical diagnosis (WHO, 2015).

During and after World War II, the use of ultrasound as a diagnostic tool greatly expanded, progressing along with imaging technology and signal enhancement and new ways of interpreting and displaying data. Ultrasonography, in Brazilian medicine, began in the 1970s, as a new professional field, mainly linked to obstetric ultrasound, with the first ultrasound device arriving in 1973, in Recife/PE (HUGO, 2012). Over the last few decades, ultrasound has become a device of paramount importance, reaching its apex in fetal assessment, with the use of color flow mapping – dopplervelocimetry (CHAZAN, 2008).

When each method of assessing fetal well-being is analyzed in terms of its positive and negative aspects, there is the assessment of fetal movement - FM, which has advantages because it is a free method and performed by pregnant women under medical supervision. It can be done without going to the medical service, this being the only exam that does not require the aid of equipment. As a disadvantage, the MF count can cause anxiety in pregnant women, leading to other tests, such as cardiotocography and medical interventions. In addition, pregnant women may not be able to perceive MF, but the absence of MF reported by the pregnant woman is an important point to be observed, and it is necessary to assess fetal vitality by another more reliable method such as cardiotocography (COSTA; GADELHA; LIMA, 2009).

Cardiotocography can be used during pregnancy. Here, considering cardiotocography before delivery, it has the advantage of reducing perinatal hospitalizations and interventions, but it does not reduce perinatal fetal morbidity and mortality. Cardiotocography can be augmented by the vibroacoustic stimulus, literally "a bicycle horn", which reduces the fetal sleep period, reducing the time to perform the exam, cardiotocography and false positives (COSTA et al., 2009).

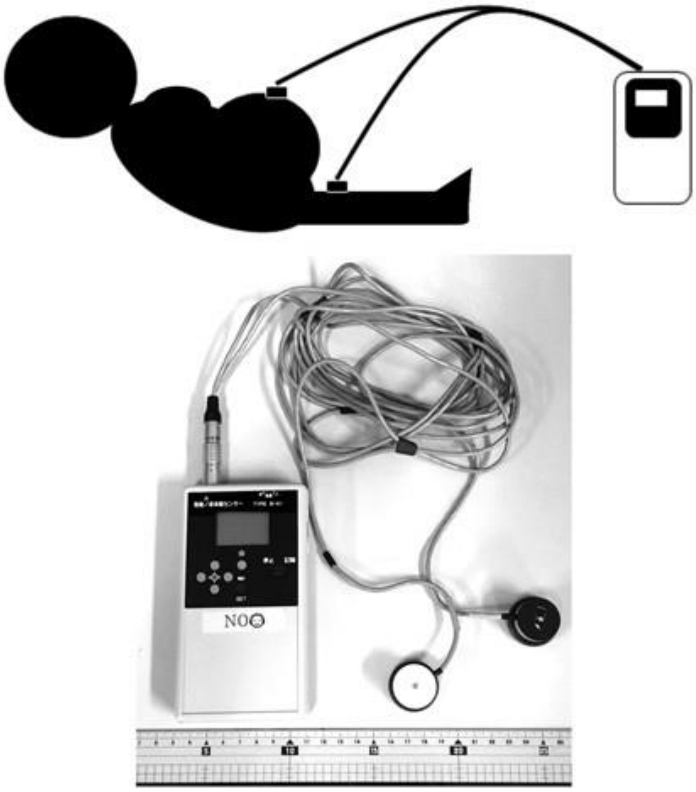
With the introduction of ultrasonography and later color mapping - Doppler, to assess fetal well-being, a reduction in fetal mortality was obtained, especially when used in pregnancies that present some maternal or fetal risk (COSTA et al., 2009). However, as a disadvantage, it might require a specific high-cost device and a trained professional to perform it, limiting its dissemination throughout the national territory.

Within this evolutionary analysis of care for pregnant women and the assessment of fetal well-being, with the objective of reducing fetal and perinatal mortality, the use of telemedicine for fetal assessment is currently being experienced. Pilot projects have been presented for joint remote evaluation of the pregnant woman and the fetus (SCHRAMN et al., 2018), with the proposal of decentralizing specialized obstetric care, serving populations that have in their territory a limiting factor to access tertiary centers, a reduction in the cost of prenatal care, as well as greater coverage of the same and, perhaps, will decrease fetal mortality and perinatal.

3 NEW TECHNOLOGIES FOR FETAL MONITORING: WHERE ARE WE AND WHERE ARE WE GOING?

In 2009, in Japan, a study group was established to identify the best way to promote fetal well-being by analyzing fetal movements recorded mainly during the night at home (F-MAM SOCIETY, 2021). For this purpose, a new patented fetal movement recording device was developed (Figure 2), in which a sensor is attached to the pregnant woman's abdomen to detect fetal movements. These data are recorded and later analyzed by a program/computer (RYO et al., 2012).

Figure 2 - Fetal Movement Acceleration Measurement Recorder



Source: Ryo *et al.,* 2012.

The way fetal movements and heartbeats are monitored has evolved over the years and, in 2015, after studies and incubation at the University of Nottingham, the company Monica Healthcare, through Catapult Ventures (WACKER-GUSSMANN et al., 2018; Catapult-Centures, 2021), launches the wireless cardiotocography system. It was later acquired by General Electric, GE Healthcare department, for hospital use (GE HEALTHCARE, 2021; L'AULNOIT et al., 2018).

Following the same trend, Schramn et al., (2018) describe a case-control study dealing with the acceptance of a new non-invasive fetal monitoring system for telemedicine approaches in obstetrics, revealing positive feedback on remote self-monitoring, concluding that these new technologies may provide more options for prenatal care for patients in the future.

In 2020, Heuvel (2020) describes an innovative way to monitor "the fetal and maternal condition at home". A portable, wireless prenatal monitoring system, the Sense4Baby (Figure 3), is a mobile version of a prenatal cardiotocography (CTG) monitor.

> A Sense4Baby unit consists of a compact kit containing the following items: a transducer, a tocodynamometer, a pulse oximeter, a small tablet that displays the readings and accessories such as chargers, gel and maternity belts. This allows pregnant women and primary care obstetricians to perform their own CTGs (HCTS, 2021). The data is streamed to a cloud portal, and the hospital can view the data on the portal in real time or at a later time. The data can also be transmitted directly to the Hospital Information System or Electronic Patient Record through a link. This remote monitoring service gives pregnant women the benefit of a consulting doctor's medical expertise, without the hassle of having to travel to the hospital - or, in some cases, having to spend the night there (HEUVEL, 2020, p. 2).

Figure 3 - Sense4Baby – Remote Cardiotocography

Source: HCTS, 2021.

In the midst of the quest to improve the quality of prenatal care and, given the health crisis created by covid, discussions regarding the quality, supply and decentralization of obstetric care with the use of telemedicine are currently growing (TAGLIAFERRI et al., 2017). But the question that remains in relation to care for pregnant women is: how to monitor the fetus remotely to assess its well-being?

In times of a pandemic, social isolation and the urgent need to maintain medical care for pregnant women, it was thought, in response to this situation, of a form of remote fetal monitoring that allows fetal assessment by telemedicine (remote fetal assessment).

A digital form of maternal monitoring in the perinatal period, with the objective of improving the care and service provided to pregnant women and providing a reduction in fetal mortality rates, could be thought of based on Tagliaferi's idea (2017).

Our idea is to propose a utility model for this purpose. The model makes use of a support and support belt for pregnant women, already produced in the national market (Figure 4) and adds an extensometer (Esp32 microcontroller – Figure 5) on each side of the belt, a total of two extensometers. At the center, a vibracall device is used to allow the pregnant woman and/or the assistant physician to perform the vibrato-acoustic stimulus (described in the evolution of medical technologies) and to identify a reduction in fetal movements, allowing the pregnant woman to drive with more speed to the obstetric emergency to be examined, from the fetal sleep period (Figures 6 and 7).

Figure 4 - Utility Model Proposed Using Support Strap for Pregnant Women

Source: Artigos bebê, 2021.

JOURNAL HEALTH AND TECHNOLOGY - JHT
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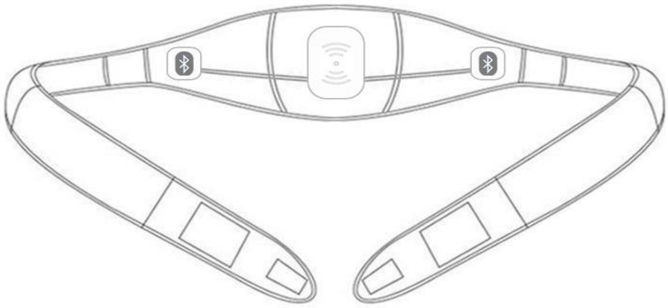
Figure 5 - Esp32 microcontroller



Source: Mercado Livre, 2021.

Figure 6 - Utility Model Prototype Design

Source: Developed by the authors together with the company Indutto, 2021.

Figure 7 - Design of Adaptation to the Pregnant Woman

Source: Developed by the authors together with the company Indutto, 2021.

ESP32 is a high-performance module for applications involving Wi-Fi (wireless connection), with very low power consumption. This board has the ESP8266 ESP32 chip (Esp32 microcontroller - Figure

5), with a built-in antenna, a usb-serial interface and a 3.3V voltage regulator. Programming can be done in LUA or using the Arduino IDE via a micro-usb cable. With 4 MB of flash memory, the ESP32 allows you to create various applications for IoT projects, remote access, webservers and dataloggers, among others.

Extensometers identify the deformation of the content, in this case, the gravid abdomen, which translates as fetal movement. The microphone to capture heartbeats would be left for a future version, due to the initial difficulty in obtaining resources for the development of the prototype and the technical difficulty in differentiating fetal and maternal heartbeats.

To absorb the generated radiation and avoid damage to the fetus and the pregnant woman, a microwave absorber based on resonant rubber will be used on the belt, as shown in Figure 8.

Figure 8 - Image of Resonant Rubber-Based Microwave Absorber

Source: Soliani EMC, 2021.

In addition to Wi-Fi technology, the proposed utility model will use an application for monitoring remotely, through a cell phone or tablet of the pregnant woman and/or health professional and/or health unit, in order to monitor and evaluate the fetal vitality.

4 DISCUSSION

According to Caetano and Vianna (2006, p. 109), the evolution described here in relation to fetal health can be summarized by the idea that, with the process of technological evolution accelerating more and more from the 1959 onwards, “Good Medicine could no longer be performed without the aid of state-of-the-art equipment and the request for a batch of complementary exams”. However, the adoption of technologies is not a linear process, as knowledge advances and new questions may arise. After the great enthusiasm with the introduction of fetal heart rate monitoring in obstetric practice in the mid-1980s, a series of randomized clinical trials began to question the effectiveness of fetal heart rate monitoring (HON, 1968).

An important aspect was the issue of reliable and reproducible interpretation of fetal heart rate (FHR) levels by health professionals. Several researchers have studied reliability and reproducibility. The results show that although there is general agreement in the patterns, the interobserver and intraobserver agreement is poor (PANETH; BOMMARITO; STRICKER, 1994).

The first randomized controlled trial on continuous electronic monitoring of FHR compared to periodic monitoring was carried out in 1976 and found no improvement in neonatal outcome with continuous monitoring of FHR, but an undesired adverse effect which was a significant increase in cesarean delivery (HAVERKAM et al., 1976).

Just as the auscultation of fetal heartbeats, initiated by Mayor and propagated by Kergaradec, led to the repulsion of the traditional medical society of the time, currently remote prenatal care has found strong opponents in academic circles and today this delay is associated with the absence of regulation and ethical issues to put into practice medical research using these new equipment/technologies.

Another point of view to be discussed is that the introduction of these new remote monitoring technologies presents the positive/beneficial and the negative/toxic sides of their medical implantation, going through a new moment of transition. A few years ago, telemedicine was taboo. It was not possible to attend to a pregnant woman or any patient without having contact with them, without being able to examine this patient.

The health crisis caused by the Coronavirus limited, stopped, broke with face-to-face care due to the need for social distance, and telemedicine, which was denied in 2018, is now seen as the salvation of health care, defended by those who until recently repudiated it. This shows that the pandemic had a very strong effect on changing behaviors and ended up accelerating the technological diffusion of telemedicine.

In addition, medical care, specifically care for pregnant women, evolved from a passive attitude, in which she received the treatment ordered by the "doctor" and fulfilled it, to a moment in which the pregnant woman and the doctor, together, make a shared decision, a new approach, shaping health care (BARTON et al., 2020), thanks to new remote monitoring technologies. And, in the very near future, with the introduction of artificial intelligence in healthcare, the world may be able to see the scenario where the patient and the doctor are guided by high technology.

FINAL CONSIDERATIONS

Medicine is on the way to breaking the barrier of distance for fetal monitoring and envisioning the decentralization and greater reach of care for pregnant women by highly specialized professionals in any part of the territory. As well as the way of monitoring fetal well-being, the way of caring for pregnant women and their adaptation to the use of new medical devices and utilities have also evolved over time.

With the advancement of technology, new tools, such as the use of electronic systems and artificial intelligence, have been proposed to eliminate the limitations of interobserver and intraobserver interpretation, thus allowing new multicenter randomized studies. The future of fetal heart monitoring has yet to be determined. As new technologies are introduced and biases eliminated, the FCF will be able to resume its past glory years.

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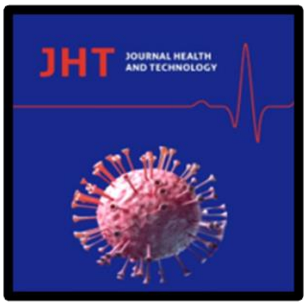

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