The use in developing countries is reimported to Japan
Mobile Fetal Monitor (iCTG) from Kagawa Prefecture recognized by WHO
～From use at individual medical institutions to networking of medical institutions in the entire region～

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Introduction

The United Nations has adopted the Sustainable Development Goals (SDGs), and 17 goals are to be achieved by 2030. SDG 3.1 is to reduce the global maternal mortality rate to less than 70 per 100,000. SDG 3.2 is to reduce the neonatal mortality rate in all countries to 12 and less per 1,000. In addition, United Nations Children's Fund, UNICEF, reports that 2 million unborn babies, one every 16 seconds, die before delivery each year in developing countries around the world. It is urgent assignment to reduce maternal, perinatal, and fetal deaths by improving pregnancy management.

As for other SDGs (e.g., carbon dioxide emissions), developed countries themselves have not yet achieved these goals, and both developed and developing countries need to make efforts to achieve them. On the other hand, Japan has already achieved the target value of SDGs 3 to a large extent. The world expects Japan to promote its excellent perinatal health care approach globally. The significant decrease in the perinatal mortality rate in Japan is due to progress in perinatal management of preterm and low birth weight infants, but also because of fetal monitoring from pregnancy to delivery at obstetric institutions throughout Japan. It is very important to promote the use of fetal monitoring in developing countries.

This paper describes the development of an ultra-compact mobile fetal monitor (iCTG), which is currently being introduced in Thailand, Myanmar, Bhutan, and other developing countries with the support of the Ministry of Internal Affairs and Communications, JICA, and United Nations Development Program, UNDP.

1. Basic Structure of Fetal Monitors and the Early Development of Mobile Fetal Monitors

Development of Fetal Monitors

Almost 50 years have already passed since the development and widespread use of fetal monitors. The central monitor is a device that continuously provides information on fetal heartbeats and uterine contractions of multiple pregnant women (hereinafter referred to as "fetal heartbeat information") to nurse stations in the hospital. However, the basic performance of the system is limited to the extent that it can be continuously monitored at a station. The fetal monitor using ultrasound consists of followings; a high-frequency oscillation circuit, a ceramic element that converts high-frequency wave into ultrasonic wave, a ceramic element that converts

reflected ultrasonic wave into high-frequency signal, a detection circuit that extracts the necessary information from the weak electrical signal, and the circuit that detects the heart rate from the resulting ultrasonic Doppler signal that is the most difficult part and that is to calculate the heart rate using the autocorrelation method, and a recording equipment that records the obtained heart rate on recording sheets of paper. With the advancement of semiconductors, it is relatively easy to miniaturize electronic circuits. However, even with the widespread use of electronic medical records, for some reason, long sheets of paper are still often used, preventing the miniaturization of devices.

More than 20 years ago, we developed a portable fetal monitor, approximately 2 kg, that eliminates the need for a recording device by displaying the fetal heart rate on an LCD screen. Initially, the information was sent over a telephone line (using an acoustic coupler). As digital communication emerges, and after the age of personal computer communication and the Internet, mobile networks were also used to send information. This is known as mobile CTG. This early stage mobile CTG was used by the loyal family, and in Tono City, Iwate Prefecture, Amami Oshima Island in Japan, and Chiang Mai, Thailand, and it received a very high evaluation.

In introducing fetal monitors to developing countries, we need to develop an ultra-compact mobile fetal monitor using the latest technology, and a network system to be used throughout the region.

2. Concept of developing an ultra-compact mobile fetal monitor (iCTG) using the latest technology

The rapid miniaturization and diffusion of mobile devices such as tablets and smartphones has since then led to the development of mobile fetal monitors. The mobile fetal monitor is also expected to be smaller than ever. We developed an ultra-compact fetal monitor (hereafter, iCTG) based on a completely new concept, without being bound by conventional technologies.

The concepts are listed below, and the most technically challenging part was to integrate analog and digital electronic circuits into the iCTG, and fit them into a transducer case.

(1) Mobile and cloud-based so that fetal heart rate can be sent from anywhere in the world.

(2) Fetal heart rate and uterine contractions will be recorded on a cloud server at the data center.

(3) Eliminate recording paper and realize a completely paperless system.

(4) The electronic circuitry of the basic part of the fetal monitor will be miniaturized, and fitted into the ultrasound transducers and labor pain transducers.

(5) The fetal heart rate and uterine contractions are displayed and connected to the Internet using a commercially available tablet.

(6) The ultrasound transducer and the tablet are connected by a Bluetooth connection.

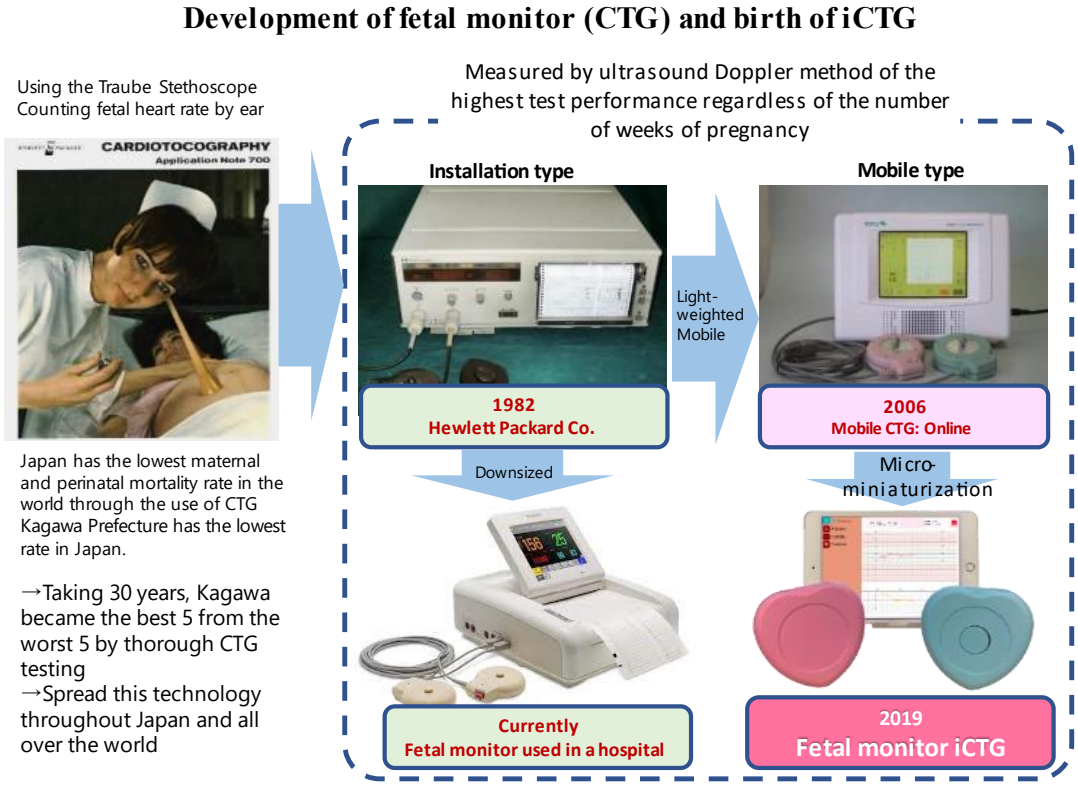
(7) A lithium-ion battery is used as the power source and the device will be cordless. (This will make it easier to use in developing countries where the power supply is unstable.)

3. The iCTG weighs about 1/50th of a conventional fetal monitor, but the heart rate detection accuracy is equal to or better than the conventional fetal monitor.

The iCTG consists of an ultrasound transducer to detect fetal heart rate, a labor pain transducer, and a tablet. The information transfer between the transducers and the tablet is

connected via Bluetooth. The information sent to the tablet is transmitted over Wi-Fi, 3G or 4G (LTE) mobile networks to a cloud server on the Internet and can be monitored in real time from the medical institutions. The fetal heart rate is transmitted and stored in a format based on the Japan Society of Obstetricians and Gynecologists (JSMG) fetal heart rate information file data format described below. The logic circuit of the autocorrelation has been further improved in terms of the accuracy of fetal heart rate detection.

The performance is equal to or better than that of conventional fetal monitors. The fetal monitors of the 1970s weighed more than 15 kg (including the cart), whereas the iCTG weighs about 300 g (including both transducers), which is almost 1/50th of the original weight (Fig. 1).



(Fig1) Fetal monitor weighed over 15 kg in 1970, whereas iCTG weighs about 300g, downsized to 1/50.

4. The need for a standardized method of transmitting and storing fetal heart rate and the Establishment of Japanese Society of Obstetricians and Gynecologists (JSMG) Fetal Heart.

Fetal Heart Rate Information File Data Format

The following is an explanation of the method of transmitting and storing fetal heart rate using a central monitor as an example. The signal is sent from the output terminal of the fetal monitor as a voltage signal (e.g., 1 V for 100 heartbeats, 2 V for 200 heartbeats, etc.). However, with voltage signals, the voltage drops over long distances, and AC noise from the outside tends to enter the signal. Therefore, nowadays, digital signals are used. However, even for digital signals, there are many systems in which digital signals are simply sent continuously. The signal itself does not contain information such as whose signals they are, what day, what time, what minute, what second, etc.

The data is recorded on the server with information such as whose signals they are, date and time, but the digital method and storage method differ from company to company. In addition, recently, information obtained from fetal monitors at multiple medical institutions is being collected at one location, and those servers are located within the medical institutions. Essentially, it is desirable to store the patient's name in the fetal monitor, weeks of gestation, date and time, etc., in a standardized format on cloud servers via Internet. A universal system can be realized by doing so.

The Committee on Information Systems of the Japanese Society of Obstetricians and Gynecologists (at that time) already proposed the standardization of fetal heart rate digitization in 1998. The proposal was approved by the Japanese Society of Obstetrics and Gynecology and the Japanese Society of Medical Informatics. When creating standardization plan, companies like Toitu, Atom Medical Corporation, and Yokogawa Hewlett-Packard (YHP), which were selling fetal monitors at the time, also approved the proposal for standardization.
(https://www.jstage.jst.go.jp/article/jami/20/2/20_143/_pdf/-char/en)

5. Establishment of Melody International, a university venture

The development of a medical device based on a completely new concept such as this, is very risky and it is difficult for existing companies to take on the challenge. Therefore, a new venture company, Melody International Inc. was established. The development of the ultra-compact mobile fetal monitor was carried out from design to commercialization in Kagawa Prefecture, which has the best perinatal mortality rate in Japan and the world. The main goal of the project is to promote the "Made in Kagawa" brand to the world. It is said that it is extremely difficult for a local start-up company to obtain certification from the national government to manufacture and sell medical devices. We are truly grateful for all the support we have received.

6. The introduction of mobile medical devices in developing countries is medically and socially significant

Initially, considerable difficulties were anticipated in introducing mobile medical devices to developing countries, but in fact the introduction went very smoothly. In developed countries, wired telecommunications were first installed nationwide over a long period of time, followed by ISDN, ADSL, and then optical fiber cable. Then, optical cables were introduced, and the speed of communication rapidly increased. The shift to mobile communications has also progressed rapidly, from i-mode to 3G, 4G (LTE), and recently to 5G (LTE), and use of smart phone is flourishing with use of 5G. In developing countries, on the other hand, where households had few wired telephones, the mobile environment was quickly developed, and smartphones have exploded into widespread use. Mobile calls and e-mails are of course useful, but the most valuable use of mobile phones is in the field of medical care. In addition, social significance is also high, as the effective use of mobile infrastructure with a huge budget will lead to a higher level of medical care. In this sense, it is fortunate that governments in developing countries, especially ministries of health and obstetricians, have shown interest in mobile fetal monitoring.

7. The excellent results of the use of iCTG in developing countries have led to its recognition as a WHO recommended medical device.

The purpose of the development of the mobile fetal monitor in Japan was to target pregnant women living in remote areas and high-risk pregnant women. In addition, obstetric care

providers throughout Japan were already using the mobile fetal monitoring system.

The conventional hospital-based fetal monitors are already well established in obstetric care facilities throughout Japan, so it was necessary to separate their use.

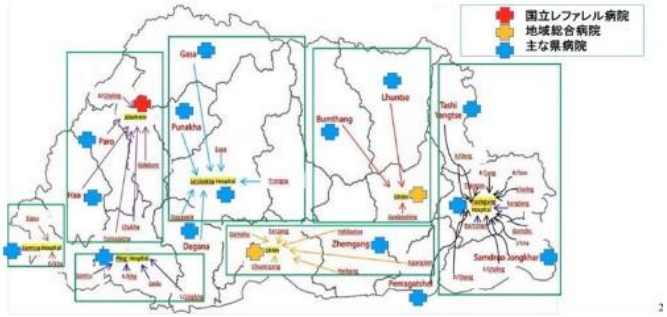
In developing countries, except for core hospitals, there are basically no fetal monitors in obstetric care facilities nationwide. As in the case of smartphones, which quickly spread without the era of fixed-line phones, there is no need to separate the two, and it is possible that all fetal monitors will be mobile. In distributing iCTG, it is often the case that physicians in urban core hospitals are the first to show interest and use it. However, priority should be given from the outset to clinics that handle pregnancies in rural areas. The diagnosis of fetal heart rate patterns should be performed by physicians at core hospitals who are experienced in the use of fetal monitors, taking advantage of the features of iCTG that can be used remotely. This will realize an efficient division of labor between core hospitals and local medical institutions.

Initially, due to budgetary constraints, the program will be started with only a few clinics. However, if the usefulness of iCTG is recognized, the system will be expanded to cover all clinics in the region. In fact, a JICA project in Chiang Mai, Thailand started with a university hospital and three maternity hospitals in remote areas and expanded to 25 medical institutions in the whole Chiang Mai province. The project has produced excellent results.

Coincidentally, at the same time, the Queen of Bhutan was pregnant with her second child and used iCTG. She liked it very much and strongly hoped that it would be used by women all over the country. The government of Bhutan was therefore introduced 55 sets of iCTGs in 46 hospitals in Bhutan with support of United Nations Development Program, UNDP and JICA, and the results were better than expected. Therefore, the iCTG system has been installed in JICA-supported project to additionally install 25 new sets of iCTGs (80 sets in total) in Bhutan. The project is scheduled to run for three years to cover Bhutan nationwide (Fig.2)

Introduction to Bhutan UNDP/JICA
Used for pregnancy management of the second child of the Queen of Bhutan

Queen of Bhutan uses it to manage second child's pregnancy



(Fig 2)

With support of UNDP and JICA, 55 sets of iCTG were introduced to Bhutan. Results were better than expected, and 25 more sets, a total of 80 sets were additionally introduced as JICA direct support project this year. Based on these achievements, iCTG has been recognized by the WHO as a new innovative medical technology and a recommended device. We consider that was a great honor.

8. Reimporting New Usage Patterns in Developing Countries Back to Japan

In developing countries, the mobile characteristics of iCTG can be used to network between core hospitals and local obstetric care facilities. In other words, it is a method to organically manage pregnancies in the entire region as a whole by connecting the core hospital and local obstetric institutions through a network. (i.e., the management of the entire region as a plane, rather than connecting local medical institutions on a point-to-point basis). In developing countries, transportation of patients is also frequent, so use of iCTG on the vehicles is also very important. The followings were found about the use of iCTG in developing countries. The use of iCTG throughout a region can accurately diagnose the condition of the fetus, and
cases transporting pregnant women to higher-level medical facilities before the condition of the fetus worsens increased. In addition, when transporting pregnant women, the condition of the fetus during transport is known, allowing the receiving medical institution to respond with more time to spare. As a result, the number of newborns in poor condition has decreased, which in turn has led to a decrease burden on neonatologists.

9. Easing of Deregulations of online medical services and Rapid Introduction of iCTG under COVID-19

In Japan, we stated that a distinction needs to be made between the use of conventional fetal monitoring and iCTG. However, the situation has changed drastically with the recent COVID-19 disaster, with the deregulation of online medical care and introduction of iCTG for pregnancy control increased nationwide.

Initially, iCTG was administered to pregnant women to prevent infection during their outpatient visits, and to reduce hospital visits by sending the baby's heartrate from home to the medical institution. In the case of pregnant women who were already infected (including those closely contacted women), pregnant women in infectious disease ward, hotels and other accommodations were remotely managed by medical institutions. Once online medical care becomes widespread, it is expected to become increasingly popular even after the end of the corona outbreak. The same is expected to be true for the remote management of pregnant women, not only in remote areas but also in urban areas.
iCTGs will be widespread throughout the country by then, facilitating the realization of a region-wide perinatal network.

Conclusion

The history of the development of the mobile fetal monitor (iCTG), its overseas deployment, and the standardization of the number of fetal heartbeats were reported. Pregnancy management methods for the entire region, which should have been realized in developed countries, are being realized first in developing countries. This means that the next step would be to reimport them. Japan should also introduce it as soon as possible, although it will be a form of back-importation. Kagawa Prefecture has the best perinatal results in the world, and since iCTG is a system developed in Kagawa Prefecture, so we

hope that a network integrating all obstetric institutions in Kagawa Prefecture will be realized.

(We sincerely appreciate the support of UNDP, JICA, and the Ministry of Internal Affairs and Communications.)