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**CURRENT STATUS OF SPERM AND OVUM DONATION IN  
INFERTILITY TREATMENT AND TEST RESULTS OF  
INFORMATION MANAGEMENT SOFTWARE  
AT ASSISTED REPRODUCTIVE FACILITIES**

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## **LIST OF PUBLISHED ARTICLES RELATED TO THE THESIS**

1. Nguyen Thi Huyen Linh, Le Hoai Chuong, Nguyen Thi Phuong Lien, Do Quan Ha (2019), "Describing the current situation of donating and receiving ovum and sperm at reproductive support centers in 2018", *Medical Magazine Preventive learning, Volume 29, No. 13 - 2019.*
2. Nguyen Thi Huyen Linh, Le Hoai Chuong, Nguyen Thi Phuong Lien, (2020), "Overview of legal issues related to sperm donation", *Journal of Preventive Medicine, Vol. 30, No. 10 - 2020. Special issue of the scientific conference on graduate students of the Central Institute of Hygiene and Epidemiology.*
3. Nguyen Thi Huyen Linh, Le Hoai Chuong, Nguyen Thi Phuong Lien (2023) "Methods and tools for managing sperm and oocyte donors and recipients at 23 hospitals with fertility departments/centers in 2018" *Journal of Preventive Medicine, Volume 33, Number 2 – 2023, pages 30-40*
4. Nguyen Thi Huyen Linh, Le Hoai Chuong, Bui Viet Anh, Nguyen Thi Phuong Lien (2023) "Effective application of information technology in managing sperm donation and receipt and oocyte donation and receipt at 3 support centers fertility in 2018" *Journal of Preventive Medicine, Volume 33, No. 2 – 2023, pages 21-29*

## **ĐẶT VẤN ĐỀ**

The need for infertile couples to donate eggs and sperm is increasing. Faced with urgent needs in the field of reproductive support, countries around the world and Vietnam have developed and issued regulations to manage sperm and oocyte donors and recipients. Regulations include, limiting the number of children born from one donor, managing genetic diseases, sexually transmitted diseases... Decree 10/2015/ND-CP 28/1/2015 states the regulations Specific regulations on sperm and oocyte donation and reporting information and storage and sharing of information stipulate that the donation, receipt, and storage of sperm and oocyte must be encrypted and entered into the database system. common, used nationwide. The current situation of information technology at hospitals recognizes that although hospitals have applied information technology to hospital management, the application of information technology has only brought certain effectiveness. The software only meets basic management needs. The software does not have the ability to connect to exchange data, leading to information having to be entered many times for different software. Lack of a comprehensive software [19].

Objectives of the study:

- (1) Describe the current situation of sperm and oocyte donation in infertility treatment at assisted reproductive facilities in 2018.
- (2) Describe the current status of sperm and oocyte donation information management at assisted reproduction facilities in 2018
- (3) Evaluate the results of testing software for managing sperm and oocyte donation information at three assisted reproduction facilities in 2018.

### ***New scientific points and practical value of the topic***

The results of the study show that the current situation of donating, receiving and managing donor information, receiving sperm and oocytes in infertility treatment at assisted reproductive facilities does not meet the management needs, and has no part. General management software to screen and identify donors and recipients; not yet guaranteed to comply with the instructions on regulations on donating, receiving and managing donors, receiving sperm and oocytes in Decree 10/2015/ND-CP.

Sperm and oocyte donation management software is built based on the results of research on the current status of sperm and oocyte donation management at target 2. Results of testing the management software at 3 hospitals show that the software Meet management needs to comply with instructions in Decree 10/2015ND-CP. The software is highly accepted by the facility, is feasible in terms of the facility's capacity to meet and technical criteria..

## **STRUCTURE OF THE THESIS**

The thesis consists of 156 pages, excluding references and appendices, with 36 tables, 2 figures, 3 diagrams and 9 charts. Set the problem 2 pages; 40-page overview; Research objects and methods 24 pages; Research results 45 pages; Discussion 42 pages; Conclusion 2 pages and recommendations 1 page.

### **Chapter 1. OVERVIEW**

#### **1.1 Current status of sperm and oocyte donation**

The use of in vitro fertilization technology (TTON) in countries around the world is increasingly popular and the demand for donated sperm and oocytes is increasing. In some countries, the number of registered sperm donors each year is >5,000 people and sperm donors

are >17,000 people; >11,000 people donated eggs and received >2,000 people [83, 112, 113]. However, the number of donated sperm and oocytes is still not enough to meet the demand. According to a report by the World Health Organization, countries are facing a shortage of donated sperm and oocytes [48].

Many reasons lead to the shortage of donated sperm and ovum: the number of registered donors is low; The regulations and requirements to become a sperm and oocyte donor are quite strict, making many people ineligible to donate; Age limits, demographics, health requirements and donation principles such as information confidentiality, financial support, number of children born... also cause the number of people to register to donate sperm. decreased ovulation [83,112,113]. To solve this situation, many places have increased propaganda campaigns, encouraging people to register to donate sperm and ovum. In addition, there are also efforts to change regulations to attract more subscribers and meet growing demand [101].

## **1.2 Regulations and current status of sperm and oocyte donation management.**

Reasons for regulation include ethical, clinical, and legal issues. The consequences of one person donating sperm or ovum many times are very serious because it will create inbreeding generations with no real connection in real life. If inbreeding generations accidentally marry, they will cause dangerous genetic diseases. Managing sperm and oocyte donation helps prevent infectious diseases and genetic diseases for children.

Countries around the world have principles and guidelines related to donation issues. However, there are differences between countries and between professional groups. Topics considered in donation

include: (1) whether or not the donor is anonymous; (2) number of children born; (3) risk of infection or genetic disease from the donor; (4) years old; (5) commercialization. Laws in different countries have many similarities as well as differences.

In Vietnam, Decree No. 10/2015/ND-CP states: 1) Sperm and oocyte donors are examined and tested to determine: Do not have genetic diseases that affect future generations; not suffer from mental illness; not infected with HIV; 2) Sperm and oocyte donation is completely voluntary and only given at a medical facility. 3) fertility center is not allowed to provide the name, age, address and photo of the sperm donor. 4) The donor's sperm and ovum can only be used for one person. If they cannot give birth successfully, they can only use it for another person. In case of successful birth, unused sperm and ovum must be destroyed or donated for scientific research. The oocyte recipient must be Vietnamese, the wife of a couple undergoing infertility treatment where the cause of infertility is that the wife does not have ovules/ovules of poor quality. Store and share information about sperm donors and recipients; Donating and receiving oocyte requests are encoded and entered into a common database system, used nationwide, ensuring an information sharing mechanism between the MOH and facilities implementing the IVF technique.

Currently in Vietnam, there is no research evaluating the current status of sperm and oocyte donation management to learn about the control of oocyte and sperm donation. Can a person donate sperm and ovum to many different places? Is there a common data system for hospitals and fertility center? Is there a general procedure for identification and donation process at fertility center? Do fertility

center ensure compliance with instructions according to Decree No. 10/2015/ND-CP?

### **1.3 Application of information technology in sperm and oocyte management in infertility treatment**

Many countries around the world have built a process for managing egg and sperm donors at the Central Registration Agency of the MOH and applied information technology to manage this system. The SSSS are required to establish a register of sperm and oocyte donation and receipt managed by the MOH. Information on the online registry of the National Donor Registry - Ministry of Health ensures that information about all donors and conceived individuals can be held. Fertility center to collect and store information on donors and women on ART treatment and provide this information to the Ministry of Health for inclusion on the Central Register. Process of integrating and unifying information between the National Donor Registry and the Register of the National Donor Registration Agency - MOH. However, there is no management that is only done within national regulations, there is no connection between countries, and although there are laws, not all countries ensure that all information is updated on the system.

In Vietnam, although IT application in hospital management is implemented by 100% of hospitals. Already, 99.5% of medical examination and treatment facilities nationwide have been connected to the assessment system of Vietnam Social Insurance, 92.3% of hospitals have deployed PMQL application for test information, 86.2% The hospital deploys administrative management software such as electronic documents and emails. But at each hospital, the management of medical records of people who examine and treat HTSS in general and oocyte and sperm donors in particular is still left open. Currently,



there are no studies or reports on medical record information of donors and recipients of sperm and oocyte managed at hospitals. Therefore, there is no picture of the level of IT application in the process of managing sperm and oocyte donor and recipient records in Vietnam.

## **Chapter 2. RESEARCH METHODS**

### **2.1. Research subjectsc**

Descriptive study: People donated and received sperm and oocytes at 23 hospitals with HTSS facilities. Medical staff at 23 hospitals include: Hospital leaders; Center leadership; Head of information technology department; Doctor, Chief Nurse. Secondary data at 23 hospitals include: Statistical reports on the number of donations and recipients; Procedure for sperm and oocyte donation; Treatment results of sperm and oocyte recipients; Human resources for health workers working at the center; IT infrastructure.

Intervention study: purposeful selection of 3 hospitals: Central Obstetrics and Gynecology, Hue Central General Hospital, Tu Du: People came to donate and receive sperm and ovum. Medical staff at 3 hospitals include: Hospital leaders; Head of IT department and all medical staff of the center.

**2.2. Research time:** descriptive study collecting data from January 1, 2018 to December 31, 2018. Intervention study in 3 months September-November 2018.

**2.3 Research location:** descriptive study of all 23 hospitals. The intervention study was conducted at 3 Central Obstetrics Hospitals, Hue Central General Hospital and Tu Du.

**2.4. Research design:** cross-sectional descriptive study; Non-controlled intervention study

**2.5 Sample size**

|                 | Descriptive research |             | Intervention research |             |
|-----------------|----------------------|-------------|-----------------------|-------------|
|                 | Quantitative         | Qualitative | Quantitative          | Qualitative |
| Sperm donation  | 517                  | 23          |                       | 6           |
| Receive sperm   | 477                  | 23          |                       | 6           |
| Oocyte donation | 611                  | 23          |                       | 6           |
| Receiving ovum  | 607                  | 23          |                       | 6           |
| health workers  | 115                  | 115         | 80                    | 80          |
| Secondary data  | 23                   |             | 3                     |             |

**2.6. Sampling:** At all 23 assisted reproduction facilities, select all sperm and oocyte donors who meet the selection and exclusion criteria, and medical staff in the selected departments; The 3 fertility facilities conducting the intervention are 3 leading hospitals representing 3 regions.

**2.7. Intervention contents:** After evaluating the current situation of sperm and oocyte donation and the current status of sperm and oocyte donation management, the research team built a technical solution, which is software to manage patient information for infertility treatment, and conducted 3-month software testing coordinates tracking, monitoring and evaluating the effectiveness of the software.

**2.8. Analyze and process data:** Data were managed using Epidata software, processed and analyzed using SPSS16. Parameters about frequency, rate, average, etc. will be used to describe characteristics of research subjects, evaluate intervention results, etc...

**2.2.3 Ethics in research:** The study was approved by the Ethics Council for Biomedical Research of the National Institute of Hygiene and Epidemiology in decision No 50/2015/HDĐĐ dated December 28, 2018. Ethical principles in biomedical research are guaranteed during the research process.

## Chapter 3. RESULTS

### 3.1 Current status of sperm and oocyte donation in infertility treatment at 23 assisted reproduction facilities in 2018

#### 3.1.1. General features

The average number of sperm donors and recipients is similar between public and private hospitals, but is more concentrated in Northern hospitals than Central and Southern hospitals: Northern hospitals are 2-2.3 times higher than those in the North. with southern hospitals. The average number of people donating and receiving eggs at private hospitals is 1.4-1.6 times higher than at public hospitals, and 1.5 times higher in the South than in the North.

#### Board 1: General information

|                |                 | Sperm donation<br>(n = 517) |             | Oocyte donation<br>(n= 611) |             | Receiving ovum<br>(n = 477) |             | Receiving ovum<br>(n = 607) |             |
|----------------|-----------------|-----------------------------|-------------|-----------------------------|-------------|-----------------------------|-------------|-----------------------------|-------------|
|                |                 | n                           | %           | n                           | %           | n                           | %           | n                           | %           |
| Age group      | <20             | 4                           | 0,8         | 3                           | 0,5         | 0                           | 0,0         | 0                           | 0,0         |
|                | 20-29           | 293                         | <b>56,7</b> | 344                         | <b>56,3</b> | 194                         | <b>40,7</b> | 47                          | 7,7         |
|                | 30-39           | 159                         | <b>30,8</b> | 264                         | <b>43,2</b> | 259                         | <b>54,3</b> | 286                         | <b>47,1</b> |
|                | 40-49           | 61                          | 11,8        | 0                           | 0,0         | 24                          | 5,0         | 274                         | <b>45,1</b> |
|                | Average age     | 30,3±6,27                   |             | 28,4 ± 4,8                  |             | 30,6 ± 4,6                  |             | 35,2 ± 5,47                 |             |
| Marital status | married         | 209                         | <b>40,4</b> | 476                         | <b>77,8</b> | 452                         | <b>94,8</b> | 607                         | <b>100</b>  |
|                | Not married yet | 264                         | <b>51,1</b> | 56                          | 9,1         | 25                          | 5,2         | 0                           | 0,0         |
|                | Divorce         | 44                          | 8,5         | 80                          | 13,1        | 0                           | 0,0         | 0                           | 0,0         |

The average age of the sperm donor group was  $30.3 \pm 6.27$  years old, higher than the oocyte donor group,  $28.4 \pm 4.8$  years old. The oocyte donor group did not have anyone over 40 years old. 11.8% of sperm donors are between 40-49 years old. The average age of the oocyte recipient group was significantly higher than the sperm recipient group. The majority of egg donors are married, while only 40.4% of sperm donors are married. Most sperm and oocyte recipients are living with their husband.

**Board 2: Obstetric history**

|                     |                     | Sperm donation<br>(n = 517) |      | Oocyte donation<br>(n = 611) |      | Receiving ovum<br>(n = 477) |      | Receiving ovum<br>(n = 607) |      |
|---------------------|---------------------|-----------------------------|------|------------------------------|------|-----------------------------|------|-----------------------------|------|
|                     |                     | n                           | %    | n                            | %    | n                           | %    | n                           | %    |
| Number of donations | First time          | 517                         | 100  | 601                          | 98,4 | 445                         | 93,3 | 580                         | 95,6 |
|                     | Have donated before | 0                           | 0,0  | 10                           | 1,6  | 32                          | 6,7  | 27                          | 4,4  |
| Have children       |                     | 243                         | 47,0 | 569                          | 93,1 | 32                          | 6,7  | 106                         | 17,5 |

The majority of women who donated eggs had children before donating, and 47.0% of sperm donors had children. 100% donated sperm for the first time, and for the oocyte donor group, 1.6% had previously donated. It was the first time for most women in the sperm and oocyte recipient group. Only 6.7% of sperm donors and 4.4% of ovum donors had applied in previous treatments but the results were unsuccessful.

**Board 3: Time period from starting treatment until receiving sperm and ovum from the recipient**

| Thông tin      | Receiving ovum<br>(n = 477) |      | Receiving ovum<br>(n = 607) |      |
|----------------|-----------------------------|------|-----------------------------|------|
|                | n                           | %    | n                           | %    |
| 1 - 3 years    | 403                         | 84,5 | 405                         | 66,7 |
| 4 - 6 years    | 62                          | 13   | 129                         | 21,3 |
| 7 - 9 years    | 10                          | 2,1  | 54                          | 8,9  |
| Over 9 years   | 2                           | 0,4  | 19                          | 3,1  |
| Average (year) | <b>1,74 ± 1,86</b>          |      | <b>3,28 ± 2,54</b>          |      |
|                | <b>(min 1 – max 10)</b>     |      | <b>(min 1 – max 16)</b>     |      |

The time from starting HTSS treatment to receiving sperm and ovum for this treatment is also relatively long. The group received sperm, on average nearly 2 years, the longest was 10 years. The average oocyte donation group is more than 3 years, the longest is 16 years.

### **3.1.2. BV Tests were performed according to regulations on sperm and oocyte donation and receipt at 23 hospitals**

The majority of donors and recipients of sperm and ovum have not been examined or tested to confirm that they do not have genetic diseases that affect the next generation and do not have mental illnesses related to cognition. Only 0.4% of sperm donors and 1.1% of oocyte donors had confirmatory testing. HIV testing is mandatory and results must be obtained to be eligible to donate or receive semen. 100% guaranteed 2 HIV tests. Tests confirming the absence of group A and B infectious diseases and sexually transmitted diseases were performed 100% in the sperm and oocyte recipient group.

### **3.2 Current status of sperm and oocyte donation information management at 23 reproductive support facilities in 2018**

#### **3.2.1 Methods and tools for managing sperm and oocyte donation and reception**

There are 19 hospitals that accept sperm donation and 23 hospitals that accept oocyte donation. 100% of fertility support centers have a hospital-wide connection network with both wired and wireless connections. All fertility centers have computers to serve administrative work at the department. There are only 4 fertility centers in the Southern region that have cameras and fingerprint scanners.

#### **Board 4: Methods of managing donors, receiving sperm and receiving oocyte donors**

|  | Type of hospital |                  | Area             |                  |                  | total<br>n=23 |
|--|------------------|------------------|------------------|------------------|------------------|---------------|
|  | public<br>(n=15) | private<br>(n=8) | public<br>(n=15) | private<br>(n=8) | public<br>(n=15) |               |
| <b>Develop, promulgate and apply procedures for managing donors, sperm recipients and oocyte donors at assisted reproduction facilities.</b> |                  |                  |                  |                  |                  |               |
| yes  | n                | 6                | 6                | 2                | 10               | 12            |
|  | %                | (40,0)           | (75,0)           | (20,0)           | 0                | (100)         |

### Applying IT in the management process

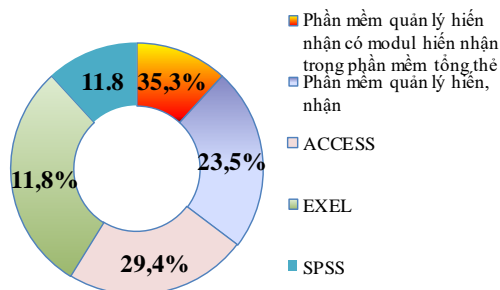
|  |   |       |        |        |       |        |           |
|--|---|-------|--------|--------|-------|--------|-----------|
| There is hospital management software                            | n | 15    | 8      | 10     | 3     | 10     | 23        |
|  | % | (100) | (100)  | (100)  | (100) | (100)  | (100)     |
| There is separate management software for donations and receipts | n | 12    | 5      | 6      | 3     | 8      | <b>17</b> |
|  | % | (80)  | (62,5) | (60,0) | 100   | (80,0) | (73,9)    |

### Method for identifying donors and recipients

|   |   |        |        |        |       |        |        |
|---|---|--------|--------|--------|-------|--------|--------|
| citizen identification card             | n | 15     | 8      | 10     | 3     | 10     | 23     |
|   | % | (100)  | (100)  | (100)  | (100) | (100)  | (100)  |
| Other method                            | n | 2      | 2      | 0      | 0     | 4      | 4      |
|   | % | (13,3) | (25,0) | 0      | 0     | (40,0) | (17,4) |
| <b>Software capable of sharing data</b> | n | 2      | 4      | 1      | 0     | 5      | 6      |
|   | % | (13,3) | (50,0) | (10,0) |       | (50,0) | (26,1) |

Southern hospitals concretize Decree 10/2015/ND-CP into step-by-step implementation & approval by the hospital. The remaining hospitals do not develop procedures - only apply the instructions in Decree 10/2015/ND-CP. 100% of hospitals have general management software for the entire hospital. There are 17 hospitals with their own software/modules. 4 Hospitals use facial recognition and fingerprint screening.

There are 6/23 hospitals, of which 2 public hospitals and 4 private hospitals have the ability to share personal profile information but have not shared it with other hospitals. 17 hospitals use software, but only 4 hospitals thoroughly manage the identification of people at the hospital through



### 3.2.2 Health workers' acceptance of the sperm and oocyte donation management process

17/23 hospitals use overall hospital management software and additional software to manage information on donor and recipient sperm and oocyte information at the department; The remaining 5 hospitals use the hospital's overall management software, so the study will evaluate 23 hospitals in general. Total 115 health workers. For hospitals with management software: *"The hospital can easily control and screen people, especially it is impossible to donate a second time at the hospital. The hospital checks with identification code, photos, and fingerprints."* CBYT-81; *"The hospital has software and fingerprint scanners to manage donors, so it can detect cases that have donated or not accepted, but cannot control them if they go elsewhere."* CBYT-103

For hospitals that do not have identification software, screening for duplicates is mainly through ID cards and the consultation process: *"There are cases of people coming to donate, using ID cards with different names, health workers due to familiarity or cross-questioning information during the application process discovered. The probability of discovery is not much, mainly due to the skills of the consultants preparing the documents."* CBYT-27

#### **Board 5: Health workers' acceptance of the management process**

| <b>Content</b>  | <b>Average score</b> |
|---|----------------------|
| Patient reception time is quick and efficient         | 3,79±0,41            |
| Each customer has a unique, non-duplicate code        | 3,92±0,27            |
| Easily search for records of customers                | 2,96±0,43            |
| Current management easily shares information          | 1,9±0,13             |
| The current management is effective                   | 2,86±0,39            |
| Meet the center's management needs                    | 3,07±0,256           |
| Appropriate and in accordance with the law            | 3,03±0,16            |
| Desire to apply common management software nationwide | 4,25±0,28            |

The average score of health workers' acceptance of the current management method is 2-3 points and they all want a new software to manage the entire reproductive support system of the country.

### **3.3 Effective application of information technology in sperm and oocyte donation management at 3 reproductive support facilities in 2018**

#### **3.3.1 Report on pre-intervention management methods and intervention activities at assisted reproduction facilities**

Before the intervention, only Tu Du Hospital had software to manage sperm and oocyte donation, but the software was only managed at the department and was not shared within the hospital or other places. Donor screening by fingerprint and facial recognition. Central Obstetrics Hospital and Hue Central General Hospital use SPSS and EXELL to synthesize donor information for statistics, reporting and scientific research. Screen donors through ID cards.

The intervention period is 3 months, operating and using the software system with the following functions: Creating and storing records of patients donating eggs and sperm; Check for duplicate egg and sperm donations at many assisted reproduction facilities across the country. Synchronize data of patients donating eggs and sperm to the national database center. Manage storage, use and retrieval of data, and report on donor and recipient lists.

During 3 months of implementation, the number of people managed by the management software was 78 sperm donors, 67 sperm recipients, 64 oocyte donors and 64 sperm donors. A total of 273 records were updated to the database.

#### **3.3.2 Evaluate the feasibility of management software based on capacity to meet reproductive support facilities**

*"The management software is very suitable for the needs of HTSS facilities, easy to install and use. The hospital only needs a computer, internet connection, fingerprint scanner and facial*



*recognition camera. can be easily used*". CBYT-29; CBYT-60; CBYT-71

*"Currently, the standard for recruiting medical staff is having an information technology certificate, so 100% of the hospital's medical staff meet this standard. All health workers can participate and implement the management software if required and trained. This can be applied not only to hospitals but also to the entire system of reproductive support facilities across the country"* CBYT-26; CBYT-56; CBYT-71.

### 3.3.3 Evaluate the feasibility of management software based on technical criteria

#### Board 6: Evaluate feasibility based on technical criteria

|  | Average score       |                    | P              |
|--|---------------------|--------------------|----------------|
|  | Before intervention | After intervention |                |
| Identify duplicates                    | 3,9±0,26            | 4,6±0,52           | 41,00 (p<0,05) |
| Search profiles                        | 3,0±0               | 4,3±0,46           | 48,1 (p<0,05)  |
| Monitor and manage examination results | 2,9±0,45            | 4,2±0,41           | 48,1 (p<0,05)  |
| Tracing pregnancy and birth outcomes   | 3,0±0,38            | 4,3±0,59           | 32,1 (p>0,05)  |
| Share and connect information          | 2,0±0               | 3,9±0,80           | 80,0 (p<0,05)  |
| synthesis report                       | 2,7±0,62            | 4,5±0,64           | 76,0 (p<0,05)  |
| Backup and restore data                | 3,1±0,26            | 4,6±0,51           | 35,0 (p<0,05)  |
| Decentralization, decentralization     | 3,1±0,26            | 4,7±0,45           | 35,0 (p<0,05)  |
| Security                               | 3,1±0,35            | 4,9±0,35           | 35,0 (p<0,05)  |

The feasibility of the software based on technical criteria is highly appreciated by health workers and donors and recipients, which shows that the ability to apply the new software is completely reasonable and appropriate:

Medical staff said: *"In the past, nurses spent a lot of time identifying duplicates. In addition to ID cards, health workers had to advise and find out. With software, the hospital only needs to scan fingerprints and face. ID card is checked and donated."* CBYT-71; Health workers - 25 *"The time to implement the process is not shorter than before applying it, but it greatly reduces the consultation time to check for duplication. The special thing is that health workers ensure that both patients and health workers do the same. Comply with state laws and decrees on sperm and oocyte donation."* CBYT-32; CBYT-56

Viewpoints of donors and recipients: *"The process of taking history, medical history and test results is very thorough and entering them into the computer. The second time you come to collect the sample, you only need to read the phone number and check your fingerprints to have all the documents. I find it very convenient."* KH-23. *"I found the screening process very careful. I feel more secure about using donated sperm samples for treatment."* KH-96; KH-64

### **3.3.4 Evaluate the feasibility of management software based on acceptance criteria**

#### **Board 7: Assess feasibility based on acceptance criteria**

|                               | Average score       |                     | P             |
|-------------------------------|---------------------|---------------------|---------------|
|                               | Before intervention | Before intervention |               |
| Easy-to-manage features       | 3,1±0,26            | 4,9±0,35            | 74,0 (p<0,05) |
| Software interface            | 3,1±0,26            | 4,6±0,51            | 78,0 (p<0,05) |
| Meet management needs         | 3,1±0,26            | 4,5±0,52            | 73,0 (p<0,05) |
| Maintain software application | 3,1±0,26            | 4,5±0,52            | 69,0 (p<0,05) |

Medical staff at 3 hospitals said that *"the new management software meets the hospital's management needs, is easy to use, has a beautiful interface and especially manages and screens information on people who have donated and received sperm. oocytes at the hospital when the hospitals synchronize donation*

*data to the central management system, health workers are completely assured about the legality and implementation of the process at the unit.”*CBYT-26; CBYT-56-CBYT-72. *“Fast implementation time, convenient, easy to use”* CBYT-30. *“The new PMQL meets the needs of managing sperm and oocyte donors and recipients. It is necessary to expand the model across all assisted reproductive facilities across the country to be able to promote the superiority of the software in thoroughly managing and managing the difficulties in the current management of sperm and oocyte donation.”* CBYT-27; CBYT-58;

For those who come to donate and receive, they all feel comfortable and have no opinion about the waiting time. *“I found the reception time and procedures to be quick, and the information I provided was updated into the software by medical staff. After scanning fingerprints and taking photos, health workers check the information very quickly.”*KH-96. *“This process is done right in the consulting and reception room so it is very convenient.”*KH-96. *“I feel a lot more secure because the source I use is not available at another hospital.”* KH- 103

## **Chapter 4. DISCUSSION**

### **4.1 Current status of sperm and oocyte donation in infertility treatment at 23 assisted reproduction facilities in 2018**

The number of people registering and undergoing procedures to donate and receive sperm and oocytes in Vietnam is 500-600/year, much less than in other countries around the world. In developed countries like the US and Europe, the number of sperm donors can reach thousands each year. According to the World Sperm Donation Organization, on average each year, about 5,000 people register to donate sperm and 17,000 people register to receive sperm in the United States, with an increase over time. The number of registrations to receive is 3 times higher than the number of registrations to donate[100]. The number of people registered to donate eggs in the

United States ranges from 20,000 to 25,000 cases per year, which is a very impressive number compared to other countries. [50, 96]. In the UK, the total number of registered sperm donors has increased from less than 1,000 per year in the early 1990s to more than 2,300 in 2019. The number of oocyte donors has also increased significantly in recent years with more than 2,000 cases. are performed every year [31, 42, 48]. Spain is known as a fertility tourism destination, so many people donate and receive sperm and oocytes for the treatment of HTSS, an estimated 11,000 cases per year, which is quite a high number compared to the number population of this country. [33].

Decree 12/2003/ND-CP of the Government stipulates that sperm and oocyte recipients must be between 20 and 45 years old. Decree 10/2015/ND-CP of the Government has adjusted the content on the age of donors and recipients to not be included in the regulations. The legal age limit for donors in Vietnam is similar to other countries around the world, but Vietnam does not regulate the maximum age for donation like other countries. Donor age is one of the important factors in choosing a qualified sperm and oocyte donor. Countries in Europe (UK), America (USA, Canada), Asia (Japan, China, Korea...) all have regulations that sperm and oocyte donors must be of legal age. *“Taking gametes from anyone under 18 years of age to treat someone else”* [46]. *“The donor must be of legal age and ideally under 40 years of age because increasing male age is associated with a gradual increase in the incidence of aneuploid sperm.”* In China, donors are required to be between the ages of 22-45 years old. [31, 48, 63, 101]. There is a clear difference in the status of having children before donation between the sperm donor group and the oocyte donor group. The rate of having children before donation of oocyte donors is 93.1%, 2 times higher than that of the sperm donor group. coincide. This result in Vietnam is equivalent to that in Russia and Ukraine, most women have children and in France >90% of donors have children. Meanwhile, the rate of having children together

in European countries is 52.3%, the lowest is in Poland, Portugal, Spain and the UK with ~35% [110]. This can be explained by the psychology of oocyte donors in Vietnam, who often tend to choose and find donors who have had children because they may have good fertility and will have good quality eggs. Good. At the same time, perhaps from a cultural and economic point of view, few young women without children or families want to donate their ovum.

#### **4.2 Current status of sperm and oocyte donation information management at 23 assisted reproduction facilities in 2018**

100% of hospitals have a network connecting the entire hospital, and all have computers to serve administrative work at the department. Only 4 hospitals in the southern region have cameras and fingerprint machines. Hospital leaders all affirmed that *"100% of doctors and nurses at the hospital have information technology certificates and can proficiently use basic software to serve their work."* Thus, the physical facilities and human resources conditions can meet the application of information technology in the management of sperm and oocyte donation and reception. The key point is the need for an overall management software for all hospitals to use.

Building a process is one of the mandatory tasks of the healthcare industry. 12/23 hospitals have built their own procedures for donating, receiving sperm and donating ovum with technical and regulatory content according to the instructions in Decree 10/2015/ND-CP. The rate of private hospitals is higher than with public hospitals at 75% and 40% respectively. Other hospitals apply the sperm and oocyte donation process with instructions in Decree 10/2015/ND-CP. Building a technical process is necessary for health workers to properly and fully follow the steps in the process. Although 12/23 hospitals have developed procedures, according to the assessment of medical staff at 23 hospitals, 100% of staff agree and strongly agree that medical staff strictly follow the procedures

and instructions of the Ministry of Health. . Thus, although they have not yet developed their own procedures, medical staff at hospitals always ensure and try to properly and fully comply with the regulations and instructions of the Ministry of Health and the law. But one of the difficulties for health workers when carrying out the process of donating and receiving sperm and ovum is that "*Finding a donor is difficult, there are many tests in the hospital for erectile dysfunction, requiring psychiatric and medical examinations and tests.*" *Genetics is too expensive, takes a lot of time, donors give up and don't donate anymore - CBYT65*" Therefore, most hospitals request but do not get a medical confirmation from the customer. Mainly assess subjective overexposure of medical staff.

In fact, 17/23 hospitals have statistical PML at TTTTSS. Most software is only for synthesizing and managing statistical data. There are 6/17 hospitals that have overall management software and can effectively manage donations and sperm. The management software of 4 hospitals has the ability to share customer profile information but has not shared it yet because there is no mechanism for managing and sharing information. Therefore, to ensure the confidentiality of customer information, the hospital is not allowed to share it. This result shows that most large hospitals in Vietnam only have basic medical information systems such as patient registration and data collection. The information system at hospitals is not complete. Within a hospital, there are many companies providing each part of management, so all hospital software cannot connect and share information with each other. This is a common difficulty in applying IT in the healthcare industry.[10]

23/23 hospitals use citizen identification cards to identify customers and only 4 hospitals use fingerprint machines and take pictures to put into management software to identify customers. These 4 hospitals are all in the South. This shows that Southern hospitals pay more attention to screening and identifying customers to

avoid the same customer donating multiple times at the hospital. Other hospitals also try to ensure compliance with the law, but due to the mechanism, they are still confused in applying IT in management. Health workers try to filter and avoid duplication in addition to ID cards. *"During the consultation process, we have many cross-questions and suggestions to find out whether the customer has donated at the hospital or elsewhere. And in many cases, because the number of donors is familiar and the number of donors is small, the center only has 1-2 people accepting donor customers, so staff-72 can be detected."*

The most difficult thing in overall management is for customers donating sperm and oocytes to ensure compliance with the instructions in Decree 10/2015/ND-CP regarding *"each donor can only donate once at one medical facility."* That is, there is no way to review at each hospital and connect between hospitals to manage the entire HTSS system. Health workers shared, *"If my hospital screens and does not accept, the patient can donate at another hospital, which we cannot manage."*

The current management method has 100% of hospitals managing paper records, only 17 hospitals have management and statistical software; 6/23 hospitals still compile sperm and oocyte donation data manually; 4/23 hospital records were partially digitized on software. Therefore, the majority of health workers believe that the current management method does not meet management needs and wish to apply a common management software with high legality for all departments and centers of medical examination and treatment. The difference between the two groups of public and private hospitals is statistically significant with  $p < 0.05$ . At the same time, the majority of health workers chose the level of no opinion and disagreed with the ease of finding information and clinical and paraclinical results of customers. This result is similar to Nguyen Hong Truong's research: 95.6% of health workers believe that it is necessary to apply

information technology in management to improve the quality of medical examination and treatment. [11]

#### **4.3 Effective application of information technology in sperm and oocyte donation management.**

One of the most important points in building PML for donors, sperm recipients and oocyte donors and recipients is to ensure the implementation of reproductive support examination and treatment for those who need to donate or receive ovum and sperm. protected according to the law stipulated in Decree No. 10/2015/ND-CP dated January 28, 2018 of the Government. The donor's sperm and ovum can only be used for one person. If the birth is not successful, they can be used for another person. At the same time, sperm and oocyte donors can only donate at one medical facility [5]. Based on the instructions in the decree and Circular No. 46/2018/TT-BYT dated December 28, 2018 of the Regulation on electronic medical records, detailing the preparation and updating of medical records. information in electronic medical records [7]. PMQL has built indicators based on medical records of donors and recipients of sperm and oocyte.

The effectiveness of the software is evaluated based on the opinions of medical staff at hospitals based on the criteria specified in Decision No. 5573/QĐ-BYT dated December 29, 2006 of the Minister of Health on promulgation of "*Software criteria and content of some hospital management information technology software modules*"[8]. Evaluation before and after using the software shows that health workers agree and completely agree with the prescribed indicators and these indicators all have statistically significant differences.

Patient identification information is one of the factors that plays an essential role in developing PMQL. Each patient has only one code for all medical examinations and treatments. In fact, different hospitals regulate different ways of issuing codes, and the lack of unified regulations hinders data interoperability. The Ministry of



Health issued Decision No. 2153/QD-BYT, dated May 25, 2020 on Regulations on establishment, use and management of medical identification codes [9]. The testing software has ensured the identification code according to the instructions of the Ministry of Health and is a unified code for updating to the common system. Although the codes and information of sperm and oocyte donors and recipients are updated in the management system, only some information is posted to the general system including full name, identity card, especially fingerprints to Determine duplication. At the same time, make sure not to provide the name and information of the donor recipient, solving the most important point in Decree 10 of the Government, which is that each person can only donate sperm and oocyte once at 1 facility.[ 5] Medical record data is a huge library that stores personal information and information related to the disease and treatment process. Preserving and backing up data is extremely important to prevent possible situations such as hardware failures. However, the Ministry of Health has not yet issued detailed regulations on output data standards when transferred to other storage units. In Article 7, exploiting medical record information for the right purpose and ensuring privacy and security is equivalent to paper medical records. Individuals and organizations wishing to use information from electronic medical records must have a written request or referral from a competent authority to use data from the records. electronic medical records. [10].

100% of health workers think that the current PMQL method meets the management needs of the unit and wishes to maintain and apply the PMQL method to all HTSS centers across the country. This result is similar to the opinion of Nguyen Hong Truong, health workers believe that it is necessary and very necessary to apply IT in hospital management, especially to improve the efficiency of using medical records (95.6%) and improve the quality of medical examination and treatment (92.8%) [11]

## CONCLUDE

1. Current status of sperm and oocyte donation at fertility facilities in 2018: The number of sperm and oocyte donations in donor banks is scarce. Successful treatment rate of oocyte injection; asking for sperm is 41.8% - 38.6%. The average age for sperm donation is not significantly higher than for oocyte donation ( $30.3 \pm 6.27$  years old compared to  $28.4 \pm 4.8$  years old). The average age of the sperm recipient group was nearly 10 years lower than the oocyte recipient group. The majority of the oocyte donor group were married (77.8%) and had children (93.1%). Meanwhile, in the sperm donor group, 40.4% were married and 47.0% had children; Most donors receive oocyte sperm for the first time. 100% complete tests for sexually transmitted diseases and group A and B infectious diseases; But no case has been examined or tested to confirm genetic or neurological diseases

2. The current situation of managing sperm and oocyte donation information at assisted reproduction facilities in 2018 shows that there is no systematic process for managing sperm and oocyte donation and reception. The management process does not meet Decree 10/2015/ND-CP, there is no common database, 100% of sperm and oocyte donation and receipt information is not encrypted and entered into the common database. Screening donors and receiving sperm and ovum through identifying patients with ID cards, only 4 hospitals use fingerprints and facial recognition photos. The software is only managed at the hospital's HTSS facility, does not share information, and some software such as SPSS and ACCESS do not meet the requirements for sperm and oocyte donation management. 4/17 hospitals have software for overall management of sperm and oocyte donation and receipt records. Evaluation of management processes and methods: 82.6% of health workers think they do not meet management needs.

3. Results of information technology application in sperm and oocyte donation management at reproductive support facilities in 2018

show that: Software for managing sperm donation and receipt and oocyte donation and receipt meets the needs management requirements to comply with the instructions in Decree 10/2015ND-CP. 100% of health workers and customers want to expand the application of sperm donation and receipt management software at all reproductive health centers, but there needs to be specific mechanisms and regulations in sharing and managing data information. Evaluation of medical staff on reception time and clinical results; about the ability to connect, share, process management, statistics, and backup; about stable interface, decentralization in management and security; There is a statistically significant difference in flexibility and development before and after intervention with  $p < 0.05$ .

### **REQUEST**

For the Ministry of Health: It is necessary to develop and promulgate procedures for donating and receiving sperm and ovum to apply throughout the HTSS system. Develop management regulations, regulatory documents, and implementation instructions on integrating and sharing information between hospitals, ensuring: Thoroughly avoiding the possibility of duplication. Management agencies have the ability to access according to authority, make statistics and reports. Hospitals have the ability to exchange and share HSBA interconnection to serve medical examination and treatment. Ensure security according to authority and scope of data access. Expand research on reasons and motivation; the effects and impacts on the psychology and health of donors and recipients of sperm and ovum; From there, there will be policy interventions to ensure the protection of benefits for donors as well as recipients of sperm and oocyte.

For assisted reproductive facilities: ensure correct and complete implementation according to the provisions of Decree 10: Compliance with the implementation process. Internal monitoring sanctions on process implementation. Enhance the quality of counseling for donors and recipients.