

## **EDITORIAL**

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At the beginning of New Year 2021, it's time for beginning good things. May this year bring happiness, new inspirations and new success to all members of Royal Thai College of Obstetricians and Gynaecologists (RTCOCG). Wish all of RTCOCG members and families safe from COVID-19.

Editor in Chief and managing staff of Thai Journal of Obstetrics and Gynaecology (TJOG) already attended "The third meeting of the quality development of Thai journals in the project TCI-TSRI-Scopus Collaboration Project: System Development and Improvement of Thai Journal Quality in the Scopus Database" on December 9, 2020 at Grand Ballroom, Holiday Inn Bangkok Sukhumvit, Sukhumvit 22, Bangkok, Thailand. Editorial Board of TJOG looks forward to continuously raising the quality of the TJOG. Since January 1, 2021, editorial manager program will be used for the submission and review process of TJOG.

RTCOCG mid year Meeting 2021 will be held during March 31, 2021 - April 2, 2021 at Royal Cliff Hotels, Pattaya, Chonburi, Thailand.

We would like to thank past RTCOCG executive board, past editor in chief, editorial board and staff, reviewers, all members of RTCOCG, and all researchers for their kind contribution and support to TJOG.

This first issue of TJOG 2021 contains many interesting articles. One special article is "Elimination of Congenital Syphilis: What's New for Obstetricians in the 2020 Thai National Guideline?"

**Happy New Year 2021**

**Prof. Vorapong Phupong, M.D.**  
**Editor in Chief**

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## SPECIAL ARTICLE

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# Elimination of Congenital Syphilis: What's New for Obstetricians in the 2020 Thai National Guideline?

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### ABSTRACT

The goal of eliminating congenital syphilis in Thailand is to reduce new cases from 50 per 100,000 live births in 2015 to 5 per 100,000 live births in 2020. This remains a challenge because the incidence of syphilis in pregnant women is rising in many regions of Thailand. Therefore, the Ministry of Public Health of Thailand has revised the national guideline to control the situation by increasing the screening for Thai people with high risk of getting the disease; early detection and treatment of pregnant women with syphilis; suggesting pathological examination of placenta as well as identification of *Treponema pallidum*; enhancing the corporation between obstetricians and pediatricians; and emphasizing the post-treatment follow-up including contact tracing.

**Keywords:** elimination, congenital syphilis, Thai, obstetricians.

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## การกำจัดซิฟิลิสแต่กำเนิด: มีอะไรใหม่สำหรับสูตินรีแพทย์ในแนวทางปฏิบัติของประเทศไทยปี 2563?

เจนจิต ฉายะจินดา, กิตติภูมิ ชินหิรัญ, สุรสิทธิ์ ชัยทองวงศ์วัฒนา, รสพร กิตติเยาวมาลย์, มานพชัย ธรรมคันโธ

### บทคัดย่อ

เป้าหมายในการกำจัดซิฟิลิสแต่กำเนิดในประเทศไทยที่ต้องการลดจาก 50 รายต่อการเกิดมีชีพ 100,000 ราย ในปี พ.ศ. 2558 เป็น 5 ราย ต่อทารกเกิดมีชีพ 100,000 รายในปีพ.ศ. 2563 ยังคงเป็นเรื่องที่ทำทนาย เมื่ออุบัติการณ์ของหญิงตั้งครรภ์ที่ติดเชื้อซิฟิลิสสูงขึ้นในหลายภูมิภาคในประเทศไทย กระทรวงสาธารณสุขจึงปรับแนวทางปฏิบัติในการลดซิฟิลิสแต่กำเนิดเพื่อแก้ไขปัญหานี้ โดยเพิ่มการค้นหาผู้ที่เป็นโรค การวินิจฉัยและรักษาหญิงตั้งครรภ์ที่ติดเชื้อซิฟิลิสให้เร็วที่สุด สนับสนุนการตรวจรอกเพื่อระบุเชื้อซิฟิลิส ส่งเสริมการประสานงานระหว่างสูติแพทย์กับกุมารแพทย์ และปรับแนวทางการตรวจติดตามภายหลังการรักษาให้เหมาะสม รวมถึงแนวทางการตรวจติดตามคู่เพศสัมพันธ์เพื่อรับการรักษาอย่างครบถ้วน

**คำสำคัญ:** กำจัด, ซิฟิลิสแต่กำเนิด, ประเทศไทย, สูติแพทย์

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## Introduction

Congenital syphilis (CS) is caused by the transmission of *Treponema pallidum subsp. pallidum* from mother to fetus during pregnancy or delivery. Its consequences include miscarriages, dead fetus in utero, stillbirth, hydrops fetalis and infected infants. The diagnosis of CS at birth is categorized into two groups: confirmed cases, or fetus or infant with detection of the organism, and probable case, or those with high suspicion of CS without detected organism<sup>(1)</sup>. The data from Siriraj Hospital, which collected 195 pregnant women with syphilis who came to Siriraj Hospital from 2006-2015, showed the complications included 58 CS (29.7%), 5 miscarriages (2.4%) and 7 stillbirths (3.6%). Factors relating to CS were teenage pregnancy, receiving treatment for less than 4 weeks before delivery, or having never received any treatment<sup>(2)</sup>. Despite the fact that CS can be treated with the basic antibiotic like penicillin, permanent damage on infant's organs lasts much longer and can result in poor long-term outcomes.

Previously, Thailand was able to meet the definition of elimination of CS provided by the World Health Organization (WHO), which is fewer than 50 new cases per 100,000 live births, in 2015 and aimed to hit the target of fewer than 5 new cases per 100,000 live births<sup>(3)</sup>. In fact, the incidence was nearly four times higher from 2015 to 2018 (11.9 vs 42.6 cases per 100,000 live births). This finding was correlated with the rising prevalence of syphilis in pregnant women from 0.14 to 0.42 percent during the same time period. The impact was apparently demonstrated among teenage pregnant women who usually had the contagious stage of syphilis<sup>(4)</sup>. No return for blood-testing result, late/inadequate treatment and no/inadequate sex partners' evaluation and treatment are therefore the challenges of tackling the problem<sup>(4)</sup>.

In 2020, with collaboration with multiple organizations, the Division of AIDS and STIs, Department of Disease Control of Thailand reviewed and revised the National Guideline on the management for the elimination of congenital syphilis in Thailand, 2015<sup>(3)</sup> in order to mitigate the problem. Apparently, obstetricians play an important role in this mission. Like the 2015 guideline, the 2020 guideline encourages thorough history-taking

and physical examination. The routine blood testing for syphilis at the first antenatal care and at 28-32 weeks gestation is shifted from traditional sequence to reverse sequence. Same-day result testing using point-of-care tests are more highlighted in settings with high loss to follow-up rate. Couple counseling and testing for these infections in their husbands is recommended at first antenatal care. Additionally, safe sex is strongly suggested throughout pregnancy, especially when sex partners are promiscuous. In accordance with the WHO guideline, the treatment regimen for all stages of syphilis are clearly stated and the referral centers for pregnant women with penicillin hypersensitivity are provided.

### Staging of syphilis

In general, syphilis is classified according to the stage as early stage consisting of primary, secondary, and early latent; and the late stage consisting of tertiary, late latent, and syphilis of unknown duration. Syphilis can also pass through blood-brain barrier leading to neurosyphilis. Instead of using two years to distinguish early from late syphilis as being suggested by the WHO<sup>(5)</sup>, the Thai 2020 national guideline uses one year like the guidelines provided by the US Center for Disease Control and Prevention<sup>(6)</sup> and by the International Union against Sexually Transmitted Infections<sup>(7)</sup> for the benefit of higher treatment coverage. As known, the early stage of the disease in pregnant women was related to the higher probability of transmission<sup>(8)</sup>.

Primary syphilis is the stage that the infection has just entered the body and causes a wound at its entry. The wound has an indurated edge and painless which can be spontaneous healing (hard chancre). Secondary syphilis is the stage after the infection enters the bloodstream and causes symptoms in various sites of the body such as moth-eaten alopecia, scaly-bordered rashes on the body, and multiple painless indurated edge rashes on genitalia, etc. Tertiary syphilis is usually the stage that the infection has been in the body for more than 10 years, causing the chronic destruction of organs such as arterioles. Both latent syphilis and syphilis of unknown duration have no symptoms.

## Diagnosis of syphilis

The vast majority of pregnant women with syphilis have no symptom. Therefore, the diagnosis is mostly obtained by serological examination which is divided into two groups. Non-treponemal test includes rapid plasma reagin (RPR) and Venereal Disease Research Laboratory (VDRL). Treponemal test includes *Treponema pallidum* haemagglutination assay (TPHA), *Treponema pallidum* particle agglutination assay (TPPA), chemiluminescence immunoassay (CMIA) and a rapid/ point-of-care syphilis testing which uses a chromatographic paper. As machine-based testing is not available in all settings, the chromatographic paper test has become more popular.

The serological diagnosis of syphilis requires the positive results of both treponemal and non-treponemal tests. Previously, the nontreponemal test was first performed and confirmed with a treponemal test (traditional sequence) but the disadvantage was the inability to diagnose very early syphilis or late syphilis. Therefore, at present, the reverse sequence, which uses an automated treponemal test followed by a non-treponemal test, is widely used all over the world. The King Chulalongkorn Memorial Hospital has changed to the reverse sequence algorithm for syphilis screening since 2011. With prevalence of syphilis of 1.98 in 1,000 pregnant women during February 2011 to January 2013, 69.6% of women with untreated syphilis would be missed diagnosed if the traditional algorithm was used<sup>(9)</sup>.

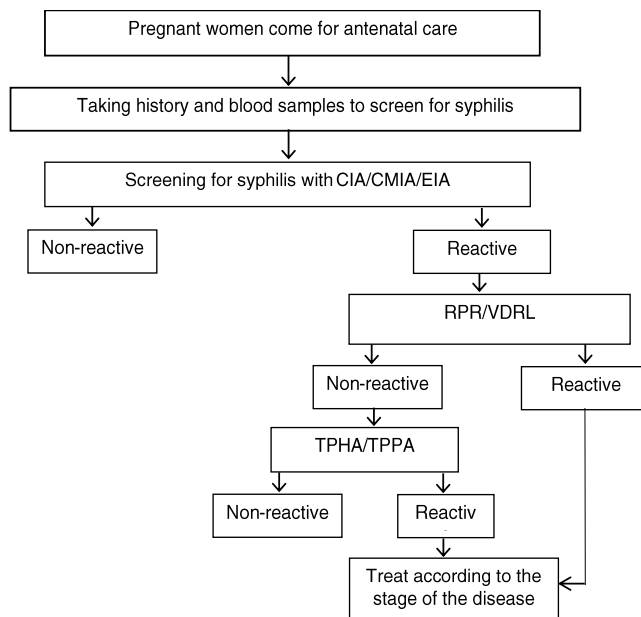
In the 2020 guideline, the reverse sequence is officially recommended. There are two algorithms for two different healthcare settings. Algorithm 1 is for those with negligible rate of loss to follow-up; (Fig. 1) and algorithm 2 is for those with high tendency of loss to follow-up cases (Fig. 2). Algorithm 1 has long been a universal practice in use all over the world. The 2020 guideline favors CMIA as the first screening tool for its affordability and high sensitivity. Algorithm 2 uses a rapid diagnostic test as the primary test followed by RPR because both of them can be reported on the same day. If the rapid test is positive but RPR is negative, another treponemal test must be done. In the 2020 guideline, either TPPA or TPHA is recommended to be the second treponemal test. As both of them take a few days to report and are not available in some local hospitals, the

2020 guideline suggests starting immediate treatment. If the second treponemal test is negative, the treatment course will be stopped. In contrast, if TPHA/TPPA is positive but the patients do not return, the benefit of the given dose of penicillin outweighs the risk of penicillin overuse<sup>(8,10)</sup>. Moreover, to date, *Treponema pallidum* has no report to be penicillin-resistant.

## Treatment guidelines for syphilis in pregnant women (Table 1.)

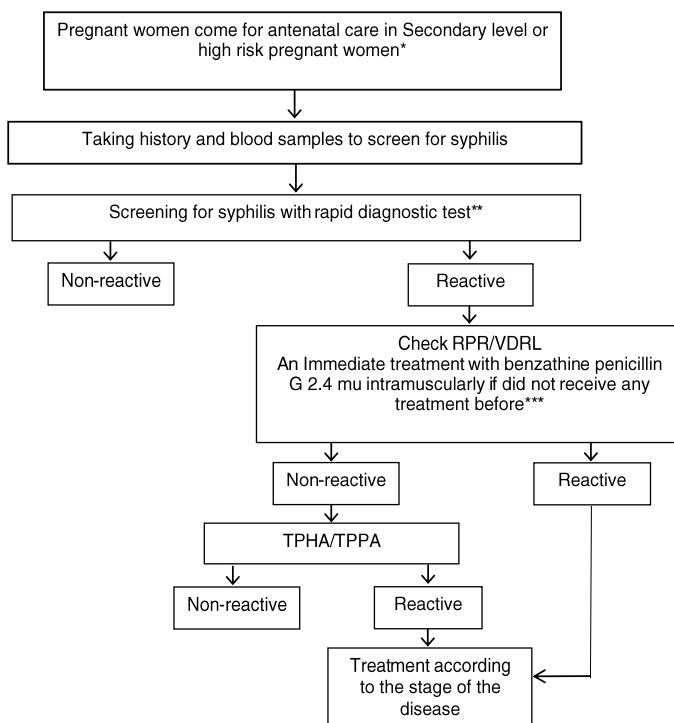
Penicillin is the only drug that can evidently prevent CS. The desired concentration of penicillin in maternal serum for killing *T. pallidum* is  $\geq 0.018 \mu\text{g/mL}$ . One dose of 2.4 million units benzathine penicillin G aims to reach the treponemicidal level for at least one week. However, 36% of the infected pregnant women had the level at  $< 0.018 \mu\text{g/mL}$  by day 7<sup>(11)</sup>. Another study showed that 4.8 million units of benzathine penicillin G can result in serum penicillin level at  $\geq 0.20 \mu\text{g/mL}$  for 30 days after treatment<sup>(12)</sup>. The large cohort study by Zhu, et al showed that out of 535,537 pregnant women in Shanghai, China during 2002-2006, there were 1,471 maternal syphilis cases. Of them, 12.5% had CS infants despite the complete treatment; and the incidence appeared more remarkable if maternal RPR titer was  $\geq 1:16$  and treatment was commenced after gestational age 20 weeks<sup>(13)</sup>. As a result, some experts suggest an additional 2.4 million units intramuscular injection of benzathine penicillin for pregnant patients<sup>(6)</sup>. From our experience, pregnant women whose skin lesions are not resolved within two weeks after the treatment are the candidates to receive the second dose.

Since the use of this drug is greatly reduced, benzathine penicillin is often out of stock. Some patients with a history of penicillin allergy require an alternative drugs. Although only 10 percent of people with a history of penicillin allergy are confirmed as being allergic to the drug, penicillin remains contraindicated. Desensitization is an option for this group of population but it requires a well-trained teamwork among obstetricians, allergist, and a team of skilled nurses with fully-equipped life-saving setting. In accordance with treatment guideline provided by WHO<sup>(14)</sup>, the recommended treatment regimen is in Table 1.



**Fig. 1.** Diagnostic method using automated machine.

\*According to Thai MOPH, syphilis screening is recommended at the first antenatal care visit and during 28-32 week gestation.



**Fig. 2.** Diagnostic method using a rapid test.

\* High risk pregnant women means teenage pregnancy, pregnancy with late ANC etc.

\*\* Rapid diagnostic tests must have reports for efficacy in at least 2 accepted journals in the WHO list of qualification testing or Department of Medical Science and have a sensitivity of at least 95%.

\*\*\* Immediate treatment can be commenced provided the result of RPR/VDRL cannot be retrieved on the same day; or TPHA/TPPA needs to be done.

**Table 1.** Treatment guidelines.

<b>Treatment</b>	
<b>Early syphilis</b>	<p><b>Recommended Regimen</b></p> <ul style="list-style-type: none"><li>- Benzathine penicillin G 2.4 million units intramuscularly in a single dose, divided into 1.2 million units per buttock</li><li>- Follow-up 3 months after treatment by blood testing for RPR/VDRL, if there is a suspicion of treatment failure.*<ul style="list-style-type: none"><li>o No history of risk of re-infection: benzathine penicillin G 2.4 million units intramuscularly weekly for 3 doses</li><li>o Having a history of risk of re-infection, benzathine penicillin G 2.4 million units intramuscularly in a single dose</li></ul></li><li>- Treat all sex partners according to the stage of syphilis**</li><li>- The RPR/VDRL must be checked before starting every new treatment.</li></ul> <p><b>Alternative Regimen</b></p> <ul style="list-style-type: none"><li>- Erythromycin base (except estolate) 500 mg orally 4 times a day for 14 days</li><li>- Ceftriaxone 1 g intramuscularly or intravenously once a day for 10 days</li><li>- Azithromycin 2 g orally single dose</li></ul>
<b>Late syphilis</b>	<p><b>Recommended Regimen</b></p> <ul style="list-style-type: none"><li>- Benzathine penicillin G 2.4 million units intramuscularly weekly for 3 consecutive doses, divided into 1.2 million units per buttock. Treatment interval can be extended up to 14 days, otherwise a new course will be required.</li><li>- Follow-up 3 months after treatment by blood testing for RPR/VDRL, if there is a suspicion of treatment failure.*<ul style="list-style-type: none"><li>o No history of risk of re-infection<ul style="list-style-type: none"><li>- Presence of neurosyphilis symptoms and signs*** or being HIV-seropositive: Treat as neurosyphilis</li><li>- No neurosyphilis symptoms and signs or HIV-seronegative: benzathine penicillin G 2.4 million units intramuscularly weekly for 3 doses</li></ul></li><li>o Having an obvious history of new infection: benzathine penicillin G 2.4 million units intramuscularly in a single dose</li></ul></li><li>- Treatment of the husband/sex partner only if the serological test results are positive</li><li>- The RPR/VDRL must be checked before starting every new treatment.</li></ul> <p><b>Alternative Regimen</b></p> <ul style="list-style-type: none"><li>- Erythromycin base (except estolate) 500 mg orally 4 times a day for 30 days</li></ul>
<b>Neurosyphilis</b>	<p><b>Recommended Regimen</b></p> <ul style="list-style-type: none"><li>- Aqueous crystalline penicillin G 18–24 million units per day intravenous, administered as 3–4 million units every 4 hours or continuous infusion, for 10–14 days</li><li>- Treatment of the husband/sex partner only if the serological test results are positive</li><li>- Lumbar puncture should be avoided in pregnant women.</li></ul>

\* Treatment failure is defined as any of the followings: no improvement in clinical symptoms, or a 4-fold rising in RPR/VDRL at 3 months after treatment, or decline in RPR/VDRL < 4-fold or 1:8 or greater after 6 months of treatment.

\*\* Treat all sex partners according to the stage of syphilis: having sexual relation with the patients within 3 months for primary syphilis, 6 months for secondary syphilis and two years for early latent syphilis. Diagnostic approach of sex partners is similar to that of pregnant women (Algorithm 1, 2).

\*\*\* Neurosyphilis symptoms and signs include eye pain, redness, photophobia, sensorineural hearing loss, etc.

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## OBSTETRICS

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# Decision-Making Regarding the Continuation of Contraceptive Implant within 1 Year of Childbirth: A Comparison between Adolescents Receiving Individual Counseling through Print Media and Adolescents Receiving Video-Based Group Counseling

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### ABSTRACT

**Objectives:** To compare the continuation rates of contraceptive implant within 1 year of childbirth between adolescents receiving individual counseling through educational brochures and adolescents receiving video-based group counseling.

**Materials and Methods:** This research was a prospective study of non-inferior trials in 272 postpartum adolescent mothers which compared between individual counseling and video-based group counseling. The video was created with introductory content about all methods of contraception including their advantages and side effects. The decision-making regarding the continuation of contraceptive implant usage would then be followed-up within 1 year. Criterion for non-inferiority was at a lower limit of  $< -7\%$  for the 95% confidence interval (CI).

**Results:** The adolescent mothers in this study were at the average age of 17 years old, and most of them were living with their husbands. The follow-up found that the decision rates of continuing the use of contraceptive implants comparing between those who received video-based group counseling and individual counseling at 6 months were 77% and 72.8% (95% CI = -5.8, 14.2), at 1 year were 69.4% and 65.0% (95% CI = -6.4, 15.3), with the lower confidence limit being inside the non-inferiority limit of  $-7\%$ . It can be interpreted that video-based group counseling was not less effective than individual counseling at 6 months and 1 year.

**Conclusion:** Evidence of non-inferiority was noted comparing individual counseling and video-based group counseling. The systematic and complete provision of information would facilitate the decision-making of adolescents, hence increasing the continuation rate of contraceptive implant.

**Keywords:** contraceptive implant, adolescents, continuation, video.

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# การเปรียบเทียบการตัดสินใจคงใช้ยาฝังคุมกำเนิดของมารดาวัยรุ่นหลังคลอดภายใน 1 ปี เปรียบเทียบกลุ่มให้คำปรึกษาแบบรายบุคคลจากแผ่นพับและป้ายให้ความรู้กับการให้ความรู้แบบกลุ่มจากสื่อวีดิทัศน์

ธีรพันธุ์ สิ้นหนาทวงศ์, สิริยา กิติโยดม

## บทคัดย่อ

**วัตถุประสงค์:** เปรียบเทียบอัตราการตัดสินใจคงใช้ยาฝังคุมกำเนิดของมารดาวัยรุ่นหลังคลอดใน 1 ปี ระหว่างให้ความรู้รายบุคคลจากแผ่นพับและป้ายให้ความรู้ กับให้ความรู้แบบกลุ่มจากสื่อวีดิทัศน์

**วัสดุและวิธีการ:** วิจัยแบบการทดสอบที่แสดงความไม่ด้อยกว่าแบบไปข้างหน้า ในมารดาวัยรุ่นหลังคลอดที่ฝังยาคุมกำเนิดจำนวน 272 คน เปรียบเทียบกลุ่มให้ความรู้แบบรายบุคคล กับกลุ่มให้ความรู้จากสื่อวีดิทัศน์โดยวิธีโอะจะแนะนำวิธีการคุมกำเนิดทั้งข้อดี ผลข้างเคียง ติดตามการตัดสินใจคงใช้ยาฝังคุมกำเนิดภายใน 1 ปี ค่าที่ยอมรับได้คือมากกว่า -7 ของค่าความเชื่อมั่นที่ 95

**ผลการศึกษา:** มารดาวัยรุ่นที่ศึกษานี้ มีอายุเฉลี่ย 17 ปี ส่วนใหญ่อยู่กับสามี พบว่า อัตราการตัดสินใจคงใช้ยาฝังคุมกำเนิดหลังคลอด เปรียบเทียบให้ความรู้แบบกลุ่มกับให้ความรู้รายบุคคลที่ 6 เดือนเท่ากับร้อยละ 77 และ 72.8 (ช่วงความเชื่อมั่นเท่ากับ -5.8, 14.2), ที่ 1 ปี เท่ากับร้อยละ 69.4% และ 65.0 (ช่วงความเชื่อมั่นเท่ากับ -6.4, 15.3), ค่าต่ำที่สุดของช่วงความเชื่อมั่นน้อยกว่า ค่าที่ยอมรับได้ที่ตั้งไว้ แปลผลว่าการให้ความรู้แบบกลุ่มมีประสิทธิภาพไม่ด้อยกว่าการให้ความรู้แบบรายบุคคลที่ 6 เดือน และ 1 ปี

**สรุป:** การให้ความรู้แบบกลุ่มมีประสิทธิภาพไม่ด้อยกว่า การให้ความรู้แบบรายบุคคล ในเรื่องอัตราการตัดสินใจคงใช้ยาฝังคุมกำเนิดที่ 6 เดือน และ 1 ปี การให้ข้อมูลอย่างเป็นระบบ ช่วยเพิ่มอัตราการตัดสินใจคงใช้ได้

**คำสำคัญ:** ยาฝังคุมกำเนิด, วัยรุ่น, การคงอยู่, สื่อวีดิทัศน์

## Introduction

Adolescent pregnancy refers to any pregnancy that occurs in females between 11 and 19 years of age<sup>(1)</sup>. Indeed, adolescent pregnancy is considered a major problem across the globe. According to the World Health Organization which conducted a study on 124,446 pregnant women, adolescent pregnancy is associated with increased risk of poorer health and well-being for both the mother and the baby<sup>(2)</sup>. With that respect, adolescent pregnancy is used as the indicator to reflect the development of population health in each country<sup>(3)</sup>. Regarding Thailand, the adolescent pregnancy rate was found to be 53.8 pregnancies per 1,000 females aged 15-19 years<sup>(6)</sup>. The Department of Health, Ministry of Public Health, has set a target to reduce the foregoing rate to 40 pregnancies per 1,000 females aged 15-19 years<sup>(6)</sup> and implemented the adolescent pregnancy prevention program. The essence of such program includes promoting the provision of contraceptive implants and intrauterine devices (IUDs) to females under 20 years of age who are in the postpartum period, have a miscarriage, or are seeking contraception, regardless of their rights to health. Ultimately, the program is aimed at providing adolescents with adequate access to permanent birth control options<sup>(5)</sup>.

Maharat Nakhon Ratchasima Hospital offers contraceptive implant services to females under 20 years of age who are in the postpartum period, have a miscarriage, or are seeking contraception, irrespective of their rights to health<sup>(5)</sup>. Prior to the administration of contraceptive implants, the hospital will provide counseling to adolescent patients who are classified into 2 groups based on the risks associated with their age group<sup>(5)</sup>; Group 1 comprises patients in early and middle adolescence who receive individual counseling with parental presence, and group 2 consists of patients in late adolescence who receive group counseling<sup>(5)</sup>. The counseling technique adopted by the hospital is the GATHER approach. According to a previous study, this approach is effective in facilitating the decision-making of patients regarding family planning. It entails a systematic process namely

greeting, active listening, telling, helping, explaining, and referring<sup>(6)</sup>.

With reference to the past data of Maharat Nakhon Ratchasima Hospital, the three-year continuation rate of contraceptive implants after 18 months of use was 55.8% in late adolescents who received group counseling, compared to 72% (2.11 times higher) in early and middle adolescents who received individual counseling with parental presence (95% confidence interval (CI) = 1.06, 4.19). The main contributor to the discontinuation of contraceptive implants was irregular bleeding. Moreover, it was found that patients who attended individual counseling sessions with their guardians were given detailed information in a systematic manner. The counselor jointly discussed and selected an appropriate contraceptive method with both the adolescent patient and the respective guardian. On the contrary, patients attending group counseling sessions were counseled by different counselors at the postnatal care facility, which could lead to insufficient information and lack of awareness of the disadvantages and side effects of contraceptive implants<sup>(5)</sup>. These results were consistent with the findings of previous studies conducted in other countries. According to the study of Grunloh et al, irregular bleeding had a significant effect on the discontinuation of contraceptive implants within 3 years of use<sup>(7)</sup>. In addition, the study of Nageso et al suggested that the discontinuation rate of contraceptive implants was statistically significantly higher in patients who were not given knowledge of the side effects prior to the implant, patients who did not choose the contraceptive method by themselves, and patients who did not visit a family planning center prior to the implant<sup>(8)</sup>.

Accordingly, the researchers are interested in developing an educational video to enhance the effectiveness of group counseling. Video will provide adolescents with information in a systematic and comprehensive manner, including the advantages, disadvantages, and side effects of contraceptive implants, while reducing the workload of instructors or counselors. Video-based group counseling is anticipated

to be as effective as individual counseling that uses brochures and boards as a means to provide knowledge to the adolescents.

## Materials and Methods

This research was a prospective study non-inferior trial of both approaches to counseling. The research was approved by the Research Ethics Committee of Maharat Nakhon Ratchasima Hospital. The sample consisted of postpartum adolescents aged 11-19 years who were desirous of receiving contraceptive implants at Maharat Nakhon Ratchasima Hospital during April 1, 2018 to August 30, 2018. Pregnant adolescents were given register at the labor room. Upon their consent to participate in the research, the participants were divided into 2 groups. The participants in group 1 were admitted to postpartum recovery building 1 and the participants in group 2 were admitted to postpartum recovery building 2.

The participants in group 1 were given individual counseling through the use of educational brochures and boards by postpartum nurses. Meanwhile, the participants in group 2 were given group counseling through the use of video. After that, interviews were conducted with the participants to collect data concerning their demographic characteristics, the decision on which method of contraception to use, and the confidence in selecting the appropriate contraceptive method. Telephone interviews were subsequently conducted with eligible participants after 6 months, and 1 year of childbirth to collect data about the side effects of the contraceptive implant and the intention to continue using the contraceptive implant for the full three-year period.

To prevent selection bias and contamination bias, it was necessary to gather all research participants (adolescent mothers who visited the hospital to give birth) and divide them into two groups from the time they were in the delivery room. Both groups would stay separately in different patient wards. After that, the two different methods of counselling would be provided. The number of people in the target group, the postpartum adolescent mothers who decided to continue using contraceptives implants, would be used

for the calculation of the primary outcome. The primary outcome was calculated and reported using the per protocol method.

The content of the video used in this study was based on credible sources. The composed content was reviewed by 3 experts from the fields of reproductive medicine, gynecology and counseling nurse to assess its accuracy and attractiveness before it was made into an animation video. The amount of time used for individual counselling was about 30-45 minutes per person, while the time for the video-based group counselling was about 30 minutes per group, divided into 10 minutes of video watching and 10-20 minutes of question and answer session.

A non-inferiority test was employed in the primary analysis to analyze the continuation rates of contraceptive implant within 1 year of childbirth, by using a one-tailed 95% confidence interval for the difference between the groups. If the lower limit of the confidence interval was  $< \delta$  (margin), it would imply that video-based group counseling is as effective as individual counseling in which educational brochures and boards are used.

The sample size was determined to be 272. According to the past data of Maharat Nakhon Ratchasima Hospital, the continuation rate of contraceptive implants was 72% in adolescents who received individual counseling through the use of educational brochures and boards<sup>(6)</sup>. Moreover, the results of a pilot study showed that the continuation rate of contraceptive implants was 55% in adolescents receiving group counseling. The researchers hypothesized that video-based group counseling was not inferior to individual counseling with respect to the adolescents' decision-making regarding the continuation of contraceptive implants within 1 year of childbirth. The minimum sample size was computed to be 136 participants per group ( $n = 272$ ) based on 80% power, two-sided  $\alpha$  level of 0.05 (i.e. the 2.5% upper limit of the CI), and the non-inferiority margin of -7%.

Student's t-test was used in the statistical analysis to compare continuous variables. Meanwhile, Pearson's chi-squared test and Fisher's exact test were employed to compare categorical variables. The

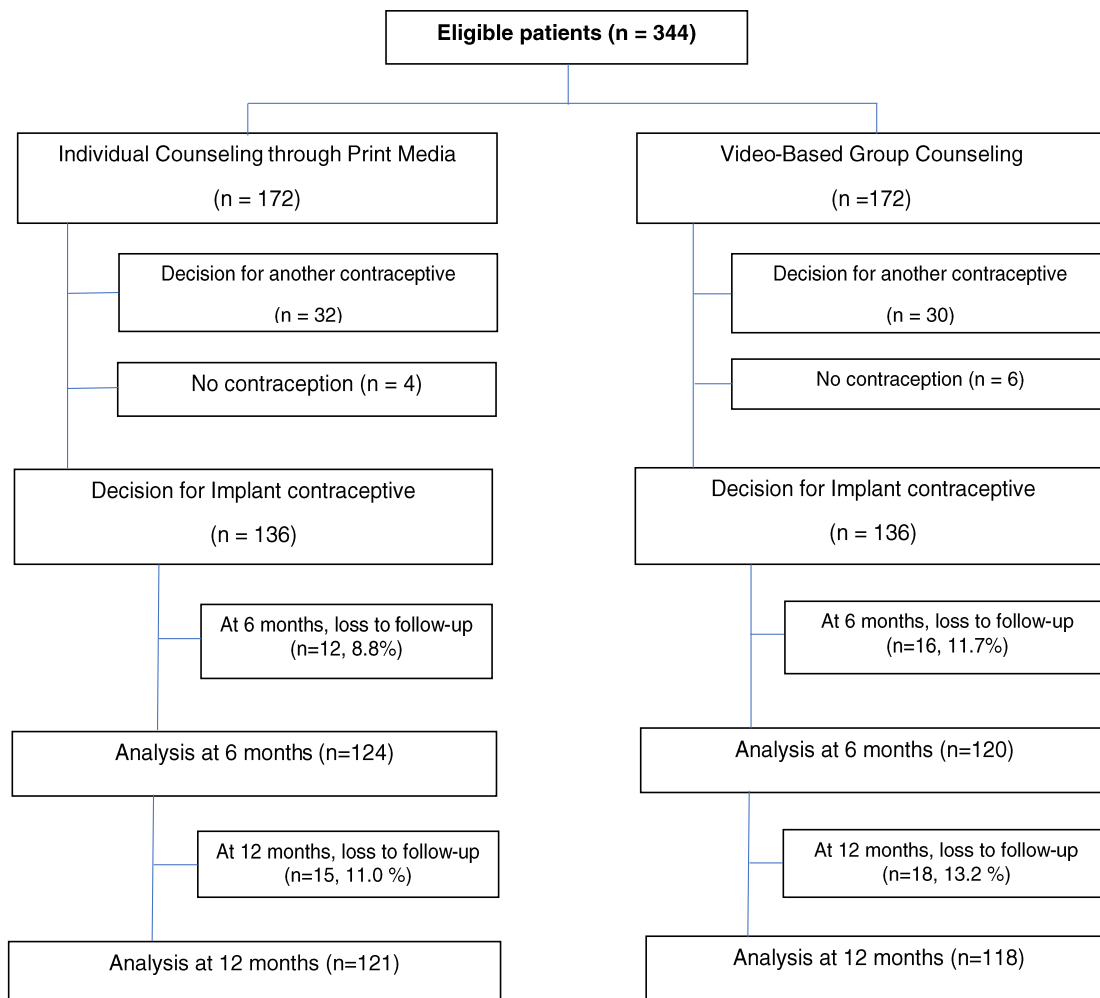
p values of less than 0.05 were regarded as statistically significant.

“Decision to discontinue using a contraceptive implant” was defined as either of the following: participants who within 1 month from the date of interview planned to have the Implanon® implant removed before 1 years of use but had not proceeded with the removal operation<sup>(5)</sup>; or participants who had the Implanon® implant removed before 1 years of use<sup>(5)</sup>.

## Results

A total of 344 adolescent mothers voluntarily agreed to participate in the research (Fig. 1). Group 1 consisted of 172 participants who received individual

counseling through the use of educational brochures and boards (print media); Group 2 consisted of 172 participants who received video-based group counseling. In group 1, 136 participants decided to use contraceptive implants, 18 decided to use contraceptive injection, 14 decided to use oral contraceptive pills, and 4 decided to terminate their contraception. In group 2, 136 participants decided to use contraceptive implants, 14 decided to use contraceptive injection, 16 decided to use oral contraceptive pills, and 6 decided to terminate their contraception. The participants were monitored, and data were collected after 6 months and 1 year of childbirth to conduct statistical analysis in order to examine the continuation rate of the contraceptive implant.



**Fig. 1.** Flow diagram of subject enrollment and follow-up.

According to Table 1, it was found that the postpartum adolescent mothers' average age was 17, and most of them were living with their husbands, currently taking leave from high school education, and would return after giving birth. Their previously used methods of contraception were condoms and oral contraceptive pills. These factors had an influence on

the decision of postpartum adolescents to use or not to use a contraceptive implant<sup>(5)</sup>, as well as affecting their decision on the continuation of a contraceptive implant for the full three-year period<sup>(5,7)</sup>. Upon analysis of the demographic characteristics of both groups, there were no significant differences between the groups.

**Table 1.** Baseline characteristic.

Baseline characteristics	Individual Counseling Through Print Media (n = 136)	Video-Based Group Counseling (n = 136)	p value
Age (years), mean ± SD	17.0 ± 1.39	17.1 ± 1.42	0.60
Parity, n (%)			
Nulliparity	124 (91.2%)	128 (94.1%)	0.72
Multiparity	12 (8.8%)	8 (5.9%)	0.71
History of abortion, n (%)	8 (5.9%)	7 (5.1%)	0.50
The highest education level, n (%)			
Grade 6	22 (16.2%)	21 (15.4%)	0.60
Grade 9	80 (58.8%)	74 (54.4%)	0.74
Grade 12	34 (25.0%)	41 (30.2%)	0.91
Relationship to husband, n (%)			
Live together	119 (87.5%)	122 (89.7%)	0.47
Divorce	10 (7.4%)	4 (2.9%)	0.25
Separate	7 (5.1%)	10 (7.4%)	0.90
Plan after delivery, n (%)			
Back to school	90 (66.2%)	95 (69.8%)	0.78
Housewife	39 (28.7%)	30 (22.1%)	0.55
Occupational	7 (5.1%)	11 (8.1%)	0.87
Experience in using other methods of contraception, n (%)			
Condom	79 (58.1%)	80 (58.8%)	0.86
Oral contraceptive	88 (64.7%)	101 (74.3%)	0.70
Emergency contraceptive	20 (14.7%)	25 (18.3%)	0.72
DMPA	35 (25.7%)	24 (17.6%)	0.53

SD: Standard deviation, DMPA: Depot Medroxyprogesterone Acetate

According to Table 2, the results showed that evidence of non-inferiority was noted comparing group counseling through the use of video with individual counseling through print media, specifically in respect of the three-year continuation of contraceptive implants after 6 months and 1 year of use. According to the data gathered from the follow-up with the participants, it

was found that 4 participants had the implant removed. Across these 4 participants, 1 had the implant removed after 3 months of use due to pain at the implant site, 2 had the implant removed after 6 months of use due to abnormal vaginal bleeding, and 1 had the implant removed after 1 year of use due to abnormal vaginal bleeding.

**Table 2.** Inferiority testing for group counseling compared with personnel counseling.

Rate for decision to continue implant for 3 year	Individual Counseling Through Print Media (N = 136)	Video-Based Group Counseling (N = 136)	Difference (95% confidence interval) <sup>a</sup>
At 6 months	105 (77.2%)	99 (72.7%)	4.2% (-5.5, 14.1)
At 12 months	93 (68.3%)	88 (64.7%)	4.0% (-6.2, 15.1)

<sup>a</sup> The criterion for non-inferiority was an lower limit of > -7% based on the upper 2.5% tail of the 95% confidence interval

According to Table 3, the follow-up on the side effects of the contraceptive implants found that the most common side effect was abnormal vaginal bleeding. Three out of 4 participants who decided to terminate their implantation reported having daily abnormal vaginal bleeding which had been occurring for several months. Even after receiving medical treatment, their abnormal bleeding did not get better and affected their daily life, thus they decided to have their implant removed. Another important side effect found was pain in the implant area which could lead to the removal of implantation. One participant was

found with too deep implantation, causing pain when lifting items. Therefore, implantation techniques are important as too-deep implantation may result in pain in the implant area, which leads to early removal of the contraceptive implantation. Other side effects found included headaches, stress, tiredness, fatigue, and weight loss which usually occurred together at the same time. These side effects may not be caused directly by contraceptive implants, but they were found as some of the reasons that make participants have their contraceptive implants removed prematurely.

**Table 3.** Rational for discontinue use implant at 12 months.

Rational for discontinue use implant at 12 months	Individual Counseling Through Print Media (N = 136)	Video-Based Group Counseling (N = 136)	p value
Abnormal vaginal bleeding, n (%)	15 (11.0%)	13 (9.6%)	0.80
Pain at insertion site, n (%)	6 (4.4 %)	7 (5.1%)	0.83
Headache, n (%)	10 (7.3%)	9 (6.6%)	0.76
Stress, n (%)	5 (3.6%)	4 (2.9%)	0.70
Fatigue, n (%)	3 (2.2%)	4 (2.9%)	0.49
Weight loss, n (%)	7 (5.1%)	3 (2.2%)	0.11
Acne, n (%)	4 (2.9%)	3 (2.2%)	0.67
Increase weight, n (%)	6 (4.4%)	3 (2.2%)	0.18
Request son, n (%)	1 (0.07%)	0 (0.0%)	0.95

## Discussion

The results of this research indicated that both approaches to counseling enhanced use rate of

contraceptive implant. Likewise, the tendency of postpartum adolescents to use contraceptive implants was found to increase from 45% in 2014 to 78% in

2019 at Maharat Nakhon Ratchasima Hospital<sup>(4)</sup>. These findings confirmed the study of Korsch et al, which found that the process of disseminating information and the content had an influence on decision to use the contraceptive implant<sup>(11)</sup>.

After monitoring the continuation rate of contraceptive implants within 1 year of use, it was apparent that evidence of non-inferiority was noted comparing video-based group counseling with individual counseling. In addition, the results of this research suggested continue rate of contraceptive implants within 1 year of use was found to increase from 55% in 2016 in group counseling<sup>(5)</sup> to 65% in 2019 after developed video-based group counseling. Thus, the decision to continue the use of contraceptive implants lies on the basis of the acquisition of clear and complete information. These results were consistent with the study of Rubenstein et al, which found that an adequate and systematic provision of information with emphasis on the side effects of contraceptive implants led to a higher continuation rate<sup>(10)</sup>. According to the results of this research, side effects could be regarded as one of the factors that impacted the continuation rate of contraceptive implants<sup>(5,11,12)</sup>. In this research, there were no significant differences between the two groups in the aspect of side effects.

The limitation of this research was that the three-year continuation rates of contraceptive implant were examined within a limited time frame of 1 year. Hence, a three-year study should be conducted to obtain a more profound insight into the effectiveness of both counseling approaches. The decision of taking off contraceptive implant doesn't mean literally taking it off, so it is not a directly indicator for contraceptive implant compliant, but it is an indicator measuring compliant in many educational researches<sup>(5,8,10,11)</sup>.

## Conclusion

The research suggested that evidence of non-inferiority was noted comparing group counseling through the use of video with individual counseling through print media. Based on the results of this

research, video-based group counseling could effectively replace the traditional approach. Moreover, video can be shared with adolescent patients at prenatal clinics to raise awareness of the importance of birth control and ensure sufficient time to make an informed decision, hence enhancing the efficiency of the adolescent pregnancy prevention program.

## Potential conflicts of interest

The authors declare no conflicts of interest.

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