



Title:

Development and Acceptability Testing of a Patient Decision Aid for Prenatal Testing amongst Asian Women and Their Spouses in the ASEAN region

Working group:

Principal Investigator: Dr Tae Sok Kun¹

Co-Investigator:

1. Prof. Dr Thong Meow Keong^{1,2},
2. Rifhan Mazlan²,
3. Associate Prof. Dr Sofiah Binti Sulaiman³,
4. Dr. Ebner Bon Maceda⁴,
5. Asst. Prof. Peter James B. Abad^{4,5},
6. Dr. Ma-am Joy Tumulak⁴,
7. Dr. Cheryll Magbanua- Calalo⁴,
8. Dr. Michelle Abadingo⁴

1. Genetic and Metabolism Unit, Department of Pediatrics, Faculty of Medicine, University of Malaya, Kuala Lumpur, Malaysia.
2. Genetic Medicine Unit, University Malaya Medical Centre, Kuala Lumpur, Malaysia
3. Department of Obstetrics and Gynaecology, Faculty of Medicine, University of Malaya, Kuala Lumpur, Malaysia.
4. Institute of Human Genetics, National Institute of Health, University of the Philippines Manila, Manila, Philippines
5. College of Nursing, University of the Philippines Manila, Manila, Philippines

Young Investigator Contact Information:

Name: Tae Sok Kun

Email: sokkun@ummc.edu.my

Phone number: +60129816742

Introduction:

Prenatal screening and diagnostic testing had become standard practice in many countries, which help to reduce the mortality rate secondary to congenital anomalies (CA). Neonatal and infant mortality rates have been stagnating for the past 2 decades in Malaysia¹. Congenital anomalies remained an important cause of death with a high health-care cost and long-term morbidities amongst the survivors. In the Philippines, congenital anomalies rank among the top 20 causes of death across the life span and are the third leading cause of death in the infancy period². Attitude and acceptance toward prenatal screening and testing among Asian women varies with regards to cultural values, religion, health awareness, and education³⁻⁶. In Malaysia, there is no standardised national guideline on prenatal screening and diagnostic testing⁷. There is only scanty research addressing Malaysian women's perception and attitude on disease specific prenatal diagnostic testing based on survey or questionnaire and none on their spouse⁸. In the Philippines, prenatal screening and genetic counselling services are limited and primarily serves to guide physicians in the management of the cases. Furthermore, pregnancy termination is not practiced in the country⁹. In view of the high economic and emotional burden of CA, prenatal screening and diagnosis is an important reproductive field to study on. The voice of Malaysian and Filipino pregnant couples on prenatal testing should be heard. The ASEAN region consists of 10 South-east Asian countries with

many shared cultural, religious, historical and economic ties and both Malaysia and the Philippines are active ASEAN members.

In Malaysia and the Philippines, information on prenatal testing is usually provided by General Practitioners (GPs), primary care physicians, or obstetricians. Referral to clinical geneticist or genetic counsellor will only be made on a case-to-case basis and in a limited way¹⁰. Thus, the information provided might vary depending on the knowledge and personal perception of the health care personnel. There is dearth in literature about the priority information needs of pregnant couple on prenatal testing and their decision-making process. Also, there is limited number of clinical geneticists and genetic counsellors in both countries who can provide pre- and post-test genetic counselling. Patient decision aids (PtDA) are a structured clinical tool that facilitates shared decision making, especially in difficult, value-sensitive decisions¹¹. User-centred PtDa is a well-established approach that help to improve patients' knowledge, their accuracy of risk perception, and the congruency of their choice to their personal values¹². To our knowledge, there is no patient decision aids for prenatal testing in Malaysia and the Philippines. In keeping with Sustainable Development Goal (SDG) 3.7, all women should be provided universal access to reproductive health-care services including for family planning, information and education, and the integration of reproductive health into national strategies and programmes¹³.

Vision

Prenatal screening and diagnostic testing are an arguable practice in ASEAN region due to ethical, legal, cultural, and religious issues. We would like to evaluate the acceptance of prenatal diagnostic testing and explore on the factors affecting reproductive decision-making among Malaysian and Filipino women and their spouse via a qualitative study. Shared decision is an important element in reproductive decision-making and is best achieved by using Patient Decision Aid (PtDA). We intended to develop a user-centred, evidence based PtDa that is tailored to patient's culture, religion and needs.

Aims

1. To determine the level of knowledge, attitude, and information needs of Malaysian and Filipino pregnant couples toward prenatal screening and diagnostic testing
2. To determine the level of knowledge, attitude, perspective and clinical experience of health care providers on prenatal screening and diagnostic testing
3. To develop a user-centred, evidence-based Patient Decision Aid using the International Patient Decision Aids Standards and access its acceptability via alpha testing.

Impact to Clinical Genomic Implementation

The Patient Decision Aid will provide a user-centred guide and support information in pre-test and post-test genetic counselling to couple who is considering prenatal testing. It will help the healthcare professional to understand and provide appropriate support. Besides that, it will help the policy maker to design and address a proper governance framework for this group of patients.

This study will help women in the ASEAN region to explain their perception, reproductive choice and experience in their own voice. It will serve as guide for development of national antenatal screening programme and provide data for us to further explore on the cost-effectiveness of prenatal testing.



Executive Plan

This study is planned over a period of 12 months:

Phase 1 (5 months): Assessment of needs and scoping of evidence

1. Client Needs

- Assessment of knowledge, attitudes, and information needs of Malaysian and Filipino pregnant couples through a qualitative study using descriptive interpretive approach
- Semi-structured in-depth interview conducted either face to face or via phone/online platform.
- Clients (pregnant lady and their spouse) are recruited and interviewed separately until saturation of theme achieved. It is estimated a total of 80 patients will be recruited with each centre contributing 40 patients to achieved saturation of theme14.
- Data was analysed using thematic approach and directive content analysis

2. Health Care Provider Views

- Assessment of the perspective, knowledge, attitudes and clinical experience of health care providers on prenatal testing via a qualitative study using descriptive interpretive approach
- Semi-structured in-depth interview conducted either face to face or via phone/online platform
- Respondents include: obstetrician, feto-maternal specialist, sonologist, pathologist, perinatologists, clinical geneticist and genetic counsellor
- Data was analysed using thematic approach and directive content analysis

3. Scoping of Evidence

- Systematic review of evidence on prenatal testing including non-invasive (screening) and diagnostic prenatal testing

Phase 2 (3 months): Development of Decision aid

- Result from phase 1 qualitative study and research evidence will be used to inform recommendations and decision-making regarding prenatal testing
- developed patient decision aid according to the International Patient Decision Aids

Phase 3 (4 months): Evaluation of Decision aid (Alpha testing)

- The prototype of the decision aid will be evaluated through alpha testing:
 - Alpha testing 1: check comprehensibility and usability with clients (the pregnant women and their spouse)
 - Alpha testing 2: check acceptability and usability with health care providers
- Semi-structured in-depth interview conducted either face to face or via phone/online platform (focus group interview)
- Analysis of the feedback, re-draft and re-design of the Patient Decision Aid

G2MC Partners:

Institute of Human Genetics, National Institute of Health, University of the Philippines Manila
University of Malaya Medical Centre

Other Organizations: nil

Future Funding

There will be a follow up project on beta testing of this Patient Decision Aids and its clinical implementation in actual clinical setting. This should include health professionals and the clients (pregnant women and their spouse) who were not involved in the previous study. Eventually, we hope to develop a web-based, interactive Patient Decision Aids that will be used amongst Asian Women and Their Spouses in the ASEAN region.

Budget

Personnel	Salary of Graduate Research Assistant Malaysia: USD650 per month for 12 months, for 2 research assistant Phillippines: USD 650 per month for 12 months for 1 research Assistant (RA)	USD 15,600 USD 7,800
Travel and meeting support	Transport allowance for research assistant (for both Malaysia and Phillipines) USD100 per month for 12 months for 3 RA Transport allowance for patient USD10 inclusive of parking x 80 patients	USD 3600 USD 800
Research Materials & Supplies (for both center)	Nvivo 12 software (USD1,847 x 2) Zoom Video Conferencing plans(USD150/year x2) Recorder (USD100x3) Rechargeble battery x 4 (USD20 x2) Battery charger (USD65 x 2) Laptop (Acer Swift 5 14-Inch i5-1035G1) (USD 900 x 3) Headset (Logitech wireless headset)(USD 170 x 3) Portable external hard disk (Western digital 1TB) (USD50 x 3) Printer (Hp laser jet all in one printer) (USD130x2) Ink (black and colour) (RM90X5, RM120X3) Handphone (vivo) (USD150x2) Telephone bill/data (for Malaysia and Philippines)	USD 3694 USD 300 USD 300 USD 40 USD 130 USD 2700 USD 510 USD150 USD 260 USD 250 USD 300 USD1500
Miscellaneous (Professional Services + Indirect cost)	Page charges for open access journal Honorarium for patient (35USD per patient x80) Statistician Tranlator Transcriber Printing Indirect cost	USD2000 USD2800 USD1350 USD1000 USD1000 USD100 USD2500
TOTAL AMOUNT (RM)		USD 49,684