PART THREE

Advancing International Pediatric Clinical Research

ASSENT AND CONSENT IN THE FIELD: Culture, Context, and Respect

29 June 2022
8:00-10:00 PM EDT

This series is supported by an FDA Scientific Conference Grant.

MULTI-REGIONAL CLINICAL TRIALS
THE MRCT CENTER of BRIGHAM AND WOMEN'S HOSPITAL and HARVARD

The MRCT Center

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Our Vision

Improve the integrity, safety, and rigor of global clinical trials.

Our Mission

Engage diverse stakeholders to define emerging issues in global clinical trials and to create and implement ethical, actionable, and practical solutions.

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Promoting Global Clinical Research in Children

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Where we started & why this is important:

- Children **deserve access** to safe and effective medicines
- Children **historically excluded** from or underrepresented in research
- **Pediatric population widely dispersed** so clinical trials must be conducted in multiple jurisdictions
- **Persistent ethical issues:** while governing ethical principles may be generally agreed upon, differences in interpretation and application of principles exist
- Differing or nonexistent pediatric **regulations**
- Challenges in **trial initiation and conduct**
- The **pediatric patient and family voice** is not routinely solicited nor included in research life-cycle**.**
- **Children are not routinely offered a seat at the table.**

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Project objectives

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Broadly, sought to identify and propose solutions to regulatory, ethical, and operational challenges

- Current global landscape of pediatric research governance, focusing on legislative, regulatory, and guidance gaps and inconsistencies
- Identify current initiatives to improve pediatric research globally
- Identify challenges related to decision making by and on behalf of children
- Address benefit and risk considerations that create barriers and inefficiencies in transnational research with children.
- Identify meaningful ways to engage patients/families/community members

- Diverse leadership (Academia, EMA, Industry, participant advocates)
- 80+ members from all stakeholder groups with geographic diversity

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Webinar Series: *Advancing International Pediatric Clinical Research*

- Funded in part through an FDA scientific conference grant award
- 5 virtual webinars; each session planned to be hosted twice, with similar content and different speakers and panelists, to allow for wide attendance and participation.
- An offshoot of the MRCT Center's *Promoting Global Clinical Research in Children* project

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Advancing international pediatric clinical research—looking ahead

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1. *Informing the future from COVID-19 lessons learned:*
   6 October 2021 & 7 October 2021
2. *Time to Listen—Hearing from young people in clinical research;* 2 February 2022
3. 28 June 2022 : *Assent and Consent in the Field: Culture, Context, and Respect*
4. Fall 2022: Regulatory convergence to facilitate international cooperation
5. Early 2023: TBD

Today:

Please see ”Bio Book” for extended introductions to the speakers and panelists

Prioritizing Young People's Voices in Clinical Research

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Advancing International Pediatric Clinical Research

ASSENT AND CONSENT IN THE FIELD: Culture, Context, and Respect

Keynote Speaker

Professor Phaik Yeong Cheah
University Of Oxford
MORU Tropical Health Network
Thailand

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Consent and assent in paediatric research: challenges in global health research

Phaik Yeong Cheah, B.Pharm, MSc (Bioethics), PhD

Professor of Global Health, University of Oxford

Head, Bioethics & Engagement, Mahidol Oxford Tropical Medicine Research Unit

29/30 June 2022

UNIVERSITY OF OXFORD

MORU Tropical Health Network

wellcome

MORU
Tropical Health Network

PLOS | MEDICINE

Short-course primaquine for the radical cure of *Plasmodium vivax* malaria: a multicentre, randomised, placebo-controlled non-inferiority trial

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RESEARCH ARTICLE

The impact of targeted malaria elimination with mass drug administrations on falciparum malaria in Southeast Asia: A cluster randomised trial

WHO GUIDELINES
for malaria
16 February 2021

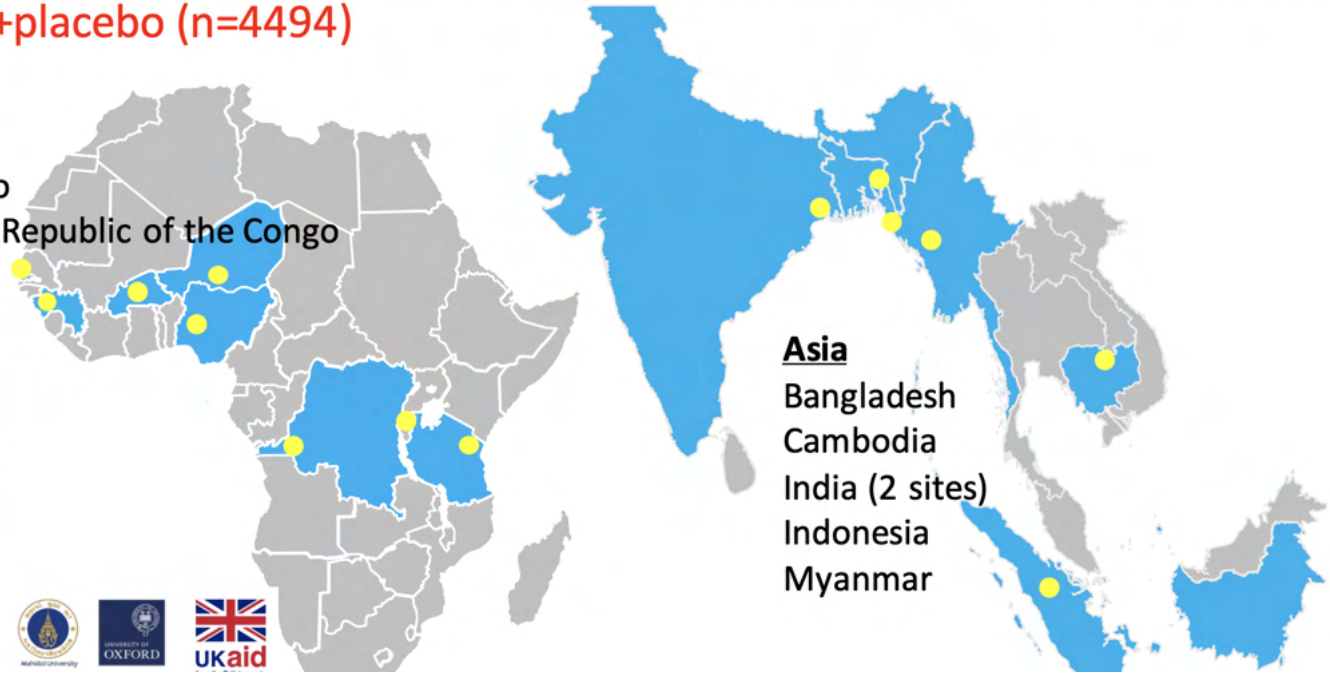
- Part of University of Oxford, collaborate with Mahidol University
- Core funded by Wellcome Trust
- Bangkok hub, but conducting clinical research internationally
- Tropical medicine and infectious diseases: Malaria, antimicrobial resistance, maternal and child health, COVID-19
- Conduct research studies (clinical trials and non trials), many them include paediatric patients

MRCT

DeTACT project

Development of Triple Artemisinin Combination Therapies

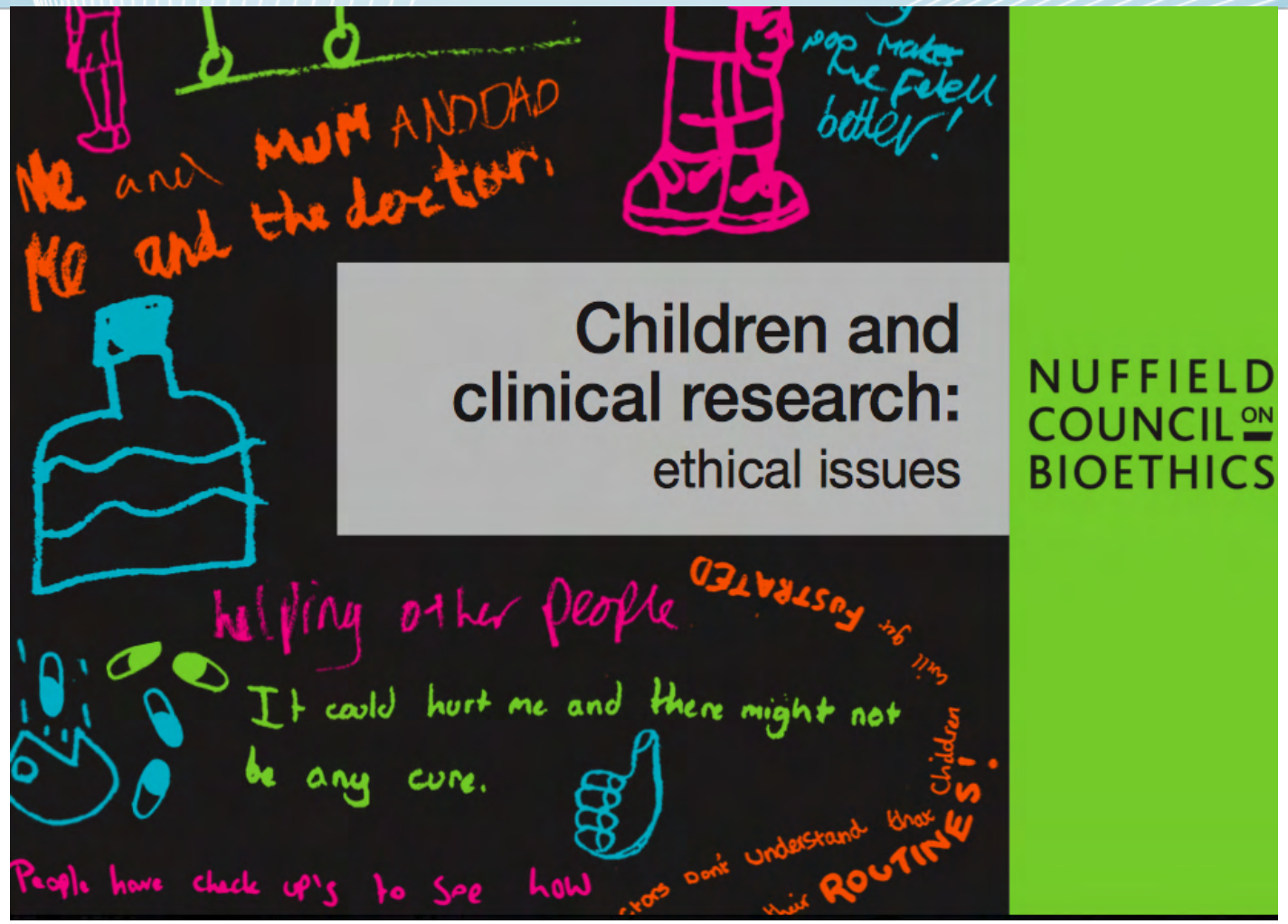
- **Clinical trial:** Randomised, partially-blinded, placebo-controlled clinical trial with TACT vs. ACT+placebo (n=4494)



MORU Tropical Health Network

Triple artemisinin combination therapy (new treatment) vs artemisinin combination therapy (current treatment using two drugs)

"We should protect children *through* research not *from* research"



http://nuffieldbioethics.org/wp-content/uploads/Children-and-clinical-research-full-report.pdf 2015

Informed Consent for Research

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A process by which a subject voluntarily confirms his or her willingness to participate in a particular trial/*research, after having been informed of all aspects of the trial/*research that are relevant to the subject's decision to participate.

(ICH GCP 2016)

*clinical research’ covers an immensely wide range of activity

Assent

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The US Code of Federal Regulations: “the IRB must determine that adequate provisions are made for soliciting the assent of the children”

When a potential research subject who is deemed incapable of giving informed consent is able to give assent to decisions about participation in research, the physician must seek that assent in addition to the consent of the legally authorised representative

(Declaration of Helsinki 2013)

Why should assent be sought?

Ethical reasons

- Respect for persons
- Respect emerging autonomy of the child
- Pedagogical reasons
- “Capacity for preference”

- A child as a rights-holder and active agent in the assent (or informed consent) process

Instrumental reasons

- To obtain cooperation from the child
- Children have their own worries that are different from adults – related to missing school, teenage problems, get teased by other kids, stigma, looking cool, boys, girls
- Scared of needles etc

Many challenges!

What does assent mean?

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Definition of assent in research guidelines

Research guideline	Text	Jurisdiction
Code of Federal Regulations[4]	"*Assent* means a child's affirmative agreement, to participate in research. Mere failure to object should not, absent affirmative agreement, be construed as consent."	USA
American Academy of Pediatrics[9]	"... active agreement by a minor, not qualified to give consent, to participate in a research study. This generally applies to children who have reached an intellectual age of 7 years or greater."	USA
Council for International Organizations of Medical Sciences[11]	"Such knowing agreement, sometimes referred to as assent..."	International
Confederation of European Specialists in Paediatrics[6]	"Informed assent means a child's agreement for medical procedures in circumstances where he or she is not legally authorised or has insufficient understanding to be competent to give full consent."	European
Royal College of Paediatrics and Child Health[5]	"... 'assent' refers to acquiescence..."	UK
Medical Research Council[13]	"... affirmative agreement to participate. Failure to object should not be construed as assent" but later on "Does the child actively object?" and if no, "research may proceed"*	UK
The Royal Australasian College of Physicians[12]	"... the term *assent* for concurrence or agreement, without the formal and legal expectations of informed consent."	Australia and New Zealand

Baines P: Assent for children's participation in research is incoherent and wrong. Arch Dis Child 2011

- If a child is deemed incompetent and therefore unable to consent to participate in a study…..

  …how is it that he or she can provide “affirmative agreement” or “acquiescence?

How much information and how to give it?

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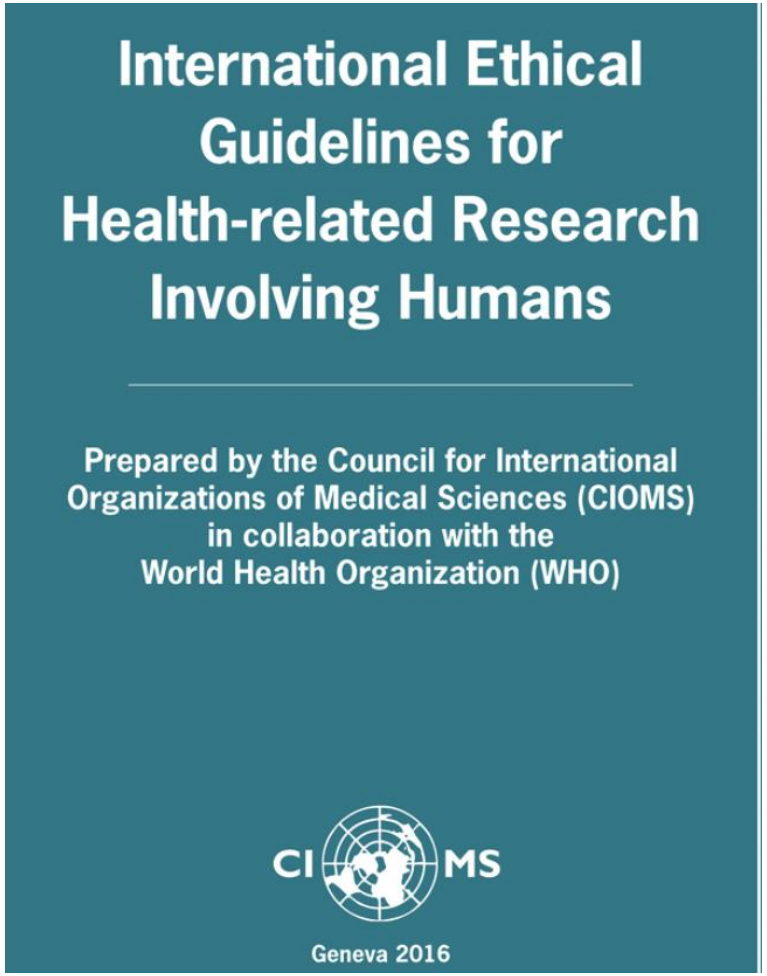
"..the agreement (assent) of the child or adolescent has been obtained in keeping with the child's or adolescent's capacity, after having been provided with adequate information about the research tailored to the child's or adolescent's level of maturity" *(CIOMS 2016)*

There is a spectrum of capacity to understand – difficult to determine, need child psychologists with a battery of tests



When should assent be sought?

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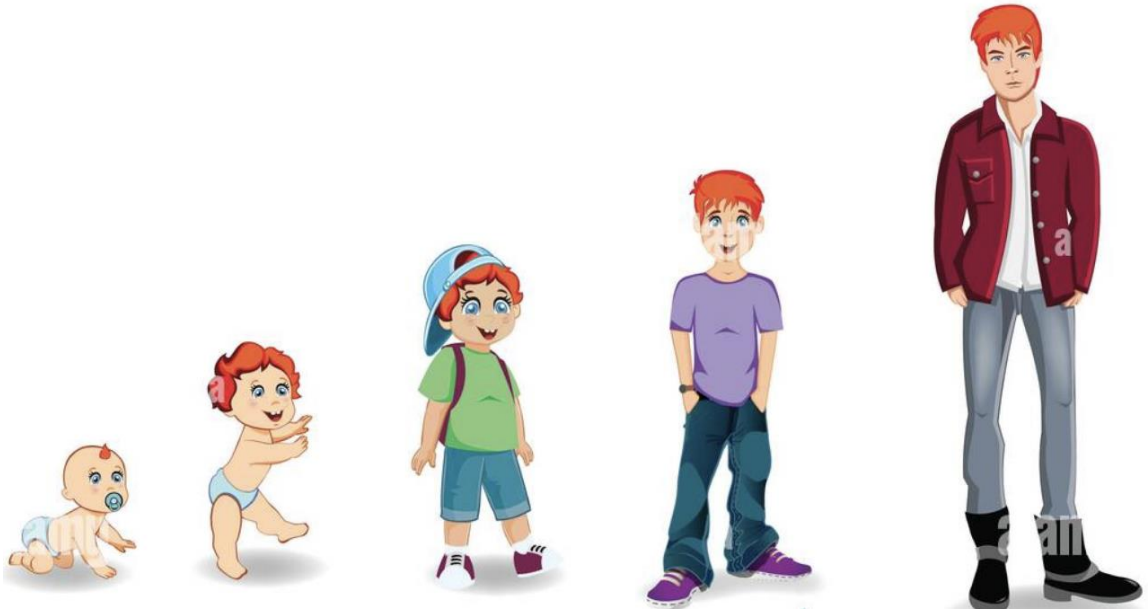
- Who is a child? From baby to age of majority
- Generally 7-18 years old, and written



Who should provide proxy consent?

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When a potential research subject who is deemed incapable of giving informed consent is able to give assent to decisions about participation in research, the physician must seek that assent in addition to the consent of the legally authorised representative

(Declaration of Helsinki 2013)

Diverse terminology

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ORIGINAL ARTICLE

bioethics WILEY

The proxy dilemma: Informed consent in paediatric clinical research - a case study of Thailand

Sheila Varadan | Salin Sirinam | Kriengsak Limkittikul | Phaik Yeong Cheah

- A wide range of terms are used
  - Earlier version of DOH – “responsible relative”
  - legally authorized representative’ (DOH 2013)
  - legally acceptable representative’ (ICH GCP 2016)
  - legally designated representative’ (EU)
  - legal guardian’, ‘parent’ and ‘representative’ etc
- with varying levels of legal authority - ‘permission’ (CIOMS 2016), ‘authorisation’ (Oviedo) and ‘informed consent’ (DOH 2013)

Who is this person??

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- Deference given to application laws – challenging in LMICs, no specific laws on paediatric clinical research (e.g. Thailand, Zimbabwe)
- Usually means biological parent/guardian?

- Intergenerational households, grandparents caring the child
  - Many parents (eg in Thailand, Cambodia) work in the cities, their children are looked after by their grandparents
- Orphans
- Children of minor parents
- Children of parents without legal status (ethnic minority)
- Children living without parental care

Leads to presumptive exclusion from clinical research

More challenges in low-income settings challenges

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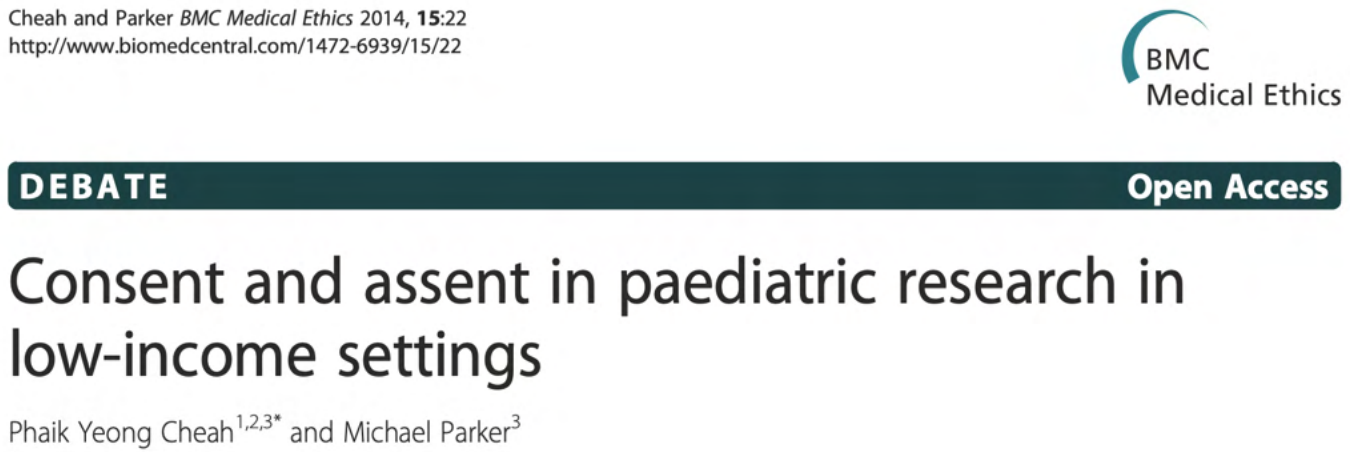
- Local paediatric research guidelines not clear or non existent
- Inexperienced personnel conducting paediatric research
- Resource starved hospitals need to cope with everyday clinical care



Cheah and Parker *BMC Medical Ethics* 2014, **15**:22
http://www.biomedcentral.com/1472-6939/15/22

BMC Medical Ethics

DEBATE Open Access

Consent and assent in paediatric research in low-income settings

Phaik Yeong Cheah[1,2,3*] and Michael Parker[3]

- Low level of formal education, literacy and health literacy – both parents & children
- Community not familiar with research and consent. Assent?
- Community not familiar with signing a document (children NEVER sign anything)

- Children do not formally assent for their own (non research) medical care
- More parental control (sometimes less)
- “Researcher may appear to insult the parent” – physician, Cambodia

- Children may be “cleverer” than their parents, more exposed
- Some (older) children take adult responsibilities and adult decisions day to day
- Some children can consent for themselves

- *Gillick competence – mainly for clinical care, not research

When should children consent in their own right?

- Competence - the ability to understand and retain relevant information, to weigh or judge the relative merits of the options and to make and communicate a decision
- Maturity a prerequisite for making decisions that are more significant in their consequences, involving perhaps substantial changes to a person's life prospects or where the decision may have irreversible effects.
- A great deal will depend on the nature of the study

Cheah PY, Parker M. Research consent from young people in resource-poor settings. *Archives of Disease in Childhood* 2015;**100:**438-440.

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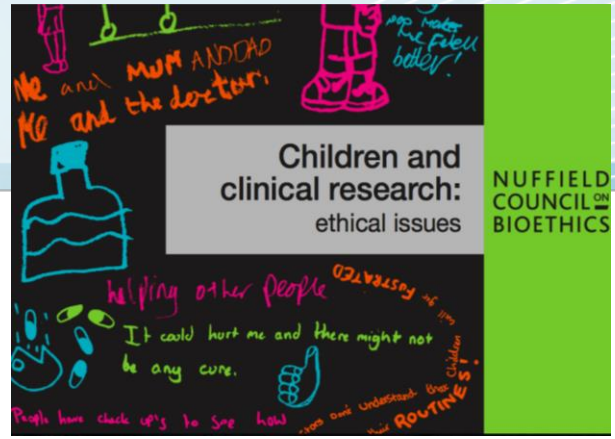
Going forward

Assent vs consent



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Case One: children who are not able at this time to contribute their own view as to whether they should take part in research, such as babies and very young children, or children who are temporarily unable to contribute because they are so unwell or are unconscious.

Case Two: children who are able at this time to form views and express wishes, but who are clearly not yet able to make their own independent decisions about research involvement

Case Three: children and young people who potentially have the intellectual capacity and maturity to make their own decisions about taking part in a particular research study, but who are still considered to be minors in their domestic legal system

http://nuffieldbioethics.org/wp-content/uploads/Children-and-clinical-research-full-report.pdf 2015

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PART TWO

TIME TO LISTEN: HEARING FROM YOUNG PEOPLE IN CLINICAL RESEARCH

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PLOS ONE

PUBLISH ABOUT BROWSE

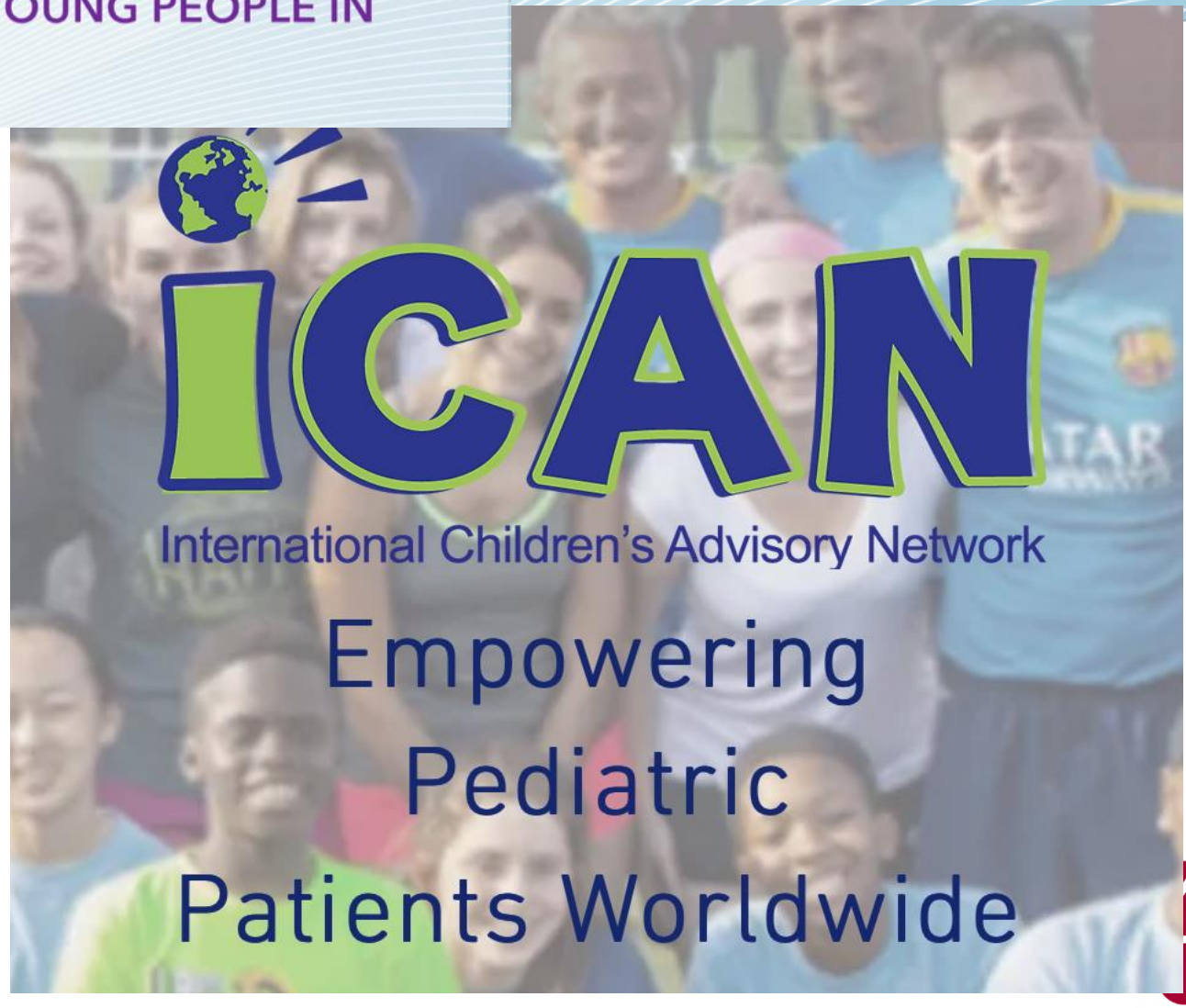
OPEN ACCESS PEER-REVIEWED

RESEARCH ARTICLE

"Know your audience": A hospital community engagement programme in a non-profit paediatric hospital in Cambodia

Sreymom Pol, Shivani Fox-Lewis, Phaik Yeong Cheah, Claudia Turner

Published: August 3, 2017 • https://doi.org/10.1371/journal.pone.0182573



Young Persons Advisory Board – Siem Pang, Cambodia

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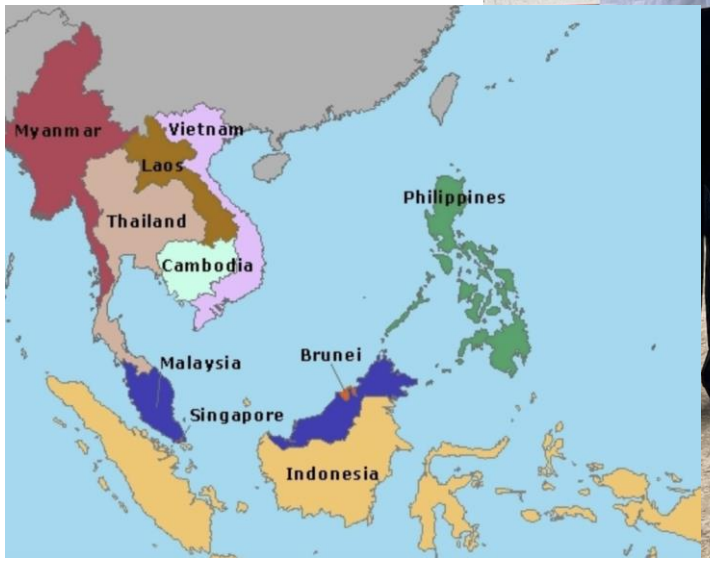

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Advancing International Pediatric Clinical Research

ASSENT AND CONSENT IN THE FIELD: Culture, Context, and Respect

PANEL DISCUSSION

Moderator
Dr. Steven Joffe
University of Pennsylvania Perelman School of Medicine
USA

Guest Speaker
Dr. Jacinto" Jojo" Blas Mantaring
UP College of Medicine
Philippines

Guest Speaker
Dr. Erwin Khoo Jiayuan
School of Medicine
International Medical University
Malaysia

Guest Speaker
Dr. Seung-min Hahn
Yonsei University College of Medicine
Korea

Guest Speaker
Dr. Wan-Ting Chou
PPD
Taiwan/Tokyo

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ASSENT AND CONSENT IN THE FIELD: Culture, Context, and Respect

Moderator

Dr. Steven Joffe
University of Pennsylvania
Perelman School of Medicine
USA

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Assent and Consent in the Field
Culture, Context, and Respect

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Steven Joffe, MD, MPH

Art and Ilene Penn Professor of Medical Ethics and Health Policy
Professor of Pediatrics
Chair, Department of Medical Ethics and Health Policy

Perelman School of Medicine
University of Pennsylvania

Multi-Regional Clinical Trials Symposium
June 29, 2022

Assent: the U.S.A. view

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- “the IRB shall determine that adequate provisions are made for soliciting the assent of the children, when in the judgment of the IRB the children are capable of providing assent.”

45 CFR 46.402(b)

Assent: the U.S.A. view

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- “the IRB shall determine that adequate provisions are made for soliciting the assent of the children, when in the judgment of the IRB the children are capable of providing assent.”
- “"Assent" means a child's affirmative agreement to participate in research. Mere failure to object should not, absent affirmative agreement, be construed as assent.”

45 CFR 46.402(b) and 408(a)

ICH
harmonisation for better health

INTERNATIONAL COUNCIL FOR HARMONISATION OF TECHNICAL REQUIREMENTS FOR PHARMACEUTICALS FOR HUMAN USE

ICH HARMONISED GUIDELINE

ADDENDUM TO ICH E11: CLINICAL INVESTIGATION OF MEDICINAL PRODUCTS IN THE PEDIATRIC POPULATION

E11 (R1)

Final version
Adopted on 18 August 2017

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ICH E11(R1) on assent

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"As a rule, a pediatric subject is legally unable to provide informed consent. Therefore pediatric study participants are dependent on their parent(s)/legal guardian to assume responsibility for their participation in clinical studies. Fully informed consent should be obtained from the legal guardian in accordance with regional laws or regulations."

ICH E11(R1) on assent

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"All participants should be informed to the fullest extent possible about the study in language and terms they are able to understand. "

ICH E11(R1) on assent

PART THREE

"Where appropriate, participants should assent to enroll in a study (age of assent to be determined by IRB's/IEC's or be consistent with local legal requirements)."

ICH E11(R1) on assent

PART THREE

"As a rule, a pediatric subject is legally unable to provide informed consent. Therefore pediatric study participants are dependent on their parent(s)/legal guardian to assume responsibility for their participation in clinical studies. Fully informed consent should be obtained from the legal guardian in accordance with regional laws or regulations."

ICH E11(R1) on assent

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"Participants of appropriate intellectual maturity should personally sign and date either a separately designed, written assent form or the written informed consent."

ICH E11(R1) on assent

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"In all cases, participants should be made aware of their rights to decline to participate or to withdraw from the study at any time."

The problems (1)

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Assent requirement is problematic in Western cultures

- When should kids be able to overrule their parents?
- How should age, maturity, the complexity of the study, the seriousness of the disease, and other factors affect the role that the kid plays in decisions?

The problems (2)

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Requirement to obtain assent may be Western-centered

- May conflict with cultural and family norms

The problems (3)

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We know little about how requirement to obtain assent is followed in practice

- How are kids involved in decisions about research participation in the USA?
- How are kids involved in decisions about research participation in diverse cultures around the world?

Thank you!

joffes@upenn.edu

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Perelman School of Medicine
University of Pennsylvania

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ASSENT AND CONSENT IN THE FIELD: Culture, Context, and Respect

Guest Speaker

Dr. Jacinto" Jojo" Blas Mantaring

UP College of Medicine
Philippines

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ASSENT AND CONSENT IN THE FIELD: Culture, Context, and Respect

Assent Issues in the Philippine Setting

Jacinto Blas V. Mantaring III, MD, MSc
Chair, University of the Philippines Research Ethics Board

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Philippines

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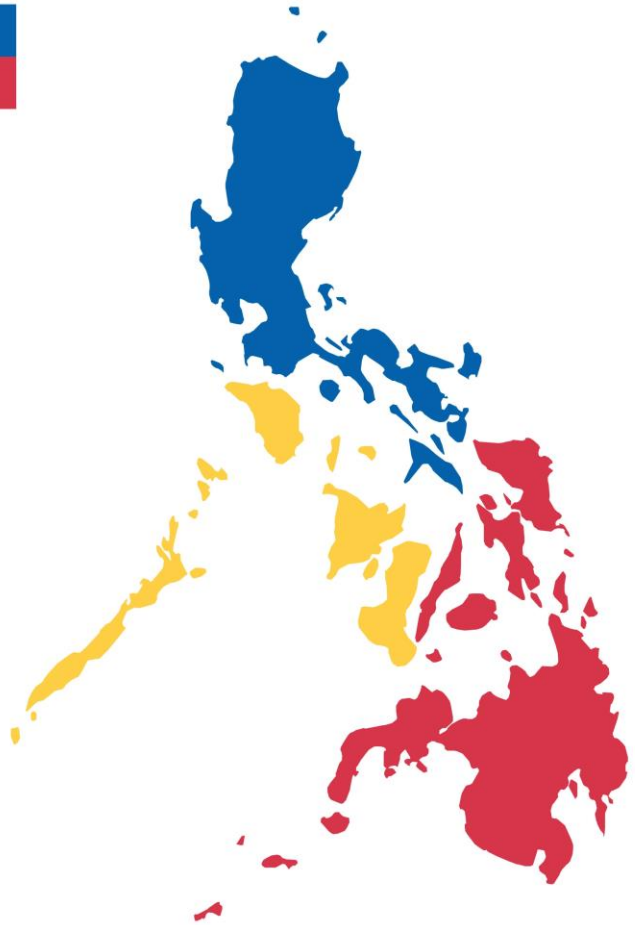
- Archipelago - 7100 islands
- Under Spanish rule for 300 years
- Predominantly Catholic
- Traditionally agricultural and fishing
- Strong sense of family and religion



Demographics

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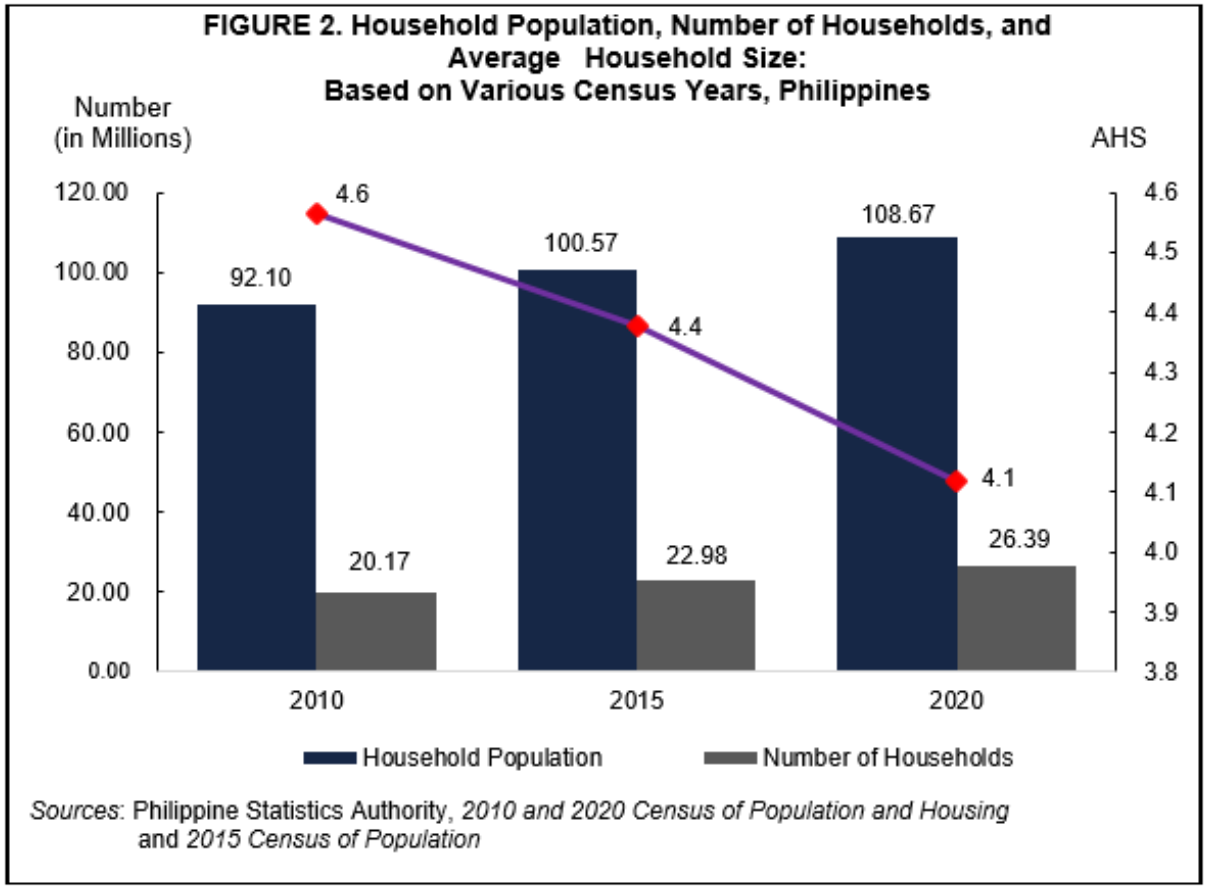
- Total population - 109,035,343
- Household population - 99.7%
- 17 regions
- 40% of the population is in Luzon an



Age Distribution

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- Predominantly young
- Median age - 23.4 years
- Dependency ratio - 61 dependents per 100 persons in the working-age group
- School age - 4 in 10,000

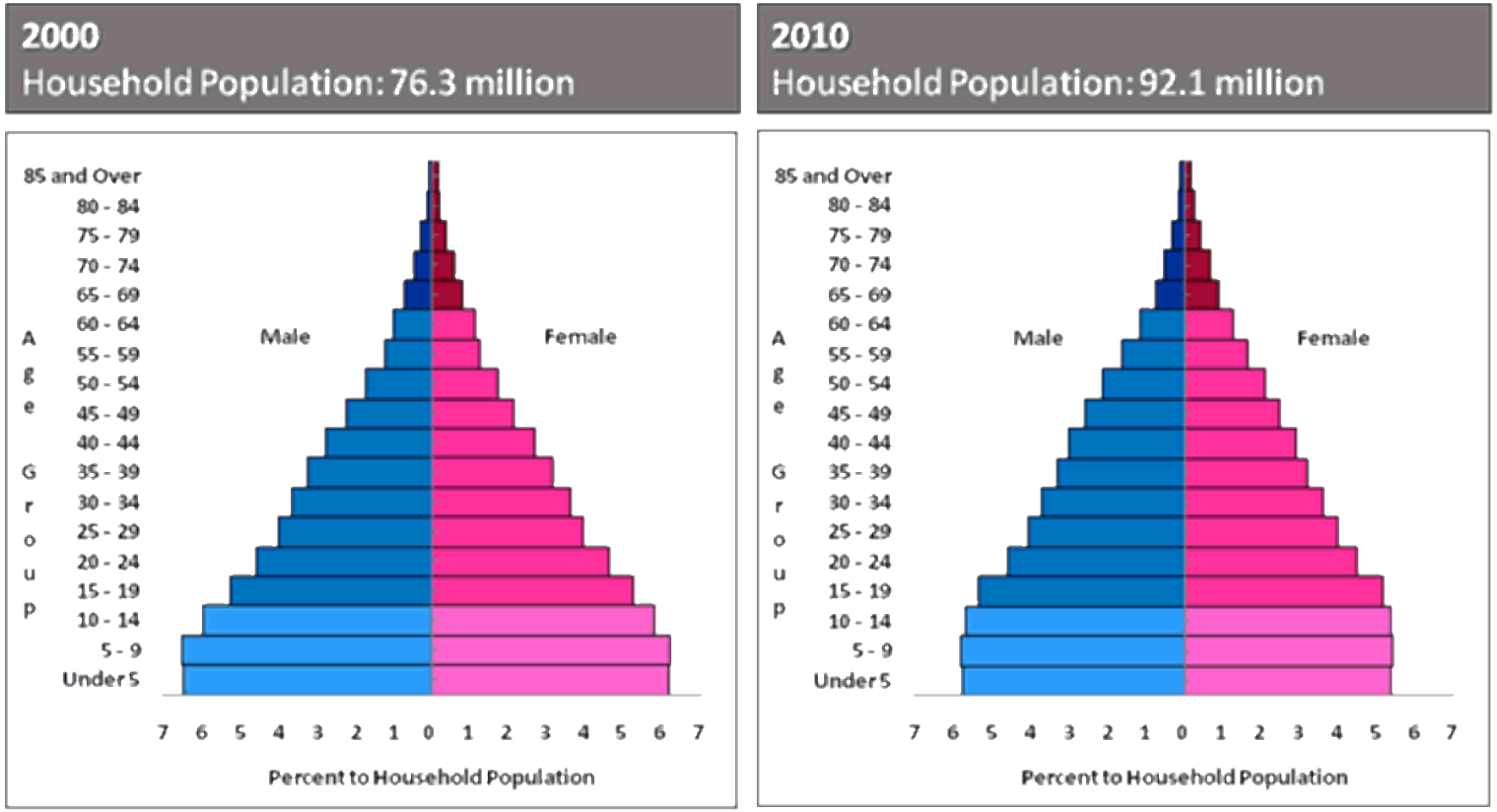

Figure 1. Age-Sex Pyramid of Household Population: Philippines

Family values

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- Family Oriented
- Respect for elders
- God-fearing
- Fellowship
- Hospitality
- Debt of Gratitude
- “Bayanihan”
- Love and Happiness

Factors affecting assent in Philippines

- Maturity and neurodevelopment
- Family factors
- “Independence” and perceptions on “self” factors
- Respect

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Advancing International Pediatric Clinical Research

ASSENT AND CONSENT IN THE FIELD: Culture, Context, and Respect

Guest Speaker

Dr. Erwin J. Khoo

School of Medicine
International Medical University
Malaysia

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ADVANCING INTERNATIONAL PEDIATRIC CLINICAL RESEARCH
Part three: Assent and consent in the field: Culture, context, and respect

Associate Professor Dr Erwin Jiayuan Khoo, MBBS, FRCPCH, AM

Head of Paediatrics Department, International Medical University, Malaysia
2022-23 Fellow, Center for Bioethics, Harvard Medical School

Assent and consent in the field: Culture, context, and respect

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Malaysia

1. **A rich, but conservative, culture**
   - Rigid social hierarchy
   - Children's rights and interests are viewed as inseparable from their parents'
2. **Seeking a child's assent may be culturally inappropriate and insulting**
   - Especially if parents have given their permission
3. **Assent**
   - Recognition of child's autonomy
   - A pedagogical tool
4. **Ubuntu ethics**
   - Conceptualizes fundamental human rights in the contexts of communal rights
   - Decision making is a collective process

Cultural accommodation

1. **Process of seeking assent should be modified to different cultural contexts**
   - Whether children's assent or parent's permission is sought first depends on cultural norms
   - The family may take priority over an individual's self-autonomy
   - Family-facilitated and collective decision making becomes a neutral consequence of this social structure
2. **Cultural humility, proper assent practices, and independent review boards**
   - Awareness of the minor's best interest and of any risk of maleficence

Challenge

1. **Assent is not just a form**
   - It is a dialogue between the researchers and the potential participants
   - Additional time to address cultural and economic differences can augment research's professional self-awareness and promote children's participation
   - This is a process and not an end in itself
2. **The key lies in the practice of listening**
   - Feedback of the child-parent unit
   - Embrace the feelings and thoughts of their decision-making process

@erwinkhoo

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ASSENT AND CONSENT IN THE FIELD: Culture, Context, and Respect

Guest Speaker

Dr. Seung-min Hahn

Yonsei University
College of Medicine
Korea

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"Korean Perspective"

Seung-min Hahn

Pediatric Hematologist-Oncology Department
Yonsei University College of Medicine, Severance hospital, Seoul, Korea

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Background Information : 'Consent'

- Laws in Korea
  - Under 'Rules regarding the Safety of Medicines'
    - 'Informed consent' is mandatory for approval, running of clinical trials in Korea
    - Content of the 'Consent form' is stipulated by law
  - Under 'Regulations on education for investigators and designation of educational institutions for clinical trials'
    - Education about 'Subject consent and understanding of recruitment process'
    - The education must be provided for investigators

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Background Information 'Assent'

- Under 'Rules regarding the Safety of Medicines' Law
  - Assent is allowed for subjects 'who are lack of understanding/expressing' their willness
  - Deputy : Legal representative → Spouse → lineal ascendant (parent/child) → other relatives

- **Guidelines/Recommendations for Clinical trials in children** by 'Ministry of Food and Drug Safety (based on ICH guidelines)
  - Children are 'vulnerable subjects'
  - Age under 19 years old (18 years 364 days old are considered legally children in Korea)
    - Term newborn infants (~28days after birth)
    - Infants and toddlers (under 24 months old)
    - Children (24 months ~ 12 years old)
    - Adolescent (12 years old~ under 19 years old)
  - **Assent of parents + Consent is also recommended from 7 years old**

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Ethical Considerations 1

- Ministry of Food and Drug Safety ‘Recommendation’
  - Special measures are needed ‘to protect the rights and interests of pediatric research participants and to protect them from serious risk’
  - Except in special circumstances discussed in ICH E6, such as non-therapeutic trials, it should be possible to benefit from clinical trials

- The problem is
  - In the clinical trial setting, often, we don’t know for sure what is a real benefit to children
  - Different ’adverse event’ in pediatric population (growth, development, long term safety issues..)

  → **Often investigator’s (doctor’s) decision is critical**

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Ethical Considerations 2

- In Korea, parent's trust and loyalty to medical staff is very high (esp. in severe, chronic diseases) – relates to parent's passion and devotion to their children, most parents seek best doctors and treatments nationwide
  - Doctors, parents together can, do discuss 'what is the best option'
  - However, usually the final decision usually rests with the doctor
  - And, often children/adolescent's own opinion is would not be considered

→ **Again, often investigator's (doctor's) decision is critical**

→ **Doctors' opinion > parents' opinion >> children's own opinion or decision**

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Investigators' Role in Pediatric Clinical Trial

- Should try to exclude prejudices
  - Affect the study design and trial performance or the presentation of results and conclusions
  - In real, investigators cannot be free from prejudice
- Should have balanced view of risks and benefits of performing the study
- Expertise of the investigator & personal ethics are important

- In real,
  - Still lack of education, programs focusing on ethical issues in pediatric clinical trials
  - Investigators (doctors) are very busy – snowed under with work, multiple roles as a clinician, researcher, and investigator of clinical trial

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Conclusion

- Informed consent/assent is required in pediatric clinical trials
- We all know the importance

- More meticulous guidelines, education programs (esp. for investigators) are “Unmet need”

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PART THREE

Advancing International Pediatric Clinical Research

ASSENT AND CONSENT IN THE FIELD: Culture, Context, and Respect

Guest Speaker

Dr. Wan-Ting Chou

PPD

Taiwan/Tokyo

This series is supported by an FDA Scientific Conference Grant.

MULTI-REGIONAL CLINICAL TRIALS

THE MRCT CENTER of BRIGHAM AND WOMEN'S HOSPITAL and HARVARD

Local Network Support

I am not familiar with preparing assent forms.

You can use a template of assent forms that are publicly available on our website.

PART THREE

1 How New Medicine is Made

A lot researchers spend a lot of time studying a new medicine before people are able to use it.

Sick people (patients) help test new medicines to see how they work in a "clinical trial."
All the researchers make sure nothing bad happens to the sick people in a trial.
The new medicine that's being tested is called an "investigational product (IP)."

Like at other hospitals, the doctors at this hospital plan and do clinical trials after discussion.

After a clinical trial proves that a new medicine is safe and works well, it can be used to help many patients.

6) Our request to young people growing up

- For girl

Body and mind, you are on your way to becoming a grown-up. If you are a girl, you may start having your period, which happens at different times to different girls and is a normal part of becoming an adult.
We cannot say how the IP will affect the part of your body where babies grow.
If you have already begun having your period, please make sure not to get pregnant during the clinical trial. If you become pregnant, please tell your family or the researchers right away so that we can make sure that you and your baby are OK.

- For boys

Body and mind, you are on your way to becoming a grown-up. If you are mature enough, you may already have sperm. When your body starts growing sperm is different for different boys and is a normal part of becoming an adult.
We cannot say if the investigational product will affect the part of your body where your sperm is made. If you are physically mature enough to have sperm, please make sure that you don't get your girlfriend

Pediatric Clinical Trials Network (Japan)

https://pctn-portal.ctdms.ncchd.go.jp/service/agree.html

How Does This Trial Work?

You will have medical examinations at the hospital as scheduled, then receive the IP.

Height

Weight

Blood pressure and pulse

Take a blood and urine test

Get a check-up

Receive the IP

Breath test

Breathe in and out as strongly as you can following instructions.
Please tell us if it's hard for you to breathe or if you feel sick.

Many thanks!

PART THREE

- Webinar recording and slides will be posted in approximately one week
- Youth video will be also be available on YouTube
- We look forward to hearing from you
- Sign up for future webinar(s)

Special Acknowledgements

Thank you to our speakers, participants, and particularly the young people who shared their stories and taught us so much.

International Children's Advisory Network (iCAN), producer of "Prioritizing Young People's Voices in Clinical Research" video

All the youth who shared their time, expertise and stories with us from iCAN and Kids Barcelona

Please follow the MRCT Center

PART THREE

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Thank you!