Session Details

No. 3.2 – Parallel session 3B – Hall 2 15.45 – 17.00 hours

Updated title

What Motivates Volunteering for Interventional Trials in a Tertiary Referral Oncology Centre in Mumbai.

Presenter - K V Ganpathy

Country - India

Institutional Affiliation - Member – Institute Ethics Committee 1; Tata Memorial Centre, Mumbai

Current Position – Member (Lay Person) - Institute Ethics Committee

Highest Education – PhD (Adolescent Psychology)

Associated with the Ethics Committee since 2015

Presented – Lay Person's challenges in SIDCER conference, New Delhi

KV Ganpathy Institutional Ethics Committee Tata Memorial Centre Mumbai

"Maximizing Benefits through Responsible Conduct of Research.

Study team – Dr Gouri Pantvaidya, Dr Nithya Gogtay, Ms Abhidnya Desai, Dr Snehal and Ms

The Three Tenets

Objectives of the trial

Trial Participant

Participants safety

What is a Clinical Trial ??

A research study that tests any medical, surgical, or behavioral intervention in participants & designed to learn and find new & effective treatment approaches or less harmful side effects than the existing treatment.

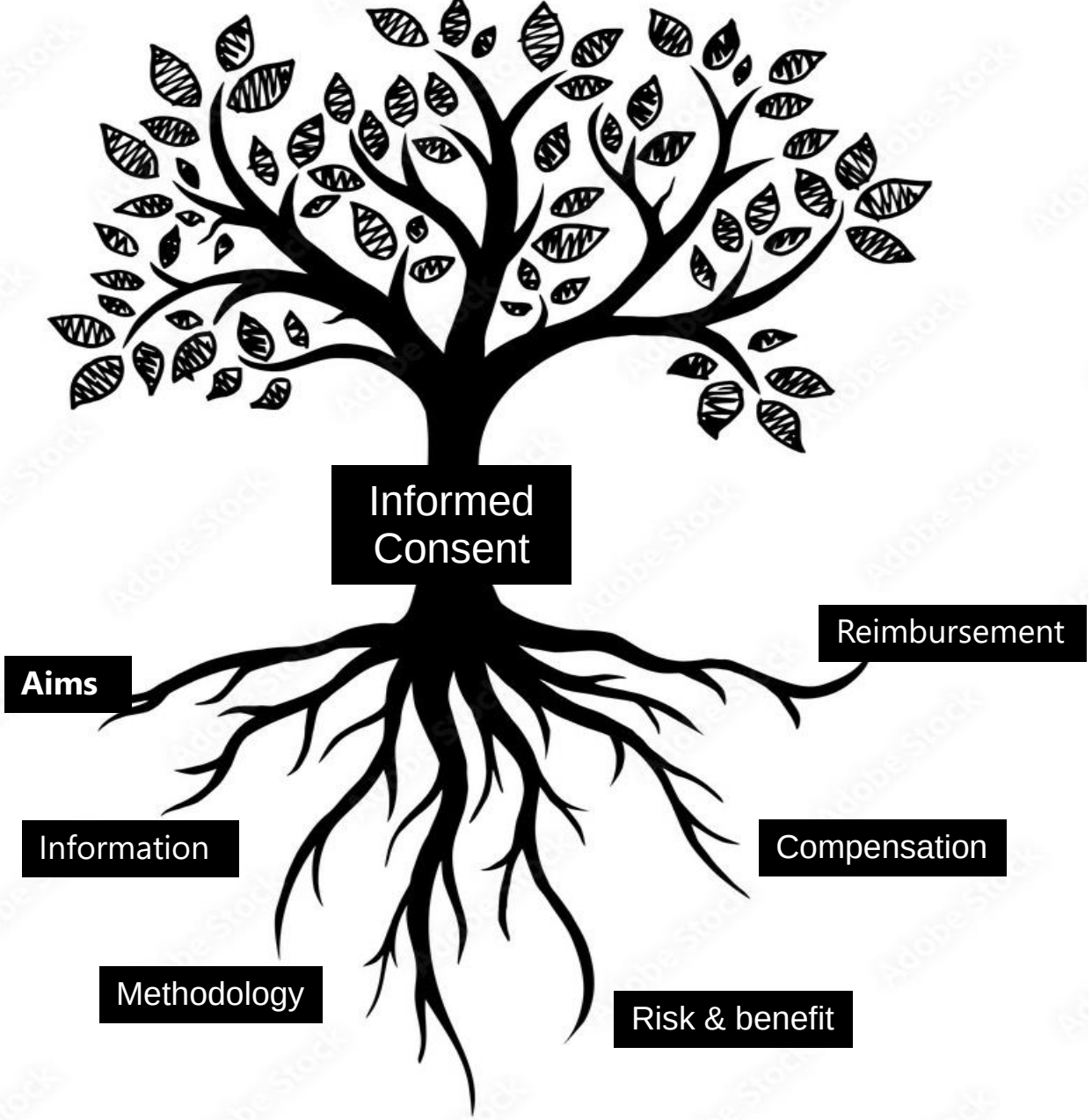
Who is a Trial participant???

Anyone who takes part in a clinical Trial; which ***voluntarily*** **people or people wi dition that the trial is testing.**

Ethics in Research – 4 Pillars

Beneficence	Non Maleficence	Autonomy	Justice
To do good for patients by promoting their well being	First do no harm to patients	Respecting the patient's right to self-determination, & Voluntary decisions	To treat equally & equitably & fair resource allocation

How Informed Are You???



- Main source of Information
- Informed choice for participation

Non coercive, Non inducing & Voluntary

Vulnerability Vs. empowerment

THE CHALLENGES

- Low- Middle-Income Countries (LMICs)
- High volume patients
- Poor Socio-Economic Status (SES)
- Religious influence
- False expectations
- Wrong perceptions

THE CRUX

ARE PARTICIPANTS CLEAR THAT THEY ARE 'TRIAL PARTICIPNATS' AND NOT *PATIENTS'* WHEN THEY CONSENT TO PARTICIPATE IN A CLINICAL TRIAL ??

The Study :

Aim

What Motivates Volunteering for Interventional Trials in a Tertiary Referral Oncology Centre in Mumbai.

Rationale

To explore the patients understanding of Clinical Trial and do they really make informed decision.

Methodology

- Exploratory study
- Ethics Committee approved
- CTRI registration
- Sample size 120 (Non probability purposive sampling (patients across different Disease Management Groups)
- Consenting process of participants in interventional trials
- All participants administered Kuppuswamy scale for slotting them in Higher, middle and lower income class

- Single Interview Question
- Each interview 15-20 minutes
- Each interview audio recorded
- Each interview narrative coded – themes extracted

Results & Themes

Only a small proportion of patients participated as an opportunity to contribute

No direct association between SES & the nature of response

Conclusion

This novel study provides an **understanding** of how patients in a Tertiary Cancer Centre perceive clinical trials.

A structured education program, considering the level of literacy, comprehension, and recall, can be designed to address lack of awareness, the negative perceptions and knowledge gaps of clinical trials among the doctors & trial coordinators.

Concerted effort is needed to educate the trial participant.

FUTURE COURSE OF ACTION

To present the findings of this study to the Hospital Administration and design a program to improve the informed consenting process

To expand this study to other TMC

INFORMED CONSENT SOUNDS SO EASY IN PRINCIPLE,

While the surgeon explains the balance of risks and benefits, the calm and rational patient decides what he wants-just like going to the supermarket and choosing from the vast array of the tooth brushes on offer.

However, the reality is *so different*

BE INFORMED

BE EMPOWERED

THANK YOU