



Vulnerable Populations in research

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Who are vulnerable population?

- Oxford dictionary defines vulnerable as
“ that which can be hurt or wounded;
open to hurt by attack or criticism.”

Some historical hallmarks

- Goldberg – Pellagra studies 1912 – Prisoners
- Weimar Republic 1931 – Protection for vulnerable population Consent as legal requirement.
- Nazi experiments- 1935-45 - Mentally retarded, Prisoners.
- Nuremberg declaration
- Tuskegee – 1935 – 1970 – Poor Blacks.
- Willobrok study – 1955 – Children
- Injectable contraceptives- 1979-1982 - Women

Vulnerable population

- The Belmont Report (1972)

Vulnerable populations as those groups that might “**bear unequal burdens in research**” because of their “**ready availability in settings where research is conducted**”, such as prisons, hospitals, institutions, and camps, and called for extra protection for these groups.

ICMR code ch111 – Vulnerable groups

- 111 iii. ***Vulnerable groups*** : Effort may be made to ensure that individuals or communities invited for research be selected in such a way that the burdens and benefits of the research are equally distributed.
- a. Research on genetics should not lead to **racial inequalities**;
 - b. Persons who are **economically or socially disadvantaged** should not be used to benefit those who are better off than them;
 - c. Rights and welfare of **mentally challenged and mentally differently able persons** who are incapable of giving informed consent or those with behavioral disorders must be protected;
 - d. Adequate justification is required for the involvement of subjects such as prisoners, students, subordinates, employees, service personnel etc. who have **reduced autonomy** as research subjects.

- Typically, the justification for including a vulnerable group in research is when a problem disproportionately affects that group.

Ethics of vulnerable population

- Based on the principle of respect for a person.
 - In exploiting others we fail to give proper consideration to the vulnerable.
 - It needs to be followed by all individuals as well as the organizations
- The more strong have a duty not to exploit the vulnerable.

Specific Vulnerable groups

- Prisoners
- Women
- Children
- Mentally incapacitated
- Refuges
- Poor
- Elderly
- Sexual minorities
- Addicts.

Cross cutting issues in research among the Vulnerable Populations

- Informed consent
- Exploitation
- Confidentiality

Respect for individuals

- The principle of respect for individuals incorporates two fundamental ethical principles:
 - Respect for autonomy
 - Protection of vulnerable people.
- These principles are commonly addressed by procedures to obtain individual informed consent that ensure that respondents understand
 - the purpose of the research,
 - the risks and benefits of participation
 - and that their participation is voluntary.

Informed consent

- Originally, the concept of informed consent was developed in order
 - (1) to promote individual autonomy and
 - (2) to encourage rational decision making.
- It should protect patients confronted with the power of the medical profession and with the financial domination of the drug industry.

Western Philosophies

- Ethical principles of Western medicine on informed consent require all adults to be primary decision makers about their own participation.
- However, the relevance and applicability of Western principles of autonomy and individualism need to be contextualised to our settings.

Difference between the Western and other Philosophies in relation to a person

- Beliefs about personhood, individual autonomy, and decision capacity are embedded within the social and cultural patterns of **family ties and community obligations**.
- The concept of an individual making a personal decision independent of the community is not common in cultures of the developing world.
- Religious, tribal, or community leaders, or the person's extended family play a significant role in decisions concerning health care and health research.
- In these communities, personhood is often defined by one's family, caste, village, or social group and therefore, decisions about consent are likely to be made at the level of the extended family, community, or village.

Asian Communities are different from African Communities

Family is more important than the tribe.

Caste is more important than the
village.

Belief in reincarnation

Community based trials and informed consent in rural north India

A DeCosta, N D'Souza, S Krishnan, M
S Chhabra, I Shihaam and K Goswami

J. Med. Ethics 2004;30;318-323

AIMS

- This study to explore the complexities involved in obtaining informed consent to participation in community research in rural north India;
- How people make decisions related to participation in clinical research?
- Who decides about a subject's consent?
- Would they allow their children to participate?
- What kind of information would they wish to know from the physician/investigator?
- What would be the motives for participation/non-participation?

Study Methods

- Conducted in a village Chhainsa, in Haryana
- Predominant population were Hindus.
- A systematic sampling was done.
- The youngest married male member was interviewed. If not present then the youngest married female member was interviewed.
- A structured questionnaire with open ended answers was administered

Who decides about the subject's participation?

- **MEN**
- 90% reported themselves to be decision makers regarding their own participation.
- 10% reported elder members of their extended families as deciding for them.
- **WOMEN**
- Three of the seven women (42.8%) -they would decide for themselves.
- Two said that their husbands would decide.
- Two women said that their mother-in-law would decide if they should participate in the research.

How would the decision maker arrive at his/her decision regarding participation?

Men

- 44.4% will decide without any consultation
- 42.2% will consult family members.
- 6.6% consult friends
- 6.6% consult friends as well as neighbors.

Women

- 6/7 women decision will be made with consultation of the family.

Willingness to participate in the study

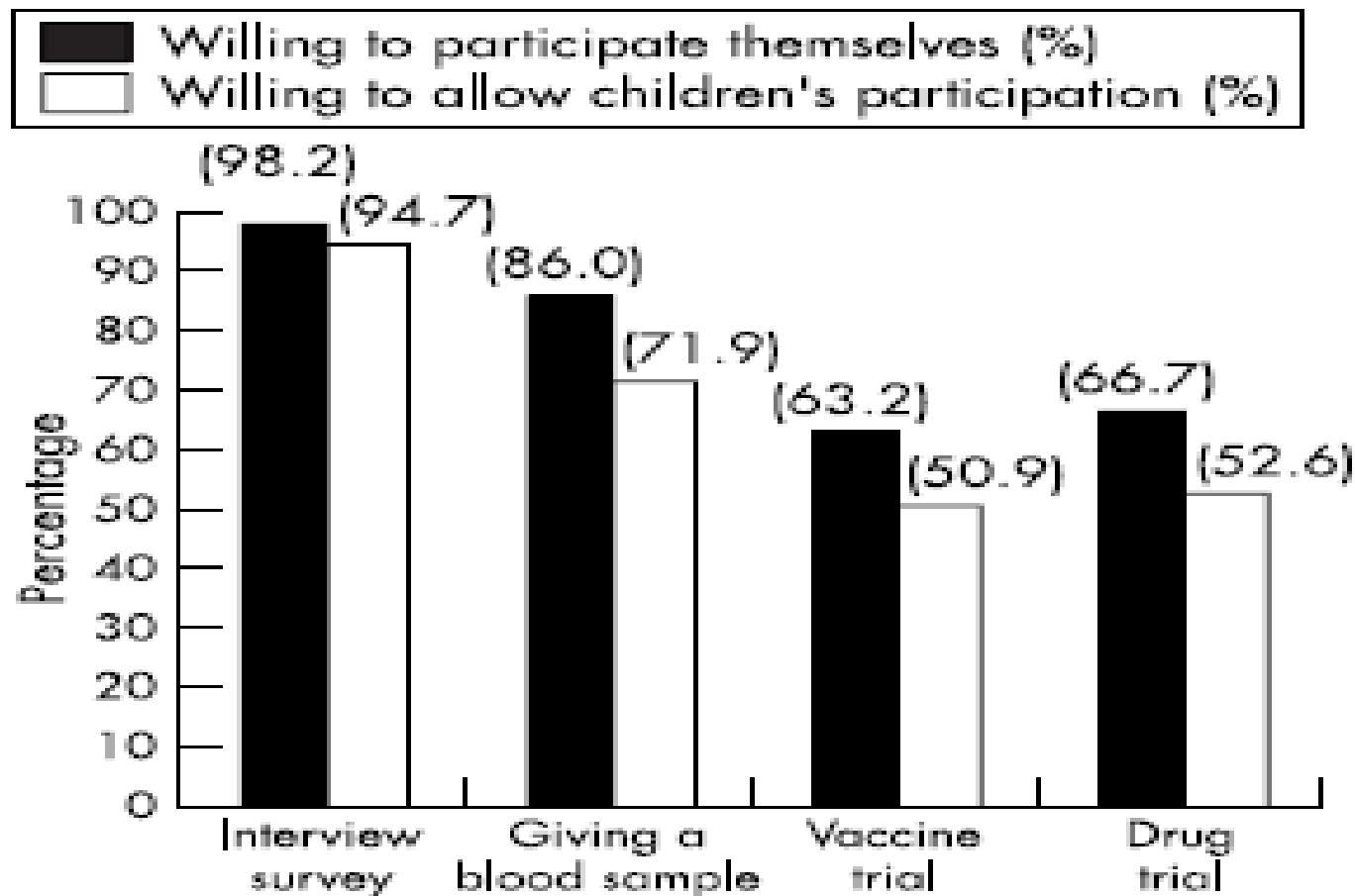


Figure 1 Willingness for participation in research studies (n = 57).

Reason for participation in the study

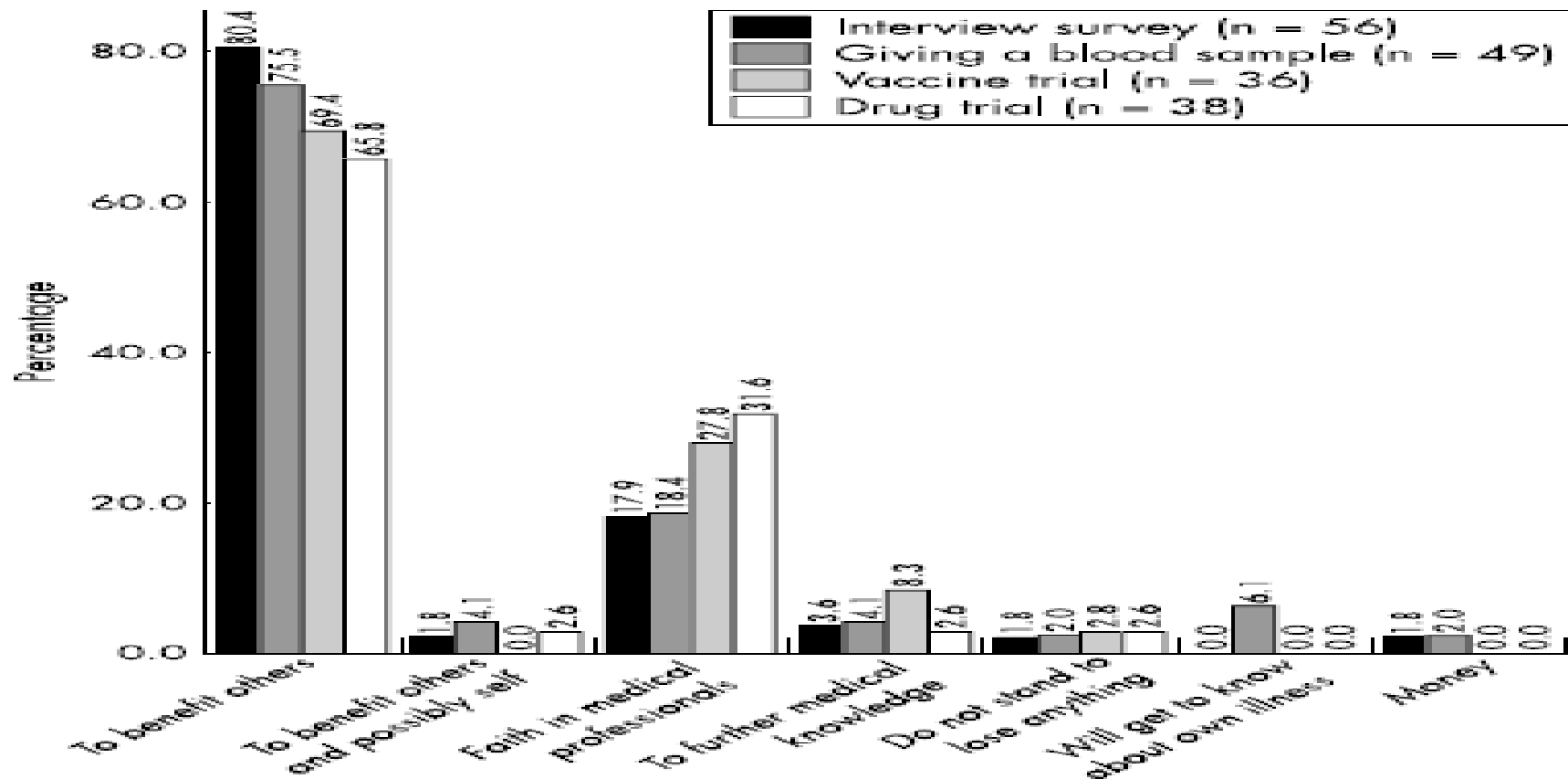


Figure 2 Reported reasons for own participation in research studies.

Reasons for non participation

Table 1 Reasons for own non-participation in research studies

Reason	Interview survey (n = 1)	Giving a blood sample (n = 8)	Vaccine trial (n = 21)	Drug trial (n = 19)
Afraid/concern about (unknown) side effects	0 (0.0)*	0 (0.0)	13 (61.9)	13 (68.4)
Am healthy/not unwell, so why should I participate	0 (0.0)	4 (50.0)	3 (14.3)	3 (15.8)
Never needed medical help (so why contribute)	1 (100.0)	1 (12.5)	1 (4.8)	1 (5.3)
Have never had to do this for myself let alone do it for others	0 (0.0)	0 (0.0)	1 (4.8)	1 (5.3)
Have less blood in the body	0 (0.0)	2 (25.0)	0 (0.0)	0 (0.0)
Afraid of injections	0 (0.0)	0 (0.0)	2 (9.5)	0 (0.0)
No reason	0 (0.0)	1 (12.5)	1 (4.8)	1 (5.3)

*Numbers in parenthesis are percentages

Reasons

For participation

- Altruism
- Trust in the doctor
- Nothing to loose.
- Money.
- Opportunity to know the disease.

For Non participation

- Fear of unknown effects
- Fear of losing blood.

Requirement of information

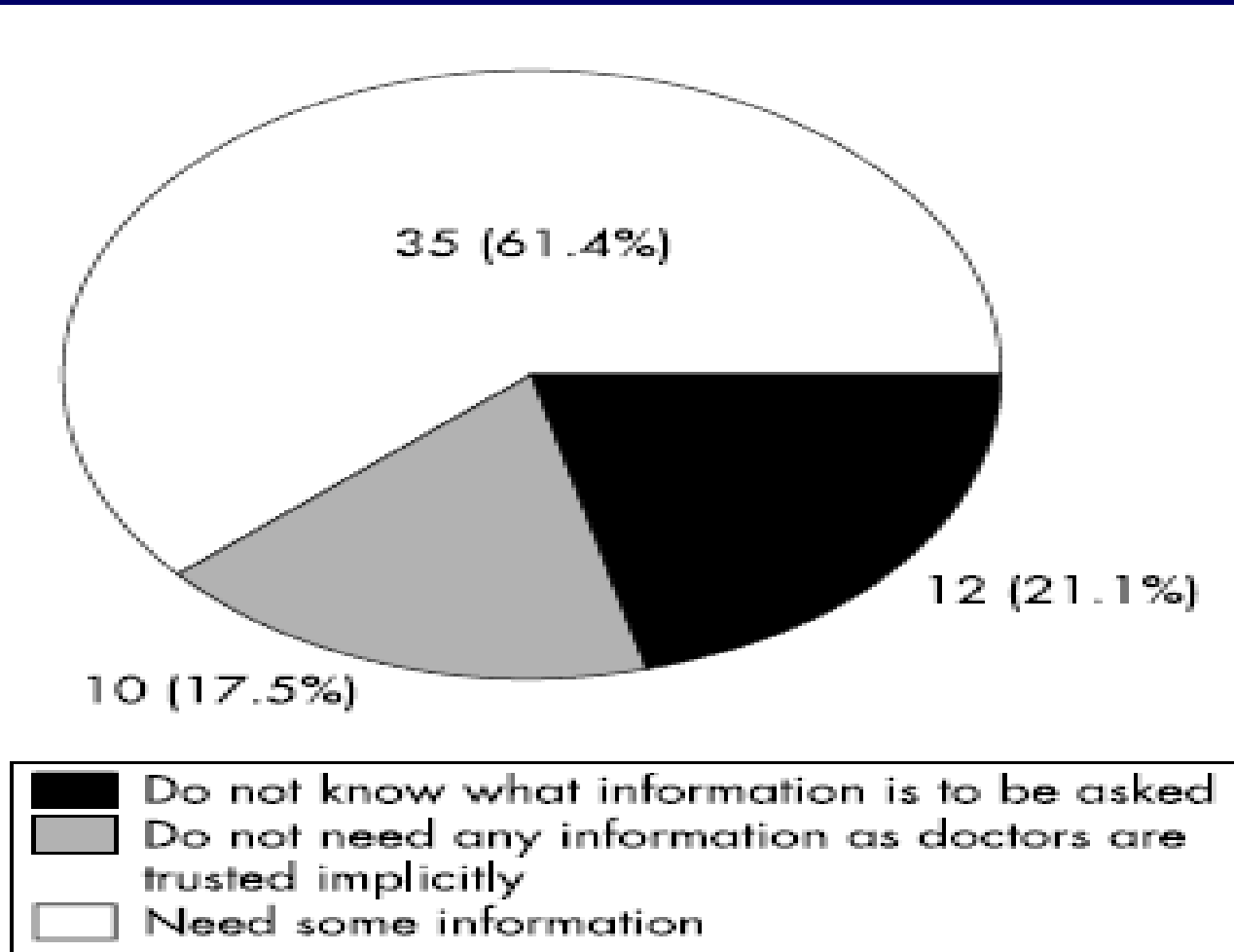


Figure 4 Requirement of information for decision making concerning participation in community based research studies (n= 57).

Questions that participants would like to be answered before they agreed to consent

Table 3 Information required before participating in a community based study (n = 35)

Information requested	Frequency (%)
What (disease) are you studying and why?	28 (80)
What authority do you have/where are you from?	5 (14.3)
Effects and side effects of drug/vaccine	4 (11.4)
Who is responsible/where can the person be found in case of a side/adverse effect?	3 (8.6)
Would there be any gain from taking the drug/vaccine?	2 (5.7)
Do you give an assurance that you will help me later in time of need if I cooperate with you in the trial?	2 (5.7)
Will participation be financially remunerative?	1 (2.9)
Will I be informed of illness if found in blood sample?	1 (2.9)
Will I be given treatment if a disease is found in my blood sample?	1 (2.9)

Multiple responses possible, percentages total >100.

Conclusion

- The majority of the community interviewed could decide about participation only after discussing it with other community members.
- Only about a third of all respondents could take an exclusively independent, non-consultative decision.
- Implicit trust which part of the community had in the medical system,
- An ignorance of what information one might want to know before consenting to be part of a research study.

Implications for future.

- Participants should be given time to decide on consent forms.
- Not only the participants but also people to whom they look up for decision making should also be given the information.
- Ascent of the community leaders can not be taken as a criteria that the community will support the research

Surrogate decision making

urrogate decision makers are persons who make decisions for an incompetent patient.

ualities of a surrogate decision maker

commitment to incompetent persons welfare.

bility to make a reasoned judgment.

Surrogate decision making

- There is a need for clear guidance on the identification of persons who are legally authorized to provide informed consent on behalf of incompetent adults.
- States should enact laws that clarify the legal status of a family member to serve as a research proxy.
- In instances in which a different person is the legally authorized research proxy, the investigator will need to obtain informed consent from both people.

Standard for surrogate decision making

Substituted judgment standard — that is, choosing what the patient would choose if he or she were capable of choosing.

Best interest standard - base the decision on the potential subject's previous wishes

Best interest principle.

Surrogate decision making

- The ethical guidelines for decision making by a Surrogate decision maker should not uniformly require the proxy to make a substituted judgment
- A surrogate decision maker cannot consistently make accurate substituted judgments for enrollment in research.
- It would be reasonable to require that the informed-consent form instruct the surrogate decision maker to base the decision on the potential subject's previous wishes
- If this information is not available then the surrogate has to make the decision on the basis of the person's best interests.

When is enrolling a non competent patient in research ever in his or her best interests?

- In most cases, a surrogate decision maker for a noncompetent adult will not have the same degree of discretion.
- The core ethical challenge is to define the limits on the kinds of research risks that the surrogate decision maker can accept on behalf of a noncompetent subject.
- A surrogate decision maker should be allowed to enroll a person
 - if the IRB finds that the research is potentially beneficial
 - or presents minimal risks
 - and that the knowledge that may be gained would be important to the class of subjects.

The legal approach to Surrogate decision making

- The legal approach to proxy decision making in the care of patients with permanent unconsciousness or terminal illness relies on obtaining informed consent from a family member, identified on the basis of a hierarchy of family relationships widely thought to reflect closeness, such as the spouse and then an adult child.
- In many instances, this hierarchy is also used to identify the person who is an ethically appropriate proxy for making decisions about participation in research
- Research regulations should permit an IRB to require that the protocol identify the ethically appropriate research proxy.

ICMR Guidelines

- Where the human subject is incapable of giving consent and it is considered essential that research or experimentation be conducted on such a person incompetent to give consent, the principle of voluntariness and informed consent shall continue to apply
- Such consent and voluntariness shall be obtained and exercised on behalf of such research subjects by someone who is empowered and under a duty to act on their behalf.

Helsinki declaration

- 24. For a research subject who is legally incompetent, physically or mentally incapable of giving consent or is a legally incompetent minor, the investigator must obtain informed consent from the legally authorized representative in accordance with applicable law.
- These groups should not be included in research unless the research is necessary to promote the health of the population represented and this research cannot instead be performed on legally competent persons.
- 25. When a subject deemed legally incompetent, such as a minor child, is able to give assent to decisions about participation in research, the investigator must obtain that assent in addition to the consent of the legally authorized representative.

Helsinki declaration

- 19. Medical research is only justified if there is a reasonable likelihood that the populations in which the research is carried out stand to benefit from the results of the research.
- 23. When obtaining informed consent for the research project the physician should be particularly cautious if the subject is in a dependent relationship with the physician or may consent under duress. In that case the informed consent should be obtained by a well-informed physician who is not engaged in the investigation and who is completely independent of this relationship.

Helsinki declaration

- 26. Research on individuals from whom it is not possible to obtain consent, including proxy or advance consent, should be done only if the physical/mental condition that prevents obtaining informed consent is a necessary characteristic of the research population.
- The specific reasons for involving research subjects with a condition that renders them unable to give informed consent should be stated in the experimental protocol for consideration and approval of the review committee. The protocol should state that consent to remain in the research should be obtained as soon as possible from the individual or a legally authorized surrogate.

Non exploitation

- This is especially important if the trial is to be conducted in a country or region where the population may be vulnerable to exploitation because
 - of pervasive poverty and disease
 - or lack of understanding of the scientific issues surrounding the health problem and the role of the clinical trial in the search for a solution.
- A trial in a developing country might be justified in a number of ways.
 - The research might address an important health problem in that country,
 - or it might represent a joint effort by the country sponsoring or conducting the study and the host country to address an important health problem in both countries.
- However, conducting a trial in a developing country because it is more convenient or efficient or less troublesome to do so is never a sufficient justification.

Nuffield Council

- We suggest that, as a matter of moral principle, the more powerful have a duty to refrain from exploiting to their own advantage the vulnerability of the weaker.
- Since those with power may always be tempted to misuse it, perhaps even for what they perceive as benevolent reasons, it is important to insist on this/

Nuffield Council

1. It can be regarded as a further implication of the principle of respect for persons, for in exploiting others we fail to give proper weight to their interests.
2. Like the requirement of sensitivity to cultural differences, the duty not to exploit the vulnerable merits special attention not least because outsiders and local citizens may well differ on just what counts as exploiting or taking advantage of the weakness of others.
3. It is important that the duty not to exploit the vulnerable be observed uniformly by all individuals and organisations involved in research, to avoid unfairness and the danger of undermining the principle in practice.
4. Although the duty not to exploit the vulnerabilities of others falls on all, the nature of the obligation may change depending on who is involved.

Nuffield Council

- 4.21 Hence, the principle of not exploiting the vulnerable does not mean that we simply take the current context of research related to healthcare in the developing world as unchallengeable and unalterable.
- Just as it is unacceptable that local political and economic elites should seek to pursue their own goals at the expense of populations participating in research, it is unacceptable that researchers should select populations which are economically or politically weak, and therefore vulnerable to exploitation, in order to test therapies more cheaply in order to benefit other, wealthier communities.

Nuffield Council

- The wider roles and obligations of all those involved in research, pharmaceutical companies, international organisations, governments, and individuals in reducing global health inequities must always be borne in mind. In particular, in the context of research, researchers have a duty to enable the participant communities in developing countries to benefit, where possible, from the research conducted on them.

Non exploitation

- An important additional safeguard is needed to avoid the exploitation of potentially vulnerable populations in developing countries
- Clinical trials sponsored or regulated by external agencies should be limited to those that are responsive to the host country's health needs.
- If the intervention being tested is not likely to be affordable in the host country or if the health care infrastructure cannot support its proper distribution and use, it is unethical to ask persons in that country to participate in the research, since they will not enjoy any of its potential benefits..

Principles of non-exploitation ICMR

- whereby as a general rule, research subjects are remunerated for their involvement in the research or experiment; and, irrespective of the social and economic condition or status, or literacy or educational levels attained by the research subjects
- The research subjects should be kept fully apprised of all the dangers arising in and out of the research so that they can appreciate all the physical and psychological risks as well as moral implications of the research whether to themselves or others, including those yet to be born.
- Such human subjects should be selected so that the burdens and benefits of the research are distributed without arbitrariness, discrimination or caprice.

Principles of non-exploitation ICMR

- Each research shall include an in-built mechanism for compensation for the human subjects either through insurance cover or any other appropriate means to cover all foreseeable and unforeseeable risks by providing for remedial action and comprehensive aftercare, including treatment during and after the research or experiment, in respect of any effect that the conduct of research or experimentation may have on the human subject and to ensure that immediate recompense and rehabilitative measures are taken in respect of all affected, if and when necessary.

Confidentiality

- Participants' information must be protected, especially if harm could result if it fell into the wrong hands.
- Confidentiality protections cannot be assessed without considering how they might interact with the broader setting of pervasive governmental authority.

Principles of privacy and confidentiality ICMR

- whereby, the identity and records of the human subjects of the research or experiment are as far as possible kept confidential; and that no details about identity of said human subjects, which would result in the disclosure of their identity, are disclosed without valid scientific and legal reasons which may be essential for the purposes of therapeutics or other interventions, without the specific consent in writing of the human subject concerned, or someone authorized on their behalf; and after ensuring that the said human subject does not suffer from any form of hardship, discrimination or stigmatisation as a consequence of having participated in the research or experiment.

Mentally incompetent

Different Roles

- The respective roles of the physician and the researcher should be clearly distinguished.
- **The physician** aims at improving the condition of the patient by establishing with him a therapeutic alliance.
- **The researcher** aims at understanding the mechanism of the disease in order to develop rational treatments, and for that purpose needs to obtain the consent of the patient.
- **The relationship between the researcher, the psychiatrist, and the patient is far from being a relationship among equals.**

Importance of research into Mental health

- The Global Burden of Disease Study established for the first time the substantial burden of mortality and disability associated with mental illnesses.
- Depression, the fourth leading disease burden in 1990, is predicted to move to second place in 2020.
- Of the ten leading causes of disability worldwide, five were psychiatric conditions.

THE NEED FOR PROGRESS IN BIOLOGICAL RESEARCH ON PSYCHIATRIC DISEASES

- Psychiatric diseases are behind as far as biological approaches are concerned.
- These delays are due to
 - The inherent complexity of the nervous system.
 - The religious and philosophical background of Western culture emphasised the “mind” aspect of psychopathology rather than its “body” side.
- In the absence or insufficiency of biological hypotheses, therapies based on the psychological and psychoanalytical approaches were developed first and have shown their usefulness.
- Till a few years ago drugs for mental disorders were developed through chance discoveries.

Present Scenario

- During the 20th century, research aimed at a biological understanding of the nervous system made remarkable progress.
- It has become multidisciplinary
- Investigations in human nervous disease has improved. It has allowed a biological approach to some of the major mental diseases.
- These developments, based on basic neurosciences and combined with modern cognitive methodologies, should open the way to a renaissance of biological research in psychiatry.

Mentally incapacitated patients

no-one can give or withhold consent to treatment on behalf of a mentally incapacitated patient.

researcher must first assess the patient's capacity to make an informed decision about the treatment.

How does an investigator decide on mental competence?

- An investigator's assessment of a person's abilities to understand information about a study and to reason and make a choice on the basis of that information is essential evidence for the judgment of whether the person is competent to provide informed consent.
- Protocols for studies that enroll cognitively impaired subjects should describe a procedure to assess these abilities.

What to do when the subject is incompetent?

- In the case of a person who is not competent, there is a general consensus that the investigator should seek the person's assent and respect his or her dissent, if the subject is capable of providing assent or dissent.
- Because there are no widely accepted standards for obtaining assent or dissent, research protocols should indicate the kinds of performance on measures of decision-making ability that show that a person can assent or dissent.
- The informed consent form should include a section to document these assessments — for example, a checklist to indicate whether the subject adequately understood key items required for assent.

Recruitment before the loss of capacity

- If subjects can be recruited before a predictable loss of capacity occurs, advance informed consent is an option.
- When advance informed consent is obtained, investigators should also ask each subject to designate a person who will serve as his or her proxy during the course of the research.
- With advance informed consent, the investigator recruits an eligible subject for a particular study before the onset of cognitive impairments but close enough to enrollment so that the informed consent form presents information that is salient and relevant to the patient.

Vulnerable children

Introduction

- Society wants to spare children from the potential risks involved in research.
- But children may be harmed if they are given medications that have been inadequately studied.
- Research that is carefully designed and conducted should help to protect children, but studies particularly studies of medications whose safety has not been established, cannot be risk-free.
- Unless more children participate, more clinical trials cannot be conducted.
- About 70 percent of children with cancer are enrolled in clinical trials sponsored by the National Cancer Institute.
- The recruitment of children, however, may raise concern that they are being exploited.

Problems of drug trials in Children

- The FDA classifies pediatric patients as
 - newborns (0 to 1 month of age),
 - infants (1 month to 2 years of age),
 - children (2 to 12 years of age),
 - or adolescents (12 to 16 years of age).
- Children cannot take medications unless they are marketed in suitable forms, such as liquids or chewable tablets.
- The formulation of medications represents a major issue for children.
- Although custom formulations of medications may be used for patients in the hospital, their bioavailability may vary.

Scientific Issues

- .As children grow, their body size and composition, physiology, and cognitive and motor function change.
- The metabolism and toxicity of medications can vary substantially in children of different ages.
- FDA regulations allow the effectiveness of a medication to be extrapolated from studies in adults if the course of the disease being treated and the effects of the drug are sufficiently similar.
- The safety of a drug in children often cannot be extrapolated from data for adults; medications may be more or less toxic in children.
- In addition, accurate information about dosages in different age groups is particularly important; otherwise, children may be under treated or over treated.
- Some medications, such as corticosteroids, can affect growth and development.

Ethical Issues

- Children are considered a vulnerable group and require additional protection as research subjects.
- Obtaining the assent of a child and the permission of a parent or guardian is not the same thing as obtaining informed consent from a competent adult

Children (ICMR)

Before undertaking trial in children the investigator must ensure that -

- a. Children will not be involved in research that could be carried out equally well with adults;
- b. The purpose of the research is to obtain knowledge relevant to health needs of children.
- c. For clinical evaluation of a new drug the study in children should always be carried out after the phase III clinical trials in adults. It can be studied earlier only if the drug has a therapeutic value in a primary disease of the children;
- c. A parent or legal guardian of each child has given proxy consent;
- d. The assent of the child should be obtained to the extent of the child's capabilities such as in the case of mature minors, adolescents etc.

Children (ICMR)

- e. Research should be conducted in settings in which the child and parent can obtain adequate medical and psychological support;
- f. Interventions intended to provide direct diagnostic, therapeutic or preventive benefit for the individual child subject must be justified in relation to anticipated risks involved in the study and anticipated benefits to society;
- g. The child's refusal to participate in research must always be respected unless there is no medically acceptable alternative to the therapy provided/ tested, provided the consent has been obtained from parents / guardian;
- h. Interventions that are intended to provide therapeutic benefit are likely to be at least as advantageous to the individual child subject as any available alternative interventions;
- i. The risk presented by interventions not intended to benefit the individual child subject is low when compared to the importance of the knowledge that is to be gained.

Children

arents or Guardians consent is essential

Mature Minor”

- Assess a child's capacity to decide whether to consent to or refuse proposed investigation or treatment before providing it.
- In general, a competent child will be able to understand the nature, purpose and possible consequences of the proposed investigation or treatment, as well as the consequences of non-treatment.

Payments for children

- Although it seems reasonable to offer payment for the time and inconvenience of participating in research, children and their families may be unduly influenced by the offer of payments that may amount to several hundred dollars or may include gift certificates to toy or record stores.
- From the perspective of sponsors, such payments may seem trivial. According to the American Academy of Pediatrics, “serious ethical questions arise when payment is offered to adults acting on behalf of minors in return for allowing minors to participate as research subjects.
- The remuneration should not be beyond a token gesture of appreciation for participation. If remuneration is to be provided to the child, it is best if it is not discussed before the study’s completion.

Refugees

Problems of refugees

- Refugees are vulnerable as subjects for research for several reasons.
 1. In terms of political status, refugees inherently **possess fewer defined political rights** than people who can claim citizenship within stable national frontiers
- The protective framework of the 1951 UN Convention on Refugees and its additional Protocols establishes only basic standards for the treatment of refugees, allowing host countries to apply additional domestic law at their discretion.
- Many countries have done little in this respect, with the result that refugees stand outside the regulatory protection of domestic legislation and are vulnerable to arbitrary action on the part of the host country.
- The status of the internally displaced in settings of collapsed or collapsing states is even more ill defined.

Problems of refugees

2. Refugee flows now usually occur in the midst of complex emergencies, where **human rights abuses** are rampant and where refugees are considered hostile targets by those who force them to flee. The prevailing powers in the region are unwilling or unable to provide adequate oversight to research involving refugees.
3. **Little technical guidance** is available from the usual international instruments on biomedical ethics, such as the Declaration of Helsinki or guidelines from the Council for International Organizations of Medical Sciences (CIOMS), because although they look at issues of vulnerability (as arising with prisoners, children, or the mentally impaired) they do not address the special circumstances of enlisting refugees or the internally displaced in research.

Problems of refugees

5. Refugee camps themselves give rise to conditions that increase the vulnerability of refugees to potentially abusive research practices.
6. Despite the best efforts of the international community, these camps or IDP settlements tend to perpetuate political persecution imported from the country or region of origin and aggravate inter group or intra group tensions, so that occupants are not free from fear of oppression, reprisal, or humiliation.

Research among Refugees

- The debate pivots on the tension between the need to develop evidence-based emergency health measures and the need to protect vulnerable populations from possible exploitation or harm.

Research categories

- Aetiology or prevalence investigations
- Assessment of operations or systems
- Clinical intervention research
- *Sometimes research findings can increase risk of violations*

Advantages of research with refugees

- The physical layout of these camps provides some accessibility and population density most amenable to rapid systematic sampling and data collection.
- This logistic appeal is often coupled with a humanitarian justification based on urgent human need (in scarce water areas it would indeed be most helpful to know the real minimum water requirements per head).
- These considerations contribute to the mounting momentum for carrying out research in these settings.

Challenges for the researcher

- The research community with unprecedented challenges in interpreting and applying the protection provided by the key principles of bioethics—
 - Informed consent,
 - confidentiality,
 - do no harm
 - beneficence.
- Language, culture, educational background, and social norms make it difficult to obtain truly informed and voluntary consent.
- Confidentiality issues are severe and perilously unpredictable.
- Sampling techniques may confer unintended negative attention or focus on particularly vulnerable subpopulations, such as women and children, and make conditions worse.
- The questions themselves likely to cause emotional upset.
- Does this continued attention expose them to risk of reprisal or humiliation?

Challenges for the researcher

- The most complex challenge arises with the principles of beneficence—in whose interest is this research being done, and who will benefit from the results?
- Because of the mobility and fluidity of many refugee populations, especially at times of acute crisis, it is difficult to design a study that has much realistic chance of conferring benefit to the specific individuals enrolled.
- In the consent process, the study participants have to be made to understand that they are agreeing not only to enter a study that has some risks (the intervention might not be as good as the control) but also to undergo something that might not give them any benefit.

Proposed guidelines for research in refugee populations

1. Undertake only those studies that are urgent and vital to the health and welfare of the study population
2. Restrict studies to those questions that cannot be addressed in any other context
3. Restrict studies to those that would provide important direct benefit to the individuals recruited to the study or to the population from which the individuals come
4. Ensure the study design imposes the absolute minimum of additional risk.

Proposed guidelines for research in refugee populations

5. Select study participants on the basis of scientific principles without bias introduced by issues of accessibility, cost, or malleability
6. Establish highest standards for obtaining informed consent from all individual study participants and where necessary and culturally appropriate from heads of household and community leaders (but this consent cannot substitute for individual consent)
7. Institute procedures to assess for, minimise, and monitor the risks to safety and confidentiality for individual subjects, their community, and for their future security
8. Promote the well-being, dignity, and autonomy of all study participants in all phases of the research study

Human rights and Research

- Violation of the rights of human participants in research is thought to be a violation of fundamental human rights.
- Risks to communities mostly occur when the findings of research, rather than the procedures, could be stigmatising to a study subgroup.

Human rights and respect for people

- Informed consent is often thought the cornerstone of research ethics. all research ethics codes require voluntary informed consent.
- Government censorship, lack of a free press or free flow of information, and denial of a right to education can diminish researchers' ability to share information.
- Moreover, in settings where individuals have little right to question, the ability to be informed is hampered.
- Valid data may not be obtained
- Data may be tailored to protect the participants.

Dangerous conditions for research staff

- In countries where human rights are not assured, risks to local and expatriate research staff must be considered, particularly if findings may be construed as critical of government policy.
- Local staff might be accused of bringing shame to the country.
- Local investigators might know that confidentiality has been compromised by government pressure to access findings, but fear repercussions for themselves and their families
- Research in countries with poor human rights records may be hampered by difficulties in obtaining valid data.
- Plans may need to be in place for evacuation of research staff should research put teams in danger. *conditions*

Issues to be considered when reviewing research proposals

Research conducted with vulnerable populations

- Has the inclusion of individuals in research who cannot consent been justified?
- Is the research question posed important to the health and well-being of this vulnerable population?
- Is the research design appropriate?
- Have safeguards been built into the research design to prevent undue coercion or influence of this group?



ethics in domestic violence research

WHO ethical and safety recommendations for domestic violence research

1. The safety of respondents and the research team is paramount, and should infuse all project decisions.
2. Protecting confidentiality is essential to ensure both women's safety and data quality.
3. All research team members should be carefully selected and receive specialised training and ongoing support.
4. The study design must include a number of actions aimed at reducing any possible distress caused to the participants by the research.

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5. Prevalence studies need to be methodologically sound and to build upon current research experience about how to minimise the under-reporting of abuse.
6. Fieldworkers should be trained to refer women requesting assistance to available sources of support. Where few resources exist, it may be necessary for the study to create short-term support mechanisms.
7. Researchers and donors have an ethical obligation to help ensure that their findings are properly interpreted and used to advance policy and intervention development. Violence questions should be incorporated into surveys designed for other purposes only when ethical and methodological requirements can be met.

Minimising harm (non-maleficence)

- The main ethical concern related to researching violence against women is the potential to inadvertently cause harm or distress.

HARM

- **Respondents**
 - Might be vulnerable to physical harm
 - May become distressed by an insensitive interview,
 - or from having to recall painful or frightening experiences. Interviews on sensitive topics can provoke powerful emotional responses in some participants.
- **Fieldworkers**
 - Physical abuse
 - or can become severely distressed by the subject matter of the interview.

Ensuring participant safety

- The WHO guidelines provide recommendations for minimising risks to respondents.
- To prevent others learning about the topic of interview they recommend interviewing only one woman per household
- Not informing the wider community that the survey includes questions on violence,
- Not doing any research on violence with men in the same communities in which women have been interviewed.
- Interviewers need to be trained
 - to be aware of the effects that their questions may have on informants,
 - and how best to respond, based on a woman's level of distress.
 - They also need to be trained to avoid their own prejudices and beliefs

Protecting privacy and confidentiality

- Protecting privacy is both important in its own right, and also an essential element to ensure women's safety.
- The WHO recommendations advise that interviews be done in complete privacy, with the exception of children who are too young to recount anything about the interview.
- Innovations can be used to ensure privacy and confidentiality.

Referrals for care and support

- The WHO guidelines¹¹ suggest that, as a minimum standard, researchers have an ethical obligation to provide respondents with information or services that can respond to their situations.
- In areas where specific violence-related services are available, research teams have developed detailed directories that interviewers can use to make referrals.
- In settings where resources are scarce or non-existent, researchers have developed interim support measures.

- A complex emergency is a social catastrophe marked by the destruction of the affected population's political, economic, sociocultural, and health care infrastructures.

Prisoners

- Respect for justice usually requires that we treat similar people in similar ways.