

Ethics in Research Involving Women

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Objectives of the Presentation

- To discuss the ethical significance of gender/women as a category of critical analysis in research
- To consider the politics and ethics of researching on gender and women
- To focus on the ethical issues relating to ‘women as a vulnerable population’ in research
- To examine ways and means of addressing ethical issues related to research on SGBV



Ignorance, Assumptions & Misconceptions in Research about Gender / Women

- **Gender insensitivity or blindness:** ignoring sex/gender as a socially important variable has led to the exclusion of women from sample research populations (pregnant women)
 - **Assumptions of similarity** (between men and women) despite females having different presentations for conditions like Cancer, Liver Disease, Osteoporosis, Parkinson's Disease and Multiple Sclerosis (Rosser 1989).
 - **Overgeneralisation:** when a study deals with only one sex but presents the findings as if applicable to both sexes. (testing of cholesterol lowering drugs / aspirin for cardiovascular disease) (Rosser 1989).
 - **Assumptions of difference** (between men and women based on biological differences (women's disease of hysteria)
 - **Sexual Dichotomism:** treating the sexes as two entirely discrete social & biological groups, rather than as two groups with overlapping characteristics.
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Ignorance, Assumptions & Misconceptions in Research about Gender / Women

- **Double standards:** though identical situations, behaviors or traits are evaluated differentially on the basis of sex. (Researchers should avoid the labeling the sexual behavior of an adolescent girl as ‘promiscuous’ while calling the equivalent behavior in a boy as ‘experimental’)
- **Stereotyping** or reduced to one gendered characteristic (all women are mothers / all men are aggressive)
- **Sex appropriateness:** descriptive terms for sex differences are used in a prescriptive manner, for e.g. labeling character traits such as compassion & sensitivity as ‘feminine,’ & leadership ability, independence & ambition as ‘masculine’. These character traits can be found in both sexes
- **Androcentricity:** the adoption of an overall perspective based on men’s dominant experiences and interests (findings based on male study populations)
- **Women’s experiences / voices as unnecessary** (Women patients’ ‘experience of illness’ not valued) (PMS)
- **Low funding** for research on diseases specific to women in western countries (incontinency in older women / dysmenorrhea)

(Based on Potigietter & Reddy, 2006)

Not taking gender differences and commonalities into account will make research

Inaccurate

Skewed

Insensitive

Invalid

Politically incorrect

Unjust

Ethically compromised

Methodologically slack



Vulnerability

- Originally based on the limitations in the capacity to provide informed consent (Belmont Report)
 - Due to dependent status
 - Due to decisional incapacity
 - Those with limitations in power, intelligence, education, resources strength etc., or the needed attributes to protect their own interests (CIOMS 2002)
 - Those who lack the rights and liberties that make them particularly open to exploitation (Zion 2002)
 - Populations include:
Children / Human Fetus / Prisoners / 'Mentally Infirm' / Disabled / Elderly / Aged / The physically sick (cognitively impaired / comatose / traumatized / terminally ill) / Orphans / Women/ Neonates / Minorities / Students / Employees / Participants in international research / Normal volunteers
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Types of Vulnerabilities (based on Kippins 2001)

- **Cognitive:** Does the research participant (RP) have the capacity to deliberate about and decide whether or not to participate in the study?
- **Juridic:** Is the (RP) liable to the authority of others who may have an independent interest in that participation?
- **Deferential:** Is the (RP) given to patterns of deferential behavior that may mask an underlying unwillingness to participate?
- **Medical:** Has the (RP) been selected, in part, because he or she has a serious health-related condition for which there are no satisfactory remedies?
- **Allocational:** Is the (RP) seriously lacking in important social goods that will be provided as a consequence of his or her participation in research?
- **Infrastructural:** Does the political, organizational, economic, and social context of the research setting possess the integrity and resources needed to manage the study?
- **Social:** Does the (RP) belong to a group whose rights and interest have been socially disvalued?

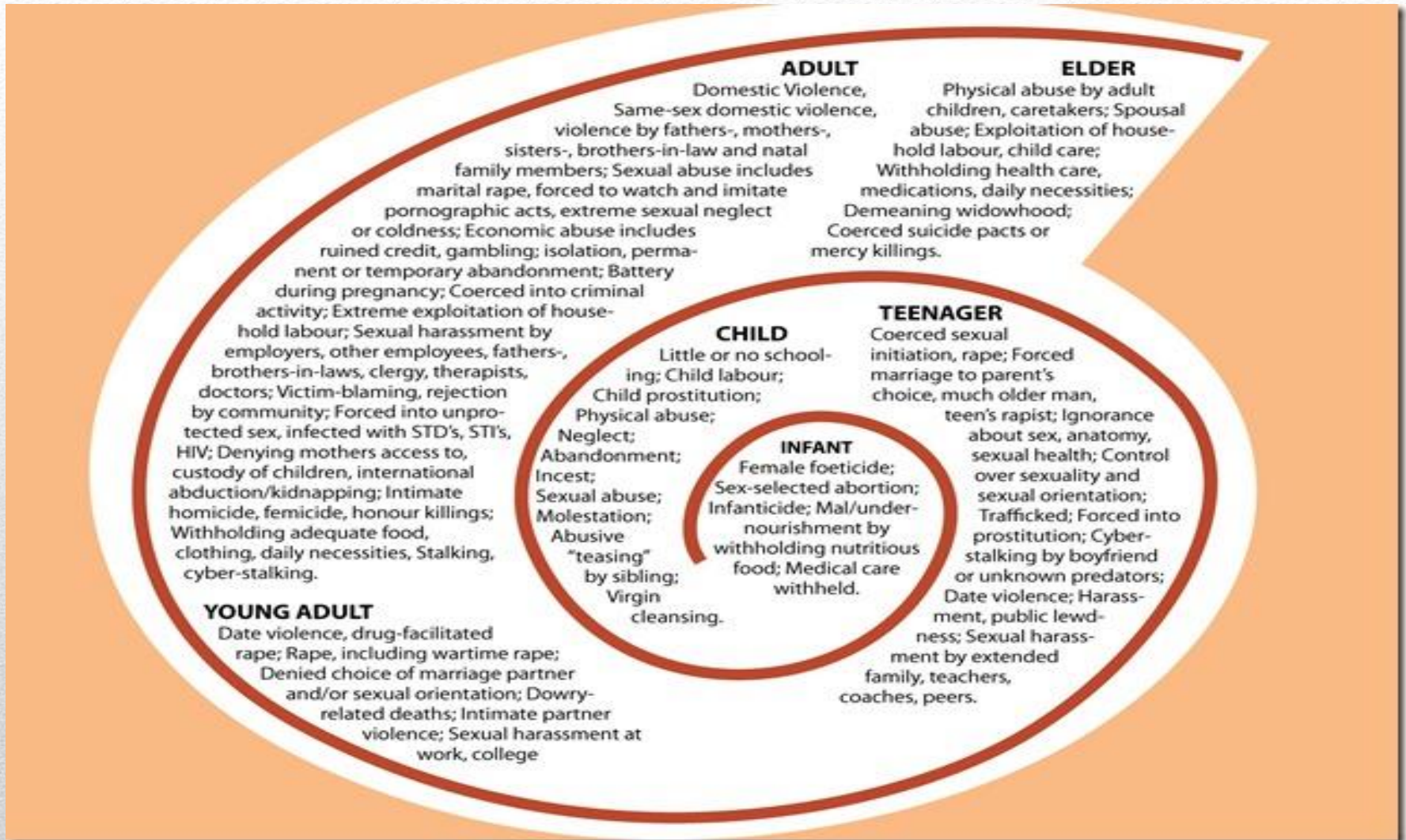
Definition SGBV

- (a) Physical, sexual and psychological violence occurring in the family, including battering, sexual abuse of female children in the household, dowry-related violence, marital rape, female genital mutilation and other traditional practices harmful to women, non-spousal violence and violence related to exploitation;*
- (b) Physical, sexual and psychological violence occurring within the general community, including rape, sexual abuse, sexual harassment and intimidation at work, in educational institutions and elsewhere, trafficking in women and forced prostitution, as well as **LGBTQI** and intimate partner violence;*
- (c) Physical, sexual and psychological violence perpetrated or condoned by the State, wherever it occurs.*

(Based on the UN Declaration on the Elimination of Violence Against Women, 1993)

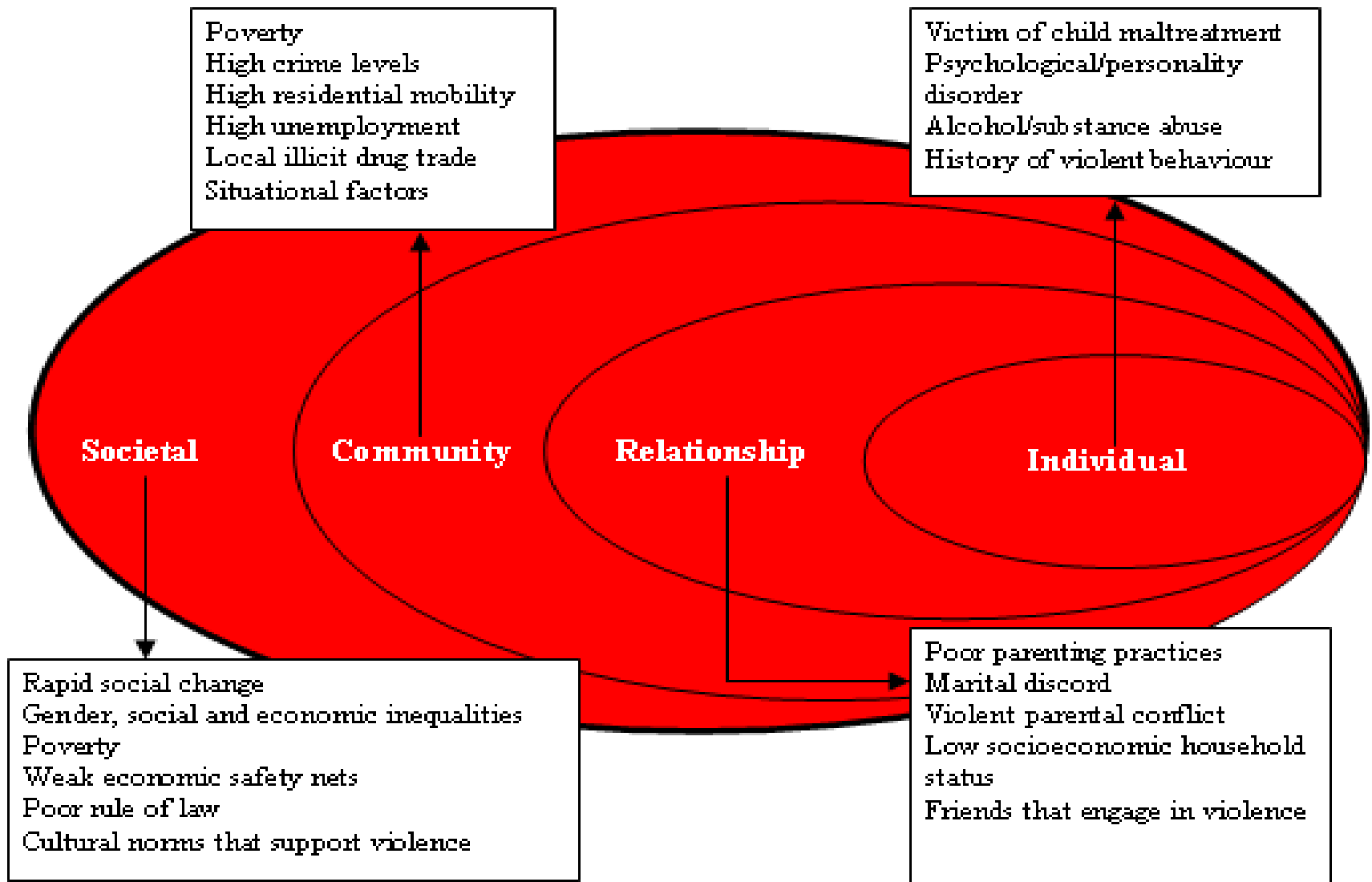
Life Spiral of Violence Against Women

Layers of Oppression / Vulnerability



The Lifetime Spiral is designed by Asian & Pacific Islander Institute on Domestic Violence (2007)

Risk Factors due to Multiple Layers of Vulnerability to SGBV (Based on the Ecological Framework)



Women as a Vulnerable Population in Researching

- Stereotypes all women as vulnerable
 - Women reduced to a singular identity
 - Ignores intersections in identities / layering of identities (sex, race, ethnicity, class, religion, language, disability, pregnancy, transgender, sexual orientation etc.,
 - Does not account for skills, capacities and privileges in women
 - Moments and periods of empowerment and disempowerment in individuals
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Critique of Vulnerability

- Perpetuation of the notion of women's vulnerability
 - Naming of women as victims who may now be defined by one sole experience
 - Survivors / victim-survivors
 - Essentialization / reduction of all women to one characteristic
 - USA – The response to vulnerability is through additional protection = exclusion (pregnant women, human fetuses, and neonates)
Schonfeld (2013)
 - Despite clear lack of probability of harm and the potential for benefit of some studies
 - Data not available for pregnant women to choose some products when they come onto the market (research involving vaginal microbicides aimed at reducing the transmission of HIV)
 - Vulnerability – negative impact
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**ADDRESSING ETHICAL ISSUES
RELATING TO RESEARCH ON
WOMEN & SGBV**

Ontological & Epistemological Issues



- SGBV or VAW - Lack of visibility
- Hegemonic masculinities (Kimmel 2000 and Connell (1987) / hegemonic or emphasized femininities (Connell and Messerschmidt, 2005)
- Violence against women is a cross-cutting phenomena existing in all communities and economic groups
- SGBV is a criminal, rights, health, development, economic (business), social, gender, sexual (and other) issue
- Violence extending beyond bruises and broken bones to severe health problems (chronic pain, disability, emotional distress, stress, trauma, depression, miscarriage, abortions)
- Significance of sex as a male entitlement
- Internalization of norms that justify violence (disobeys, refuses sex, does not complete housework in time, unfaithful etc.)
- A culture of impunity prevents perpetrators from experiencing consequences for their actions
- The norm of court delays results in SGBV cases taking many years to be legally resolved
- Need for multiple research methods to engage with SGBV (QI & Qn)



Ethical Standards

- Permission and ethical clearance from institutional or national ethics review boards
 - Ethics training for field workers, interviewers, supervisors, study coordinators, researchers ...
 - Documentation of safety and ethical issues that could arise:
 - Respondents' safety or victims' safety
 - Interviewer safety
 - Household lists and consent forms compromised (and perpetrators arrested)
 - Any incident pertaining to serious injury / death / arrest
 - Crisis or disaster in study site
 - National level issue that could affect the integrity of the study
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Information Sheet / Consent Form



- Assurance of Confidentiality
- Voluntary participation
- Reassurance of no negative consequences due to refusal to participate or withdrawal from study
- Freedom to skip / stop when it comes to difficult questions
- Warning about topics on violence and sexuality
- *‘some of the topics discussed may be personal and difficult to discuss about, but many ‘women’ have found it useful to have the opportunity to talk’*
- Second consent form before asking questions on abuse
- Contact details of the research team made available
- Information sheet should not be left behind unless requested (safety)
- Prepare list of responses for any questions that respondents may have
- ~~No inducements (expenses for transport only)~~

Confidentiality



- Anonymity (code / no names)
- Household identifiers kept separate from questionnaires or interview schedules / identifiers destroyed after research completed
- Tapes - anonymous / kept locked or password protected / safe from hackers
- Ensure anonymity when presenting findings / case details changed
- Self-administrated Qs or PDA to record experience of sexual abuse / perpetration of sexual abuse
- Name change of the title of research (in a community) as the act of participating in a study may provoke further abuse
- Interviews conducted in a private setting (only children under 2 years / in a field, clinic, temple/church)
- Participants free to reschedule interview to a time / place convenient (safety / gender roles & responsibilities)
- Interviewers trained to terminate or change the subject if privacy compromised

Do No Harm



- All questions to be asked in a sensitive, non-judgmental, supportive manner (minimize distress)
 - In-depth training for interviewers (how to support / terminate if the effects are negative / not to force)
 - Exercises to address staff negative attitudes, stereotyping, and biases
 - Self administered methodology to ensure confidential perpetration disclosure so that there is no identification of victims, reportage of crimes, use of data in legal proceedings or perceived interviewer collusion in crimes
 - Q on most serious consequences in perpetration to convey message of non-collusion and non-acceptability of violence by researchers
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Safety

- Interviewers should not conduct interviews in their own community
- Inform community about research but not about the interest in violence
- Should not research violence on women in the same clusters where men have been interviewed
- Interviewing one woman per house (prevent others from finding out about the research topic)
- Prepare dummy questions / questionnaires
- Sweets and games to distract children
- Companion fieldworkers to distract other members of the household
- End the interview on a positive note that emphasizes women's strengths
- Ensure that interviewers are not ethically compromised if men respondents admit to criminal behavior (should not be able to identify / report to the Police)
- ~~Decision not to conduct or abandon research if its too risky for respondents~~



Researcher / Interviewer / Fieldworker Needs

- Gender Training
- Training on research
- Training on safety strategies – mobiles phones, dress codes, provision for quick exits
- Debriefings (to deal with safety issues, emotional trauma, stress, negative consequences of listening to accounts of violence)
- Possibility of being given less emotionally taxing tasks, breaks and withdrawal altogether (10% of interviewer attrition rate)



Provision of Support / Crisis Intervention

- Women may open up more to women researchers - to the extent of confiding sensitive issues (confidentiality / empathy from interviewer)
- Eliminate power-play in interviewer / interviewee relationship
- Multiple layers of oppression may lead to expectations on the part of the interviewee / guilt on the part of the interviewer – provision of non-monetary assistance
- Knowledge of / dissemination of service providers (health/ legal / social / educational etc.) and informal sources of support (religious leaders / community representatives / women's organizations / traditional healers)
- Violence not explicitly mentioned in provision of written information
- If possible a counselor to be present during interviews



Dissemination / Publicity

- Acknowledgement of violence against women is a cross-cutting phenomena existing in all communities and economic groups
 - Findings not described as worse in one group as opposed to another
 - Findings are not allowed to be misinterpreted and sensationalized
 - Findings to reach general public
 - Findings to advance policy and redress interventions
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The American College of
Obstetricians and Gynecologists
WOMEN'S HEALTH CARE PHYSICIANS

COMMITTEE OPINION

NO 646 NOVEMBER 2015
American College of
Obstetricians and Gynecologists

<http://www.acog.org/Resources-And-Publications/Committee-Opinions/Committee-on-Ethics/Ethical-Considerations-for-Including-Women-as-Research-Participants>

POINTS FOR DISCUSSION



....Participation in important areas of research continues to lag among women.

If the medical treatment of women is based on studies from which women were excluded as research participants, then a concern for generalizability must be raised, and women are at risk of not receiving the same level of evidence-based care available to men.

Justice requires that women be included in studies in sufficient numbers to determine whether their responses to treatment are different from those of men and whether treatment options derived from research are equivalently applicable to women and men.

In order to aid in the recruitment of women, researchers should specifically address obstacles to participation that may be experienced disproportionately by women, such as the lack of adequate child care during time spent as a research participant.



Improved medical management of conditions that previously may have precluded pregnancy, such as cystic fibrosis or organ transplantation, has expanded the population of women able to achieve pregnancy.

Women who have significant medical conditions often will require pharmacologic management, and many of these conditions and disease processes (eg, diabetes mellitus, inflammatory bowel disease, depression, and epilepsy) are known to have negative effects on the fetus, the pregnant woman, or both if poorly controlled.

Yet pregnant women often are not permitted to enroll in studies of novel treatments for complex or chronic medical conditions. Such broad exclusion without assessing potential benefits against the potential risks of the pharmacologic agent is short sighted.

For example, if an agent being studied would allow pregnant women to gain better control of their disease than current treatment regimens and potentially lead to better maternal and fetal outcomes, enrollment in studies of such agents should be considered.

Along these lines, consider the case of a woman participating in a research study who subsequently becomes pregnant, an outcome that could be related to her improved health status after enrollment. Should she be removed from the trial because of her pregnancy, despite the possibility of achieving improved health by use of the study agent? The decision should include consideration of the principles of autonomy, justice, beneficence, and nonmaleficence.



One of the reasons that pregnant women have been systematically excluded from research is their perceived status as “vulnerable.” In 2010, the NIH Office of Research on Women’s Health supported a workshop to address ethical, regulatory, and scientific issues raised by the enrollment of pregnant women in research studies.

One of the recommendations from the workshop was that pregnant women in research trials should be defined as a “scientifically complex” rather than a “vulnerable” population. Participants in the workshop argued that a vulnerable population is one that has a compromised ability to protect its interests and provide informed consent. Pregnant women do not, as a group, meet this definition. Pregnant women have the same capacity for autonomous decision making as their nonpregnant counterparts, including decisions regarding whether or not to participate in appropriate research studies.

Pregnant women are scientifically complex, reflecting a combination of physiologic and ethical complexity. The ethical complexity is reflected in the need to balance the interests of the pregnant woman and the fetus.

Maternal and fetal interests usually align, as appropriate care of the woman is necessary for the health of the fetus, but these interests may diverge in the setting of research, especially research that is not focused on concerns of pregnancy, labor, or fetal health.

Bibliography

- American College of Obstetricians and Gynecologists (2015) Committee Opinion - Ethical Considerations for Including Women as Research Participants, posted at <http://www.acog.org/Resources-And-Publications/Committee-Opinions/Committee-on-Ethics/Ethical-Considerations-for-Including-Women-as-Research-Participants>
 - Cambell, A., Groundwater-Smith, S. 2007 *An Ethical Approach to Practitioner Research*, London / New York, Routledge
 - Christians, C. G. (2005), 'Ethics and Politics in Qualitative Research'. In N. K. Denzin & Y. S. Lincoln (ed.), *The Sage Handbook of Qualitative Research* Thousand Oaks / London / New Delhi: Sage Publications
 - Denzin, N. K. (2005), 'Emancipatory Discourses and the Ethics and Politics of Interpretation'. In N. K. Denzin & Y. S. Lincoln (ed.), *The Sage Handbook of Qualitative Research - Third Edition* Thousand Oaks / London / New Delhi: Sage Publications
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Bibliography

- Markham, A. N. (2005) The Methods, Politics, and Ethics of Representation in Online Ethnography, in N. K. Denzin & Y. S. Lincoln (ed.), *The Sage Handbook of Qualitative Research - Third Edition* Thousand Oaks / London / New Delhi: Sage Publications
 - Mauthner, M., et al., eds. 2002. *Ethics in qualitative research*. London: Sage.
 - Oakley, A. (1981) Interviewing women: A contradiction in terms. In Helen Roberts (Ed.), *Doing feminist research* (pp. 30–61). London: Routledge & Kegan Paul.
-

Bibliography

- Partners for Prevention, *Ethical and Safety Guidelines for Research on Gender-based Violence – Replicating the UN Multi-Country Study on Men and Violence: Understanding How Some Men Use Violence Against Women and How We can Prevent it* posted at partners4prevention.org
 - Potgieter, C & Reddy, V. (2006) Presentation to Ethics Committee on *Gender Mainstreaming: A Research Ethics Issue?*
www.hsrc.ac.za/module-KTree-doc_request-docid-1025.phtml
 - Rosser, S. V. (1989). Re-Visioning Clinical Research: Gender and the Ethics of Experimental Design. *Hypatia*, 4(2), 125–139. Retrieved from <http://www.jstor.org/stable/3809810>
 - Scheyvens, R & Leslie, H (2000) Gender, Ethics and Empowerment: Dilemmas of Development Fieldwork, *Women's Studies International Forum*, Vol. 23, No. 1, (pp. 119–130)
 - Schonfeld, Toby (2013) The perils of protection: vulnerability and women in clinical research in *Theor Med Bioeth* (2013) 34:189–206
 - Wickramasinghe, M (2010) *Feminist Research Methodology – Making Meaning of Meaning Making*, London New York, Routledge.
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Thank You

