Vulnerability and research ethics

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11 October 2017, Bond University
Outline

1. Vulnerability in research ethics
2. Philosophical conceptions of vulnerability
3. A taxonomy of vulnerability
   - inherent
   - situational
   - pathogenic
3. Addressing vulnerability in research
Vulnerability in research ethics (1)

Belmont Report (1979) regarding vulnerable participants:

- Inducements may become unacceptable if subject especially vulnerable
- Need for demonstration of “appropriateness” of involving vulnerable populations given risks and benefits
- Need for protection against exploitation/over-participation in research for readily available (“captive”) populations
Vulnerability in research ethics (2)

“Special vulnerability” (Belmont):
   i. lack of capacity to consent
   ii. susceptibility to coercion or exploitation
   iii. increased risk of harm

Especially vulnerable: “racial minorities, the economically disadvantaged, the very sick, and the institutionalized”

Cf Nuremburg: mandated informed consent as major protection for patients/subjects – no “special vulnerability”
“Vulnerability’ refers to a substantial incapacity to protect one’s own interests owing to such impediments as lack of capability to give informed consent, lack of alternative means of obtaining medical care or other expensive necessities, or being a junior or subordinate member of a hierarchical group”

(CIOMS p. 18)
Dominance of sub-population or “labelling” approach

- Identification of individuals or groups who are presumed to need extra protections

Long lists grouped by:

- social status or situation (prisoners, economically disadvantaged, members of ethnic/cultural groups, patients in emergency settings ….)
- patient/participant condition (children, elderly, persons with mental illnesses, pregnant or breast-feeding women ….)

(Bracken-Roche et al 2017)
Section 4: list of ‘vulnerable populations’

Vulnerable/vulnerability explicitly mentioned in:

- Chapter 4.2: *Children and young people*
- Chapter 4.3: *People in dependent or unequal relationships*
- Chapter 4.4: *People highly dependent on medical care who may be unable to give consent*
- Chapter 4.5: *People with a cognitive impairment, an intellectual disability, or a mental illness and*
- Chapter 4.6: *People who may be involved in illegal activities.*
Criticisms of labelling ‘vulnerable populations’ (1)

This approach is too narrow (e.g., Levine et al. 2004; Macklin 2003; Nickel, 2006):

- reduces vulnerability to incompetence to consent
- risks paternalism
- fails to address full range of moral issues raised by vulnerability
This approach is too broad (eg Hurst 2008; Luna 2009):
- obscures context-specific nature of vulnerability
- may lead to stereotyping, discrimination, paternalism
Philosophical conceptions of vulnerability (1)

To be vulnerable is to be fragile: to be susceptible to wounding and to suffering.

This susceptibility is an inherent and inevitable feature of our corporeal humanity.

eg Fineman (2008): vulnerability is “a universal, inevitable, enduring aspect of the human condition”

Philosophical conceptions of vulnerability (2)

To be vulnerable is to be susceptible to harmful wrongs, exploitation, or threats to one’s interests or autonomy, and to have reduced power or capacity to protect oneself.

eg Goodin 1985, Macklin 2004, Hurst 2008
Sources of vulnerability that are inherent to the human condition and that arise from our corporeality, neediness, dependence on others, and affective and social natures.
Situational vulnerability

- Context-specific sources of vulnerability (e.g., personal, social, political, economic, or environmental)
- Both inherent and situational vulnerability may be dispositional or occurrent
Pathogenic vulnerability

i) Situational vulnerabilities that are caused or exacerbated by morally dysfunctional social relationships; structural injustices

ii) Vulnerability arising from interventions designed to ameliorate inherent or situational vulnerability that instead compound vulnerability
Moral demands of vulnerability

An adequate understanding of the duties involved in responding to vulnerability must avoid stereotyping and paternalism and be guided by the overall aim of fostering autonomy, whenever possible:

i) To counter the sense of powerlessness and loss of agency that is often associated with vulnerability. Pathogenic responses compound powerlessness.

ii) To counter the risks of paternalistic interventions, ie those that express or perpetuate relationships of domination and inequality between persons (Smiley, 1989).
Addressing vulnerability in research ethics

1. Avoid exacerbating occurrent vulnerability and/or making dispositional vulnerability occurrent
   a) Minimise risks specifically attributable to the trial intervention
   b) Beware of creating or exacerbating dependency
2. Avoid generating pathogenic vulnerabilities
3. Promote autonomy to the extent possible
   (Lange, Rogers and Dodds 2013)
 Revision of Section 4 of the *National Statement*

What would you like to see change?
Thank you

This presentation draws upon research performed as part of an ARC Discovery Project. CIs: C Mackenzie, W Rogers, S Dodds, with assistance from M Meek Lange