ETHICAL ISSUES IN IMPLEMENTATION RESEARCH

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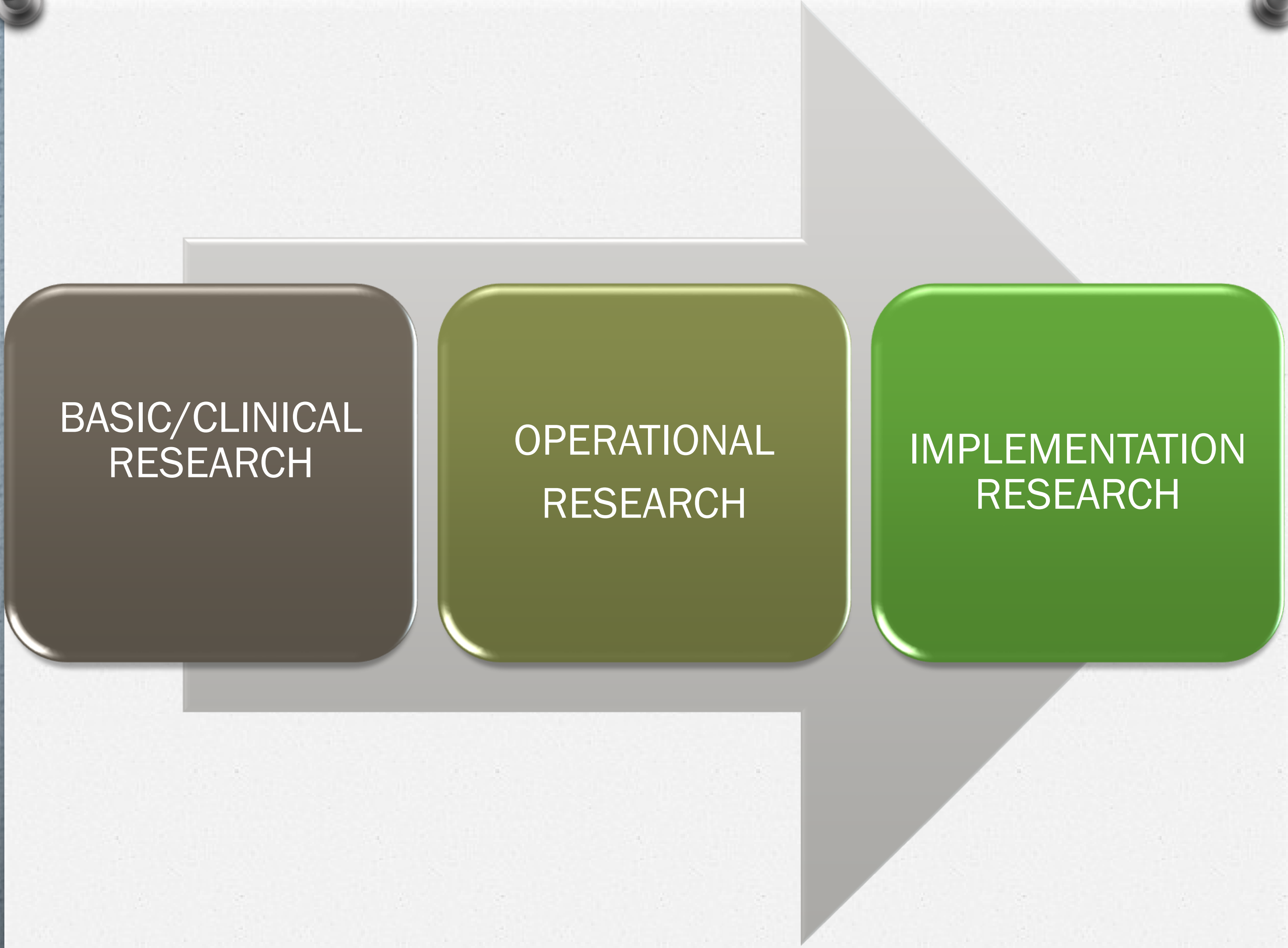
Lesson

- Comparison between traditional research and implementation
- Ethical issues in implementation research

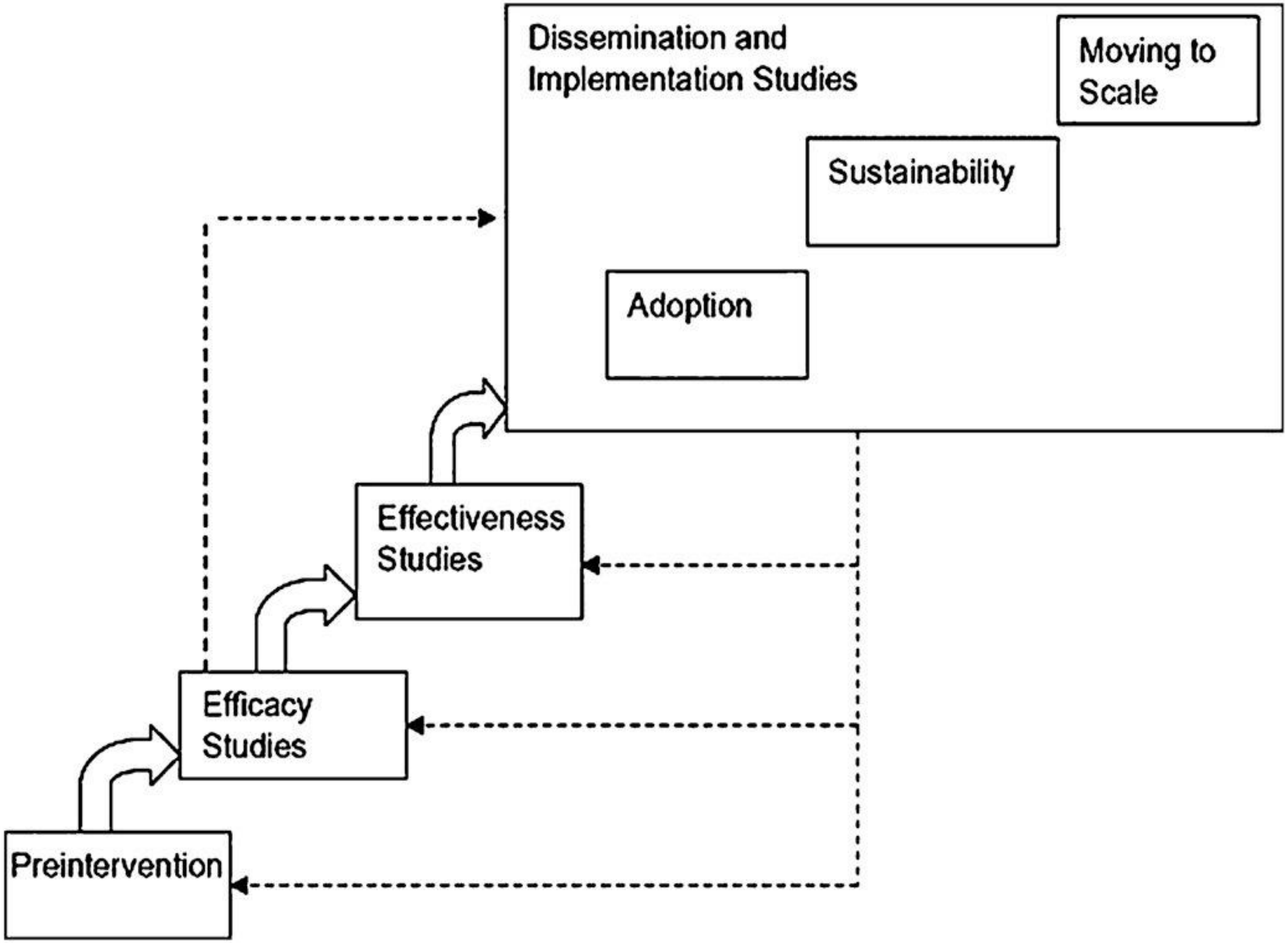
How does implementation research differ from traditional (clinical) research?



BASIC/CLINICAL RESEARCH

OPERATIONAL RESEARCH

IMPLEMENTATION RESEARCH



Dissemination and Implementation Studies

Moving to Scale

Sustainability

Adoption

Effectiveness Studies

Efficacy Studies

Preintervention

FOCUS OF IR

- Social and contextual factors of intervention
- The process of implementation
- The out-comes of implementation

Differences between clinical & implementation research

Domain	CR	IR
Research focus	Proof of principle.	Address priority health needs.
Participants.	Individuals	Communities
Informed consent	By competent individuals	By gate keepers and individuals
Research conditions	Controlled research environment	Real life & programmatic environment

Differences between clinical & implementation research

Domain	CR	IR
Integration within health system	No a priori plan for health system integration	Strong health system strengthening focus.
Types of research question	Efficacy and safety of a therapeutic strategy in the individual	Operationalization of an intervention in local context, Scale-up
Anticipated outcomes	Well-defined hypothesis at the beginning of the clinical research. Expected outcomes clearly stated	Multifaceted holistic impact on health systems. Sometimes outcomes may be unexpected

Differences between clinical & implementation research

Domain	CR	IR
Risks	Risks are for the study participants.	Usually population level risks.
Benefits accrued by	Benefits accrue to the participants, community.	Individuals, communities, health system, institutions. The people accruing benefits may be different from those who suffer risks

Differences between clinical & implementation research

Domain	CR	IR
• Generalizability	• Possible in multicentric and well sampled studies. • However most studies are specific to the target populations.	• Limited by contextual factors. • Findings may be generalizable to similar contexts.

Differences between clinical & implementation research

Domain	CR	IR
• Social justice implications	• Usually not a primary consideration. • Research on vulnerable participants is often contentious because of compromised autonomy.	• Social justice considerations are primary. • Working with vulnerable groups essential to understand implementation issues in these groups so that the intervention can reach them.

Are there ethical considerations which apply particularly to implementation research?

Ethical considerations in various phases of Implementation Research

Planning Phase

- Responsiveness to local needs and priorities.
- Equipoise.
- Study design.
- Stakeholder and community engagement.
- Balance between risks and benefits.

Implementation Phase

- Autonomy and informed consent.
- Privacy and confidentiality.
- Standard Care.
- Ancillary care.
- Community/Health system empowerment.

Post-research Phase

- Dissemination of research findings.
- Data ownership.
- Translating findings into public health action.
- Scalability and sustainability.
- Benefit sharing.

ETHICAL CONSIDERATIONS DURING THE

PLANNING PHASE

1. Responsiveness of IR to local needs and priorities

Principle

- Problems addressed by IR must be of high local priority to justify the research

Ethical issue 1

- Unmet IR need
- Available need
- Imperative to Conduct IR to address barriers

Evidence for priorities

- Epidemiological and routine data
- Not always optimal

Ethical issue 2

- If a particular problem is not perceived to be a local health priority, the ethics of conducting IR becomes questionable

2. Equipoise

Equipoise in CR

- No fore-knowledge of whether RCT new intervention is better than comparison.
- This justifies the conduct of CR

Equipoise in IR

- Fore-knowledge of effectiveness in new intervention.
- Contextual equipoise justifies conduct of IR.
- To ethically justify IR, equipoise regarding the effectiveness of the implementation processes must be preserved.

3. Study designs

No opt-out option within cluster

Ethics of with holding known effective intervention in the control group

Consenting in cluster interventions has little effect

4. Stakeholder and community engagement

Stakeholders	• Persons with an interest, involvement, or investment in something. • People who will be affected by a project, or who can influence it, but who are not directly involved in doing the work.
Examples	• Policy-makers, Funders, program managers, community leaders, community members, …….
Examples of ethical issues	• Ensure intervention will address a local priority health need. • Ensures acceptability and maximize uptake. • Ensure inclusion of vulnerable populations. • The selection of community representatives must be an inclusive and fair process, guided by the community itself, to ensure appropriate, acceptable, and comprehensive representation of all sectors of the community

5. Balance between the risks and benefits

In CR

Clinical efficacy and safety of intervention is known before research is conducted.

Risks and benefits are usually borne by the same individual.

E.G., in clinical research testing the efficacy of a new vaccine:

→the benefit of personal protection, and the risk of side- effects are borne by the individuals who participate in the study

5. Balance between the risks and benefits

In IR

E.G. 1. Mass Drug Administration

→Benefits – community

→Risks – individuals that take the drugs

E.G. 2. Community screening for STIs

→ Successful in one community.

→ Unsuccessful in another:

→→Social discrimination/stigma

Risks in IR not always obvious to determine, and vary between settings

ETHICAL CONSIDERATIONS DURING THE

IMPLEMENTATION PHASE

1. Autonomy and informed consent

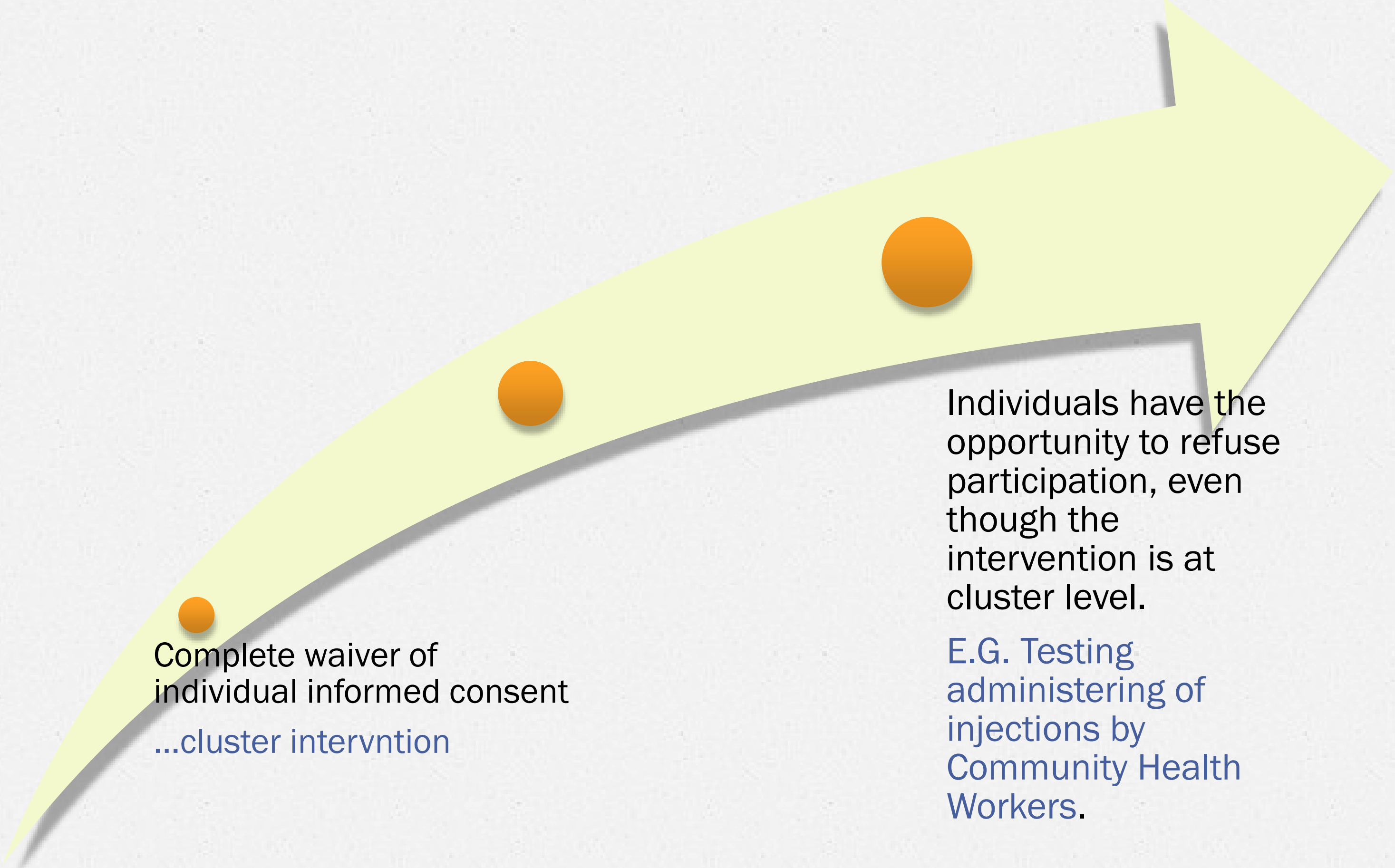
In CR

- Individual consents based of fill information of intervention.

Difficulties in IR

- Individuals in a cluster in a RCT may not have the chance to decide and give consent to **randomization** … at the cluster level.
- In environmental manipulation it’s not possible to opt out.

Spectrum of consenting in IR



Complete waiver of individual informed consent

...cluster intervntion

Individuals have the opportunity to refuse participation, even though the intervention is at cluster level.

E.G. Testing administering of injections by Community Health Workers.

Gate keepers

Challenges with use of gate keepers

In traditional communities community leader = gate keeper

Instances when community leader might not be the best…

→elderly male village leader consenting for pregnant women in a IR.

Alternative:

Inclusion of a variety of representative stakeholders, to ensure transparency of the process, interests met….

Ultimately, its important to ensure that the appropriate informed consent process is followed, maximally respecting autonomy of individuals in the study

2. Privacy and confidentiality

IR often requires that facility level data on patient outcomes be available.

Confidentiality restrictions on access to data may hamper effectiveness analyses of intervention impact.

Options:

→the data should either be anonymised.

→individuals about whom data is being sought should provide consent for their data.

→the researcher to obtain a waiver of consent from ethics board, and put in place mechanisms to ensure confidentiality of the patient information

3. Standard of care or prevention

Ethical principle

- Unethical to deny participants effective intervention because of research.

Option 1

- Allocate the *local de facto* existing standard.
- Challenge: *local de facto* might be no treatment.

Option 2

- To provide the *local de jure* standard of care
- ==agreed upon by experts in the region and is acceptable to the community.
- Challenge: standard may be unsustainable for the local health system after IR is completed.

4. Ancillary care

Refers to the identification of problems that may contribute to ill-health that are beyond the scope of the study in question.

- Ancillary care obligations are present when the need is serious in terms of severity or urgency.
- Ethical to provide when there is a possibility of provision of care within the scope of the research.

ETHICAL CONSIDERATIONS DURING THE

POST-IMPLEMENTATION PHASE

1. Dissemination of research findings

Issues

Ethical obligation to disseminate the research findings widely.

→→Stakeholders, community.

Both positive and negative results to be disseminated for lessons learned.

Important to global community for determining generalization of implementation strategies that have been tested in different settings.

2. Translating findings into public health action

Ethical obligation for IR

- IR findings should be used to inform effective and equitable public health action.

Potential barriers to translating knowledge into action

- Lack of prior consultation with policy-makers
- Lack of funding.
- Weak health systems.
- Poor communication of findings by researchers to policy-makers.
- Absence of a culture of evidence-based decision-making among others

To translate the research into public health action

- Researchers should engage with policy-makers and health system officials, import- ant stakeholders in IR, upfront.
- Propose actionable suggestions based on the research findings to facilitate uptake and scale-up of successful interventions.

3. Scalability and sustainability

Ethical requirement

- If access to a proposed public health intervention cannot be ensured for a community after the IR, it may not be ethical to carry out such a research activity.

Scalability and Sustainability

- Multiple stakeholders must come together to promote this goal which requires ongoing stakeholder engagement throughout the IR process.

CONCLUSION

- Putting public health evidence into practice requires the generation of knowledge about the feasibility of interventions within a specific context, the relative harms and benefits, how an intervention is taken up, whether it reaches the most vulnerable populations, and the logistics of the implementation process.

- The ethical principles pertaining to IR are not unique to IR, but may require adaptation in application given the particularities of IR.

END