
Managing your project- who, what, where, when & how

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Outline

- Define a research question
 - Build a research team
 - Design your project
 - Prepare for your project
 - Collect and manage data
 - Prepare a budget – exercise
 - Knowledge transfer and next projects
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What is your question?

What is already known?

- Natural history
 - Defining features
 - Epidemiological
 - Causal factors, modes of transmission
 - Risk factors
 - Effectiveness of treatments, interventions
 - What is missing, gaps, hunches, new directions
-

What do you want to know?

- Natural history
 - Defining features – exposure, disease, injury condition, injury, attribute, behaviour
 - Epidemiological – person, place, time
 - Causal factors, modes of transmission
 - Naturally occurring, social-politically controlled, individual can manipulate exposure
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What do you want to know?

- Risk factors
 - Age, exposure, peer group norms, SES, employment, mental health status
 - Meanings, beliefs, social contexts
 - Social discourse
 - Cost effectiveness
 - Macro social factors and processes
 - Effectiveness of treatments, interventions
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Scope of question & career stage

- MSc projects
 - Develop and demonstrate research skills
 - Collection, analyses, interpretation
 - 1 publishable paper
 - PhD project
 - Demonstrate independence in project development, implementation
 - Demonstrate 'novelty' and theory development
 - 3 publishable papers
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Methodological issues

- Potential to manipulate independent variable
 - Gender, race, education
 - Identify or create a suitable comparison group
 - Crack smokers who have no history or prior drug use vs. those who do
 - Potential for random assignment
 - Crack smoking versus crack injection & HCV
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Feasibility issues

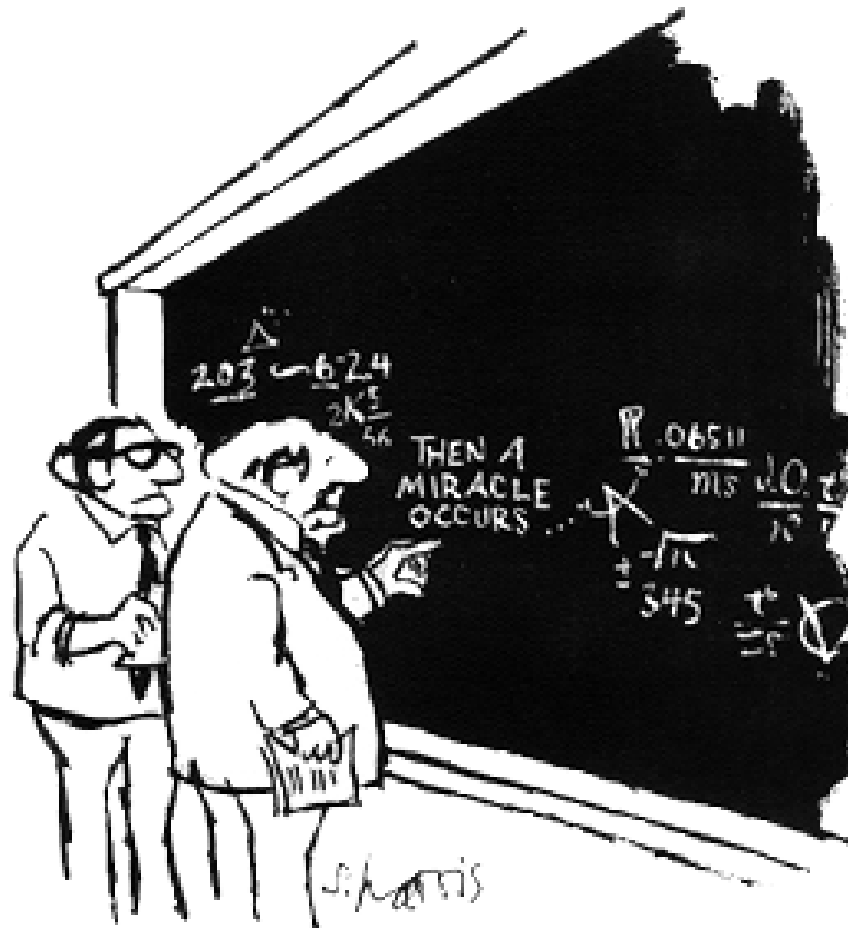
- Access to subjects, records, treatments
 - Cost – follow up, sample size
 - Time and timeliness e.g., outbreak
 - Personal and team expertise
 - Substantive and methodological
 - How many questions can you ask?
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Ethical considerations

- Harm to the individual or groups
 - Physical, emotional, occupational etc.
 - Privacy, confidentiality and anonymity
 - Treatment issues
 - Sufficient doubt about treatment to withhold from some balanced with sufficient belief in the treatment to justify exposing some
 - Sufficient uncertainty to justify conducting the study
 - Informed consent
 - Scientific relevance
 - Scientific validity
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Goal when developing questions

- Clear
 - Concise
 - Complete
 - Feasible
 - Interesting, novel, ground breaking....
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- Change your question?
 - Refine your question?
 - Change focus from one group to another?
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"I think you should be more explicit here in step two."

Who should be on your team?

What is a team

- A group of individuals
 - Organized to work together
 - To accomplish a common objective
 - Complimentary skills and knowledge
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Selecting team members

- What are your skills?
 - Humility
 - What experience do you have?
 - New topic, technique, design
 - Are you junior, mid career or senior?
 - What is your question?
 - What skills do you need?
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GIPA principles

- *The success of our national, regional and global programmes to confront HIV/AIDS effectively requires the greater involvement of people living with HIV/AIDS... through an initiative to strengthen the capacity and coordination of networks of people living with HIV/AIDS... By ensuring their full involvement in our common response to HIV/AIDS at all - national, regional and global - levels, this initiative will, in particular, stimulate the creation of supportive political, legal and social environments.*
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GIPA

UNAIDS POLICY BRIEF : The Greater Involvement of People Living with HIV (GIPA)

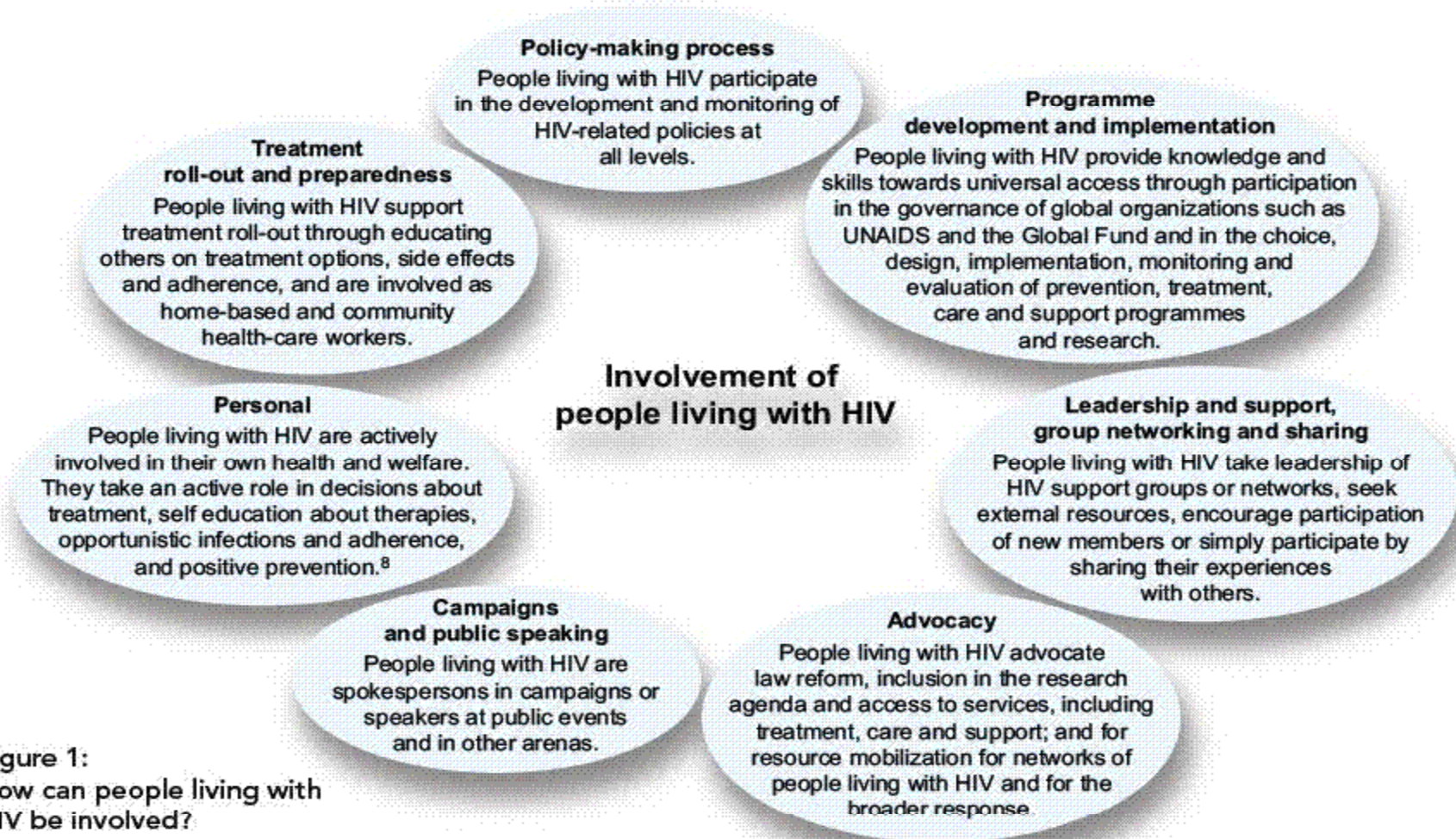


Figure 1:
How can people living with HIV be involved?

Nothing about us without us

- Greater, Meaningful Involvement of People Who Use Illegal Drugs: A Public Health, Ethical, and Human Rights Imperative (Canadian HIV/AIDS Legal Network)
 - **WE** have the right to become involved in activities that affect our health and well-being.
 - **WE** have the right to be able to make informed decisions about our health, including what we do or do not put into our bodies.
 - **WE** have unique expertise and experiences and have a vital role to play in defining the health, social, legal, and research policies that affect us.
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HIV/AIDS community based research

PRINCIPLES

- Community driven
 - Community relevance
 - Equitable Partnerships & collaboration
 - Capacity Building
 - Anti-Oppression
 - Framework
 - Attending to Process
 - Multiple Forms of
 - Knowledge
 - Action Outcomes
-

Selecting team members

- Defining/rationalizing the question
 - Getting funded!
 - Designing the methods
 - Working with industry
 - Recruiting participants
 - Collecting data
 - Analyzing data
 - Interpretation
 - Dissemination and influencing policy
-

Building your team

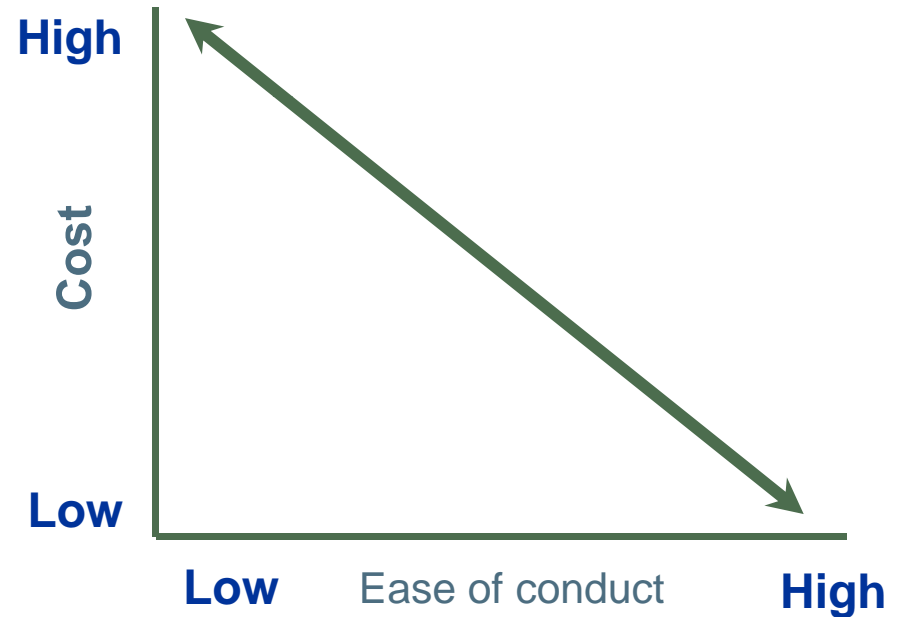
- Provide meaningful opportunities to contribute
 - Discuss roles, responsibilities, expectations - ongoing
 - Build skills (including your own) where needed
 - Select members who are:
 - Available
 - Dependable
 - Interested and committed
 - The closer the correspondence between team goals and individual goals, the greater the sum of individual motivations for succeeding together
 - Politics
 - Conflict of interest / competitiveness
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Design your project

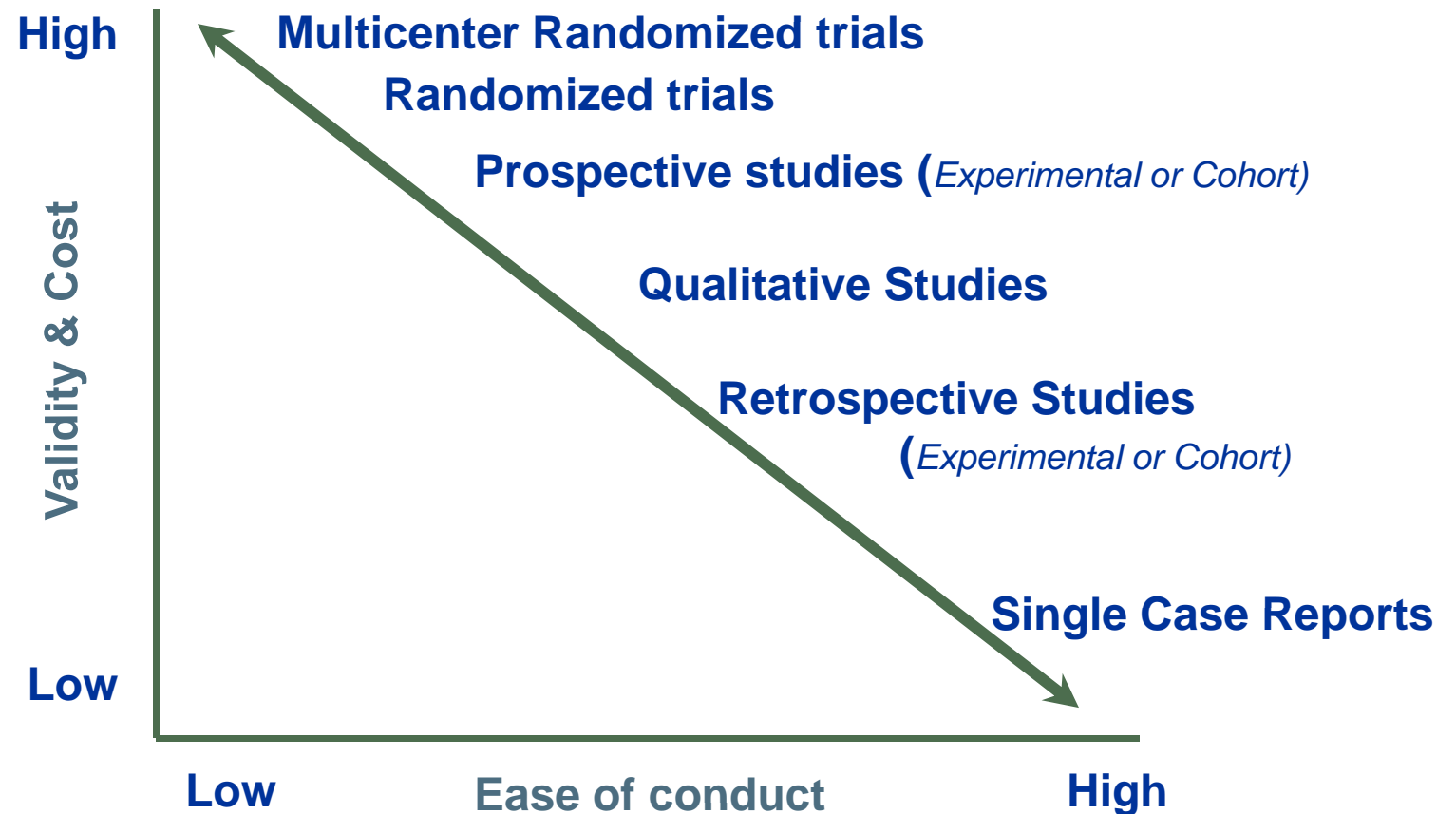
Sahar Saeed M.Sc CCRP
Project Manager

What study design is right for you?

- What is the question you are trying to answer?
- How much time, money and resources do you have?



Types of studies



Treatment studies

Randomized controlled trial

- Gold Standard of clinical studies

Features:

- Treatment sequences
 - Single, parallel groups, crossover, withdrawal, factorial or survival
 - Blinding/masking
 - Open, single blind, double blind
 - Control
 - Active control, placebo, no treatment
 - Methods of assigning treatment
 - Randomization or stratification
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Observational Studies

- Cohort study (Prospective or Retrospective)
 - A group of people who share a common characteristic or experience within a defined period (i.e. exposure to a drug or vaccine). The comparison group maybe the general population, another cohort (thought to have little or no exposure to the what is under investigation or a subgroup within the cohort)
 - Case-control study
 - Used to identify factors that may contribute to a medical condition by comparing subjects who have that condition (the 'cases') with patients who do not have the condition but are otherwise similar (the 'controls')
 - Cross-sectional study
 - Involve data collected at a single point in time, often using survey research methods
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“Not everything that can be counted counts,
and not everything that counts can be
counted.”

-Albert Einstein

Observational – qualitative studies

- Goal in-depth understanding of human lives, experiences, beliefs, culture, organizations, social movements
 - Theory development is a key goal
 - Data are textual, visual, audio and/or audio-visual; not numerical
 - Analysis is interpretive and non-statistical

 - **Grounded theory** - study of social processes and interactions with a goal is to derive a general, abstract theory grounded in the view of the participants

 - **Ethnography** - study of a cultural group in a natural setting (e.g., drug culture, community group, workers) using fieldwork

 - **Discourse analysis** - analysis of systems of thought that construct subjects and their worlds (e.g., sexuality)
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Experimental

- What model do you choose? And knowing what are the limitations
 - Choosing a controls (positive or negative), sham, or vehicle controls
 - What are the limitations of the assays you choose?
 - Repeatability?
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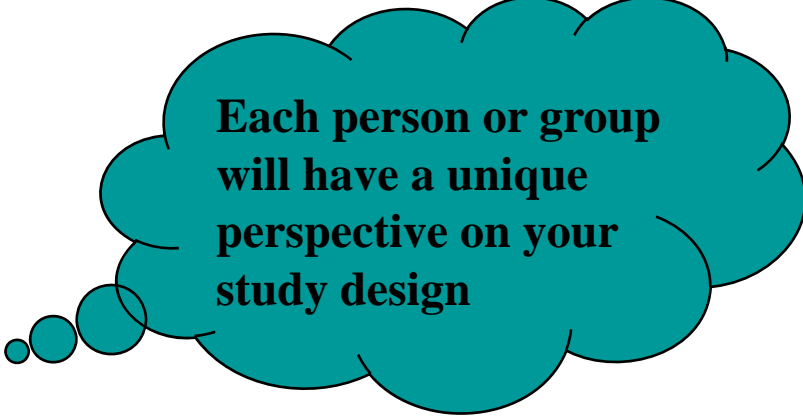
Define the Key Elements of Your Study

- Study population
- Endpoints
- Choice of comparator
- Inclusion/Exclusion criteria
- Statistical consideration (including sample size)
- Study design features
 - randomization, blinding



Where do I start?

- 1) Review Literature
- 2) Draw on the experience of...
 - Mentor
 - Biostatistician
 - Coordinator
 - REB
 - Clinicians/Scientists
 - Community
- 3) Assess your personal situation
- 4) Make a detailed list with a timeline



**Each person or group
will have a unique
perspective on your
study design**

What next?

1. Evaluate your responsibilities as an investigator
 2. Create a detailed list of the key elements of your study design and all expected activities
 3. Think of all the steps in sequential order to prepare an operation proposal
 - Who am I collaborating with?
 - What variables am I analyzing?
 - Where am I getting the samples, patients or data from?
 - Do I need approval from REB, DPS, Department Leaders?
 - How long will this take?
-

“time is at once the most valuable and the most perishable of all our possessions”

- John Randolph (American Legislator)

Time Commitment

- Consider the timing of activities in relation to the overall timeline of the project:
 - Do activities need to be done sequentially?
 - Can activities be overlapped?
 - Who is responsible for which activities?
 - Deadlines for conferences?
 - Will there be enough time for analysis and reports before grant needs to be reviewed?
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Contingency

- Build in a 'cushion' for problems, errors, unexpected opportunities
 - Recruitment slower than expected
 - Colonies of cells or mice getting contamination
 - Staff leaving the institution
 - Vacations
 - Equipment breaking down
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Preparing for your Project

Preparation – REB Approval

- Timing can vary 1 month to 6 months
 - Multiple sites (University, Hospitals) – delays the process
 - If graduate student or postdoctoral fellow – supervisor as ‘site principal investigator’.
 - Check REB website for all required forms and signatures
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Preparation – REB Approval

- If possible, ask REB officer to review documents before submission
 - Fewer mistakes/omissions = shorter process
 - REB forms, cover letter, protocol, budget, questionnaires, interview guides, recruitment materials (e.g. brochures, posters), and consent forms
 - Clearly label all appendices
-

Preparation – REB Approval

- May have different versions of consent forms if multiple sites.
 - ‘Date Last Revised’ in footer on any forms
 - Revised submissions (track change / clean versions).
 - Amendments sometimes required.
 - Annual review
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Preparation – Research Team

- Discuss process for working as a team
 - Roles and responsibilities
 - Communication - regular meetings
 - Budget updates
 - Timelines
 - Contract negotiations (among multiple sites, with funding partners)
 - Negotiations with new staff (research associates, coordinators)
 - Discuss authorship early on and continually revisit throughout.
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Preparation – Hire and Train Staff

- Timing can vary 1 month to 6 months
 - Multiple sites – more planning/supervision
 - Training
 - Overview of study
 - Roles and responsibilities
 - Communication with research team and Community Advisory Committee
 - Mock sessions / interviews
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Preparation – Hire and Train Staff

- Prepare a Training or Operations Manual
 - Recruitment
 - Informed consent process
 - Instructions on how to complete questionnaires
 - Include section on interviewing skills, drugs (street names), what they do, referrals to different health and social services in the area).
 - Logistical operations – how to conduct randomization. Interaction with vulnerable populations
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Preparing for Data Collection

- Specimen Collection
 - Where to get specimens?
 - Where to obtain samples?
 - What contracts need to be in place?
 - Working with Animals
 - Institutional Agreements Between Sites (Contracts)
 - How funds will be managed
 - Payment for operational costs
 - Authorship
 - Copyright fees for questionnaires
-

Preparation - Recruitment

- Set up account for honoraria
 - Advertisements
 - Preparation and approval
 - Printing/email/website posting
 - Newspaper - payment
 - Finalize recruitment process
 - Where, who, when, how?
 - Permission granted from site
 - Sampling Frame
 - Telephone and password protected voice mail to receive call from interested volunteers Process for storing contact information of participants
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Preparing for Data Collection - Pilot

- **Pilot Test – Instruments and Process**
 - Questionnaires and discussion guides
 - Process for recruitment
 - Ensure all phone numbers and email addresses work!
 - Survey methods (mail, telephone or internet)
 - Brochures and Posters - review
 - REVISE, REVISE, REVISE!
 - Finalize content
 - Translation
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Preparation – Data Collection

- Finalize data collection location(s)
 - Office space, interview rooms
 - ‘Sound’ proof
 - Storage for confidential documents
 - Process for transporting data to study office,
 - Process for transporting electronic files
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Preparation - Data Processing

- Specific tasks may include:
 - Creation of data entry system
 - Transcription
 - Data coding scheme / code books
 - Quality control
 - Data editing/corrections
 - Data entry
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Preparation - Data Processing

Pilot test data entry system early on (will prevent hassles later)

- Data entry fields too small
 - Data entry field missing
 - Character versus numeric
 - Data re-entry to ensure accuracy.
 - Backup regularly
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Collecting & Managing Data

Data Collection

Keep in mind:

- The type of data collected
- The amount of data collected
- The way the data are recorded and archived



Data Collection

Specific tasks may include:

1. What variables are necessary to collect? Data coding scheme
 2. How are you going to capture this data?
 - Questionnaires, Case Report Forms, Patient Charts, audio/video recordings?
 3. Creation of data entry system
 - Consult your statistician
 4. Quality control
 5. Data editing/corrections
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What variables are collected?

Four types of data are collected in most studies:

- Baseline data (i.e. Table 1.)
 - Inclusion/exclusion criteria
 - Demographics, medical history, baseline lab data, vital signs and physical exam, previous medications
 - Efficacy data and follow up data
 - Assessments specific to the objective of the study
 - Safety data
 - Ongoing records of vital signs, physical exam, lab data and adverse events
 - Compliance data
 - Test medication, concurrent/concomitant medications, ~~confounders, withdrawal/end of study records~~
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Data collection and processing

- Careful review of all initial questionnaires/data to detect problems
 - Standardize how data will be entered and keep a master list
 - i.e. coding yes/no/missing: 1,0,2
 - **Dates** 01/04/07: April 1/2007, Jan 4/2007 or April 7/2001?
 - Prompt correction of problems
 - Logic checks (electronic or manual) e.g. married in 1990 but marital status is never married
 - Dates 31/April/07 (April 31st?)
 - Double/Triple entry
 - Computer software that permits easy comparison
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Documentation

“ If its not written down then it never happened”

Antoine El Hage, PhD

Chief, Good Clinical Trials Practise Branch II

All study related activities should be documented
which allows all aspects of a study to be
reconstructed

Paper trail is necessary!

Why Quality Matters

“Good Clinical Practice (GCP) is an international ethical and scientific quality standard for designing, conducting, recording and reporting trials that involve the participation of human subjects. Compliance with this standard provides public assurance that:

The rights, safety and well-being of study subjects are protected and that the clinical data are credible”

Why Quality Matters

Good Laboratory Practice (GLP) embodies a set of principles that provides a framework within which laboratory studies are planned, performed, monitored, recorded, reported and archived. These studies are undertaken to generate data by which the hazards and risks to users, consumers and third parties, including the environment, can be assessed for pharmaceuticals (only preclinical studies), agrochemicals, cosmetics, food additives, feed additives and contaminants, novel foods, biocides, detergents etc.... GLP helps assure regulatory authorities that the data submitted are a true reflection of the results obtained during the study and can therefore be relied upon when making risk/safety assessments.

Quality is teamwork

There are many people/groups involved in the regulation and quality of research studies

- Investigators and study team
 - Protocol compliance
 - On-site monitoring
 - Regulatory authorities
 - Inspections from Health Canada or Sponsors
 - IRB
 - Continuing review
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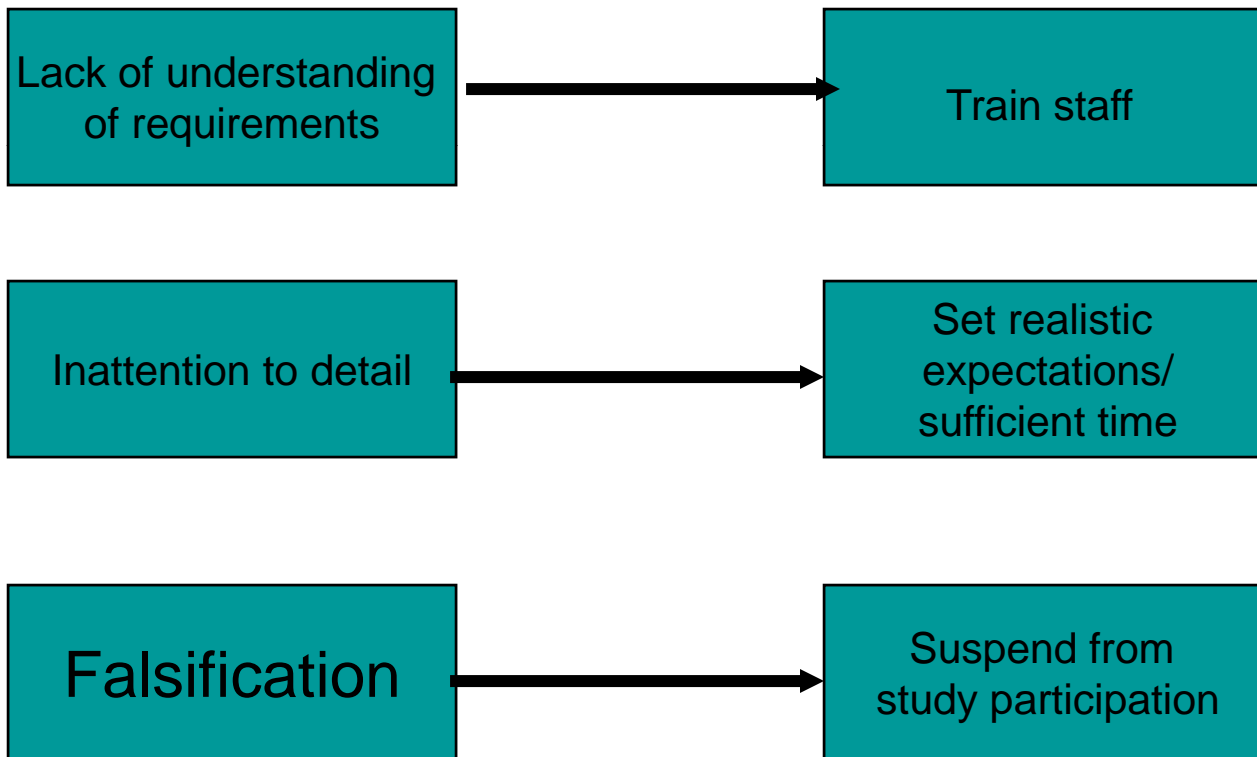
Quality control vs. Quality assurance

	QC	QA
Role	Part of the process of ensuring quality	Third-party assurance of quality
Responsibility	Study Team	Audit group
Approach	Surveillance	Systematic
Examples	Data check of CRFs against source documents (monitoring)	Sample check of CRF data (auditor)
Summary	Procedure that ensure that the process is in control and data is being recorded accurately	Procedure that verify that QC procedures are effective

Data Errors

Scale of Seriousness

Action Plan



How much will the project
cost ?

Knowledge Translation

Definition

- *Knowledge translation is a dynamic and iterative process that includes synthesis, dissemination, exchange and ethically sound application of knowledge to improve the health of Canadians, provide more effective health services and products and strengthen the health care system. (Canadian Institutes of Health Research, 2008)*
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Other Terms

- Knowledge Mobilization
 - Knowledge Exchange
 - Knowledge Transfer
 - Dissemination
 - Research Utilization
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Knowledge Translation

- Good to think about in all 4 tracks.
 - Establish process for KT in the proposal.
 - Engage Community early
 - Who will take lead with KT?
 - Joint presentations (think about the audience)
 - Authorship discussion early on and revisit
 - guidelines for authorship
 - creative opportunities for contributions to authorship
-

Knowledge Translation

- Ongoing consultations with Community Advisory Committee, collaborators and decision makers
 - Present preliminary findings back to participants (interpretations, refinements)
 - Dual validity check possibilities
 - Provide method for participants to receive final study results if interested.
 - Consider KT activities throughout study and at study completion.
 - Good to have a timeline
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Knowledge Translation

Academic

- Podium or poster presentations at scientific meetings
 - Presentations at hospital rounds, universities.
 - Education in academic health curricula programs.
 - Continuing education courses, mentorship programs
 - Invited speakers
 - Peer reviewed publications
 - Open access journals
 - Community members as co-authors and co-presenters.
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Knowledge Translation

Community

- Presentations at community-based organizations or recruitment sites
 - staff meetings
 - annual general meetings
 - research days
 - workshops
 - Fact sheets, Summaries, Key Messages
 - Practical 'tool kits', or 'products' that can be used in programs in the community.
 - Newsletters available on websites
 - Consider the 'audience' (e.g. health providers, PHAs)
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Knowledge Translation

Policy

- Impact of research on programs and policy.
 - Links to provincial or federal programs.
 - Media releases, briefing notes
 - Consider engaging policy stakeholders early on in project (advisory committee).
 - Presentations to Policy Makers
 - Ontario Advisory Committee on HIV/AIDS (OACHA)
 - Federal Ministers
 - Medical Officers of Health
 - Consider Multi-stakeholder Sessions –
 - targeting multiple stakeholders at the same time with goal of changing policy and practice.
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Next Steps

- Use Knowledge Translation as way to discuss implications of research, next steps.
 - Generate new project ideas based on study findings.
 - Consider team members for new phase of research.
 - Review upcoming funding opportunities, deadlines.
 - Continue to publish from previous work to build foundation for future research.
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Thank You

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