MODULE 4: SCIENTIFIC COMMUNICATION

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SESSION 2: METHODS

AIM OF THE SESSION

This session will introduce you to:

- The main components of method section,
- The appropriate tenses and appropriate flow of the session.
- The common method section pitfalls

Contains information that was available to you during the planning process ... Not what you learnt in the process..

The method section should be clear enough to allow:

- Replication of findings,
- Proper interpretation of results and most importantly
- Allow assessment of the quality of the study and validity of your conclusions.
  - Appropriateness of study design
  - Adequate quality assurance and bias control
  - Proper statistical analysis

CONTENT AND LEARNING OUTCOMES OF THE SESSION

The method section has 3 learning outcomes:

- Describe main components of the method section
- Assess the clarity and flow of the method section by applying CONSORT and STROBE
- Use appropriate tenses as required by journals

Normally the method session covers the following:

- Study design
- Study population and sample size
- Sample collection and processing
- Data storage and analysis
- Ethical review

THE METHOD SECTION SHOULD:

- About 6-7 paragraphs
- Should have a logical order – usually time order
- Use flow chart if necessary
- Use past tense
- Use passive case- again check the journal's guidelines for authors
- Use appropriate reference
- Ethical approval

GENERAL CONSIDERATIONS

- Some researchers choose to start by the method section:
  - The section responds to the question of "HOW"
- The Method section should follow time and logical order:
  - What starts first, .. And then what follows, etc.:
    - Selection of study subjects
    - Selection of sample (demographic, clinical and laboratory)
    - How the subjects, parasite were identified ?
    - How the variable of interest was determined, treated ?(How the antibiotic sensitivity was determined)

GENERAL CONSIDERATIONS

- When reviewing the method section:
  - All readers should be able to follow what you did (what start first, and then… and then…)
  - Integrity: you should be honest and say if there were errors made
  - Subheadings of the method section should follow the journal's requirement

  - >>>> Most importantly, you should use

GENERAL CONSIDERATIONS

- Use existing protocol depending on the study design I
- Use analysis plan
- Involve a statistician (write or review)
- Follow guidelines as appropriate for improving reporting process:
- http://www.consort-statement.org
  - **CONSORT** (CONsolidated Standards Of Reporting Trials)
- http://www.strobe-statement.org/
  - **STROBE** (STrengthening the Reporting of OBservational studies in Epidemiology)

GENERAL CONSIDERATIONS: TENSES: PAST TENSE AND PASSIVE

- Always the method section uses past tense:
  - It is a description of what you did in the past (in the time-order)
  - Passive voice is generally recommended (please check the journal website)
    - The slides were stained and examined for COVID-19
  - You need to relate to what was exactly done vs what you hoped was done

WHY PASSIVE CASE?

- Some journals prefer to use passive voice:
  - Because – there is no interest to know who did it as opposed to what was done or how the technique was done
  - Even when authors report that " we stained"… technically technician did it or was instructed to do it

THE FLOW

1. Study design (based on your research question)
2. Study population and sample size
   - Study population incl. control groups
   - Sample size, selection criteria
3. Sample collection and processing
   - Procedures that were used
   - Laboratory techniques
   - Quality control
4. Data storage and analysis
   - Kind of statistical tests used
5. Ethical review
   - Approval given by ……

Or the content can cover the following:

- 1. Data Collection Methods
- 2. Materials
- 3. Statistical Methods

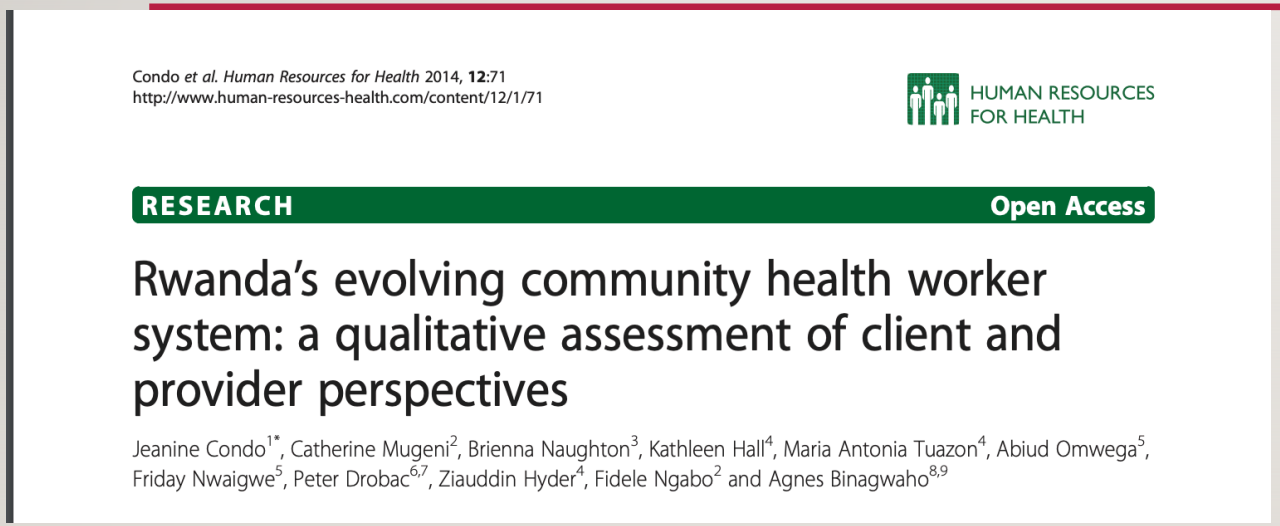
1. DATA COLLECTION METHODS (1)

- Study Design >> *appropriateness of the design / objectives*
  - Type of study
  - Schedule of data collection contacts
- Subjects/participants & Settings >> *generalizability*
  - Location and relevant dates
  - Inclusion/exclusion criteria
  - Methods for participant recruitment/selection (random sample, convenient sample, etc)
  - Any specimen (appropriate, storage, quality control, treatment of the specimen)
- Main Variables >> *clinical relevancy and appropriateness of the outcome*
  - Definitions (outcomes, exposures, predictors, confounders)
  - Data collection methods and study procedures(e.g., lab tests, questionnaires)

1. DATA COLLECTION METHODS (2)

- Other bias control procedures
  - Randomization
  - Allocation of study participants
  - Blinding
  - Compliance monitoring
  - Participant retention procedures
  - Quality control procedures
  - Standardization
- Data Management procedures

1. DATA COLLECTION METHODS (3): EXAMPLE



Condo *et al. Human Resources for Health* 2014, **12**:71
http://www.human-resources-health.com/content/12/1/71

HUMAN RESOURCES FOR HEALTH

RESEARCH **Open Access**

Rwanda's evolving community health worker system: a qualitative assessment of client and provider perspectives

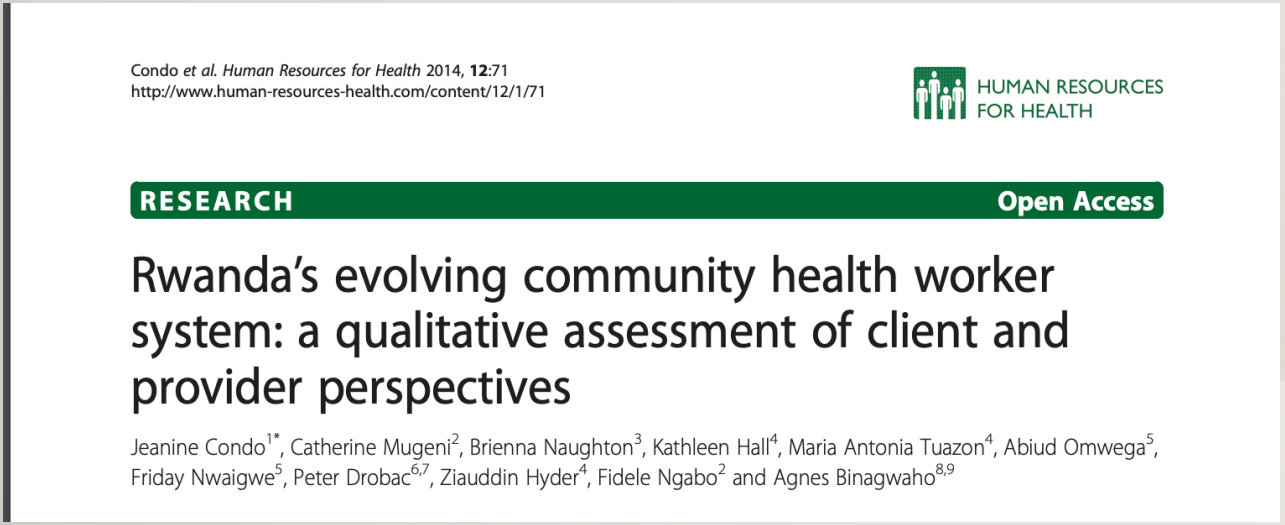
Jeanine Condo[1*], Catherine Mugeni[2], Brienna Naughton[3], Kathleen Hall[4], Maria Antonia Tuazon[4], Abiud Omwega[5], Friday Nwaigwe[5], Peter Drobac[6,7], Ziauddin Hyder[4], Fidele Ngabo[2] and Agnes Binagwaho[8,9]

- Study design and population
- Data collection
- Data processing and analysis
- Ethical considerations

1. DATA COLLECTION METHODS (4): EXAMPLE

Example:

"A cross-sectional descriptive study was conducted to collect qualitative information regarding educational background, knowledge, and practices of CHWs, as well as the perception of CHWs from the beneficiaries, including women of reproductive age. Focus group discussions (FGDs) for both CHWs and their beneficiaries were conducted, which included the collection of demographic data. These data were collected as part of a larger assessment of CHW capacity relating to community-based nutrition (CBN) programmes, as commissioned by the Rwanda Ministry of Health (MoH) with the support from World Bank and UNICEF Rwanda. The study was held from 10 to 20 May 2011, i).



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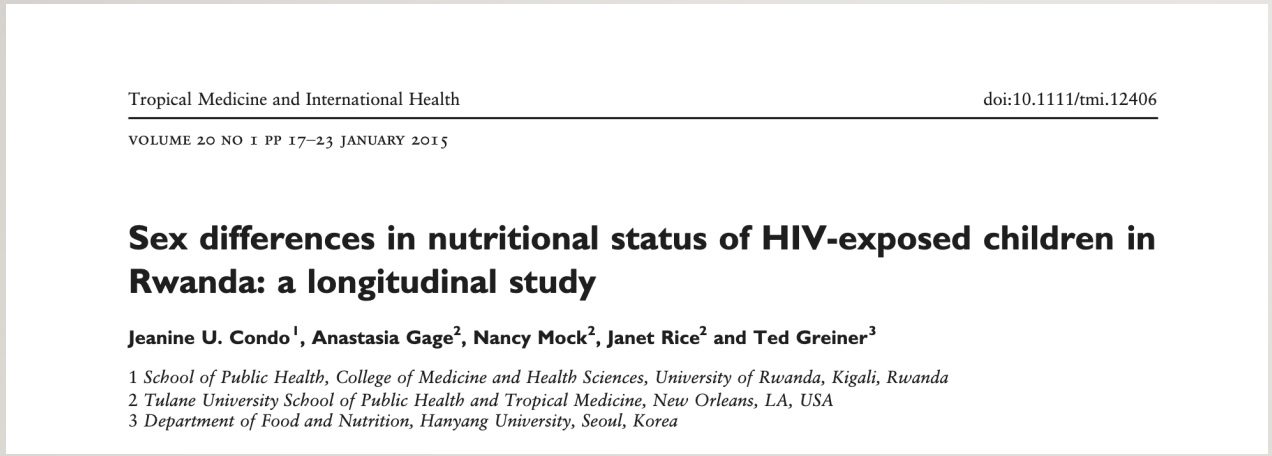
1. DATA COLLECTION METHODS (5): EXAMPLE



Tropical Medicine and International Health doi:10.1111/tmi.12406

VOLUME 20 NO 1 PP 17–23 JANUARY 2015

Sex differences in nutritional status of HIV-exposed children in Rwanda: a longitudinal study

Jeanine U. Condo[1], Anastasia Gage[2], Nancy Mock[2], Janet Rice[2] and Ted Greiner[3]

1 *School of Public Health, College of Medicine and Health Sciences, University of Rwanda, Kigali, Rwanda*
2 *Tulane University School of Public Health and Tropical Medicine, New Orleans, LA, USA*
3 *Department of Food and Nutrition, Hanyang University, Seoul, Korea*

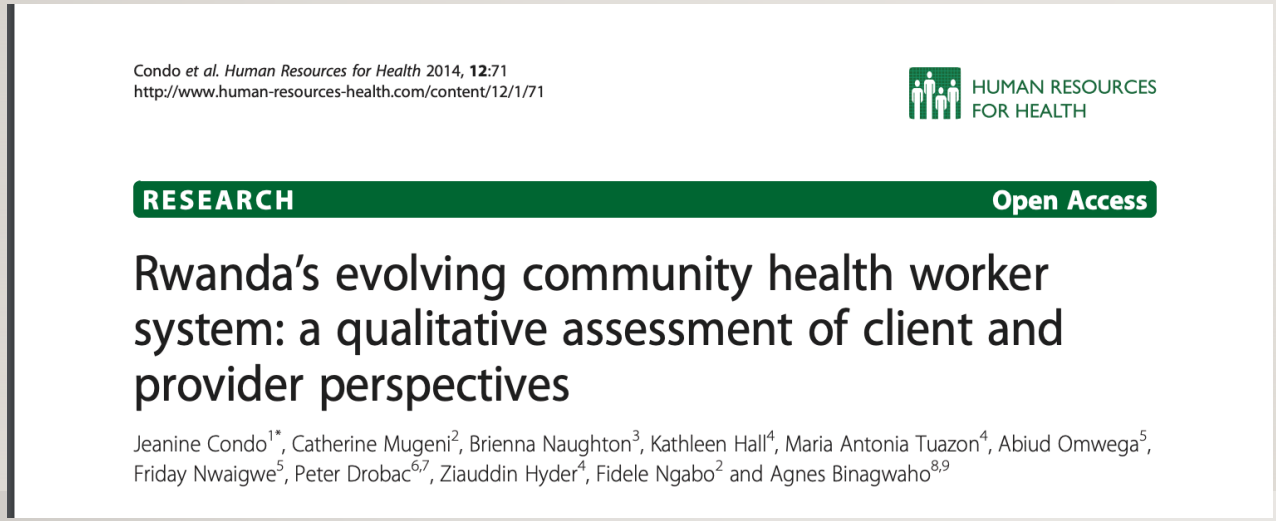
Example:

- "We used a prospective, longitudinal cohort study design among HIV-exposed children participating in a supplementary feeding programme providing fortified corn soy blend (CSB). By the time of the data collection, the programme was implemented in roughly half of Rwanda's 400 health centres. Of a total of 3144 children enrolled in the programme, 1085 infants were 6–12 months of age. We used a simple random sampling method without replacement to select 485 study participants, the sample size required to identify reasonable differences in the infant and child feeding index (ICFI) score (defined below).

2. MATERIALS (1)

- Interventions
  - Drugs (treatment, placebos, dosing)
  - Techniques, training, informational material
  - Standardization
- Materials and Equipment
  - Purpose
  - Characteristics (e.g., type, manufacturer, calibration)
  - Lab procedures
  - Development and validation

2. MATERIALS (2): EXAMPLE



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- Data collection:
  - Focus group guides for beneficiaries and CHWs were developed following meetings with Government of Rwanda health officials, pretested and translated into the local language of Kinyarwanda. The FGD guides included demographic data. Data were collected over a 10-day period in May 2011. The FGDs were conducted by experienced and trained enumerators, and were audio-recorded, transcribed in the local language of Kinyarwanda, and then translated into French by a professional translator.

3. STATISTICAL METHODS (1)

- Data analysis methods:
  - Analysis Populations (e.g., ITT, per protocol)
- Sample size
    - Justification in terms of power or precision for the primary objective and primary endpoint
    - Method used to calculate the sample size
    - Consistent with the analysis
    - Historical data to support the assumptions
- Procedures for irregularities:
    - Missing data,
    - Subject noncompliance, or
    - Protocol violations
- Descriptive statistics (e.g. geometric means, tables, plots)
- Hypothesis testing:
    - Statistical Hypotheses (implicit)
    - Statistical Tests (e.g., t-test, Wilcoxon test, regression model)
    - Significance Level
    - One vs. two sided
    - Presentation of p-values and CIs

3. STATISTICAL METHODS (2): EXAMPLE

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- Example:

"The translated transcripts collected from the field were assessed by two coder clerks who identified emergent codes from the FGDs. Once the final set of codes was agreed upon, they were analyzed using qualitative analysis software, Atlas.ti. Beneficiaries' demographic characteristics, CHWs' demographic characteristics and educational background were also recorded.

3. STATISTICAL METHODS (3)

- Hierarchy of analyses (primary, secondary, sensitivity analysis)
- Planned vs. unplanned
- Interim analysis methods

4. ETHICS

- Seek approval by all concerned ethical review boards
- Consent forms (statement that it was obtained)

POINTS TO REMEMBER

- Presenting methods logically
  - Chronologically
  - Grouping related methods together
- Aligned with Results and link with objectives
  - Rationale for analysis strategy / analysis plan
- Using subheadings
- Citing references
- Using tables

SMALL POINTS TO REMEMBER (1)

- Geographic names?
- Check consistency and accuracy of the words used (men/women, participants/ patients, male/female)
- Acronyms (define what they mean for the first time and when to use them)
-

- References:
  - If well known (book): no need for reference
  - New (give original reference)
  - New and modified (give original reference and state the modification you made)

SMALL POINTS TO REMEMBER (2)

- Statistical software?
- Registration of Clinical Trials
- Conflicts of interest disclosures:
  - Role of the funding source (Lancet)

COMMON PITFALS

- Insufficient details:
  - Novel procedures
  - Subject selection
  - Randomization methods
  - Allocation concealment
  - Blinding
  - Statistical methods

} **See CONSORT**

- Excessive detail on routine well-known procedures
- Some methods not described until the Results section

FINAL REMARKS

- Report all you have done for the objectives you are reporting.
- Allows for proper peer review
- Use protocol and analysis plan
- Follow guidelines as appropriate, CONSORT, STROBE
- Involved a statistician (write or review)
- Use published articles as examples for style and format
- Use references effectively and appropriately
- Clarity is paramount!
- Check for consistency

REMEMBER…

Replication

Interpretation

Quality

E-TIVITY: GUIDELINES

- Purpose: To understand key components of the method section and its appropriate flow.
- Preparatory research/ over to you:
  - Use presentations of session 2 of scientific communication course: this will introduce you to the main and critical components of the method section and how each section relates to the previous one and prepare the next sub-headings.
  - Watch the recorded video on method section related to common pitfalls, tenses and use of CONSORT and STROBE

E-TIVITY 2.1:

- You are given an article and focus on the method section. You are assigned in the group (refer to the class 1) and based on the key components of the method section, identify these components in the method section. Use CONSORT and STROBE and assess the:
  - (1) appropriateness of study design,
  - (2) the Adequacy of the quality assurance and bias control and
  - (3) strength of the statistical analysis method use. Submit your observation to your group assigned to you and comment to your peer observation and respond to their feedbacks addressed to you to your post. You will then choose one group member to represent your group during the plenary session.

Table 1

STROBE guidelines

STROBE guidelines		
Section/topic	**Item number**	**Recommendation**
Title and abstract	1	Indicate the study's design with a commonly used term in the title or the abstract Provide in the abstract an informative and balanced summary of what was done and what was found
Introduction		
Background/rationale	2	Explain the scientific background and rationale for the investigation being reported
Objectives	3	State specific objectives, including any prespecified hypotheses
Methods		
Study design	4	Present key elements of study design early in the manuscript
Setting	5	Describe the setting, locations, and relevant dates, including periods of recruitment, exposure, follow-up, and data collection
Participants	6	Cohort study - give the eligibility criteria, and the sources and methods of selection of participants; describe methods of follow-up Case-control study - give the eligibility criteria, and the sources and methods of case ascertainment and control selection; give the rationale for the choice of cases and controls Cross-sectional study - give the eligibility criteria, and the sources and methods of selection of participants Cohort study - for matched studies, give matching criteria and number of exposed and unexposed Case-control study - for matched studies, give matching criteria and the number of controls per case
Variables	7	Clearly define all outcomes, exposures, predictors, potential confounders, and effect modifiers; give diagnostic criteria, if applicable
Data sources/measurement	8*	For each variable of interest, give sources of data and details of methods of assessment (measurement); describe comparability of assessment methods if there is more than one group
Bias	9	Describe any efforts to address potential sources of bias
Study size	10	Explain how the study size was arrived at

*Give information separately for cases and controls in case-control studies and, if applicable, for exposed and unexposed groups in cohort and cross-sectional studies

Table 1

STROBE guidelines

Study size	10	Explain how the study size was arrived at
Quantitative variables	11	Explain how quantitative variables were handled in the analyses; if applicable, describe which groupings were chosen and why
Statistical methods	12	Describe all statistical methods, including those used to control for confounding
		Describe any methods used to examine subgroups and interactions
		Explain how missing data were addressed
		Cohort study - if applicable, explain how loss to follow-up was addressed
		Case-control study - if applicable, explain how matching of cases and controls was addressed
		Cross-sectional study - if applicable, describe analytical methods taking account of sampling strategy
		Describe any sensitivity analyses

E-TIVITY 2.2: GROUP ASSIGNMENT

- You are requested to develop your method section for your activity. Your work will be assessed by your peer and you will assess your peer's method section. The following are tasks you need to report on (max 2-3 page):
  - (1) What is the problem you are studying (1 paragraph)
  - (2) What is your research question
  - (3) What is your dependent variable (outcome of the interest, only one variable)
  - (4) What are your independent variables (not more than 10)
  - (5) Develop all main components of the method section

E-TIVITY 2.2: PEER ASSESSMENT

What will you assess from your peer:

(1) Are all key components of the method section developed and appropriate?

(2) Did your classmate author (s) apply appropriate study design?

(3) Were the flow and tenses used appropriately as described during the course,

(4) Was there any issue with quality assurance and bias control?,

(5) Assess appropriateness of statistical analysis.

Every member should comment on the reasons of his/her choice. Lastly, each of the group representative should submit the final activity using Moodle (no more than 2-3 pages)

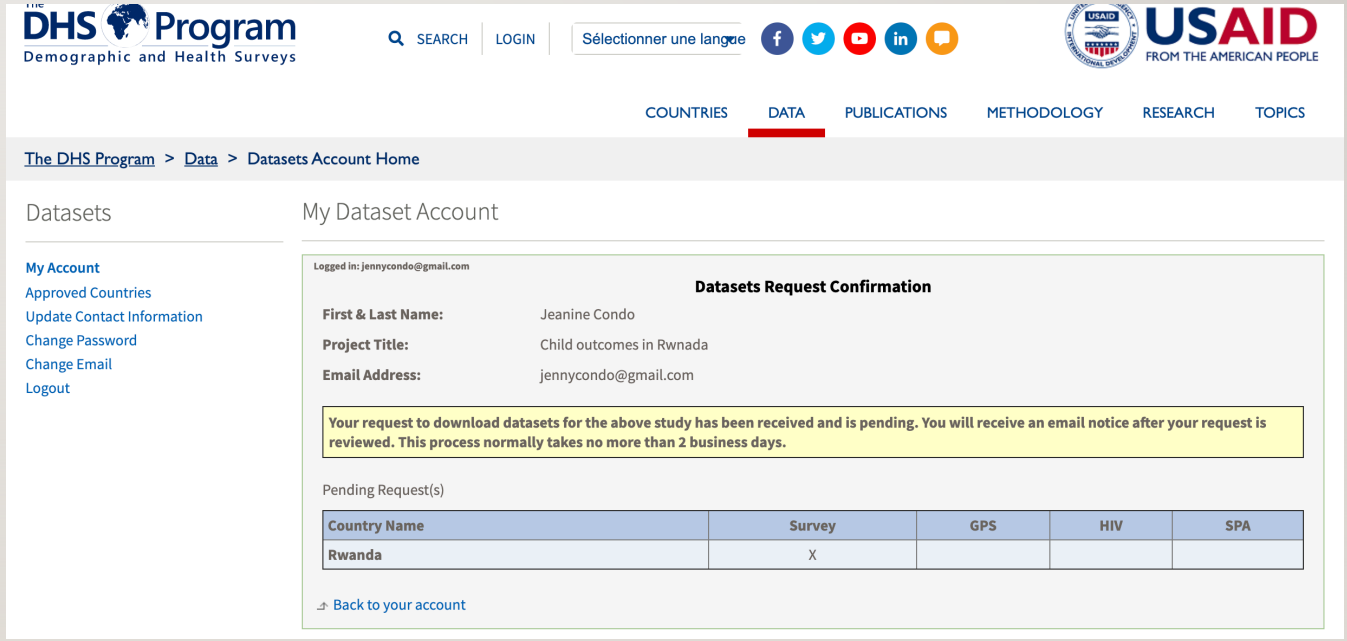
E TIVITY 2.2 (CONT'D)

- Use the website below to download the RDHS:
  - https://dhsprogram.com/data/dataset/Rwanda_Standard-DHS_2015.cfm

  (follow instructions by typing your paragraph explaining your research outcomes including Dependent and independent variables). Request the child database for Rwanda and submit.

  You will wait for 2 days and the dataset will be granted.

  Download and start the analysis of the dataset using STATA



LEARNING RESOURCES

- Power point presentations, notes introducing the section, book and weblink to articles
- http://www.consort-statement.org/checklists/view/32--consort-2010/96-statistical-methods
- https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4520133/: Consort: When and how to use it
- https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6398292/: The STROBE guidelines