Challenges in Implementing an International Multi-site Tobacco Use Survey of Pregnant Women

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Global Network: Background

Funding from the National Institutes of Health (NIH) and the Bill and Melinda Gates Foundation established the Global Network for Women's and Children's Health Research (GN) to expand scientific knowledge relevant to improving health outcomes for women and children in developing countries.

Global Network: Participating NIH Institutes & Centers

- National Institute of Child Health and Human Development (NICHD)
- National Cancer Institute (NCI)
- National Institute of Dental and Craniofacial Research (NIDCR)
- National Center for Complementary and Alternative Medicine (NCCAM)
- Fogarty International Center (FIC)

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Global Network: Goals

- To strengthen international collaborative research arrangements that focus on the leading causes of morbidity and mortality during pregnancy and early childhood
- To develop sustainable research infrastructures and public health intervention capabilities in developing countries

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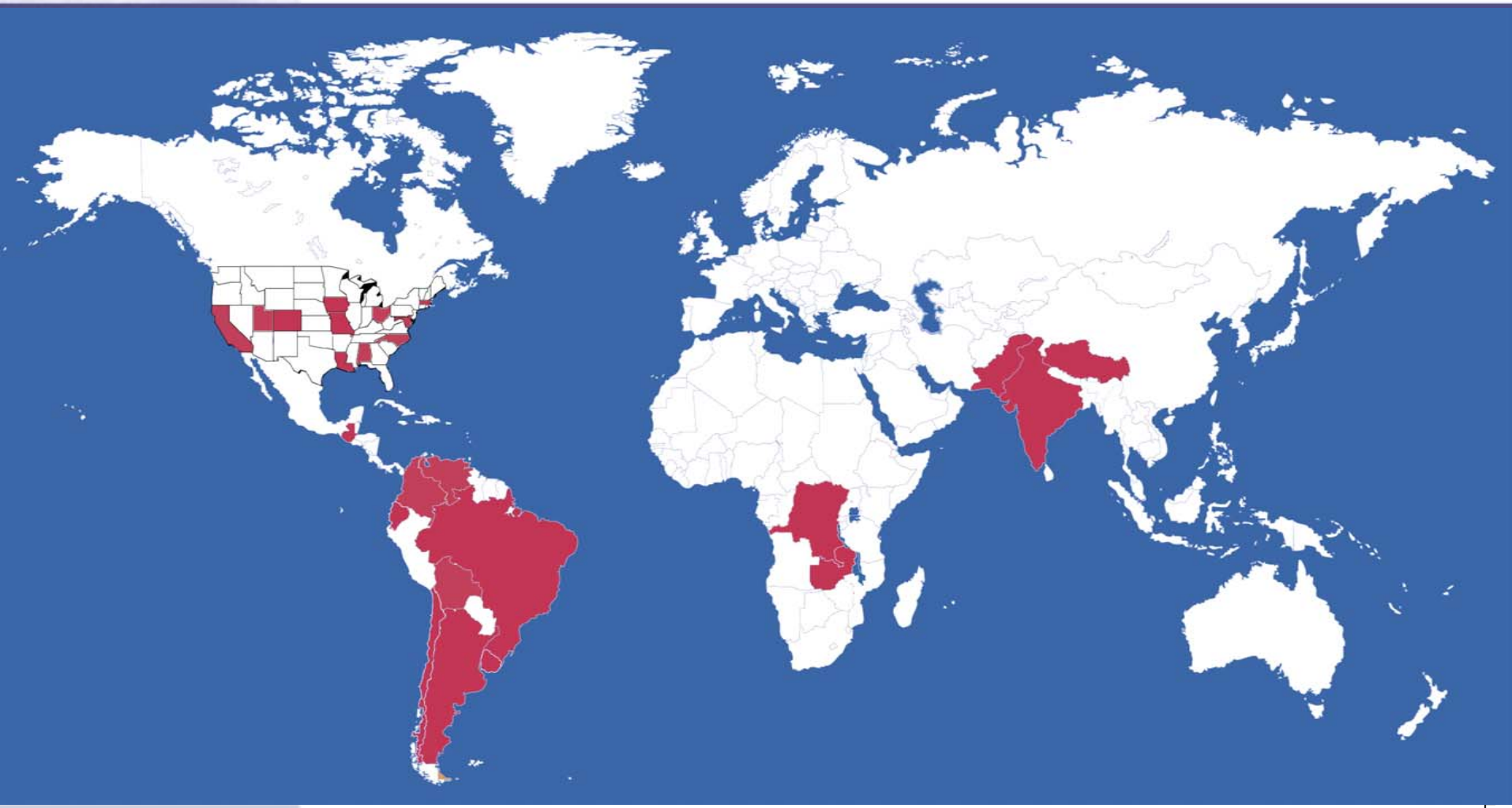
The Global Network is composed of 10 research units in Latin America, Asia and Africa that are affiliated with 9 U.S. universities, a data coordinating center (DCC), and scientific staff at the NICHD



Global Network: Research

- To date, each of the 10 research units has established at least one core study in the field, and the GN is in the process of launching its second common protocol
- The Tobacco Use Survey in Pregnant Women was the first common protocol to be implemented

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Tobacco Use Survey: Background

- Globally, tobacco use ranks among the leading causes of preventable, premature death
- Tobacco use is stable or decreasing in most high-income nations; however, in developing nations tobacco use is increasing

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Tobacco Use Survey: Objectives

- To obtain information on knowledge, attitudes and behaviors regarding tobacco use of pregnant women in developing countries
- To examine pregnant women's and children's exposure to environmental tobacco smoke (ETS)
- To examine knowledge of and attitudes toward health hazards of tobacco use and ETS exposure
- To serve as a baseline for future interventions

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Tobacco Use Survey: Methods

- Convenience sample of 750 women in 9 countries (DR Congo, Zambia, Uruguay, Argentina, Brazil, Ecuador, Guatemala, India, and Pakistan)
  - 18-46 years of age
  - At least 3 months pregnant
- Women are identified in hospitals and clinics
- 20- to 40-minute, face-to-face interview

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Main Challenges Identified

- Developing an appropriate questionnaire with common yet country-specific content
- Facilitating timely ethics review by several IRBs, each with a unique perspective on the conduct of research
- Coordinating the translation of study documents into several languages
- Long distance training to ensure standardization at low cost
- Developing a standard data entry program for multiple sites

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Developing an Appropriate Questionnaire with Common Yet Country-specific Content

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Questionnaire Content

- Demographic information
- Cigarette use and other tobacco use behavior based on use status
- Exposure to tobacco smoke
- Knowledge of hazards of tobacco use
- Exposure to pro-tobacco and anti-tobacco marketing

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Sources of Questionnaire Content

- Global Network principal investigators
- U.S. national tobacco questionnaires
- WHO's "seven standard tobacco questions"
- Global Youth Tobacco Survey (GYTS)
- Content experts
- DHS questionnaires (for SES variables)

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Tailoring Questionnaire for Individual Sites

- Race/ethnicity/caste/country of origin
- Socio-economic status (SES)
- Knowledge of hazards of the use of specific tobacco products, other than cigarettes

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Formatting the Questionnaire to Facilitate Administration

- Color-coded sections to distinguish between never, current and past smokers or users
- Developed section supplements
  - To list additional household members
  - To report behavior, based on use status, for up to four other tobacco products
- Used questionnaire administration conventions

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Observations from Site Investigators on Questionnaire

- Respondents were unclear why SES questions were asked on a *tobacco* survey
- Recommended reordering of questionnaire for countries where use of other tobacco products is more prominent than cigarettes

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Lessons Learned – Instrument Creation

- A complex questionnaire requires experts in both content and survey methodology
- Having many people involved in developing a questionnaire can be necessary and useful but presents challenges
- Cultural diversity impedes standardization across countries, especially in developing demographic items
- This is new territory. We are not aware that there has been an effort to collect information on pregnant women's knowledge, attitudes, and behaviors towards tobacco use and environmental tobacco smoke exposure in a standardized way in multiple developing countries.

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Recommendations

- Keep questionnaires simple and limit subtopics if necessary
- Utilize formative research to ensure appropriate content and format for adaptation to local use
- Maintain use of core group of researchers to develop and oversee administration of the questionnaire

Facilitating Timely Ethics Review by Several IRBs

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Ethics Review Experience

- 11 US and 11 field site IRBs involved in ethics review process
- Diversity of submission requirements (language, general vs. site specific documentation)
- Ethics approval varied by site: type of approval (phased approach vs. full approval) and timing (six weeks to several months)
- Verbal consent vs. signed, written consent of up to 2.5 pages
- Ethics of conducting the survey in only one language

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Observations from Site Investigators on Consent Process

- Consent process for some respondents in India was reported to be > 45 minutes
- Lengthy consent process inappropriate for many of the populations studied

Suggested Ethics Review Process for International Multisite Research

1. Send communication to all stakeholders informing of ethics review process and suggested timeline
2. Distribute study protocol, data collection instruments and model informed consent to US and field site IRBs
3. Communicate questions and concerns from IRBs with lead investigators

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Suggested Ethics Review Process for International Multisite Research

4. Hold teleconference with representatives from field site and US ethics committees and lead investigators to review risks to human subjects and recommend consent procedures
5. Conduct independent reviews by field site and US ethics committees
6. Local IRB should ultimately determine content and format of consent procedures

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Coordinating the Translation of Study Documents into Several Languages

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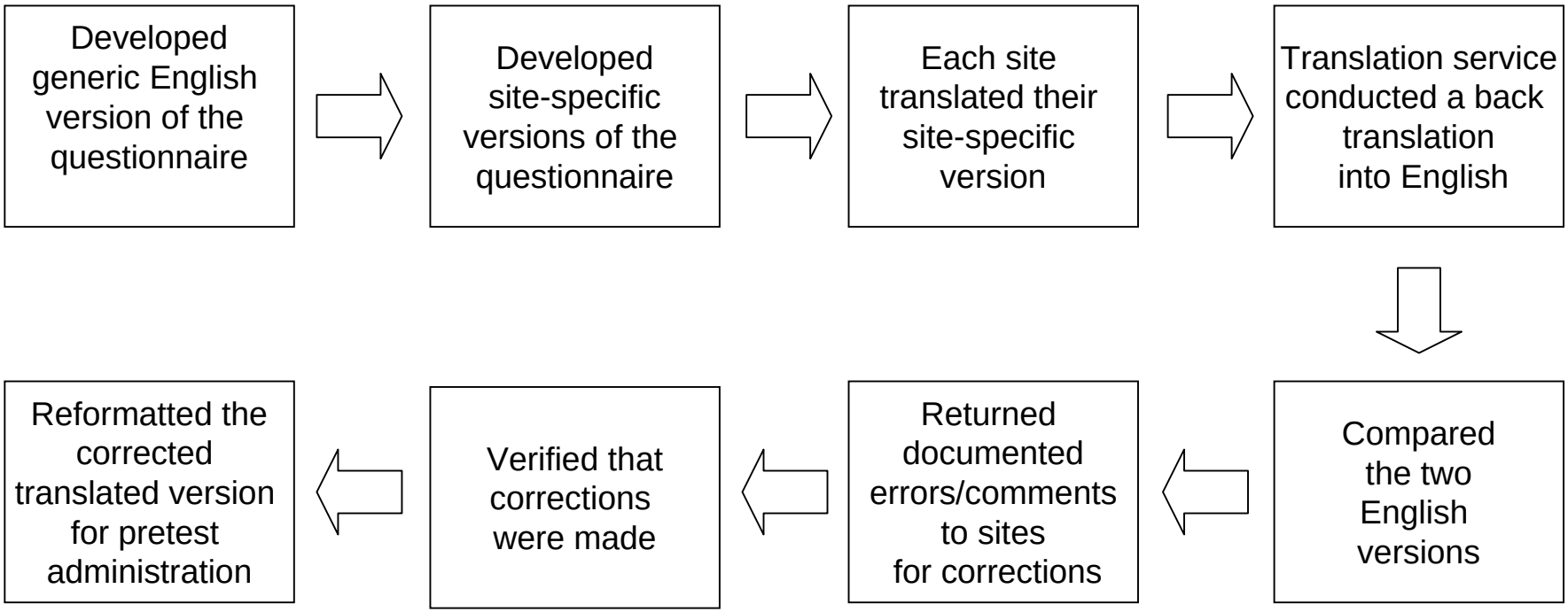
The Translation Process



Coordinating the Translation of Study Documents into Several Languages

- Task of translation of questionnaire was given to site teams as country specific questionnaire in English was available
- Site staff or local service conducted translation
- Complexity and length of questionnaire delayed translation process
- Backtranslation and resolution of errors required additional time and effort to finalize questionnaires

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Issues and Problems with the Translation Process

- Sometimes only parts of the questionnaire were translated
- Sometimes subtle differences in similar questions were missed when translators used “cut-and-paste” techniques
- Some translators changed the question or suggested alternatives
- In two sites, an intermediate language translation had to be done

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Issues and Problems with the Translation Process

- For some languages, the sites were asked to conduct additional independent verification that corrections were made
- For some languages, the sites reformatted the translated version

Lessons Learned - Translations

- The complexity and length of the questionnaire made the quality control measures to check language translations an arduous process
- Translators should have been given an overview of the questionnaire, pointing out similarities and differences in sections
- Translators should have been given explicit instructions and expectations of the translation process

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Lessons Learned – Translations

- Formatting conventions used in English are not always appropriate in other languages
- Maintaining complete control of the process or the outcome is difficult without some fluency in the language

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Recommendations for Multisite Research Translation Process

1. Centralize control of translation process by contracting language service to conduct primary translation from language of source document
2. Provide detailed instructions to translation service: selection of translator (cultural background and professional knowledge), objectives of survey, formatting, software
3. Have field team conduct backtranslation, providing specific instructions to maintain formatting to facilitate comparisons with original documents

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Recommendations for Multisite Research Translation Process

4. Compare source document with backtranslation, identify discrepancies and revise translated document with participation of original translator and field team
5. Have several representatives from field site review final product for appropriate language, reading level and comprehension before pretesting
6. Pretest translated instruments and revise accordingly to prepare final instrument

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Distance Training to Ensure Standardization at Minimal Cost

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Training Approach

- Distance training of trainers
- Provision of detailed documentation: questionnaire administration, field procedures, study coordination
- Training agenda with topics and time allocation
- Scripts for round robin and paired mock interviews
- Conference calls to review materials and training techniques
- Certification exam for data collectors

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Feedback on Training from Site Coordinators

- Detailed and thorough documentation was ideal for preparing site training sessions
- Agenda was flexible to accommodate needs of each site
- Additional visuals would be helpful to clearly provide an overview of the activities involved in the interview process

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Lessons Learned – Training

- Distance training can be successful with thorough preparation and planning
- Although materials provided beforehand, in some cases coordinators were not fully prepared for the review conference calls
- Field trainers benefit from adapting training materials to local needs

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Recommendations for Distance Training

- The training experience of this study should be documented to guide others that intend to implement a similar approach
- Web-conferencing should be explored to aid review of training materials and techniques and facilitate interactive learning to strengthen distance training approach

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Development of Data Management System

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Characteristics of Data Management System

- Data management system developed in English
- Free text responses recorded in original language but translated into English
- Extensive controls for data entry (pre-selected ID numbers, range checks, skip logic, required entry, interform edits) programmed to limit data entry errors
- Error messages programmed in English

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Lessons learned – Data Management

- Direct access to servers and contact with the local IT staff was instrumental to the success of technical communications and software installation
- Communication with programmer via email and instant messaging was essential for troubleshooting during data entry
- Date formats can be inadvertently converted by system configuration of data entry PC
- Uncertainty of how quality of data entry may have been affected by having system formatted in English

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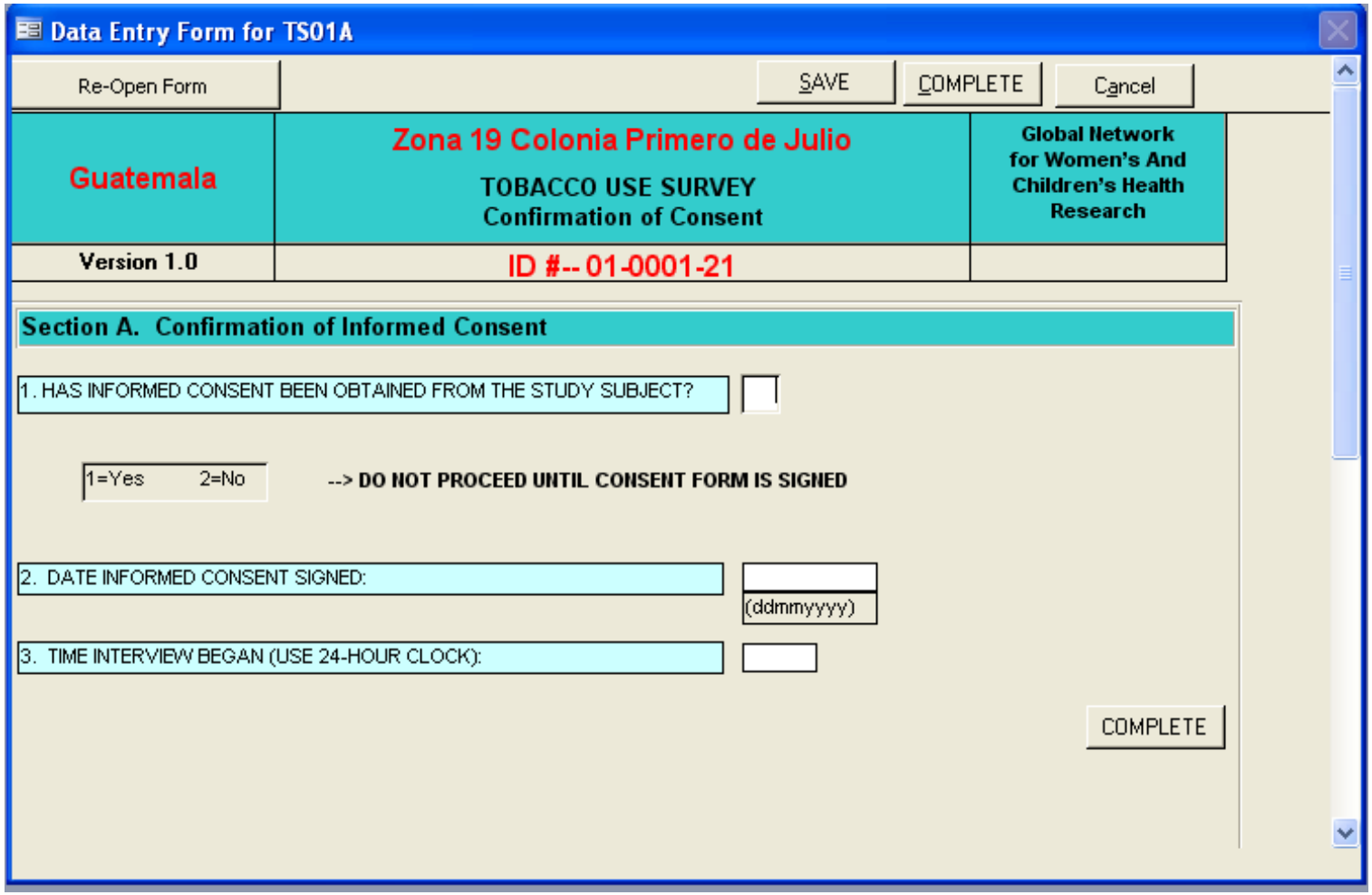

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چاپي جي تاريخ:2004-10(آخري)

سيڪشن A. جاڻ ڏنل راضي نامي جي تصديق

1. ڇا عورت جي رضامندي حاصل ڪئي وئي آهي؟

1 ☐ ها 2 ☐ نه ← رضامندي حاصل ڪرڻ کان اڳ اڳتي نه وڌو

2. تاريخ جنهن تي رضامندي حاصل ڪئي وئي|__|__| - |__|__| - |__|__| :
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3. وقت جنهن تي انٽرويو شروع ٿيو (24 ڪلاڪن وارو گھڙيال استعمال ڪريو) |__|__| : |__|__|

DMS Recommendations

- Data entry screens should closely mirror the questionnaire in language and format
- Data elements should be programmed as separate variables to avoid system conversions
- Open ended responses should be further limited with the addition of potential site specific responses identified in pretesting

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Summary Recommendations

- Conduct more formative research for questionnaire development
- Centralization of ethics oversight
- Giving precedence to local ethics committees for informed consent
- Consolidating control of the translation process
- Documenting the distance training experience
- Designing a data entry system that closely mirrors the questionnaire

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Conclusions

- Conducting international multisite surveys poses several challenges due to diversity in language, culture and distance
- Standardization can be achieved with thorough preparation and planning
- Best to keep instruments and methods simple and facilitate adaptation to local needs

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