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COMPLIANCE ADVISOR/OMBUDSMAN

TERMS OF REFERENCE

Epidemiology Scoping Study for Chronic Renal Insufficiency in Nicaragua

Overview

The Office of the Compliance Advisor/Ombudsman (CAO) is the independent recourse mechanism for the International Finance Corporation (IFC) and the Multilateral Investment Guarantee Agency (MIGA) of the World Bank Group. The CAO reports directly to the President of the World Bank Group, and its mandate is to assist in addressing complaints from people affected by projects in a manner that is fair, objective, and constructive and to enhance the social and environmental outcomes of projects in which IFC and MIGA play a role. In the first instance, complaints are responded to by the CAO's Ombudsman function.

On March 31, 2008 the CAO received notice of concerns presented on behalf of communities from the Departments of León and Chinandega, Nicaragua, relating to impacts to the health, environment, and livelihoods of community members. Community members live in the vicinity of the Ingenio San Antonio, owned by Nicaragua Sugar Estates Limited (NSEL), a client of IFC. The CAO Ombudsman conducted a field assessment in June 2008.

In November 2008, the CAO returned to Nicaragua to negotiate a framework agreement that commits NSEL and the local claimant group (ASOCHIVIDA) to work with the Ombudsman on health issues. As presented in the Assessment Report (http://www.cao-ombudsman.org/html-english/Nicaragua_sugar.htm) and the framework agreement, the two courses of action for addressing CRI are:

- (i) Explore options for improved care for affected community members; and
- (ii) Conduct a study to better understand the causes of CRI in the region.

The CAO is separately contracting a community health advisor to address the first course of action.

The participants in the CAO process have identified the need for support from a team of epidemiologists to address the second course of action, and this work is the subject of this Terms of Reference (TOR). The epidemiologists will be contracted by the CAO.

Objectives

The objective of this work is to answer two broad questions identified during a meeting between NSEL and ASOCHIVIDA on February 12, 2009:



- 1) What are the causes of CRI in the Western Zone (Zona del Occidente) of Nicaragua – an area that includes the Ingenio San Antonio and its sugarcane plantations?
- 2) Is there any relationship between the practices of the Ingenio San Antonio and the causes of CRI?

These questions will be refined and augmented through further consultation with local participants after the competitive selection process is completed. Because of the existing controversy associated with the causes of CRI in Nicaragua, the study must make every effort to be independent, professional, and scientifically credible in an international context. The study should be designed to encourage the highest level of trust in the study team, methods and findings. To meet this objective, the study design should consider: participation; transparency of process and results; and external peer review processes.

The overall study is required to have two stages. The first stage is a scoping assessment. The outcome should be an analysis of the range of epidemiological study options available to answer the questions proposed by the participants. The analysis should specifically address the likelihood of achieving conclusive answers to these questions, including an assessment of the effort and time required to complete each study option proposed and an objective evaluation of the associated limitations and uncertainty.

The second stage, study plan implementation, is dependent on the decisions taken by the participants in response to the scoping assessment.

Tasks

The CAO has identified four tasks necessary to complete the scoping study.

1. Summarize available information and literature, including:
 - a. A general review of environmental, health and demographic data that would be necessary to conduct an epidemiological study, focusing on information available for Nicaragua that can be accessed from abroad;
 - b. A review of medical literature on the epidemiology of CRI, including incidence and prevalence, temporal and geographic trends, and known and potential risk factors (environmental pollutants, infectious agents, genetic factors, etc.);
 - c. Studies on occupational and environmental exposure to CRI risk factors in the sugar cane industry;
 - d. Studies linking CRI to sugar cane or other agricultural production;
 - e. Other relevant studies and information in relation to CRI.

The CAO has prepared an initial literature review that will be made available to the consultant. The consultant will prepare a brief summary of the findings of this task with an annotated bibliography.



2. Prepare an assessment of the availability and quality of existing clinical/ household or other epidemiological data relating to CRI available in Nicaragua, with particular reference to the western zone, including information from:
 - a. Public health institutions and the Ministry of Health;
 - b. Universities;
 - c. Other medical research institutes;
 - d. NSEL.

Use this analysis to identify opportunities and gaps that guide definition of the potential study design options. It is expected that this task will require travel to Nicaragua (Managua, León, Chinandega, Chichigalpa, and perhaps other locations in the Western Zone, as necessary).

3. Prepare a draft study design options report based on the results of the literature and data quality review and best professional judgment. The study design options report would serve as a basis for implementation of the second phase of the work – the CRI epidemiology study.

The report should include a presentation of additional work that would need to be conducted to achieve the objectives outlined at the beginning of this TOR, as well as a detailed discussion of potential costs, timeframes, limitations and uncertainties that are likely to be associated with a particular approach. Any issues that could complicate study plan implementation and the interpretation of results should also be highlighted. We anticipate that study approaches proposed by the consultant should consider:

- a. Collection and analysis of additional epidemiological data that would be necessary to accurately determine incidence and prevalence and temporal and geographic trends;
- b. Further field analysis of known and potential risk factors, including but not limited to collecting data to determine the distribution of environmental pollutants and infectious agents or assessment of genetic factors;
- c. Collection of medical information and examinations that may be necessary to identify the specific pathology of CRI in former sugarcane workers, including but not limited to ultrasound and biopsy of the kidneys of a selected group from the affected population.

The study design options report would be submitted to a peer review panel consisting of experts identified by CAO, ASOCHIVIDA and NSEL. The consultant would incorporate comments from the panel into a final study design report to be presented to participants as described in Task 4.

4. Take part in a workshop with the participants to present and discuss the results of the scoping study (including study design options), and to assist the participants as they refine study questions and select the most appropriate option for study implementation. This workshop would be held in León, Nicaragua.



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CAO expects that the first stage of work should be completed within 3 months after contracts are agreed.

Selection criteria

The CAO requests proposals from suitably qualified, internationally credible organizations. The preferred candidate will be able to demonstrate:

1. Proven and internationally recognized scientific experience and capacity to complete this study;
2. A multidisciplinary team that can address the issues of concern, including, but not limited to, epidemiologists, toxicologists and nephrologists;
3. Absolute neutrality: it will have no bias towards corporate, government or community interests and will have no political affiliation;
4. Familiarity with participatory processes and the ability to communicate complex technical information to lay people so that participants can make informed decisions. Spanish language competency is helpful but not absolutely necessary;

Proposal Submission Requirements

Interested organizations should reply no later than April 3, 2009 to Andrea Repetto Vargas (repettovargas@ifc.org) with:

1. A statement of interest that addresses the selection criteria presented above;
2. A technical proposal that describes the scoping study methods;
3. A cost proposal for the scoping study, including budget assumptions;
4. CVs for the proposed project personnel.

This TOR requires travel to Nicaragua (at least one data collection trip and one trip to present results to participants), and may require that the consultant(s) travel to Washington, DC, for a planning workshop with CAO.

The CAO will review all proposals received and prepare a short list of three candidates using the criteria outlined above. The short list will then be shared with representatives from NSEL and ASOCHIVIDA. The CAO will then facilitate a dialog meeting with these representatives to discuss the proposals and the representatives will select a finalist.