



Terms of reference for the International Rectal Microbicides Working Group (IRMWG) October 9, 2006

Mission

- To promote and facilitate the ethical research and development of safe and effective rectal microbicides for all those that need them

Objectives

- To advocate for accelerated research, development and access to safe and effective rectal microbicides
- To promote rectal safety studies on all Phase III vaginal candidate microbicides
- To support, where appropriate, the research of other new prevention technologies, such as vaccines and oral prevention (PrEP), and to promote existing prevention methods such as male and female condoms as part of a range of prevention options
- To serve as a central forum for exchange, debate, networking on rectal microbicides
- To convene diverse perspectives and scientific disciplines to improve understanding and action

Structure: The IRMWG is a network of organizational representatives and non-affiliated individuals committed to supporting the mission and forwarding the objectives of the IRMWG. It includes both an informal structure of members who subscribe to a moderated listserv, and a more formal Steering Committee (SC) and sub-working groups. Sub-working groups report to the SC and the SC reports regularly to the full IRMWG through the listserv.

Participation and communications: Participation in the IRMWG is voluntary, individual, organizational, open, and with no financial obligations. The IRMWG will communicate primarily through moderated listservs, including a main listserv for all members, and additional listservs for its steering group and working groups. Project working groups (such as for report research and writing, or other meeting-specific or topic-specific efforts) will be established as needed by the SC. The IRMWG will use teleconferences as a means to provide information to IRMWG members, and to obtain input into SC and WG activities. The SC will also look for ways beyond the teleconferences (moderated listserv discussions, etc.) to communicate with members who are unable to participate in the teleconferences.

Funding: The IRMWG SC encourages participating organizations to contribute (and fundraise for) funds for a variety of areas such as the listserv moderation, conference calls, printing and communication, commissioning reports, conference fees, and other specific projects. The SC will monitor funds, and be responsible for securing resources as necessary. AIDS Foundation of Chicago (AFC) will continue to provide fiduciary responsibilities for the IRMWG as funds become available.

Review: The terms of reference of the IRMWG will be reviewed annually to ensure that they meet the needs of the group.

Function, structure, and implementation of the SC

Function: To provide strategic leadership for the implementation of the IRMWG's mission and objectives. To develop work plans to meet the mission and objectives, to instigate action, to monitor and review this action, and to regularly report back to the wider IRMWG on its work.

Number: The SC is ideally comprised of between 10-15 members

Representation: The SC will strive for diverse representation across a number of areas, which include:

- *Geography:* ensuring that the six UN world regions Africa, Asia, Europe, Latin America, North America and Oceania (see <http://www.un.org/depts/dhl/maplib/worldregions.htm> for definitive list) are represented (at least one member from each region)
- *Type of organisation and individuals:* striving for representation from organisations and individuals representing women, gay men and males who have sex with males, transgendered people, people living with HIV, and researchers, AIDS service organisations and sexual and reproductive health organisations.

Gender: the SC will strive for an equal number of women and men on the SC.

Language: the working language of the SC will be English, but support will be provided for non-English speakers to participate where necessary.

Expectations: Members representing organizations will need to be clear about the type and amount of resources and support offered by their organizations.

Skills mix: the SC will strive to ensure its members offer an adequate and appropriate mix of skills and resources.

Individuals: Individuals can be members of the SC based on their skills and dedication to the mission and objectives of the IRMWG.

Responsibility of SC members: SC members will be responsible for reading background papers, taking part in teleconferences, e-mail communications, attending face-to-face meetings where possible, and for other responsibilities as agreed to by the SC. A chair, secretary and treasurer will be selected. The chair will be responsible for calling and chairing meetings, although chairing of actual meetings could be a shared responsibility amongst all SC members. The secretary will be the main point of contact for communications with the SC and will email out meeting agendas, provide minutes, etc. The treasurer will ensure records are kept of monies received and expended. The SC will be clear and overt about expectations with regard to both organisational representatives and individuals (i.e. what resources they can bring to the SC).

Accountability: the SC will work to fulfil the mission and objectives of the IRMWG and to act on any agreed work plan.

Commitment: SC members must commit to working on the SC for at least a year.

Workable: It is important that decisions can be made effectively and in a timely manner. The SC will make decisions on behalf of the entire IRMWG and will do so by a consensus process. Consensus will always be sought, but where this is not possible, decisions receiving two thirds support of steering committee members will be carried.

Dynamic and contingent: The SC should not be seen as a static body, but will have the flexibility to add new and remove members as necessary.

Redundancy: Back-up chairs, secretaries and treasurers will be appointed to deal with absence etc.

Clarity, openness and accountability: Clear and simple records of all SC meetings will be provided by the secretary and sent to all IRMWG members, and regular reports of the work of the SC and its working groups will be provided to all IRMWG members.

Action: the SC will be empowered to engage additional people and acquire resources as necessary to fulfil its aims and objectives.

Working methods: The SC will communicate regularly (at least every three months) to review the strategic directions and accomplishments of the IRMWG. It will establish working groups as necessary, support these groups, and receive regular reports from these working groups. It will help recruit new IRMWG participants, and develop a centralised budget for listserv moderating, conference calls, and individual project budgets.

Membership: Whilst the first SC will be selected from amongst active member of the IRMWG, and those that are nominated or self-nominated, each year the SC will formally review its membership and ask the whole membership for volunteers, taking into account the representation and gender balance requirements.

IRMWG steering committee sub-working groups: *(each of the following three groups will manage its own membership and communications, and will select at least one person to serve as a contact and representative of the committee's decisions/process/communications to the SC)*

Policy, advocacy and resource tracking group

- Participate in the design and advocacy around official local, national and international policy, rule making and authority efforts which support the IRMWG's mission
- Will monitor and report on resources available for RM pre-clinical, behavioural, clinical evaluation work, and advocacy work
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Communications and education group

- Facilitate the establishment of media and communications mechanisms for public, government and community education/information furthering the IRMWG's goals (including press policy, reports, language-specific, geographic region-specific, and community-focused listservs and community education, and translation between these as appropriate)
- Support in the development of materials for the IRMWG members to use in their own communities

Research and clinical evaluation advisory group

- Exchange of information and research focused on:
 - Normal dynamics and ranges of genital mucosal inflammation, and associated cytokines, CD4+ cells, and IgA, in women and men, including effect of STIs, semen or trauma on normal rectal ecology
 - Dynamics of HIV infection in the rectum/colon, including:
 - virology: cell-associated or cell-free, CCR5 or CXCR4, threshold concentration/volume of virus, etc.
 - immunology: sites of infection, cell types involved (epithelial, microfold, Langerhans or DC, transmigrating cell-associated), timing/dynamics of virus-cell contact
 - association between genital mucosal inflammation and HIV/STI acquisition, and establishing correlations between human and pre-clinical/model data
 - Development and use of pre-clinical model systems (cell lines, intestinal explants (biopsies), and macaque studies) for evaluating absorption, adsorption, distribution, and the impact of microbicides on the innate and adaptive mucosal immune responses
 - Interdisciplinary collaborations among immunologists, microbiologists, reproductive biologists, gastroenterologists, and gynaecologists
- What do microbicide clinical trial participants (now mostly women) say about the rate of anal intercourse and related use of lubricants in heterosexual populations?
- Are results from clinical trials of vaginal microbicides confounded by unreported anal sex?
- What is the prevalence of rectal STIs among people who engage in receptive anal intercourse?
- What are some valid, reliable, and standardized measures of acceptability, behaviours, and attitudes about anal intercourse that could be used across various populations to allow comparison of different anal/rectal practices and potential use of rectal microbicides?