Microbicides Readiness Assessment Tool

A tool for diagnosing and planning for the introduction of microbicides in public-sector health facilities

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BACKGROUND

This tool is intended to help evaluate the extent to which a facility has in place the anticipated material, technical, and human resources necessary to provide microbicides. The tool is the product of a study entitled "Preparing for Microbicide Service Delivery: Examining Implementation of Integrated Reproductive Health–HIV Services in Kenya," implemented under the Preventive Technologies Agreement and funded by the U.S. Agency for International Development (USAID). This mixed-methods study, which took place from March 2013 to August 2014, examined the implementation of Kenya's *Minimum Package for Reproductive Health–HIV Integrated Services*[2] in public-sector health centers. The "minimum package" is a set of recommendations for different types of integrated services in Kenya, developed with the goal of operationalizing the country's National Reproductive Health–HIV Integration Strategy.

The World Health Organization defines microbicides as "compounds that can be applied inside the vagina or rectum to protect against sexually transmitted infections including HIV. They can be formulated as gels, creams, films, or suppositories." While several microbicides are being tested in clinical trials, there is currently no microbicide product that has been approved for licensure or introduction in routine heath care settings.[1]

The study focused on implementation of the minimum package because it is assumed that microbicide service delivery will be added to existing health services, thereby constituting another form of service integration. Researchers believe that many of the challenges (and their solutions) to implementing the minimum package would likely apply to provision of topical microbicides. The components of the minimum package that the research focused on are provision of care and prevention services at HIV/AIDS comprehensive care centers (CCCs) to HIV-positive clients who are not yet eligible for antiretroviral therapy, HIV testing and counseling (HTC) offered within family planning services, and provision of HTC within general outpatient services. The study's resulting quantitative and qualitative data, along with input from health sector partners in Kenya, informed the development of the Microbicides Readiness Assessment Tool presented here. This product builds on Population Council's "Introducing Tenofovir Gel: A Checklist for Service Delivery"[3] and John Snow, Inc.'s "Tool to Assess Site Readiness for Initiating Antiretroviral Therapy (ART) or Capacity for Existing ART Sites."[4] The tool is now ready for field-testing to ensure its appropriateness and usability in your context.

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[1] Accessed from http://www.who.int/hiv/topics/microbicides/microbicides/en/ on Aug 6, 2014.
[2] Kenya Ministry of Public Health and Sanitation and Ministry of Medical Services. 2012. Minimum Package for Reproductive Health–HIV Integrated Services. Nairobi: Ministry of Health.
[3] Population Council. 2012. A Toolkit for Strategic Decision-making and Planning for Microbicides. New York, NY: Population Council.
[4] Hirschhorn L, Fullem A, Farabaugh M, Noguera M. 2007. Tool to Assess Site Readiness for Initiating Antiretroviral Therapy (ART) or Capacity for Existing ART Sites, Version 1.3. Boston, MA: John Snow, Inc.

OVERVIEW OF THE MICROBICIDES READINESS ASSESSMENT TOOL

The "why"

This tool focuses on assessing the provision of reproductive health (RH) and/or HIV-prevention services, including HTC, family planning counseling, contraceptive method provision, and other services similar to those mandated by the minimum package. The tool is intended to be used now, before the licensing and introduction of a microbicide product in service delivery settings. In so doing, it will help identify the service delivery and health system reinforcements needed to prepare for eventual microbicide delivery in the facility.

The "what"

The tool is designed to be filled out, scored, and used to assess a health facility's readiness to integrate microbicides with respect to five domains. These five domains correspond to the WHO's Health System Building Blocks: health workforce, essential medicines, information and research, service delivery, and leadership and governance.[5] (Because this tool is intended for use in facilities that have limited influence over financing services, the WHO's sixth building block, financing, is not included.) For each of the five domains, several criteria are provided, each with a corresponding score indicating the strength of service delivery in that area. The continuum of scores ranges from one to five with a score of one representing the weakest and five representing the strongest illustration of that component.

The "who"

Unit or facility-level managers are probably best suited to use the tool to assess service delivery strength, although teams can also consider utilizing someone who works outside the facility to reduce the likelihood of bias. Whoever fills out the tool should seek input and information from facility staff. Results should be reported and discussed with the next level of administrative authority (district/county/province).

The "how"

The tool should be applied to specific units of a facility in which RH and/or HIV services are provided (e.g., maternity, outpatient, FP), or wherever facility management staff would like to consider eventually introducing microbicides. For each domain, tool users should read each component and the corresponding continuum of criteria and then circle the number that best represents the status of that component with regard to the provision of RH and/or HIV services. All available data should be used to assess the components within the domains, including routine service statistics, results from service provision assessments or other facility assessments, and discussions with staff.

After all components of each domain have been rated, the circled numbers should be summed to arrive at a score for each domain. Several score ranges are provided at the bottom of each domain with suggestions for needed reinforcements. This tool does not include guidance for prioritizing reinforcements. Rather, staff and management will need to undergo a subsequent exercise to prioritize among the requisite reinforcements identified.

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[5] World Health Organization. 2007. Everybody's Business: Strengthening Health Systems to Improve Health Outcomes. WHO's Framework for Action. Geneva: World Health Organization.

Unit being assessed: _____

Domain: Health Workforce	***Circle one number per row corresponding to the statement that most accurately reflects your health facility's experience for that component.***				
Documenting and planning staff training related to RH and/or HIV service provision	Facility has no records of staff training (pre-service and in-service) related to RH and/or HIV service provision.	Facility records on staff training for RH and/or HIV service provision exist for some providers but are not comprehensive and are out of date.	Facility records on staff training are mostly comprehensive but updated less frequently than yearly.	Facility records on staff training are comprehensive and updated annually. In addition, a staff training plan exists to document RH and/or HIV training needs but it is financially unrealistic.	Facility records on staff training are comprehensive and updated annually. A financially feasible staff training plan exists to document RH and/or HIV training needs.
	1	2	3	4	5
Post-service training (in-service or off-site) or continuing education relevant to RH and/or HIV services	No staff received post-service training (in-service or off-site) or continuing education that was directly relevant to the provision of RH and/or HIV services in past 5 years.	1–25% of staff received training/continuing education directly relevant to the provision of RH and/or HIV services in past 5 years.	26–50% of staff received training/continuing education directly relevant to the provision of RH and/or HIV services in past 5 years.	51–75% of staff received training/continuing education directly relevant to the provision of RH and/or HIV services in past 5 years.	76–100% of staff received training/continuing education directly relevant to the provision of RH and/or HIV services in past 5 years.
	1	2	3	4	5
Staff retention and turn-over	When a staff member leaves the facility, there are no routine procedures to replace the skills lost.	When a staff member leaves the facility, in some cases the manager is able to replace the lost skills by training existing staff or hiring new staff.	When a staff member leaves, the facility manager routinely fills the gap by training current staff or hiring new staff, but this does not occur until after the departure of the staff member.	Less than half the time, when the facility manager learns that a staff member is leaving, he or she routinely ensures that another staff member (either new or shifted staff) is trained in the skill set of the departing employee before that person leaves.	When the facility manager learns that a staff member is leaving, he or she routinely ensures that another staff member (either new or shifted staff) is trained in the skill set of the departing employee before that person leaves.
	1	2	3	4	5

Current staffing needs	Facility has multiple clinical/technical vacancies or positions and no plan or resources to fill them.	Facility has key clinical/technical staff but insufficient support staff and no resources to fill current vacancies or create new posts.	Facility has key clinical/technical staff and some support staff sufficient to maintain current RH and/or HIV services but not to expand them. Has documented staffing needs but no plan to fill them.	Facility has sufficient clinical/technical and support staff to maintain current RH and/or HIV services but not to expand them. Has plan to fill future gaps in staffing needs.	Facility has sufficient clinical/technical and support staff to expand RH and/or HIV services.
	1	2	3	4	5
Supervision and performance management	Facility does not have a standardized, transparent system in place to monitor staff performance.	Facility has a standardized, transparent system in place to monitor staff performance, but it is rarely implemented (less frequently than annually) and does not provide feedback directly to staff.	Facility implements standardized, trans-parent performance monitoring at least once each year but does not provide feedback directly to staff (only reports to next level of administrative authority).	Facility implements standardized, transparent performance monitoring more than once each year and provides some feedback on corrective actions.	Facility continuously monitors staff performance (using standardized, transparent system); provides feedback on corrective actions; and recognizes good performance. Staff feel that supervision is supportive.
	1	2	3	4	5

Add all the circled numbers in the HEALTH WORKFORCE domain. Enter that sum here: _____

Score 5–10: *Significant efforts to improve facility workforce and staffing for RH and/or HIV services are needed. Develop a human resources plan that includes supervision and performance management, skills tracking and training needs, and staff retention. Identify resources for staff training in RH and/or HIV service provision and new hires. Helpful resources can be found at http://www.capacityplus.org/ and https://www.k4health.org/toolkits/leadershipmgmt/human-resources.*

Score 11–19: *Improve methods for monitoring staff training and performance. Find (better) ways to shift responsibilities when staff leave and to hire replacement staff. Seek additional opportunities for staff training.*

Score 20–25: *Very good! Look for small improvements in areas that ranked less than 5 and consider how you will manage staff if new services are added. What problems or issues do you anticipate? How could you resolve them?*

Domain: Essential Medicines	***Circle one number per row corresponding to the statement that most accurately reflects your health facility's experience for that component.***				
Stock-outs*: Co-trimoxazole ***For all stock-out components, a sample of essential RH/HIV supplies is used to provide a snapshot of the frequency of stock-outs within the facility.**	Entirely stocked out for the past 3 months.	Out of stock for 30 or more consecutive days during the past 3 months.	Out of stock for more than 5 but fewer than 30 consecutive days during the past 3 months.	Out of stock for 1-5 consecutive days during the past 3 months.	No stock-out during the past 3 months.
	1	2	3	4	5
Stock-outs: HIV test kits	Entirely stocked out for the past 3 months.	Out of stock for 30 or more consecutive days during the past 3 months.	Out of stock for more than 5 but fewer than 30 consecutive days during the past 3 months.	Out of stock for 1-5 consecutive days during the past 3 months.	No stock-out during the past 3 months.
	1	2	3	4	5
Stock-outs: Injectable contraception	Entirely stocked out for the past 3 months.	Out of stock for 30 or more consecutive days during the past 3 months.	Out of stock for more than 5 but fewer than 30 consecutive days during the past 3 months.	Out of stock for 1-5 consecutive days during the past 3 months.	No stock-out during the past 3 months.
	1	2	3	4	5
Stock-outs: Male condoms	Entirely stocked out for the past 3 months.	Out of stock for 30 or more consecutive days during the past 3 months.	Out of stock for more than 5 but fewer than 30 consecutive days during the past 3 months.	Out of stock for 1-5 consecutive days during the past 3 months.	No stock-out during the past 3 months.
	1	2	3	4	5

Supplies management	Facility has no logistics management information system (LMIS) and no inventory control and resupply system (including tools and procedures for forecasting/ calculating resupply orders).	Facility has either an LMIS or an inventory control and resupply system, but not both. System is used inconsistently, resulting in incorrect reporting and stock problems.	Facility has either an LMIS or an inventory control and resupply system, but not both. Existing system is used consistently and correctly.	Facility has both an LMIS and an inventory control and resupply system. Staff are using them consistently but do not receive supervision or capacity building.	Facility consistently and correctly uses both an LMIS and an inventory control and resupply system. Staff use of system is regularly monitored by supervisors.
	1	2	3	4	5
Storage capacity, security, and conditions	No storage room in facility.	Storage room exists in facility but provides insufficient space for medical supplies.	Storage space is sufficient, but conditions are inadequate (e.g., exposed to elements, disorganized, dirty).	Facility has storage space for current supplies and its condition is adequate, including electricity and refrigeration, if needed. There is no room to accommodate more/new supplies.	Facility has storage space for current supplies and its condition is adequate, including electricity and refrigeration, if needed. There is space to accommodate more/new supplies.
	1	2	3	4	5

Add all the circled numbers in the ESSENTIAL MEDICINES domain. Enter that sum here: _____

Score 6–12: *Substantial work in all areas of supply chain management and storage is needed. Develop or strengthen the LMIS system and train relevant staff. Identify space that can be used for storage and ensure proper storage conditions. Helpful resources include http://deliver.jsi.com/dhome/ and* Logistics Handbook: A Practical Guide for the Supply Chain Management of Health Commodities.

Score 13–23: *Work is still needed to strengthen some aspects of supply chain management and storage. Target areas with the lowest scores, but work in all areas.*

Score 24–30: *Very good! Look for small improvements in areas that ranked less than 5 and consider how a new microbicide product may have an impact on current supply-chain processes or space issues. What problems or issues do you anticipate? How could you resolve them?*

Domain: Information and Research	***Circle one number per row corresponding to the statement that most accurately reflects your health facility's experience for that component.***				
Registers and medical records	Facility has no system for tracking patients or medical records.	Facility has client registers for RH and/or HIV services, but no individual medical records (e.g., client cards).	Facility has client registers for RH and/or HIV services and individual medical records, but they are not consistently used or updated.	Facility has client registers for RH and/or HIV services and individual medical records are updated at every visit.	Facility has client registers for RH and/or HIV services and individual medical records are updated at every visit, used for decisions regarding client care, and aggregated and reviewed as part of larger health management information system (HMIS).
	1	2	3	4	5
Service statistics for RH and/or HIV services: Completeness	No service statistics are collected for RH and/or HIV services.	25% of the required service statistics for RH and/or HIV services are collected.	50% of the required service statistics for RH and/or HIV services are collected.	75% of the required service statistics for RH and/or HIV services are collected.	Almost 100% of the required service statistics for RH and/or HIV services are collected.
	1	2	3	4	5
Service statistics for RH and/or HIV services: HMIS and feedback loops	Service statistics for RH and/or HIV services are not reported within the HMIS.	Service statistics for RH and/or HIV services are reported within the HMIS but are not analyzed, not shared with staff, and not used for facility-level decision-making.	Service statistics for RH and/or HIV services are reported within the HMIS system and are occasionally analyzed, shared with staff, and used for facility-level decision-making.	Service statistics for RH and/or HIV services are reported within the HMIS system and are usually analyzed, shared with staff, and used for facility-level decision-making.	Service statistics for RH and/or HIV services are reported within the HMIS system and are routinely analyzed, shared with staff, and used for facility-level decision-making.
	1	2	3	4	5

Add all the circled numbers in the INFORMATION AND RESEARCH domain. Enter that sum here: _____

Score 3–6: *Substantial work is needed on documenting and tracking clients receiving RH and/or HIV services and analyzing data for effective decision-making. Establish clear systems and tools for documenting service provision and monitor their use by providers. Collect, analyze, and share data internally and use data for decision-making. Helpful resources can be found at http://www.cpc.unc.edu/measure/tools/monitoring-evaluation-systems.*

Score 7–11: *Streamline systems for tracking clients, improve consistency and completeness in record-keeping, use data to monitor improvement.*

Score 12–15: *Very good! Look for small improvements in areas that ranked less than 5 and consider how to add microbicides to existing record-keeping and reporting systems. What problems or issues do you anticipate? How could you resolve them?*

Domain: Service Delivery	***Circle one number per row corresponding to the statement that most accurately reflects your health facility's experience for that component.***				
Guidelines, protocols, and standards for RH and/or HIV services	Facility has no copies of written guidelines, protocols, or standards for RH and/or HIV services based on either global guidance (WHO, etc.) or national guidance documents.	Facility has at least one type of document (guideline, protocol, or standards) for RH and/or HIV services, but few copies are available on site.	Facility has full complement of guidelines, protocols, and standards for RH and/or HIV services and has at least one copy of each readily accessible on site.	Facility has full complement of guidelines, protocols, and standards for RH and/or HIV services; has multiple copies readily accessible on site; and documents include clear descriptions for each cadre of provider.	Facility has full complement of guidelines, protocols, and standards for RH and/or HIV services; has multiple copies readily accessible on site; documents include clear descriptions for each cadre of provider; and provider knowledge of document contents is verified by managers/ supervisors.
	1	2	3	4	5
Information, education, and communication (IEC) materials and provider job aids: Availability and use *These are materials intended either to help providers counsel clients or to be provided to clients as education supports.*	No materials at facility.	Limited materials available.	Some materials are available but they are insufficient in number for use at every counseling session.	There are sufficient materials for use at every counseling session, but there are insufficient materials for clients to take home.	There are sufficient materials for use at every counseling session. There are also sufficient materials for clients to take home.
	1	2	3	4	5

IEC materials and provider job aids: Quality and appropriateness *These are materials intended either to help providers counsel clients or to be provided to clients as education supports.*	No materials at facility.		Materials are deficient in one or more of the following: 1) technical accuracy, 2) appropriate literacy level for clients and providers, 3) relevancy of topics.		Materials are of good quality (are not deficient in any of the ways previously cited).
	1		3		5
HIV testing and counseling (HTC): Availability	HTC services not available at facility.	HTC services available 25% of the time.	HTC services available 50% of the time.	HTC services available 75% of the time.	HTC services available nearly 100% of the time.
	1	2	3	4	5
HTC: Quality and completeness	No HIV counseling available at facility.	HIV counseling involves only sharing test results.	Providers counsel some clients who have been tested for HIV on one or two of the following: testing procedures, HIV-prevention options tailored to clients' needs, partner testing, condom use, and follow-up actions.	Providers counsel most clients on testing procedures, HIV-prevention options tailored to clients' needs, partner testing, condom use, and follow-up actions, time-permitting.	Providers counsel every client who is tested on HIV-prevention options tailored to clients' needs, partner testing, condom use, and follow-up actions.
	1	2	3	4	5
Counseling on reproductive intentions	Providers do not discuss pregnancy intentions and use of contraception with clients.	Providers discuss pregnancy intentions and use of contraception with clients, but do not offer contraceptive methods or referrals to contraceptive services.	Providers discuss pregnancy intentions and use of contraception with clients and refer clients outside of the facility for contraceptive services.	Providers discuss pregnancy intentions, counsel clients on contraceptive options, and refer within facility for contraceptive methods.	Providers discuss, counsel, and provide contraceptive options at the same time, in the same place.
	1	2	3	4	5

Privacy (visual/auditory) for service provision and counseling	Facility has no private room for RH and/or HIV services (including pelvic examinations, IUD insertions, or confidential HTC).	Facility has dedicated room for RH and/or HIV services, but multiple clients are seen in the room at the same time with no or limited privacy.	Facility has dedicated room for RH and/or HIV services, only one client is in the room at a time, but room is not private (e.g., no curtain on window).	Facility has dedicated room for RH and/or HIV services and privacy is maintained, but one room is not sufficient (more clients than space) and some clients receive services outside of the room.	Facility has dedicated space(s) for RH and/or HIV services that provide visual and auditory privacy. Space is adequate to accommodate client volume.
	1	2	3	4	5
Infection prevention and medical waste	Facility has no guidelines for infection prevention and safe disposal of medical waste.	Facility has guidelines for infection prevention and safe disposal of medical waste but most staff are unaware of them.	Facility has guidelines for infection prevention and safe disposal of medical waste and most staff are aware of them. However, providers infrequently follow guidelines (less than 25% of the time).	Providers follow guidelines for infection prevention and safe disposal of medical waste about 50% of the time.	Providers follow guidelines for infection prevention and safe disposal of medical waste about 100% of the time and facility enforces adherence.
	1	2	3	4	5
Integrated RH/HIV services	RH and HIV services are not integrated at all (no combined sensitization, counseling, screening or provision of services).	Facility has guidelines for providing limited integrated RH/HIV services (simple messages and referrals), but these are not enforced or followed in practice.	Facility has guidelines for providing comprehensive integrated RH/HIV services, but these are not enforced or followed in practice.	Facility has guidelines for providing comprehensive integrated RH/HIV services. Implementation occurs about 50% of the time.	Facility has guidelines for providing comprehensive integrated RH/HIV services. These are monitored and enforced and implemented nearly 100% of the time.
	1	2	3	4	5
A range of HIV prevention options is available to all clients, including adolescents and unmarried individuals	HIV prevention options not discussed with clients.	Multiple HIV prevention options discussed, but not with adolescents and unmarried individuals.	Multiple HIV prevention options sometimes discussed with adolescents and unmarried individuals.	Multiple HIV prevention options usually discussed with adolescents and unmarried individuals.	Multiple HIV prevention options almost always discussed with adolescents and unmarried individuals.
	1	2	3	4	5

Facility-based RH and/or HIV-focused health education and client support	Facility neither conducts nor supports (does not provide financial or technical assistance) any RH and/or HIV-focused health education activities (group talks, video screenings, peer support groups, etc.) at facility.	Facility conducts and/or supports limited RH and/or HIV-focused health education activities (less than one type, less than once per quarter).	Facility conducts and/or supports at least one type of RH and/or HIV-focused health education activity monthly.	Facility conducts and/or supports at least one type of RH and/or HIV-focused health education activity weekly.	Facility conducts and/or supports a variety of RH and/or HIV-focused health education activities weekly.
	1	2	3	4	5
Off-site community outreach	Facility neither conducts nor supports (does not provide financial resources or technical assistance, including supervision) off-site community outreach (community-level health talks, community-based provision of services, etc.)	Facility infrequently supervises community-level activities (site visits and/or supervision meetings with community agents less than quarterly).	Facility actively supervises community-level activities (site visits and/or supervision meetings with community agents at least quarterly).	Facility actively supervises and participates in (via presence of facility-based staff) community-level activities at least quarterly.	Facility actively supervises and participates in community-level activities at least monthly.
	1	2	3	4	5

Add all the circled numbers in the SERVICE DELIVERY domain. Enter that sum here: _____

Score 12–22: *Many aspects of RH and/or HIV service delivery require strengthening. Ensure that providers have the necessary guidance and tools to provide quality counseling, that confidential space exists, and that clients can receive information and services at convenient places and times via on- and off-site options and through integrated services. Chapter 1 of this WHO tool may be helpful: http://www.who.int/healthinfo/systems/monitoring/en/. See also this WHO brief on integrated services: http://www.who.int/healthsystems/technical_brief_final.pdf?ua=1.*

Score 23–36: *Several aspects of RH and/or HIV service delivery require strengthening. Focus efforts on areas ranked 3 or lower.*

Score 37–60: *Very good! Look for small improvements in areas that ranked less than 5 and consider how the addition of microbicides may necessitate additional inputs. What problems or issues do you anticipate? How could you resolve them?*

Domain: Leadership and Governance	***Circle one number per row corresponding to the statement that most accurately reflects your health facility's experience for that component.***				
Authority and accountability for RH and/or HIV services	Facility has no staff person with authority, responsibility, or accountability for RH and/or HIV services.	Facility has a staff person who has been assigned authority, responsibility, or accountability for RH and/or HIV services but this role has not been operationalized (other staff are unaware, no specific job responsi-bilities outlined, etc.).	Facility has a staff person with authority, responsibility, or accountability for RH and/or HIV services, and role has been partially operationalized.	Staff person with authority, responsibility, or accountability for RH and/or HIV services usually supervises staff providing these services.	Staff person with authority, responsibility, or accountability for RH and/or HIV services routinely offers supportive supervision to staff providing these services.
	1	2	3	4	5
Operational plan with RH and/or HIV services *This is a document, often produced annually, that includes inputs, activities, outputs, people responsible, and timelines needed to achieve the facility's objectives.*	No operational plan exists that includes RH and/or HIV services.	An operational plan including RH and/or HIV services exists but it is only high level (broad objectives, no specific inputs, activities, etc.) and is not used to monitor activities and outputs.	An operational plan including RH and/or HIV services exists and is detailed (includes specific RH and/or HIV objectives, inputs, activities, etc.) but is not routinely used to monitor activities and outputs.	An operational plan including detailed RH and/or HIV services exists and is used to monitor activities and outputs.	An operational plan including detailed RH and/or HIV services exists and is used to monitor activities and outputs. A corresponding budget for the RH and/or HIV portion also exists.
	1	2	3	4	5

Add all the circled numbers in the LEADERSHIP AND GOVERNANCE domain. Enter that sum here: _____

Score 2–4: *Leadership and governance processes need to be developed or significantly strengthened. Identify a staff position who will have responsibility for RH and/or HIV services, work with him/her to document the position's duties, and operationalize them. Develop an operational plan with specific RH and/or HIV objectives and detailed inputs, activities, outputs, people responsible and timelines. Helpful resources can be found here: https://www.k4health.org/toolkits/leadershipmgmt.*

Score 5–7: *Strengthen the quality of the RH and/or HIV portion of the operational plan and/or refine and clarify the responsibilities for a position tasked with oversight of and accountability for RH and/or HIV services.*

Score 8–10: *Very good! Look for ways to further ensure clear management of and accountability for RH and/or HIV services within the facility and consider how microbicides can be efficiently incorporated into current management plans and structures. What problems or issues do you anticipate? How could you resolve them?*