AMENDMENT 0009

BROAD AGENCY ANNOUNCEMENT (BAA)
Number DHAPP-BAA-15-002

"FY15 – FY16 Department of Defense HIV/AIDS Prevention Program: Military Specific HIV/AIDS Prevention, Care, and Treatment Program for PEPFAR (President's Emergency Plan for AIDS Relief) Funded Countries"

The purpose of this Amendment 0009 is to respond to questions submitted in response to Amendment 0008: Request Concept Papers for Mozambique and extend the concept papers acceptance due date from 11 September 2015 to **25 September 2015**.

Question: There are three budget lines (HTXS, HBHC, and HVTB) and six technical areas (HTXS/HBHC, HTXS, HVTB, MTCT, Clinical Laboratory Support, and HIV Clinical Monitoring Systems). Could DOD provide information on the budget allocation for MTCT, Clinical Lab Support, and HIV Clinical Monitoring Systems? How should the HTXS budget line be allocated between HIV/AIDS Care and Treatment (HTXS and HBHC in the amendment) and HIV/AIDS Testing Services (HTXS in the amendment)?

Answer: The budget code allocation provided in the BAA reflects the source funding DHAPP has received for this project. Proposals should aim to stay beneath the total budget ceiling per year. Allocations across the technical areas should reflect the activities that the IP is proposing under this grant and not the budget code allocation provided in the BAA. The partner's proposed budget and activities should reflect their ability to reach the targets provided in the BAA.

Question. Could DOD confirm that each of the three Phases is one year, and that this is a three year project?

Answer: Correct. Each phase is intended to last 12 months for a total of 36 months

Question: The budget amounts provided are the same for all three phases. The solicitation provides Year 1 (Phase 1) targets, but there are no targets for Years 2 and 3. We would expect that Years 2 and 3 would require increased funding, as the number of patients on follow-up/ART would increase each year—Year 2 patients would include the patients at the beginning of Year 1 plus all the newly initiated patients over Year 1, and Year 3 would include the patients at the beginning of Year 1 plus all the newly initiated patients over Years 1 and 2. Therefore, would increasing funding be available each year? Or would it be acceptable to reduce targets for Years 2 and 3 in order to fit the budget?

Answer: The total budget for Years 2 and 3 may increase, but this will be dependent on the ability of the IP to reach the proposed targets each year. Yearly budgets for treatment will be determined by PEPFAR Mozambique's estimated unit cost per patient on ART. In addition, the cost to identify, link, and enroll a new patient on ART (TX_NEW) is estimated to be higher than the cost of maintaining a patient on ART (TX_CURR). The majority of newly enrolled patients should occur during Year 1 and Year 2 as the project is intended to reach 80% coverage of PLHIV for military personnel rapidly.

Question: Is the budget intended to support the procurement of clinical equipment, drugs, and supplies (mobile clinics, laboratory equipment, reagents, Gene Xpert cartridges, drugs, etc.), or will such procurement be provided by a different budget source or program?

Answer: It is intended that the majority of equipment, drugs, and supplies will be provided through the national system and/or through other PEPFAR commodity support mechanisms. 4x Mobile Clinics have already been procured through the DOD/FADM program and are estimated to be delivered before the end of calendar year 2015. DOD/FADM is also in the process of procuring additional clinical laboratory equipment for the 3 fixed laboratories. Currently, there is no lab equipment in Year 1 that is anticipated to be procured through this Grant. If the applicant feels that they would like to set aside a specified amount within their budget for unanticipated commodity needs that may arise, this is an acceptable approach

a. Will the mobile clinics include small level lab capacity (for CD4 counting, creatinine, hemoglobin, etc.)? Is the project expected to procure this?

Mobile clinics will include PIMA point-of-care CD4 in addition to limited microscopy for malaria and urine. The laboratory equipment for the 4x mobile units is already in the process of being procured. The project is not expected to procure these.

b. FADM depends entirely on the MOH for drugs, lab reagents, HIV tests, etc., and the MOH has stock outs of these consumables regularly. How will the project deal with MOH stock outs? Given the funding amount, there does not seem to be space in the budget for procurement of these drugs.

Stock-outs of essential commodities will need to be handled on a case-by-case basis. The proposed project should not include budget for handling stock-outs of commodities. In the case that there is a stock-out that cannot be solved through other mechanisms in country, additional funding from DOD may be available to bridge any commodity gaps. If the applicant feels that they would like to set aside a specified amount within their budget for unanticipated commodity needs that may arise, this is an acceptable approach.

Question: Is the budget intended to support the procurement of hardware and software requested in the amendment, or will that be provided by a different budget source or program?

Answer: Some hardware is already available at the Maputo Military Hospital site. However, no hardware is currently available at the other 2 fixed sites. The budget will need to provide sufficient hardware to cover the 3x existing sites.

Question: Given the funding amount, does DOD prioritize certain listed activities/expected outcomes over others? Is it acceptable for the applicant to propose the activities that are feasible within the budget ceiling, rather than all activities?

Answer: It is acceptable to propose activities that are feasible within the budget ceiling.

Question: For the collection of patient-level data, does the DOD envision this being disease-specific to HIV/AIDS or integrated within a larger national EMR effort? Does the DOD envision this program only supporting an EMR or also a larger HMIS?

Answer: DOD does not envision this program supporting a larger HMIS at this point in time. Any EMR activities should be focused primarily on the HIV/AIDS program. Any application benefits and/or use beyond HIV/AIDS are encouraged, but not required. The partner may propose to tap into existing EMR efforts. However, any EMR efforts must respect the sensitivity of military data.

Question: Which ART guidelines will be used, the Mozambique National Guidelines, or WHO/UNAIDS guidelines? The Mozambique National Guidelines (revised in 2014) recommend initiation of ART (for asymptomatic patients) if CD4≤350.

Answer: The FADM program will be required to follow the Mozambique National Guidelines of CD4≤350 until such a time as these guidelines change. Given the results of the START trial, it is likely that WHO/UNAIDS guidelines will recommend a test-and-treat approach worldwide in the next couple of months. This may have effects on Mozambique National Guidelines sooner rather than later. In addition, DOD/FADM are currently in discussions regarding piloting “test-and-treat” for military personnel in the absence of more aggressive national guidelines.

Question: Is DOD able to provide the number of military personnel who are currently receiving ART, and what % of those are in Beira, Maputo, and Nampula? How are HIV+ military personnel being treated in other provinces and locations outside those three sites? How many are they, and how are they distributed nationwide?

Answer: Due to data collection in addition to site support limitations, the exact number of military personnel on ART is unknown. There is an estimated 2,300 military personnel on ART between the 3 fixed ART sites, with the vast majority >60% estimated at the Maputo site. The number of military personnel being seen at civilian sites in locations beyond the 3 military ART sites is unknown, but likely only comprise a small number given the high mobility of the population and limitations on the ability of active-duty soldiers to leave their bases for medical reasons without disclosing their HIV status. The largest concentration of HIV+ military personnel will be found in Maputo Province, followed by Nampula, Cabo Delgado, Sofala, and Tete.

Question: On page 2, there are care and treatment targets call for enrolling new civilian PLHIV. May we assume that, because this is passive enrollment, that this target is primarily for planning purposes, and the IP will not be penalized if fewer new patients enroll?

Answer: Correct. The IP will not be penalized if the fewer new civilian patients enroll than anticipated.

Question: The current targets assume a program yield from testing military of approximately 15% (13,300/2045). Can you please clarify your assumptions about how the IP will increase yield? What support from the FADM leadership can the IP expect to help military men at high risk for HIV come forward for testing and enroll in ART?

Answer: HIV yield within the VMMC program is expected to be lower than targeted HTC yield as the men that come forward for VMMC often perceive themselves to already be negative. A 15% yield would still be significantly less that the overall prevalence of HIV within the FADM. The IP should work with the FADM to identify sub-populations of soldiers within the bases who are likely at higher risk of being HIV positive. This may include but is not limited to older men, higher rank, length of deployment, etc. among other factors. Testing will be a critical component of this program and will require close coordination with the FADM leadership to support any innovative strategies the partner may propose to reach military PLHIV.

Question: On page 2, the CARE_NEW targets call for 2,600 military PLHIV initiated on care. On page 5, the first bullet states that 2,045 military PLHIV are to be identified through testing. Can you please clarify where the remaining 555 military PLHIV to be enrolled in care will come from?

Answer: The remaining PLHIV that will be enrolled in care will come through the VMMC program, TB screening, PITC, and existing care cohort.

Question: Can you please clarify who will staff the mobile testing units: the IP or the FADM?

Answer: We can likely expect a mixed-staffing model between the IP and the FADM for the mobile testing strategies.

Question: Can you please clarify if the IP will be required to purchase any commodities? (lab reagents, hospital supplies, etc)

Answer: It is intended that the majority of equipment, drugs, and supplies will be provided through the national system and/or through other PEPFAR commodity support mechanisms. 4x Mobile Clinics have already been procured through the DOD/FADM program and are estimated to be delivered before the end of calendar year 2015. DOD/FADM is also in the process of procuring additional clinical laboratory equipment for the 3 fixed laboratories. Currently, there is no lab equipment in Year 1 that is anticipated to be procured through this Grant. If the applicant feels that they would like to set aside a specified amount within their budget for unanticipated commodity needs that may arise, this is an acceptable approach.

Question: On page 4, the BAA states that the partner will link FADM personnel to other local HIV IP's. Can you please clarify the expected outcomes of this linkage?

Answer: As other local IPs provide trainings, workshops, or other technical assistance within the regions, the partner should work to make sure that FADM clinical staff are included in any relevant USG-funded HIV activities through other partners.