

Justification for the modification of 0920-0740, Medical Monitoring Project (MMP)

The Centers for Disease Control and Prevention (CDC) requests to make non-substantive changes to the currently approved Medical Monitoring Project (MMP) OMB No. 0920-0740; expiration date 5/31/2015). The proposed changes are for the questionnaire. All other project activities and methods remain the same as in the previously approved information collection request. The proposed changes do not change the burden shown in the current inventory.

This submission includes “redlined” and “clean” versions of the MMP questionnaire. Changes from 2013 are detailed in “MMP 2014 Summary of Changes to Questionnaire.”

Please see the following attachments for additional detail as needed:

MMP 2014 interview v10.0.2 clean.docx
MMP 2014 interview v10.0.2 redlined.docx
MMP 2014 Summary of Changes to Questionnaire.docx

Overview of MMP

MMP’s data collection supplements the HIV/AIDS surveillance programs in 23 selected state and local health departments, which collect information on persons diagnosed with, living with, and dying from HIV infection and AIDS. MMP is designed to obtain locally and nationally representative data on behaviors and clinical outcomes of a national probability sample of patients in care for HIV infection. MMP data are used for tracking national trends in HIV-related morbidity, and service access and utilization, for focusing and prioritizing national initiatives to improve the provision of treatment and prevention resources, and for benchmarking and evaluating progress toward national prevention and treatment initiatives.

Data collected from in-person and telephone interviews with HIV-infected patients include patient demographics and behaviors that may facilitate HIV transmission, such as sexual and drug use behaviors; patients' access to, use of and barriers to receiving HIV-related secondary prevention services; utilization of HIV-related medical services; and adherence to drug regimens. Data abstracted from patient medical records include demographics and insurance status; the prevalence and incidence of AIDS-defining opportunistic illnesses and co-morbidities related to HIV disease; the receipt of prophylactic and antiretroviral medications; and whether patients are receiving screening and treatment according to Public Health Service guidelines. A minimum dataset that contains demographic and HIV-related laboratory information on sampled participants is extracted from an existing HIV case surveillance database (NHSS, OMB Control No. 0920-0573: Adult and Pediatric Confidential HIV/AIDS Case Report). CDC’s current goal remains the same as for the past cycle: to interview 80% of 9,400 sampled patients (7,520 total).

No other Federal agency collects national population-based behavioral and clinical information from HIV-infected adults in care. The data are expected to have significant implications for policy, program development, and resource allocation at the state/local and national levels.

Proposed Changes and Justification

The estimated burden of the MMP interview is expected to be same in 2014 as in 2013 (45 minutes on average for patients who complete the entire interview).

We propose to 1) delete a section of the questionnaire (the sexually transmitted diseases section), 2) add a newly approved drug to the response set for questions regarding antiretroviral medications prescribed for HIV treatment, and 3) replace the currently approved sexual behavior questions, which ask about total numbers of partners with whom respondents engaged in sexual activities, with a series of questions that elicits this information about each individual sexual partner (up to five partners in the past 12 months); questions about any additional partners (beyond five) refer to the additional partners in aggregate. As for the currently approved data collection, no personally identifying information will be collected from respondents about themselves or their sexual partners. In total, 166 questions have been deleted and 211 questions have been added. The overall increase of 45 questions is not expected to change the estimated average time it takes for respondents to complete the interview because more than three-fourths of participants will have less than two sexual partners. Those who have not had a sexual partner in the past 12 months will not answer the questions in this section and those with 1-2 partners will answer only a fraction of the questions in this section. All proposed changes are consistent with the purpose and use of the information collection as stated in the OMB-approved project and do not change the burden to respondents.

The proposed changes are based on: 1) experiences with implementation of previous cycles of data collection, weighting, and analysis; 2) the need to provide information to monitor CDC's Division of HIV/AIDS Prevention's Strategic Plan's goals and objectives related to unprotected intercourse among HIV discordant partners; and 3) recommendations from subject matter experts and CDC programs. The proposed changes to the interview questionnaire are detailed below and in the attached "MMP 2014 Summary of Changes to Data Collection." The changes are also noted in the attached redlined version of the questionnaire.

Interview questionnaire

1. Deletion of sexually transmitted diseases (STD) section

We propose to delete this section because information about STDs are already collected in the medical record abstraction component of MMP. In addition, MMP interviewers reported lack of knowledge about these conditions and/or poor recall of whether they were screened for these conditions among many patients.

2. Addition of dolutegravir to list of antiretroviral medications

Dolutegravir is a new FDA-approved antiretroviral therapy medication for the treatment of HIV. This addition is necessary to assess use of and adherence to this medication among the HIV-infected population.

3. Changes to the sexual behavior section

The Medical Monitoring Project (MMP) is the only nationally representative sample of HIV-infected adults in care in the U.S. that collects information on sexual behavior relevant to the transmission of HIV. As a result, MMP is responsible for generating estimates to measure progress towards the Division of HIV/AIDS Prevention's Strategic Plan Goal B, Objective 4: By 2015, reduce the percentage of HIV-diagnosed persons in care who report unprotected anal or vaginal intercourse during the last 12 months with partners of discordant or unknown HIV status by 33%.

However, the 2013 MMP sexual behavior questions have limitations. The primary problems are: 1) the section is unnecessarily complicated, which has led to errors in programming the data collection application and creating analytic variables), 2) the section collects sexual behavior information by asking about sexual partners in aggregate, an approach that has been shown to be methodologically inferior to asking questions that pertain to each partner individually because recall is poorer. These problems limit the usefulness of key sexual behavior data from MMP.

To inform the proposed changes, we performed a literature review on the measurement of sexual behavior; reviewed other surveys (National Survey of Family Growth, Project Involvement, National Sexual Health Survey, Inspire, Explore Risk Assessment); and consulted CDC and Emory University experts on sexual behavior measurement.

Our findings indicated that a new approach to the sexual behavior section is warranted, i.e., replacing the currently approved sexual behavior questions with a series of questions that 1) elicit information about each sexual relationship, partner by partner, for up to 5 partners in the past 12 months, and 2) elicit aggregate information only on additional partners, from respondents having six or more partners in the past 12 months (who are estimated to represent approximately 6% of the MMP sample, based on previous MMP data collection cycles).

The anticipated advantages of the partner-by-partner approach are that it will:

- enable collection of more accurate information than aggregate questions,
- allow collection of critical information relevant to HIV transmission potential that can only be collected by asking questions about activities with individual partners (e.g., whether or not an HIV-positive respondent who reported unprotected sex with an uninfected partner disclosed his/her HIV status prior to first sex with that partner),
- expand the collection of critical information related to HIV transmission potential by eliminating conditions for asking certain key questions (e.g., only if the respondent reports unprotected vaginal or anal sex with any partner does the currently approved instrument ask about those individual partners' HIV status; because the new approach includes questions about unprotected sex with each individual partner, as well as questions about each individual partner's HIV status, it allows description of the frequency of protected and unprotected by HIV-positive respondents with partners who are infected, uninfected or of unknown status).
- reduce the complexity of programming, recoding and analyses.

Impact of Changes on the Estimated Burden

The proposed non-substantive changes to the data collection instruments will not change the overall estimated burden of this project. This assertion is supported by evidence from comparing the time required to conduct mock interviews using the current and revised instruments for respondents having varying numbers of sex partners. In summary, the deletion of the 19-question section on sexually

transmitted diseases will reduce the interview time for all participants by 4 minutes. The revised sexual behavior section will not add any time to the interview for the estimated 38% of respondents who report no sexual partners in the past 12 months; for these respondents, there will be a net decrease in the amount of time to complete the interview with the revised instrument. For an estimated additional 38% of respondents who have had only 1 partner in the past 12 months, there will also be a net decrease in the interview time because the revised sexual behavior section will add less time than will be subtracted by deleting the sexually transmitted disease section (i.e., $1.25 - 4 = -2.75$). The remaining 24% of respondents will have a net increase in the amount of time to complete the interview, with the amount of the increase varying according to the number of sexual partners they report (see table below for results). The average burden per participant will remain the same because the shorter interview time for the majority of respondents will balance out the longer time for the remainder. The number of participants and the annual reporting and recordkeeping burden will also remain the same. The proposed changes to the interview questionnaire are consistent with the previously approved domains and with the purpose and use of the currently approved data collection

Comparison of Estimated Time Required to Complete the Sexual Behavior Section of the MMP Questionnaire, from Mock Interviews

<u>Number partners</u>	<u>Percentage of Respondents</u>	<u>Current Sexual Behavior Section: Estimated Minutes per Respondent</u>	<u>Revised Sexual Behavior Section: Estimated Minutes per Respondent</u>	<u>Estimated Change in Minutes to Complete Sexual Behavior Section per Respondent</u>
0	38	0	0	0
1	38	4	5.25	1.25
2	9	6	11	5
3 to 5	9	7.5	21.5	14
6	1	9	32	23
7 or more	5	9	32	23