mChoice: Improving PrEP Uptake and Adherence among Minority MSM through Provider Training and Adherence Assistance in Two High Priority Settings

OMB # 0920-1428

Approved January 3, 2024

Summary of Changes

We are requesting non-substantial changes to the information collection request (ICR) for mChoice: Improving PrEP Uptake and Adherence among Minority MSM through Provider Training and Adherence Assistance in Two High Priority Settings (OMB #0920-1428).

We are requesting a change to the sexual behavior inclusion criteria. Specifically, we will change 'sex with a man' to 'sex with a person' and remove the 12-month time frame. The change will be more inclusive to a broader range of gender identities for a participant's sexual partners and expand the timeframe in which a participant may have been sexually active.

We are also requesting a change to the sexual behavior screening question. Current CDC PrEP guidelines note that that patients often do not disclose stigmatized sexual behaviors to their health care providers [1-5]. We believe that some of our respondents may be reluctant to disclose what may be perceived as stigmatizing sexual behavior and, as a result, they are not eligible to participate in the study. Therefore, we propose removing 'anal sex' and replacing it with 'sex' in order to minimize any perceived stigma and mitigate any reluctance to respond. We also propose removing the time frame in order to bring the screening question into line with the proposed change to the inclusion criteria. This also benefits participants as they will not have to rely on memory in order to respond to a strict timeline.

We are requesting these changes in response to key stakeholder recommendations to implement changes that will allow participants greater freedom in how they define sex and how they describe the gender identities of their sexual partners. Study stakeholders also recommended that we expand the timeframe in which a participant was sexually active in order to be more inclusive of persons who may be in different stages of their lives and sexual relationships. We expect these changes will result in a broader participant pool and more robust data for this important HIV prevention study. These changes will also better acknowledge and respect how participants define themselves and their relationships. These changes are consistent with stakeholder input and align with the goals and plans of this project.

In addition to changes to the inclusion criteria and sexual behavior screening question, we are also revising the SSA and SSB to reflect changes in CDC staffing on the project. We are also updating the race and ethnicity questions to reflect the new standards announced by the Management and Budget Office on 03/29/2024 (Revisions to OMB's Statistical Policy Directive No. 15: Standards for Maintaining, Collecting, and Presenting Federal Data on Race and Ethnicity, 89 FR 22182).

These changes affect the following attachments:

- Att 4a_Patient Screener English/Spanish
- SSA mChoice
- SSB mChoice

There were no changes to the burden table. The proposed revisions did not change the average estimated time it took to complete the Patient Screener and no other data collection instruments were changed.

References

1. Qiao S, Zhou G, Li X. Disclosure of same-sex behaviors to health-care providers and uptake of HIV testing for men who have sex with men: A systematic review. Am j Mens Health. 2018;12(5):11971214.
2. Petroll AE, Mosack KE. Physician awareness of sexual orientation and preventive health recommendations to men who have sex with men. Sex Transm Dis. 2011;38(1):63. 22. U.S. Preventive Services Task Force. Screening for Illicit Drug Use. Accessed 20 August 2013, http://www.uspreventiveservicestaskforce.org/uspstf08/druguse/drugrs.htm#summary
3. McDonell MG, Graves MC, West II, et al. Utility of point of care urine drug tests in the treatment of primary care patients with drug use disorders. Journal Addict Med. 2016;10(3):196.
4. Chasnoff IJ, Landress HJ, Barrett ME. The prevalence of illicit-drug or alcohol use during pregnancy and discrepancies in mandatory reporting in Pinellas County, Florida. N Engl J Med. 1990;322(17):1202-1206.
5. White D, Rosenberg ES, Cooper HL, et al. Racial differences in the validity of self-reported drug use among men who have sex with men in Atlanta, GA. Drug Alcohol Depend. 2014;138:146-153. 1.

Table 1. Summary of Changes

Instrument and Summary of Changes	Original Question	Proposed Change	Reason for Change Proposed
Att 4a Patient Screener (English and Spanish) Question 4: Race and ethnicity questions were updated to the new OMB race/ethnicity standard.	4) Please indicate your race or ethnic background. Are you…? Please select one. ❑ Hispanic or Latino ❑ Not Hispanic or Latino 5a) *NOT PARTICIPANT FACING* STAFF: If person doesn't know ethnicity or refuses to pick a response option, indicate below: ❑ Ethnicity unknown ❑ Ethnicity refused 5) What race or races do you consider yourself to be? (CHOOSE ALL THAT APPLY) ❑ African American or Black ❑ American Indian or Alaska Native ❑ Asian ❑ Native Hawaiian or Other Pacific Islander ❑ White	4) What is your race and/or ethnicity? Select all that apply and enter additional details in the spaces below. ❑ American Indian or Alaska Native – *Enter, for example, Navajo Nation, Blackfeet Tribe of the Blackfeet Indian Reservation of Montana, Native Village of Barrow Inupiat Traditional Government, Nome Eskimo Community, Aztec, Maya, etc.*_____ ❑ Asian – Provide details below. o Chinese o Asian Indian o Filipino o Vietnamese o Korean o Japanese *Enter, for example, Pakistani, Hmong, Afghan, etc.* _____ ❑ Black or African American - Provide details below. o African American o Jamaican o Haitian o Nigerian o Ethiopian o Somali *Enter, for example, Trinidadian and*	Compliance with the new OMB race/ethnicity data collection standards. This change was made to align the project's race and ethnicity questions with the new standards announced by the Management and Budget Office on 03/29/2024 (Revisions to OMB's Statistical Policy Directive No. 15: Standards for Maintaining, Collecting, and Presenting Federal Data on Race and Ethnicity, 89 FR 22182)

Instrument and Summary of Changes	Original Question	Proposed Change	Reason for Change Proposed
		Tobagonian, *Ghanaian*, *Congolese*, *etc.*_____ ❑ Hispanic or Latino – Provide details below. o Mexican o Puerto Rican o Salvadoran o Cuban o Dominican o Guatemalan *Enter, for example, Colombian, Honduran, Spaniard, etc.* _____ ❑ Middle Eastern or North African – Provide details below. o Lebanese o Iranian o Egyptian o Syrian o Iraqi o Israeli *Enter, for example, Moroccan, Yemeni, Kurdish, etc.*_____ ❑ Native Hawaiian or Pacific Islander – Provide details below. o Native Hawaiian o Samoan o Chamorro o Tongan o Fijian o Marshallese *Enter, for example, Chuukese, Palauan,*	

Instrument and Summary of Changes	Original Question	Proposed Change	Reason for Change Proposed
		*Tahitian, etc.*_____ ❑ White – Provide details below. o English o German o Irish o Italian o Polish o Scottish *Enter, for example, French, Swedish, Norwegian, etc.* _____	
Att 4a Patient Screener (English and Spanish) Question 6a: Response options were updated to include ethnicity.	6a) *NOT PARTICIPANT FACING* STAFF: If person doesn't know race or refuses to pick a response option, indicate below: ❑ Race unknown ❑ Race refused	4a) *NOT PARTICIPANT FACING* STAFF: If person doesn't know race/ethnicity or refuses to pick a response option, indicate below: ❑ Race/ethnicity unknown ❑ Race/ethnicity refused	Compliance with the new OMB race/ethnicity data collection standards. Response options were updated to harmonize with the new OMB combined race/ethnicity question format.

Instrument and Summary of Changes	Original Question	Proposed Change	Reason for Change Proposed
Att 4a Patient Screener (English and Spanish) Question 11: The word 'anal' was removed and the time frame was removed.	11) Have you ever had anal sex (as a top or bottom, insertive or receptive) with a person who has a penis in the past 12 months? ❑ Yes ❑ No	10) Have you ever had sex (as a top or bottom, insertive or receptive) with a person who has a penis?	Key stakeholder input. This question was revised to in response to recommendations from key stakeholders to allow a broader definition of sex and remove the time limits on sexual activity.

Instrument and Summary of Changes	Original Question	Proposed Change	Reason for Change Proposed
SSA mChoice Page 1 (Cover page): CDC staffing information has been updated	**OMB 0920-XXXX** **Section A: Supporting Statement** **June 9, 2023** **CONTACT** Mary Tanner, MD, FAAP, Project Officer Carla Galindo, MPH, Project Officer Centers for Disease Control and Prevention Division of HIV/AIDS Prevention 1600 Clifton Road, NE, Mailstop US8-5 Atlanta, GA 30333 Phone: 404-639-6376 E-mail: mtanner@cdc.gov	**OMB 0920-1428** **Section A: Supporting Statement** **June 9, 2023** **CONTACT** Katrina Byrd, MD Project Officer Carla Galindo, MPH, Project Officer Centers for Disease Control and Prevention Division of HIV/AIDS Prevention 1600 Clifton Road, NE, Mailstop H24-5 Atlanta, GA 30329 Phone: 404-639-1902 E-mail: cgalindo@cdc.gov	CDC staffing change. CDC staffing for this project has changed. Katrina Byrd is replacing Mary Tanner. Carla Galindo is the new point of contact.

Instrument and Summary of Changes	Original Question	Proposed Change	Reason for Change Proposed
SSB mChoice Page 1 (Cover page): CDC staffing information has been updated	**OMB 0920-XXXX** **Section B: Supporting Statement** **June 9, 2023** **CONTACT** Mary Tanner, MD, FAAP, Project Officer Carla Galindo, MPH, Project Officer Pat Bessler, MPH, Project Coordinator Centers for Disease Control and Prevention Division of HIV/AIDS Prevention 1600 Clifton Road, NE, Mailstop US8-5 Atlanta, GA 30333 Phone: 404-639-6376 E-mail: mtanner@cdc.gov	**OMB 0920-1428** **Section B: Supporting Statement** **June 9, 2023** **CONTACT** Katrina Byrd, MD Project Officer Carla Galindo, MPH, Project Officer Pat Bessler, MPH, Project Coordinator Centers for Disease Control and Prevention Division of HIV/AIDS Prevention 1600 Clifton Road, NE, Mailstop H24-5 Atlanta, GA 30329 Phone: 404-639-1902 E-mail: cgalindo@cdc.gov	CDC staffing change. CDC staffing for this project has changed. Katrina Byrd is replacing Mary Tanner. Carla Galindo is the new point of contact.

Instrument and Summary of Changes	Original Question	Proposed Change	Reason for Change Proposed
SSB mChoice Page 4: Inclusion criteria was revised	[Page 4, Inclusion criteria list] ▪ Has had sex with a man within the past 12 months	[Page 4, Inclusion criteria list] ▪ Ever had sex with a person who has a penis	Key stakeholder input. This inclusion criteria was updated in response to key stakeholder recommendations to include a broader range of gender identities for a respondent's sexual partners and to remove the time limits for sexual activity.
SSB mChoice Page 4: Inclusion criteria was revised	[Page 4, Exhibit 1.1: Summary of Recruitment Targets] ▪ Has had sex with a man within the past 12 months	[Page 4, Exhibit 1.1: Summary of Recruitment Targets] ▪ Ever had sex with a person who has a penis	Key stakeholder input. This inclusion criteria was updated in response to key stakeholder recommendations to include a broader range of gender identities for a respondent's sexual partners and to remove the time limits for sexual activity.
SSB mChoice Page 10, Exhibit 5.1: CDC staffing information was updated	[Page 10, Exhibit 5.1: Statistical Consultants] Mary Tanner, Project Officer, CDC, mtanner@cdc.gov	[Page 10, Exhibit 5.1: Statistical Consultants] Katrina Byrd, Project Officer, CDC, tqo7@cdc.gov	CDC staffing change. CDC staffing for this project has changed. Katrina Byrd is replacing Mary Tanner. Carla Galindo is the new point of contact.

Attachments:

- Att 4a_Patient Screener English_clean
- Att 4a_Patient Screener English_tracked
- Att 4a_Patient Screener Spanish_clean
- Att 4a_Patient Screener Spanish_tracked
- SSA mChoice tracked
- SSA mChoice clean
- SSB mChoice tracked
- SSA mChoice clean