Response to "PEPFAR Program Expenditures" [Form Number: DS-4213, OMB Control Number: 1405-0208] – Third Revision

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Thank you for the opportunity to provide feedback to "PEPFAR Program Expenditures" [Form Number: DS-4213, OMB Control Number: 1405-0208]. This response document will briefly address concerns about the ethical, legal and methodological flaws with past research informing aspects of present PEPFAR program areas; concerns about adverse consequences of PEPFAR program areas; and concerns about the absence of oversight of the activities of PEPFAR funding recipients.

Ethical, Legal and Methodological Flaws with Past Research informing present PEPFAR Program Areas

In 2011 and 2012, the Department of Health and Human Services Office of Inspector General [OIG] published a series of audit reports revealing that throughout fiscal years 2000-2010, the National Institute of Allergy and Infections Diseases [NIAID], did not comply with the time and amount requirements specified in appropriations statutes, in awarding several federal contracts to commercial partners, committing the federal government to tens of millions of dollars of expenditure ahead of appropriation of funds from Congress (OIG 2011a; OIG 2011b; OIG 2011c; OIG 2011d; OIG 2012a; OIG 2012b). During this time, NIAID also funded and sponsored research conducted abroad, that would be unlikely to receive ethical approval to be conducted in the United States, incorporating the excision of healthy tissue from subjects in the absence of a clear and present immediate medical indication, specifically ClinicalTrials.gov registered trials NCT00059371 and NCT00425984 ['the African circumcision trials'] (NIH 2008; NIH 2007), the methodology, conclusions, ethics and legality of which have been questioned in the professional medical literature (Boyle & Hill 2011; Green et al 2010). In the years following publication of the African circumcision trials, regulatory agencies under the aegis of the Department of Health and Human Services have moved to strengthen protections afforded human research subjects and to increase the rigor with which trials conducted abroad are assessed as a basis for seeking approval of new drugs and medical devices in the U.S. market (FDA 2012; OHRP 2011), although concerns continue to be raised about the capability of National Institutes of Health [NIH] Data and Safety Monitoring Boards to ensure the safety of study subjects and validity and integrity of the data for clinical trials (OIG 2013a).

Adverse Consequences of PEPFAR Program Funding Areas

Despite the concerns identified above, the results of the African circumcision trials continue to be used to justify the en masse circumcision of men in Africa using PEPFAR funds and to justify the circumcision of boys and male infants - both in the United States and abroad - in the absence of clear and present immediate medical indications, and in the latter instance, with the tacit endorsement of U.S. government agencies in receipt of PEPFAR program funding (CDC 2011; Llewellyn 2012). In the wake of PEPFAR funding for mass circumcision programs in Africa, human rights organisations and local media in the region have reported coercion of men and boys to be circumcised (AFP 2012; Ahlberg & Njoroge 2013; Aluru 2013; Amnesty International 2013; Chibaya 2013a; Chibaya 2013b; Chirombo 2013; Dube 2012; Echwala 2013; Handable 2013; Hatyoka 2013; Langa 2012; Layoo 2013; Mbanje 2013; Mhlanga 2012; News24 2013; Ngwega 2012; Okwii 2013; Onyango 2012; Otieno 2013; Towindo 2012) and misdirection of limited medical resources from other priority areas to male circumcision (AHN 2012; Gonzalez 2012; ZimEye 2013).

Absence of Oversight

On the 15 June 2011, the OIG published a report critical of the Centers for Disease Control and Prevention's [CDC's] failure to oversee recipientss use of PEPFAR funds, concluding that the “lack of required documentation demonstrates that CDC has not exercised proper stewardship over Federal PEPFAR funds because it did not consistently follow departmental and other Federal requirements in monitoring PEPFAR recipients” (OIG 2011e). Further investigations by the OIG have also revealed specific failures of the CDC to monitor recipients use of PEPFAR funds in Namibia (OIG 2013c; OIG 2013d) and South Africa (OIG 2013b; OIG 2013e; OIG 2013f; OIG 2013g). In 2013, the OIG also published a report critical of the CDC's failure to oversee use of PEPFAR funds by the Vietnam Administration for HIV/AIDS Control (OIG 2013h), suggesting the possibility that more systemic problems may exist within the CDC, impacting the agency's ability to effectively oversee the activities of grantees in receipt of federal funds, and that this is not specific to difficulty with oversight of grantees in the African region.

Conclusion

Valid concerns exist about the ethical, legal and methodological flaws with past research informing aspects of present PEPFAR program areas; adverse consequences of PEPFAR program areas; and the absence of oversight of the activities of PEPFAR funding recipients. It is therefore imperative that full and complete disclosure and oversight in the proposed information collection activity take precedence over the CDC's and PEPFAR funding recipients' professed concerns for increased regulatory and administrative 'burden'.

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