Meeting Minutes for the VQA Advisory Board Conference Call

February 21, 2020
Taken by Miranda Carper, Duke VQA

Attendees:

VQAAB Voting Members

☒Bill Meyer (Chair)	☒Robert Coombs (ACTG/HVTN)	☒Nicole Tobin (IMPAACT)
☒Joan Dragavon (ACTG/HVTN)	☒Urvi Parikh (MTN)	☒Jessica Fogel (HPTN)
☒Belinda Yen-Lieberman (ACTG)	☒Grace Aldrovandi	☒Marco Schito

VQAAB Non-Voting Members

☒Ron Bosch (SDAC)	☒Diane Costello (IMPAACT/ACTG)	☐Meghal Patel(NICHD)
☒Lori Merrill (NICHD)		

HANC

☒Tyler Brown

NIAID/DAIDS

☒Joe Fitzgibbon	☒Keith Crawford

Virology Quality Assurance / Duke Human Vaccine Institute

☒Thomas Denny (PI)	☒Raul Louzao	☒Feng Gao
☒Andrea Pappas	☒Sal Scianna	☒Heidi Register
☒Wes Rountree	☒Katelyn Xiang	☒Marcella Sarzotti-Kelsoe
☐Kristen Skinner	☒Chris Todd	☒Miranda Carper

Virology Quality Assurance Sub-Contractor

☒Mike Busch (Vitalant Research Institute)

Action Items

- VQA: Put together a list of considerations and costs for adjusting the current PT program schedule

Meeting Minutes

- Opening remarks and roll call (Thomas Denny and Miranda Carper)
  - Thomas Denny welcomed the Advisory Board Members to the call
  - There were a total of 9 voting members on the call
- Presentation on the VQA goals for 2020 and Discussion regarding VQA proposal to 1) un-blind the VQA Qualitative HIV-1 Nucleic Acid Testing (NAT) controls, 2) decrease the number of PT samples for the Qual NAT program (from 8 to 5) and 3) remove the penalty associated with missing or invalid VQA 200 control.
  - Thomas Denny, started the presentation by welcoming Marco Schito to the VQA Advisory Board
  - Presented the timeline for the planned PTs for 2020

- VQA Advisory Board suggested decreasing the RNA PT program from six to three times a year starting 2020 and increasing the HIV-1 Qual NAT and Drug Resistance Sequencing PTs from two to three times a year starting 2021
    - Duke VQA said they will map out the costs and considerations for making these changes and present them to the VQA Advisory board and NIAID.

- The overarching goal for VQA for this 2020 is to be innovative, strive for continued advancement of the VQA mission, and to ensure the scientific relevance of each program
    - This will be achieved through fostering communication with NIAID and the Advisory Board and critical review of each PT
        - VQA will have first face-to-face VQA Advisory Board Meeting Fall of 2020, where we can disseminate data and receive critique and advice for future directions to remain innovative and relevant
        - Lastly, the VQA will perform critical review of the VQA HIV-1 Quantitative RNA, Qualitative DNA, and Drug Resistance Sequencing PT Programs. Propose changes that will be brought to NIAID and VQAAB for discussion and approval
- VQA has already begun the critical review of the VQA PT programs and has three items to discuss with the VQA Advisory board
    - Currently, Frontier Science provides the verification of the Qualitative Nucleic Acid Testing (NAT) samples through their LDMS system and email. The LDMS verification process is automated, but in order for Frontier Science to continue the blinded verification through email would cost $10,000 for 2020.
        - Questions posed to VQAAB
            - Are external controls needed for clinical studies?
                - External controls are still needed for clinical testing
            - Could the controls be un-blinded?
                - Historically controls were blinded to prevent labs from fabricating control results obtained with EIA-based qualitative HIV-1 Nucleic Acid assays
                - The Advisory Board agreed that the controls can be un-blinded, removing the additional $10,000 dollar expense
                    - Duke VQA will contact Frontier Science to see if programing will be needed so labs can still upload clinical results into LDMS without issues.
    - Duke VQA proposes to decrease sample number for the Qualitative NAT PTs from 8 samples to 5 samples
        - Historically, each PT had 8 samples (four donors in duplicate; coincided with culture send-outs)
        - With the onset of improved technology, we are proposing to decrease the number of samples to 5
        - VQAAB requested the VQA include the reduction of samples in the model of adjusting the frequency of VQA PTs

- Duke VQA proposed removing the non-technical penalty for missing or invalid VQA 200 data in the Quantitative HIV-1 RNA PT
    - VQA200 copy control data is not used in PT scoring
    - Laboratories will still be required to run the VQA200 copy control
    - Currently, labs are penalized for missing or invalid VQA200 data designated as C1V, which is worth two points instead of 1.
        - Penalty can cause labs to lose approval status or prevent them from being newly approved for testing.
    - VQAAB remarks
        - If a VQA 200 fails during clinical testing, the sample and run needs to be repeated. The VQA200 information has been useful in the past when looking at trends
        - The VQAAB votes to keep the penalty because it mimics what would happen in a clinical setting.
- Thomas Denny, Miranda Carper, and Sal Scianna

- Discussion of data
    - VQA highlighted labs that received a PC or P, had a change in status, or non-technical penalty in the VQAAB reports for the Quant HIV-1 RNA and Qual HIV-1 NAT PT programs
    - All discussions were in a blinded manner
- HIV-1 Quant RNA036 samples 26-30
    - Out of `04 datasets, 3 (2.9%) received a score of PC or P
    - Change in status
        - 1 lab is re-approved for testing, 2 labs are newly approved for testing, and 1 lab received provisionally approved status after completing a Quant RNA qualification panel.
    - Two labs have non-technical penalties for missing or invalid VQA200 data. They will receive a score of C1V, which will be worth two points in their overall score.
- HIV-1 Qualitative Nucleic Acid Testing (NAT) PT
    - There were seven datasets analyzed between December 20 to February 21.
        - One data set had two false negative results final score P
            - Samples for the false negative were from the same donor
        - One dataset had one invalid sample designated by the GeneXpert
    - Probe check for GeneXpert failed background check for analyte, however internal control passed QC. CT value for invalid sample was 35, putting it in the positive range.
        - VQA Advisory Board recommends the invalid sample be considered an indeterminate sample and the lab get a PC score
            - VQA highlighted that the current scoring documents need updating and does not take in account the technology that is used today. VQA plans to update the HIV-1 Qual NAT scoring and participation documents in the near future.
- Questions and Closing Remarks
    - Duke VQA asked if the networks would still like to receive individual reports for labs doing clinical testing.
        - Yes, the networks would still like receive all reports. VQA will contact the networks to determine the best way for disseminating the reports.