***Attachment 4***

***Developmental Project Reports***

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Reports on Developmental Project are below:

**Pilot test - Liver Ultrasound Elastography (LUE)**

Between February, 2016 and May, 2016 NHANES conducted a pilot test for liver ultrasound Elastography (LUE) to measure liver stiffness (an indicator of liver disease). The pilot test was designed to determine if this examine could be completed in the NHANES setting, if the equipment could be transported and operate within specific parameters, and if participants would agree to this exam. The pilot was held in two NHANES locations, and the equipment operated as expected in both locations. For these locations, Appoximately 400 eligible people ages 12 years and older who came for a MEC exam were invited to receive a LUE during their exam.  Over 95% of these eligible person agreed to receive the exam and nearly 90% completed the exam. As a result, approximately 90% of persons who were eligible for the pilot receive liver results that were considered valid. By all criteria considered this pilot was considered successful and supports the full implementation of this new exam component in the full NHANES starting in 2017.

**Human Papillomavirus (HPV) Provider Record Check Pilot Study**

This component was designed to perform provider record checks of vaccination histories, with a focus on the human papillomavirus (HPV) vaccine, on an estimated 240 NHANES interviewees ages 14-29 years in 4 stands of the 2016 NHANES.

The pilot started January 16th and was completed in May 2016, after four NHANES locations. There were no adverse events reported with this pilot. A total of 235 SPs ages 14-29 years were asked to participate in the pilot, of which 182 (or 77.4%) agreed. There was a total of 270 different SP-provider pairs in the pilot (some SPs reported more than one provider), of which complete contact information was determined for 218 SP-provider pairs. Thus, a total of 218 SP-provider pairs were mailed a request for immunization records on June 3, 2016. Reminder post-cards will be sent on June 17, 2016. Once immunization records have been returned additional analyses will be conducted to determine provider response rates and completeness of the returned records. If the response rates and completeness of the data are satisfactory, the NHANES program may consider inclusion of a provider record check of vaccination histories in future NHANES surveys.

**Equipment test – Digital Imaging of Over-the-counter Dietary Supplement Containers**

In order to improve data quality on the National Health and Nutrition Examination Survey (NHANES), we conducted a feasibility study to assess if using digital imaging technology could be pilot tested in the current NHANES, for eventual inclusion.  Over-the-counter dietary supplement containers were the sole focus of this feasibility study as they present several challenges for data entry and data quality.  WESTAT and staff at the National Center for Health Statistics (NCHS) worked to identify a product that would be most appropriate to eventually incorporate into NHANES.

The Ziggi-HD USB Document Camera (IPEVO-camera) was selected for the feasibility test.  Another product selected but already tested by the Centers for Medicaid and Medicare Services, was the RxLabelReader.  The recommendations from that testing were that this product needed to be improved further if it is to be incorporated into large National studies conducted in respondents homes.

The IPEVO-camera was the other option and is the sole focus of this feasibility testing.  The primary purpose of the feasibility study was to assess the IPEVO-camera device in terms of accuracy and time relative to manually keying data. WESTAT also assessed or is in the process of assessing the IPEVO-camera on several other dimensions, including the reliability and performance of the device, integration of the device into the Blaise survey software, data compatibility and how images will be used for other interviews in NHANES (Equipment Test).

There are two parts of the feasibility study: an Equipment Test and a User Test.  WESTAT has/is conducting the Equipment Test.  WESTAT and NCHS conducted a User Test that included 9 WESTAT current field interviewers (FI) to assess the accuracy and speed of taking images using the IPEVO-camera relative to manual entry. WESTAT created a stand-alone instrument based on the current design of the Dietary Supplement and Prescription Medication Questionnaire (DSQ) in NHANES. The survey instrument consisted of three pathways or experimental arms: 1) manual entry to capture data, 2) camera only to capture data and 3) manual entry and camera images to capture data.  WESTAT and staff at NCHS selected dietary supplement containers that ranged in both physical size and varied in font size of the product labels for use in the User Test.  User Test participants were trained on how to use the IPEVO-camera and how to manually enter dietary supplement label information into the DSQ questionnaire.

The User Test results indicated that data captured by using the IPEVO-camera to image the entire product label was more accurate than data entered manually by test participants. Additionally, the IPEVO-camera images produced high quality images, even of the Supplement Facts Panel (SFP) that often includes very small font.  The information from the SFP is not currently collected in NHANES and requires great effort, time and assumptions back at NCHS is order to obtain and use this critical information to provide the nutrient contribution of supplements to the public and researchers.  Being able to capture this information in the field would increase the accuracy of NHANES dietary supplement data and reduce the effort and time it takes for NCHS to prepare this data for public release.

In contrast, data collection by manual data entry was slightly faster than data entry using the IPEVO-camera.  Timing increased further for pathway 3, where data was collected both by manual and IPEVO-camera entry.  Pathway 3 would be the ideal pathway logistically since this data is imported into other interviews in NHANES and an image may be difficult to import.  However, the added time may be too much of a burden on both the respondent and interviewer in NHANES.  It is important to note that we observed a clear training effect, so it is likely that with practice and time, timing would decrease in the field.

In general, participants of the User Test stated that the IPEVO-camera was fairly easy to use and seemed to take less time than manual entry. They also noted that the instructions for using the IPEVO-camera were clear, the process was straightforward, and in general they were able to capture all the information from the label.  However, they also noted that the IPEVO-camera was tested in ideal circumstances and that it may be difficult in the field when sufficient counter or table-top surface to accommodate the tablet, IPEVO-camera, and other interview materials is not available.

In conclusion, the User Test did indicate that the IPEVO-camera may be successful in improving accuracy of the dietary supplement data collected in NHANES.  The User Test provided necessary information to help highlight potential barriers to implementation and to improve the protocol and training.