**PHCM9498 Supplementary Assessment Task**

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*The completed assessment task must be submitted by* ***5pm, Friday 18 July 2014****.*

*There are 2 questions totalling 50 marks. A minimum mark of 25 must be achieved to pass the assessment task and the course. The work must be your own and must not be discussed with anyone.*

**Question 1 *[31 marks]***

A study was conducted to assess the effectiveness of a health promotion program to improve the level of fitness of children aged 5-9 years. The fitness of 25 children who participated in the study was determined by measuring the total distance each child could run in a 9-minute period. The researchers calculated the *difference* in the distance (in metres) ran before the health promotion program commenced and after it was completed (i.e. the distance ran after the program minus the distance ran before the program).

1. What are the study factor and the primary outcome factor? [2 marks]
2. State the null and alternative hypotheses of the study. [3 marks]
3. Which of the two statistical tests shown in the Appendix (pages 3-6) would be appropriate to evaluate the hypotheses you have stated in Question 1(b)? Explain the reasons for your decision based on the information provided in the Appendix. [4 marks]
4. Interpret the result of the test you have chosen in 1(b). [5 marks]
5. Write a brief conclusion about the results of the study. [5 marks]
6. Considering the design of this epidemiological study: [12 marks]
	1. What is the best feasible type of study to determine whether the health promotion program was associated with a change in children’s fitness? Provide reasons for your answer.
	2. If the researchers used the study design you recommended in Q1fi, what advice would you give them about selecting the study participants to minimise selection bias?
	3. What advice would you give to the researchers about how to avoid measurement error when assessing the outcome factor if they used the study design you recommended in Q1fi?

**Question 2 *[19 marks]***

*Answer the following questions using the information in the Extract of a published systematic review shown in the Appendix (page 7).*

1. What was the research question for the systematic review summarised in this Extract? *(PICO format is not required)* [2 marks]
2. Based on the information provided, do the methods used by the investigators to identify the studies that were to be included in the systematic review meet accepted standards? Explain your answer. [7 marks]
3. Briefly describe the meaning of the values shown in Table (page 7 of the Appendix) for the sensitivity, specificity and positive predictive value of the oral fluid test. [6 marks]
4. Compare the values for the oral fluid test with those for the blood test shown in the Table. From the information provided, would you recommend that one or both HIV screening test methods should be used in low prevalence settings? Provide a reason for your answe [4 marks]

# Appendix

**Question 1**

|  |
| --- |
| **Descriptive statistics of distance** |
|  | Statistic | Std. Error |
| Distance | Mean | 149.4000 | 9.10018 |
| 95% Confidence Interval for Mean | Lower Bound | 130.6181 |  |
| Upper Bound | 168.1819 |  |
| 5% Trimmed Mean | 149.2333 |  |
| Median | 144.0000 |  |
| Variance | 2070.333 |  |
| Std. Deviation | 45.50092 |  |
| Minimum | 63.00 |  |
| Maximum | 242.00 |  |
| Range | 179.00 |  |
| Interquartile Range | 72.00 |  |
| Skewness | .115 | .464 |
| Kurtosis | -.442 | .902 |



**T-Test**

|  |
| --- |
| **Paired Samples Statistics** |
|  | Mean | N | Std. Deviation | Std. Error Mean |
| Pair 1 | After | 1351.6 | 25 | 201.2 | 40.24 |
| Before | 1202.2 | 25 | 198.2 | 39.64 |
| **Paired Samples Correlations** |
|  | N | Correlation | Sig. |
| Pair 1 | After & Before | 25 | .386 | .057 |
| **Paired Samples Test** |
|  | Paired Differences | t | df | Sig. (2-tailed) |
| Mean | Std. Deviation | Std. Error Mean | 95% Confidence Interval of the Difference |
| Lower | Upper |
| Pair 1 | After - Before | 149.400 | 45.501 | 9.100 | 130.618 | 168.182 | 16.417 | 24 | .000 |

**Wilcoxon Signed Ranks Test**

|  |
| --- |
| **Ranks** |
|  | N | Mean Rank | Sum of Ranks |
| After - Before | Negative Ranks | 0a | .00 | .00 |
| Positive Ranks | 25b | 13.00 | 325.00 |
| Ties | 0c |  |  |
| Total | 25 |  |  |
| a. After < Before |
| b. After > Before |
| c. After = Before |

|  |
| --- |
| **Test Statisticsa** |
|  | After - Before |
| Z | -4.373b |
| Asymp. Sig. (2-tailed) | .000 |
| a. Wilcoxon Signed Ranks Test |
| b. Based on negative ranks. |

**Question 2 - Extract**

**Background**

The focus on prevention strategies aimed at curbing the HIV epidemic is growing, and therefore screening for HIV has again taken centre stage. Our aim was to establish whether a convenient non-invasive HIV test that uses oral fluid was accurate compared with the same test using blood-based specimens.

**Objectives**

Our primary objective was to compare the diagnostic accuracy of a rapid HIV test using oral fluid and blood-based specimens in adults. Our secondary objective was to explore the variations in positive predictive values (PPVs) in high and low prevalence settings.

**Methods**

**Search strategy and selection criteria**

In accordance with the Preferred Reporting Items for Systematic Reviews and Meta-Analyses guidelines we undertook a systematic review and meta-analysis. We searched the Cumulative Index to Nursing and Allied Health Literature, Medline, Embase, BIOSIS, and Web of Science databases between January 1, 2000, and June 1, 2011. We also searched databases from key HIV conferences (International AIDS Society, Conference on Retroviruses and Opportunistic Infections, Interscience Conference on Antimicrobial Agents and Chemotherapy, Canadian Association for HIV/AIDS Research, and International Society for Sexually Transmitted Diseases).

We searched bibliographies of primary studies and review articles, and contacted authors for additional data. We used abstracts and brief reports when full-text articles were not available, if they contained sufficient data.

We developed a search strategy using key words to search the databases. Two reviewers independently searched each database using the same search strategy and to identify studies; a third reviewer was consulted to resolve discrepancies.

Our review focused on adult populations at risk for HIV. We excluded studies that were in children or that had inferior reference standards or incomplete reporting of key data items. We also excluded editorials, opinion pieces, manufacturer reports, and studies involving other types of specimens.

***Data extraction and appraisal***

We used a pre-piloted form to identify and enter information reported in each study including the study setting, objectives, populations, sample size, reference standard, sensitivity, specificity, and raw cell values (true positive, false positive, false negative, true negative). We classified reference standards in accordance with the guidelines of the US Centers for Disease Control and Prevention (CDC) and the WHO. Finally, we scored each paper against the 14-item Quality Assessment tool for Diagnostic Accuracy Studies (QUADAS) checklist as yes, no, or unclear.

Two reviewers conducted the data extraction and quality critique appraisal independently; disagreements were resolved by consensus with the third reviewer.

In the final statistical analysis we included only studies that contained complete data and were conducted in real-life settings with cross-sectional designs, surveys or intervention trials. We excluded case-control studies and studies with incomplete data (Figure 1).

***Statistical analysis***

For the assessment of diagnostic accuracy we calculated the pooled sensitivity and pooled specificity of the test for oral fluid and whole blood and the 95% confidence intervals of these values using computer regression analysis.

Using data on true positives and false positives from each study, we computed pooled PPVs for oral fluid and whole blood specimens and explored differences in PPV in low-prevalence and high-prevalence settings. We defined low-prevalence at a conservative prevalence of disease in the study sample of less than or equal to 1%. Populations in this group included outpatients from general clinics and general population-based surveys. We defined high-prevalence as greater than 1% prevalence. Populations in this group included intravenous drug users, sex workers, those who attended clinics for sexually transmitted diseases, men who have sex with men, and prison populations.

**Results**

A total of 24 studies were included in the assessment of diagnostic accuracy and 23 studies were included in the assessment of PPV (Figure 1). The pooled values estimated for the sensitivity, specificity and PPV of oral fluid and blood specimens are shown in Table 1.

***Figure 1: Study selection***



***Table 1: Comparing HIV test characteristics for oral fluid and whole blood specimens***

|  |  |  |
| --- | --- | --- |
| ***Characteristic*** | ***Oral fluid*** ***% (95% CI)*** | ***Whole blood******% (95% CI)*** |
| Sensitivity | 98.0 (95.9 - 99.1) | 99.7 (97.3 – 99.9) |
| Specificity | 99.7 (99.5 – 99.9) | 99.9 (99.8 – 100.0) |
| Positive predictive value: |  |  |
| High prevalence settings | 98.6 (87.7 – 99.9) | 98.5 (93.1 – 99.8) |
| Low prevalence settings | 88.5 (77.3 – 95.9) | 97.6 (95.5 – 99.1) |

*High prevalence settings: prevalence of >1% e.g. injecting drug users, sex workers and prisoners*

*Low prevalence settings: prevalence of ≤1% e.g. outpatients in general clinics and the general population*