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Characteristics of ‘lost to follow up’ patients on antiretroviral treatment (ART) defaulting at Tshwane District Hospital

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APPENDIX 1A: CORRECTIONS AS SUGGESTED BY EXAMINER 1 (9 pages)				
Page 1		**Section 1.8**	**Examiner's comments**	**Corrections done**
1	1	Section 1.8	Purpose of the study. 1)To examine pattern of default cases, 2) To promote ART compliance and put in put in place proper monitoring and evaluation systems. Are the second and third issues part of the study or something you can do if you have the pattern of default cases?	The purpose of the study is now section 1.10 (pg 12). This paragraph has been reframed and its reads: "The purpose of the study was to determine the characteristics of patients who are 'lost to follow-up' at the ARV clinic of Tshwane District Hospital in a bid to find ways to minimize it".
2	2		There needs to be overall consistency in the use of the terms default and 'lost to follow up' and adherence. The study is looking at patients who are 'lost to follow-up' . This term needs to be defined.	This concern has been addressed and 'lost to follow' up is defined in section 2.1, second paragraph (pg 14) which reads "However, for the purpose of this study an individual/patient is regarded as 'lost to follow-up' if placed on ART and decides to stop for a month during the course of treatment in 2007 and 2008".
	3	Chapter 3		This is a new chapter: Propositions as per the suggestion of Examiner 2 (pg 25-27).
3	Objectives		Objectives: You do not meet the first objective because it will require some comparison between what should happen and what does happen.	Section 1.11, Page 12. Objectives have been changed to the following To determine the demographic profile and socio-economic profiles such as age, sex, race, marital status, residential area, educational levels and employment status of patients that are 'lost to follow-up'; and To identify how far into the treatment period did HIV infected people default on ART treatment.
	3iii		In the results section you do not meet the third objective.	Corrections done as stated above (page 12).Objectives amended as a result of Examiner's comments.

Page 2			Examiner's comments	Corrections done
	3iv		You do not meet the fourth objective, There is no discussion around this.	
	v		The last objective repeats the second one.	Corrections done as stated above. Objectives amended as a result of Examiner's comments.
4	4 (a)	Literature review (i)	On page 14 you start to give information on the study you are doing and what variables you used. I think that you need to give references for some and expand on this section as this is fundamentally what your research is about. Residence, Storage, Alcohol, Support and who they disclose to. Regimen and how complicated this is.	The paragraph has been moved to under methodology.
		ii	Page 13 at the bottom of Section 2.1 you define "lost to follow' up for this study. This needs to be lifted out of the literature review as it is critical.	This paragraph has been lifted to the introductory chapter section 1.4 (Emergence of antiretroviral on pg 3) as the last paragraph.
			The section of treatment readiness should really be in the background. There is no reference to any literature.	The section has been moved to Chapter 1 as section 1.7 before the problem statement (pg 11).

Page 3			Examiner's comments	Corrections done
	4 (c)		You focus a little more on the reasons that patients default as this is what you are looking at, and perhaps the data/studies that have looked at this issue before. There is too much on the burden of disease which is less relevant for your work.	The third paragraph on communicable diseases has been taken off.
		i	On page 14 you start to talk about a few factors that influence adherence. I have listed them below. I think you need to give references for some and expand on the section as this is fundamentally what you research is about: Residence , Storage, Alcohol, Support and who they disclosed to and Regimen and how complicated this is.	There is a new sub heading section 2.4, Relationship between ART, adherence and gender (pg 17). In Section 2.5 (ART and Residential area) there are 3 paragraphs added that dealt more on residence and relationship to ART (pg 19). Under the previous section 2.8 (Alcohol and HIV) which has now become 2.9, two paragraphs have been added after the first paragraph under this heading (pg 22-23). The section ART and residential area now has three added paragraphs (pg 19). Former section 2.5, HIV,Stigma and Disclosure becomes section 2.6 and the title of this section also changed to HIV, Support and disclosure (pg 19). Addition of new subsections (2.7) ART regimens and complications (pg 20) and section 2.3 HIV, sex and employment status and relationship with adherence (pg 16). Literature about storage has been taken off.
		ii	The purpose of including a literature review about CD4 count is not clear. Are you suggesting that viral load should be a measure of adherence?	Former Section 2.3 (Relationship between HIV, Viral load, Log value, CD4 count and non adherence) has been taken off.

Page 4		iii	In the section 2.4, you refer to a number of articles and the link between HIV status, sex and employment. It would be more relevant to have reference on the relationship between adherence, sex and employment.	Former section 2.4 is now section 2.3 (pg 16). Two new paragraphs have been added to show relationship between adherence and employment.
5	Chapter 5	Methodology (a)		
			You need to give more detail on your population.	The study population was all HIV positive patients who are 'lost to follow-up' since 2004.
		(a)i	Study Population- What time period are you looking here. Since the clinic opened , or only two years-2007-2008?	The study population was all HIV positive patients 'lost to follow-up' since the inception of the clinic in 2004. The sample is all HIV positive patients 'lost to follow-up' in 2007 & 2008.
		(a)ii	Sample population. How did you know that patients were lost to follow up and how did you identify them?	In this clinic as at 2007 and 2008, patient tracing system was not in place. The clinic relied solely on relatives to call in and report deaths or relocation; as a result self reporting was the only patient tracing system in place. Therefore all patients that have not turned up for treatment or medication pick up after a month were regarded as 'lost to follow up'. The sampling strategy adopted was using convenience sample of those HIV positive patients 'lost to follow up' in 2007 and 2008 respectively. These are patients that have not turned up for scheduled clinic visit/ and or for medication pickup.

Page 5		(a)iii	You only presented data for 2 years 2007-2008. How are the 'lost to follow-up' patients identified in each year. If a patient started treatment in 2005 and then disappeared in 2007 were they included?	ART is a continuous regime for life. So a patient who started ART in 2005 and was 'lost to follow-up' in 2007 will be included in the study. The patient who was on ART the longest in this study was on ART for 40 months. He was first seen at the clinic in August 2004 and last seen in December 2007. The researcher is aware of the selection bias since some of these patients might have died or relocated to other locality but unreported and as a result are erroneously classified as 'lost to follow-up'.
		Methodology (b)	I am unclear if you used the sheet in Appendix 3 or the sheet in Appendix 3b	Data collection tool Appendix 3 revised to 3b.The data collection tool used for the study is 3b. Data collection tool 3a has been taken off and 3b changed to 3.
		Methodology (c)	In the second paragraph of the method section, you state that "certain items" which according to the clinical manager were not of significant clinical value were taken out and others added" It is really not clear what you are referring to here?	The clinical manager of the clinic was of the opinion that the data collection tool was not robust enough (appendix 3:11 items on the tool) and that was why there was a lot of inclusions to make the up the revised data collection tool used (3b). Appendix 3 has now been taken off to ensure clarity and to minimize confusion.
		Methodology (d)	What data collection tool has five parts? Appendix 3 has three parts and Appendix 3b has more than five.	The paragraph has been reframed to read "There were four categories to the data collection tool. These statements are stated below for ease of reference" Demographic enquiries, psychological enquiries, clinical conditions and Medication : ART (pg 31-33).
		Methodology (e)	I am unclear why you collected information on viral loads and CD4 counts.	According to the clinical manager. Viral loads and CD4 counts could be used to measure adherence. For instance if the patients was too sick or at a late stage of the disease at the time of visit it could be an indication for compliance or non-compliance to ART. Thus if the viral load is undetectable or CD 4 count very high, patients might assume that they are now well and discontinue ART. These statements have been take off.

Page 6		Methodology (f)	On page 24 you refer to using a cross sectional study as it determines the relationship between outcome and exposure . You should define these terms	The paragraph has been taken off.
		Methodology (g)	You mention that the clinical manager established face validity and what did they established the validity of the data collection tool and how did they do this?	The clinical manager read through the data collection tool and made suggestions which was the reason why there was a revised tool which included more clinical information unlike the previous. Face validity refers to the validity "on the face of it" and refers to the extent which the measure makes sense (Katzenellenogen et al., 2005:92).
		Methodology (h)	You mentioned the established face validity of the questions however this is a retrospective study. Which questions were they?	The study was indeed cross section retrospective method (pg 31 paragraph 1 under Method) . Question used as a word in this instance was used wrongly. All information and statements were retrieved from patients' files.
		Methodology (i)	Is Appendix 4 a data collection tool? Who administered this and did you get the information from the patients' files	Appendix 4 is a form filled out for patients who defaulted but returned to the clinic at a later stage. This has been taken off.
		Methodology (j)	Table 3 outlines a number of variables-body weight etc. There is no mention of why you are collecting this data in a study of adherence-unless you are saying that the stage of HIV infection affects adherence.	The idea was that when patients start ART at a late stage of HIV infection, such as in stages 3 or 4, adherence to medication might be poorer as compared to stages 1 or 2. This section has been taken off.
		Methodology (k)	Unclear how information on refrigeration affects adherence.	This section has been taken off.
		Methodology (l)	Are the remaining appendices data collection tools? There is no mention in the methodology section what all these forms are used for?	Appendices 5, 6 & 7 are the three versions of counseling forms used in the clinic. These have been removed for clarification. Appendix 8 has been changed to Appendix 4. It is a form that is mandatory for all HIV positive patients by the National Department of Health for Comprehensive HIV management. It is now mentioned in Chapter 4 section 4.6 (Method) and mentioned as appendix 4.

Page 7			Examiner's comments	Corrections done
	Chapter 6:Results section	a	You collected a great deal of information that is not presented - CD4 count, body weights, changes to ART regime.	CD4 count is presented in section 2.3 (pg 17). Body weights and changes in ART regime are presented in 5.2.21 (pg 53).
		b	I think it would be useful if we had some sense of the total number of files and how many defaulted. Again we need to be clear how many defaulted . Again we need to be clear how you selected "defaulters"	There was no patient tracing system in place. The clinic was reliant on self reporting by relatives for death and relocation of patient. A system that was irregular and inconsistent . All those who do not fall into this category and have stopped coming to the clinic were assumed as 'lost to follow up'. Element of bias is noted.
		c	You mentioned 1st and last visits - how were these determined?	These were information available in the files. 1st and the last days of visit to the clinic are available in the patients' files.
		d	In section 4.2.7 you stated that " this question was not put to 25 patients". This is difficult to understand as the study is a record review.	The study is indeed a record review. Counselors working in the clinic were supposed to ask the patients at the time of previous visits about social support and relevant responses were supposed to be documented and written in the files. However, when going through the files it was discovered that either patients were not asked about their social support or the responses given by patients were not documented. Therefore an assumption was made that the patients were not asked about social support for proper documentation. The statement now reads (section 5.2.16 :Patient Accompanied/Supported paragraph 2) In 2007, the record review showed that 52 (29%) patients were accompanied to the clinic by family members, while 68 (37%) came by themselves to the clinic. There was no documented record for 25 patients. Unavoidable information bias.

Page 8		e	Section 4.2.9- you need to include in the data analysis section how you determine the residential status.	The patients' files have a lot of information. The NGO (FPD) who partners with the institution in the clinic collects a lot of personal information from the patients as part of the patients' profile. The information regarding residential status was readily available and was retrieved from the patients' files.
		f	Section 4.15-Why did you choose these categories?	Section 5.219 (Duration on ART treatment). Literature consulted showed that most outcome measures of ART seem to happen after 6/12/18 months period into the therapy (Metha, Moore & Graham 2000; Sethi, 2004; Boulle, Culsen. Cohen, et al., 2008; Ncholo, 2009) as time to account or start measuring the effect or outcomes of intervention as the case maybe in the different research studies. As a result I came up with the 3 categories (6-12 months; 12-18 months and 18 months and above.
		g	You have not presented any data on missing appointments	Data on missing appointments presented on page 54-55.
		h	Section 4.3 - It is not clear what statistical tests you actually performed.	At the suggestion of the examiner to consult a statistician, the statistician is of the opinion that no statistical test is neccessary and descriptive statistics would be sufficient for the study.
		i	Section 4.4. You referred to Ho- that there was no significant differences in the ages of participants between 2007 and 2008. I am not sure why you are comparing this. If you are just describing your study population and want to look at whether they change between 2007 and 2008, then may be you should do these for all the variables. sex, employment etc.	This has been deleted.

Page 9			Examiner's comments	Corrections done
		j	At the bottom of section 4,,4 you have a paragraph which refers to missed appointments and again I would like to see the results presented. How many people missed appointments? How many appointment do you miss to be considered " lost to follow up"?	Missed appointment presented on page 54-55.
		k	In section 4.4 you also look at the differences in the ages of people who missed appointments (did anyone who missed even one appointment get included here?) . Again why have you looked at the ages as opposed to other patient characteristics?	Any one that has missed an appointment is included.
			In section 4.5- what test did you use. In the correlation table you look at many factors which do not seem to be immediately obvious as relevant to your study. I am referring to looking at association between age and race . Financial support and race, education and race, TB and age, race , gender substance abuse and social support.	I used a Statistical Package called Statistica version 8. But now at the suggestion of the statistician, I have been told to use the Stata version 10 and Excel for descriptive statistics only.
		m	I would strongly suggest that you consider consulting a statistician who might be able to make sense of this.	Statisticans have been consulted.

Page 9			Examiner's comments	Corrections done
7	Chapter 5		There is no discussion of results in this section. Most of the discussion of the results refers to some limitation of the study(missing information) and to problematic variables .What is really described is significant challenges with data collection rather than the results of the study. Significant work needs to be done here.	A new chapter (chapter 6) interpretation of the result has been added (pg 56-66).
	Recommendations	a	In the absence of a discussion of the results, it is difficult to comment on the recommendations. There are a number of recommendations referring to using doctors rather than nurses, reviewing the relationship between government and NGOs and agenda items at the management meetings. It is unclear how the recommendations can come out of these results. A discussion may help.	There is a new chapter of interpretation of the results (Chapter 6, pp 56-66), and former chapters for discussion and recommendation chapters have been consolidated to one new chapter as Conclusion and suggestion for further research. (Chapter 7- pg 67-69)
	Appendices		There is no reference to several of the forms in the appendices . What is the definition of "default" used for this ?	The forms not mentioned in the main text have been taken off.

