

Improving the care for type 2 diabetes mellitus associated with obesity in semirural Lesotho

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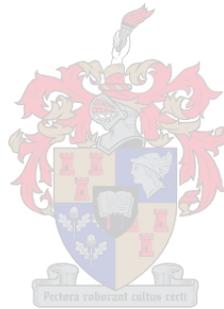
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ABSTRACT

Background: Managing diabetes associated with obesity remains challenging in developing countries including Lesotho. General measures need to be improved and encouraged for prevention countrywide.

Aim: The aim of the project was to improve the quality of care of obese diabetic patients attending the St Joseph's Hospital in Maseru district, Lesotho.

Methods: A quality improvement cycle process was followed.

Results: A total number of 122 patients were included in the quality improvement cycle. We proceeded with a baseline audit and set standards that we then re audited after three months of agreed intervention on the same sample of patient. We included three groups of criteria in each audit: structural, process and outcome. The baseline audit indicated that the results in general were not satisfactory with only one achieved structural target standard. From the re-audit, all seven target standards from structural, two out of four from the process and none of the three from outcome criteria were achieved, although there was a significant drop in the mean BMI ($p < 0.001$) at patient level; during the re-audit, the 95% confidence interval showed that patients had a drop in their BMI measurement of between -4.8 and +1.8 units.

Conclusion: At baseline, the quality of care was poor. After implementing an intervention, there were considerable and average improvements from the structure and process criteria of care, respectively. Although, the improvements in the outcome criteria were not very satisfactory due to the limited time available for the intervention, there was a reduction in the recorded BMI calculations. The quality improvement of the health system is a process which needs maintenance of the reached targets and improvement of the unreached targets; the lessons learnt may be applicable to similar institutions.



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"Declaration

I, the undersigned, hereby declare that the work contained in this assignment is my original work and that I have not previously submitted it, in its entirety or in part, at any university for a degree. I also declare that ethical approval for the study was obtained from the Health Research Ethics Committee of Stellenbosch University (Reference number:..18.68.5.1.33.)

Signature:



..... Date:

26/09/2019

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List of abbreviations

AIDS: Acquired immune deficiency syndrome

BMI: Body mass index

DM2: Diabetes mellitus type 2

HBA1C: Glycated hemoglobin

MPhil Fam Med: Master of philosophy of family medicine

1. INTRODUCTION

Treating patients living with diabetes mellitus type 2 (DM2) is challenging. The health care system should not only consider the drug aspect of the management of the disease but should also play an effective role in the nondrug component thereof. As 90% of patients living with DM2 are obese, one of the challenges at hospital and district level is how to assess, monitor and treat obese patients living with this disease.[1]

Globally, the number of patients living with DM2 is increasing, particularly in developing countries such as Lesotho. The Lesotho Ministry of Health has been focusing more on communicable diseases such as HIV/AIDS while the incidence of non-communicable diseases, including DM2, has been increasing. Lesotho is one of the 32 countries included in the International Diabetes Federation of Africa Region. Four hundred and fifteen million people globally and more than 14 million people in Africa have diabetes; by 2040 this figure will almost be double. There were 32 300 cases of diabetes in Lesotho in 2015.[2] In 2001, the percentage of the total population living with diabetes was 1.5%; by 2008, the number had increased by around 50% (2.6% of the total population).[2]

The literature shows that obesity and weight gain are determinants of insulin resistance in DM2.[1] The risk of developing DM2 increases tenfold in people with a body mass index (BMI) of above 30 kg/m². [3,4] Diet thus plays an important role in the management of patients living with DM2.[1,4,5,6] The starch-based dietary preferences of the local community have contributed to the ongoing challenge of obesity. Local data showed that among 50 participants with diabetes selected in Scott Hospital in Maseru, aged above 50 years, the average weight of participants was approximately 84.22 kg and height was 157.76 ± 6.10 cm.[4] Of these participants, 78% were obese with BMIs of above 40 kg/m². This data on the high prevalence of obesity in local diabetic patients links closely with the international data.[3] Culturally, obesity is considered as a point of pride for women and there is evidence that people do not want to lose weight for fear of being stigmatised as having acquired immune deficiency syndrome (AIDS); this supports the ongoing effort to create awareness of the medical consequences of obesity for the health of the community.[7,8]

Within the local context, there is paucity of available literature on using quality improvement initiatives when managing obesity in patients living with DM2. [9] This supports the need to take action in order to improve the quality of care at St Joseph's Hospital, Maseru/ Lesotho, where the proposed research study was carried out.

2. PROJECT AIM AND OBJECTIVES

2.1 Aim

How to improve the quality of care provided to obese patients with DM2 at St Joseph's Hospital.

2.2 Objectives

- To assess the current quality of care of obese patients with DM2 at St Joseph's Hospital.
- To plan and implement changes to improve the quality of care of obese patients with DM2 at St Joseph's Hospital.
- To determine whether the new implementations are associated with a measurable improvement in the quality of care of obese patients with DM2 at St Joseph's Hospital.

3. METHODS

3.1 Study design

A quality improvement design was selected for this study. Considering that such a design serves to assess and improve the quality of care in a particular institution, it appears to be the best design for this study which was aimed at improving the care and management of obese patients with DM2.

An audit team that was asked to agree on the target performance level to be measured was formed at St Joseph's Hospital.

The quality improvement cycle followed the four essential steps:

- Agree on criteria and set the target standards.
- Observe the practice and collect data.
- Evaluate information, and compare performance with agreed target standards.
- Implement change.

A subsequent cycle was done to review and reflect on the changes implemented.

The quality improvement cycle is illustrated in the figure 1.[10]



Figure 1: The quality improvement cycle.[10]

3.2 Study setting

St Joseph's is a district hospital with a capacity of 120 beds located in Roma/ Maseru a semirural area in Lesotho. The hospital is situated about 45 km south of Maseru city and is run by the board members under the auspices of the Catholic Church of Lesotho. The facility management consists of the medical superintendent, the nursing manager, the matron, the administrator, the accountant and the human resource officer. The hospital has five doctors and 75 nursing staff members; among these are clinical health workers, approximately 35 of which are managing DM patients. Ten members of this group are based in the outpatient department, and the remaining 25 work in different wards (female, male and paediatric). The hospital provides clinical services to a population of more than 14 000 with a catchment area of six health centres. The hospital has also a nursing school that offers training in nursing and midwifery.

3.3 Study population and sample size

The study only included patients with DM2 with a BMI of above 25 kg/m². The exclusion criteria was patients with a BMI below or equal to 25 kg/m², patients with DM type 1 and patients below 18 years old. The sample size required for this research was calculated in consultation with the biostatistics department of Stellenbosch University. The sample size was calculated according to the pre-post evaluation of these indicators: completeness of records (from 75% at baseline to 85%); control of blood glucose from 70% to 80%; and, a percentage decrease in weight. A one-sample t-test based on the effect size and standard

deviation (SD) of a study from 2007 on the percentage weight change achieved in a sample of diabetic patients, showed a 80% power to detect a 1.8% mean decrease in weight with the SD=7% with a sample of 122.[9] The sample size of 122 patients met most of the requirements for evaluating the effect of the intervention implemented during the quality improvement cycle.

3.4 Practice team involvement

The management was involved to help decide on the composition of the quality improvement team to ensure a good representation of the departments dealing with chronic patients at St Joseph Hospital. The audit team consisted of nurses, pharmacist, laboratory staff and the dietician (the group was limited to ten role players).

3.5 Criteria and targets standards

Lesotho does not have its own well-developed guidelines on diabetes mellitus. For the purpose of this study, I made use of the South African guidelines.[11] Below are the criteria and their target standards which have been discussed with the quality improvement team during the pre-audit phase.

3.5.1 Structural criteria

- Diagnostic material for obesity and diabetes: weighing scale, measuring tape, height scale and glucometer. The equipment needs to be found in the outpatient and inpatient departments. Target = 90%.
- Possibility of more laboratory investigations of carbohydrate metabolism (HbA₁C, random and fasting blood glucose and lipogram). Target = 90%.
- Availability of guidelines on obesity and diabetes management in each consulting room. Target = 90%.
- Availability of lifestyle leaflets in each consulting room. Target = 90%.
- Possibility of referral for behavioural change counselling. Target = 80%.
- Availability of first-line anti-diabetic drugs. Target = 95%.

The sheet for data collection contained the criteria and showed whether these have been met or not.

3.5.2 Process criteria

- Records of weight, height, BMI and random or fasting blood glucose at each visit.
Target = 85%.
- Documented lifestyle modification talks. Target = 85%.
- Prescription according to the guidelines. Target = 90%.
- Recording of fasting blood glucose level at each visit and HbA₁C once yearly.
Target = 80%.

The process sheet contained the number of patients selected and the different criteria and showed whether the patients' records contain the criteria or not.

3.5.3 Outcome criteria

- Control of fasting blood glucose level. Target = 80%.
- BMI of 18 to 25 kg/m². Target = 80%.
- Incidence of complications (retinopathy, nephropathy and diabetic foot). Target = 10%.

The outcome sheet contained the number of patients selected and the different criteria and showed whether the patients' records contain the criteria or not and whether they are well or poorly controlled.

3.6 Data collection

Data was collected in cooperation with the staff providing care, namely the five doctors and approximately 35 nurses working with these patients. Data was collected during service delivery on the two days allocated to chronic diseases (Wednesdays and Thursdays) in January and February 2017. This data was collected onto a data collection sheet. Both verbal and written information was collected. Retrospective information (from patients' booklets) and prospective information (parameters being monitored) were combined.

3.7 Data analysis

The data was analysed by comparing the current performance to the target standard performance against the agreed targets standards. I collected data at St Joseph Hospital for about two months. The data was from the records of 122 overweight and obese patients. Data was captured using Microsoft Excel spreadsheet and analysed with the biostatistics unit at the faculty of medicine and health sciences at Stellenbosch University.[12]

3.8 Evaluation of results and plan for change

Results were evaluated, discussed by the quality improvement team for the future change at St Joseph Hospital. The team then discussed, interpreted and agreed on any changes required in the management of obese patients with DM2.

3.9 Implementation of change

The agreed changes were implemented and a follow-up audit was performed three months later.

3.10 Repeat data collection

A follow-up audit was performed by assessing the same group of patients from the first audit.

3.11 Repeat data analysis and evaluation of findings

The baseline and follow-up findings were analysed using bivariate analysis (one-sample t-test) for each criterion.[13] The team used the analysis to identify any significant change from time one to time two and also review the number of target standards met or not met.

3.12 ETHICAL CONSIDERATIONS

In this study, ethical considerations of fair selection and treatment, informed consent, risk-benefit ratio as well as independent review were considered in keeping with the Helsinki declaration. Interventions such as lifestyle, service of a nutritionist, laboratory investigations and treatment adjustment were provided to all selected participants as part of routine care. Participants were included in the study only after they had clearly been informed in either English or Sesotho and signed a consent form. The study did not involve any experimental aspect in any steps of its quality improvement cycle, hence no harm was expected and no harm transpired in its course. The intention was to apply best-practice guidelines to the selected sample. The research proposal was approved by the Health Research Ethics Committee of Stellenbosch University, as well as the Lesotho Ministry of Health.

4. RESULTS

4.1 THE BASELINE AUDIT

4.1.1 Structure criteria

The researcher started with structure criteria at Saint Joseph Hospital.

The outpatient department has three consulting rooms and one triage room. I assessed the four rooms for weighing scale, height scale, measuring tape and glucometer. None of these instruments was found in the department apart from one glucometer in the triage room out of four assessed at the baseline assessment which represents 25%. There was no specific guideline on chronic non-communicable diseases especially related to diabetes or obesity in any of the consulting rooms. There was neither proper referral system nor existence of information leaflets at the outpatient department.

The audit of the laboratory department showed that the chemistry machine was able to perform the HbA1C and lipogram, but there was no supply of the necessary reagents from the Ministry of Health. Hence, HbA1C and lipogram have never been performed at the hospital and all patients in need were either referred or treated with available resources. The fasting blood glucose level was being done by both rapid glucometer and laboratory testing which was 50%.

All first line medications were available from the pharmacy, including fast-acting insulin (Actrapid), biphasic insulin (Actraphane), glibenclamide (Daonil) and biguanides such as metformin which was 100%.

4.1.2 Process criteria

The researcher checked the health booklets of the 122 obese diabetic patients within 2 months and 2 weeks who attended the outpatients department. There were 25 male and 97 female patients.

The researcher checked these records for information on weight, height, BMI, random/fasting blood sugar levels. I also checked for a documented lifestyle modification talk, prescription according to the guidelines, recording of fasting blood glucose level at each visit and HbA1c once yearly. These were the findings:

- Concerning recordings of weight, height and glucose levels in the health booklets: one out of 122 showed that the weight was recorded, which is 0.81% of the total number of patients. None of the booklets showed that the height was recorded. 120 out of 122 patients' fasting blood glucose levels were recorded, which is 98.3% of the total number of patients. Overall for these recordings, there was an achievement of 33%.
- Documented lifestyle talks: seven out of 122 lifestyle talks were recorded in the booklet, which is 5.7% of the total number of patients.
- Prescription according to guidelines: The prescription was analyzed from different consultations based on dosages of the medication in relation to the level of blood sugar, also in relation to the associated or complications of diabetes such as hypertension, retinopathy, nephropathy etc. Here, 30 out of 122 patients showed adherence to the guidelines. This is 24.6% of adherence and 75.4 % of non-adherence of the total number of patients.
- None of the 122 patients had glycated hemoglobin (HbA1C) recorded in their booklets.

4.1.3 Outcome criteria

The WHO classifies obesity into the following three grades based on the BMI of the patient:[13]

- Grade 1 (overweight) with a BMI of 25-29.9kg/m².
- Grade 2 (obesity) with a BMI of 30-39.9kg/m².
- Grade 3 (severe obesity) with a BMI of greater than or equal to 40kg/m².

In our sample of 122 patients, 52 (42%) patients were classified as grade 1 (overweight), whereas 65 (53%) patients were grade 2 (obesity), and five patients (3%) were grade 3 (severe obesity).

All blood collection for glucose levels were performed early morning before consultations and patients were already informed to come fasting. Hence all recordings of blood glucose were fasting. Fasting blood glucose levels were classified into three categories (see table 1).

Table 1: Classification of fasting blood glucose.[14]

Parameter	Optimal	Acceptable	Additional action suggested
Capillary blood glucose values	4-6 mmol/l	6-8 mmol/l	Above 8 mmol/l

Our findings from the 122 patients were that the blood glucose of ten patients was in optimal range, 35 patients were in acceptable range, and 77 patients were in additional action suggested range. Therefore, the blood glucose of 45(36.9%) patients was normal.

When analyzing the incidence of complications of obesity associated with DM2, we found that among the sample of 122 obese patients, 31 (25.4%) patients had no complications.

4.2 INTERVENTION

After data collection, I analyzed the data and presented to the team, which consisted of the medical superintendent and the members of the quality improvement team.

4.2.1 Leadership roles and empowerment of the team

During discussions with the quality improvement team, I noticed that the team had difficulties to integrate this research into their preexisting plan but at least their leader managed to integrate this research into their plan and was attempting to invite into perspective the whole team. Hence, the team appeared differently oriented as seen during presentation of results. Upon reflection, my assessment of the group is that they could have been in transition between forming and storming stages considering that they appeared not to be pursuing the same objectives, nor sharing authority and responsibilities which were left to the team leader alone.[16] Again it appeared that the team was partly at norming stage,[17] problem-solving process. I encouraged the team to set its values and cohesion by increasing the number of meetings to allow the team to know each other. With time, I thought they could improve their role of observer, facilitator and mentor.[18] The final stage had not yet been reached. The team was encouraged to even consult with me for assistance when improving the entire team even for other purposes.

I discussed again with the team concerning the possibility of achieving improvement. So for us to achieve change, we revised and adjusted our targets in terms of percentage to allow for achievable improvement.[10,19] We first presented the results with the quality improvement committee to the management. Then we started revising criteria with the quality improvement team as follows:

4.2.2 Structure Criteria Plan for Change

- **Diagnosis materials of obesity** (Weight scale, tape measure and height scale): they felt that it would have been difficult that instruments be used only on doctors' request, hence it was suggested to be routine for all diabetic patients. Implementation

was agreed by all and the target for this criteria remained 90%. Hence, so scales were to be found at the outpatient department.

- **Diagnostic materials for diabetes:** Glucometer: The team agreed to keep the glucometer in the triage room only and all patients were to be checked from the triage room as it was revealed in our findings.
- **Diagnostic chemistry machine for lipogram, glycated hemoglobin, and fasting and random blood sugar level:** blood sugar levels were to be checked at the outpatient department. For newly diagnosed patients, blood samples were to be taken to the laboratory for confirmation. Lipogram and glycated hemoglobin were not at that time done at the hospital because reagents for the two tests were not available at the laboratory. The quality improvement team contacted the management and the pharmacy to see the feasibility of sending the sample to the central laboratory for yearly checkup of the two investigations. After discussion, they found that the challenge was to mobilize financial resources for this program because it involved transport and blood sample bottle for collection. They believed that with the following budget they would include it in the next financial year. The suggestions were that the patients were to be informed about the need for performing the test directly from the central laboratory at their own cost.
- **The guidelines on obesity and diabetes mellitus management:** The team with the medical superintendent elected to follow the South African guidelines as, there are no local guidelines.[14] The hard copies and soft copies were available in three consulting rooms and the triage room. The target remained 90% for the hard copies.
- **Availability of lifestyle leaflets:** The team discussed the leaflet; they acknowledged that they have a leaflet for lifestyle which was not available in the consulting room or in the booklet of the patient. Leaflets were to be reintroduced in the outpatient department after they had been updated to the standard of the guidelines and availed to patients.[14] Leaflets were to be attached to each patient's booklet(as they usually carry booklets with them). The target remained 90%.
- **Availability of recorded referral for behavior change counseling:** There is no proper referral system at the hospital. The team thought that it needed first to reinforce patient information and education then they tried to get support from the district level especially on dietary issues and were to avail a professional dietician from the district. They were to focus on reinforcing the referral system first for specific patients. The new target became 60%.
- **Availability of first-line anti-diabetic drugs.** The team recommended maintenance of this performance at 100%.

4.2.3 Process Criteria Plan for change

- Weight, height and blood glucose were to be taken and recorded at each visit for all diabetic patients.
- Documented lifestyle modifications: The outpatients department was to make sure that each patient received the leaflet and it was to be stapled or documented in the patient's booklet, as well as clear explanation of its content provided.
- Prescriptions according to the guidelines: Prescriptions were to be made according to guidelines recommendations; this was to be checked in patients' booklet and needed also to be considerate of other patients' conditions.
- HbAc1 needed to be checked yearly and recorded in patients' booklets. If the laboratory was not able to perform these investigations, patients were to be sent to the central laboratory for the purpose.

4.2.4 Outcome Criteria Plan for Change

- The BMI of the patients' were to be checked and recorded at each visit. If the BMI was not improved, measures on the lifestyle needed to be reinforced with a possible referral to the dietician.
- Blood glucose control of patient with obesity associated with DM2.
- The incidence of complications depended on actions on the other criteria (as described above).

4.3 RE-AUDIT

Data collection was repeated three months after the result from baseline audit. It was again followed with a discussion of the plan to change with the quality improvement team and the management team (medical superintendent). Results were presented in tables together with the previous ones from the baseline audit (see table 2).

The researcher collected data from 122 patients (the same patients included in the baseline audit), as well as a repeat assessment of all criteria.

4.3.1 STRUCTURE CRITERIA

As previously found, the glucometer was available in the triage room, the chemistry machine was able to perform HbAc1 and lipogram with lack of reagents, fasting blood glucose level was being performed (fasting and random). Guidelines were found in each consulting room in the form of hard copy and soft copy.

All first line medications were available at the pharmacy: fast-acting insulin (Actrapid), biphasic insulin (Actraphane), glibenclamide (Daonil) and biguanides such as metformin.

See table 2 for combined results.

4.3.2 PROCESS CRITERIA

During this exercise, I re-checked patients' records after a period of three months. These were the same patients who were included in the baseline audit.

The researcher rechecked the records on weight, height, BMI, random/fasting blood sugar level, documented lifestyle modification talks, the prescriptions according to the guidelines, the recording of fasting blood glucose level at each visit and the HbA1c once yearly at each visit.

- This time around the records showed that the weight was checked for 114 out of 122 which is 93.4% of total number of patients.
- The height was checked in 122 out of 122 which is 100% of the total number of patients.
- Blood glucose records were indicated in 122 out of 122 patients' glucose which is 100% of the total number of patients.
- Behaviour change modifications were recorded in 73 out of 122 booklets, leaflets of lifestyle modification were also found in those booklets, about 60% of 122 booklets.
- Concerning prescriptions, it was found that 82 out of 122 were in alignment with the guidelines, which about 67.2% of patients.

See table 2 below including the baseline audit findings.

4.3.3 OUTCOME CRITERIA

The blood glucose of 82 patients was controlled which is 67.2% of the total number. Among the 122 patients, 11 patients' BMI decreased to normal during the re-audit (about 9% of the total number). When analyzing the incidence of complications associated with DM2 and obesity, we found that among the 122 obese diabetic patients, 68 (55.7%) patients had no complications. See table 2 below including the first findings.

Table 2: Comparison of results for baseline and the re-audit target standards

Standard	BASELINE AUDIT			RE-AUDIT		
	Score (%)	Target Standard	Achieved Standard	Score (%)	Target Standard	Achieved Standard
STRUCTURE						
Diagnostic materials obesity: weighing scale, tape measure and height scale	0%	90%	NO	100%	90%	YES

Diagnostic materials for diabetes: glucometer	25%	90%	NO	100%	90%	YES
Laboratory investigations: HbA1c, fasting and random blood sugar level and lipogram	50%	90%	NO	100%	70%	YES
Guideline on obesity and diabetes mellitus management	0%	90%	NO	100%	90%	YES
Lifestyle leaflets in each consulting room	0%	90%	NO	100%	90%	YES
Availability of referral on behavior change counseling	0%	80%	NO	100%	80%	YES
Availability of first-line anti-diabetic drugs	100%	95%	YES	100%	100%	YES
PROCESS						
Weight and height recorded at each visit fasting blood glucose level at each visit	33%	85%	NO	97%	85%	YES
Documented lifestyle modification talks	5.7%	60%	NO	60%	60%	YES
Prescription according to the guidelines	24.6	85%	NO	67%	85%	NO
HbA1c yearly check-up	0%	80%	NO	32.8	85%	NO
OUTCOME						
BMI of 18 to 25 kg/m ²	0%	80%	NO	9%	80%	NO
Blood glucose control	36.9%	80%	NO	68%	80%	NO
Absence of complications in patients with obesity associated with DM2	25.4%	80%	NO	55%	80%	NO

It should be noted that there was a significant drop in the mean BMI ($p < 0.001$) at patient level; during the re-audit, the 95% confidence interval showed that patients had a drop in their BMI measurement of between -4.8 and +1.8 units.

5. DISCUSSION

This study appeared to be one of the first ones at Saint Joseph Hospital in the area of care of patients with diabetes and obesity, considering that there was no prior documentation guiding the hospital in this area. Between our baseline audit and the re-audit, the team reviewed and adjusted the target standards to fit in the hospital context. The baseline audit indicated that the results in general were not satisfactory but improved at the re-audit. In terms of specific criteria, from the structural ones, six out of seven target standards were not achieved, for the process ones, none out of four were achieved and none out of three as well were achieved for the outcome criteria. During the re-audit, all seven structural target standards were achieved, only two achieved out of four of the process target standards, and none of the three outcome target standards were achieved; however, there was some improvement in the outcome criteria, especially with BMI reduction. Overall, improvement from baseline to re-audit was encouraging for all actions taken during our intervention.

From the baseline assessment, this study shows that the structural requirements for the care of patients were poorly used with only availability of drugs in the system. None of the process and outcome criteria were achieved. Hence, this setting predisposes to difficulties to intervene with general measures on parameters such as lifestyle modifications and on co-morbidity of obesity. This contrasts with the recommendations from the guidelines where care for obesity with DM2 should be provided in a multi-modal, integrated manner (and not only focused on medication).[1,3,5,6,14]

Concerning the intervention stage, planning appeared to have challenges with the team itself as well as the targeted standard that we used for the baseline. There were difficulties to know at which stage the team was, as well as with a new plan for change that I was bringing in. Hence, we sat and agreed on new standard to allow for team input.[10,16,17,18] These interventions mainly required mobilization of pre-existing equipment and application of the recommended guidelines.[14] On the other hand, challenges encountered, such as lack of reagent for HbA1c, required funding to either transfer specimens (outsource) or purchase the missing reagents. These findings (mobilization of equipment, financial constraints) demonstrate that locally, efforts are directed mainly towards communicable diseases such as HIV and TB, rather than non-communicable ones. This observation is also supported by other studies where need is identified in support of management of non-communicable diseases in low income countries.[20,21]

From our re-audit after three months of intervention, all seven target standards from structural, two out of four from the process and none of the three from outcome criteria were achieved, although there was a significant drop in the mean BMI ($p < 0.001$) at patient level. These changes in a short period of time may be as a result of our intervention, or may be due to other external factors. However, any systematic effort aimed at both the knowledge of patients and staff, as well technical and financial support may improve the quality of data collected on obese DM2 patients, which may potentially help us to improve the prevention

of many complications, such as retinopathy, nephropathy and diabetic foot complications.[1,14,20,21]

Limitations

Going through this quality improvement cycle was a unique experience. We were faced with the logistical challenges in our setting and limitations directly related to the QI method. On the one hand, there was a sense of achievement as stated above and on the other hand, some challenges were also inevitable. Maintaining the enthusiasm of the quality assurance team was challenging, as attendance was poor at times with members being overloaded with routine duty, leaving us mainly with the focus person who was the head of the laboratory department. There was no doctor in the team due to the workload at the hospital and the health centre surrounding the hospital even though the outpatient department was represented. The lack of dietician made it difficult for elaboration of specific diet program for particular patients. Lifestyle plays a major role in the management of those patients.[1,3,8,5] Poor information recording in the booklet of patient made difficult to assess and manage complications related to DM such as nephropathy and retinopathy. The use of investigations was limited by the performance of the hospital-based laboratory, with lack of reagents for the chemistry investigations where machines are available. The investigations such as HbA1c and lipogram were not done at the facility, which required patients to travel long distances to the referral hospital. As this transport to the referral hospital was typically self-financed, this option became quite difficult for most patients. The outcome was not very satisfactory due to the period allocated for change in the region where communicable diseases are still remaining a challenge among the community. DM associated with obesity remains a very big challenge in assessing, monitoring and treating.[1]

Recommendations

- All structural standards need to be maintained for all patients with DM2 and obesity in terms of usage of diagnostic materials, laboratory investigations, guidelines, lifestyle leaflets, availability of system of referral, behaviour change counseling and the first line anti-diabetic medication.
- All doctors and nurses at OPD need to ensure that patients received an information leaflet stapled in the patient-retained booklet. The team took action to introduce the leaflet with explanation to the management team (medical superintendent and the staff at OPD). The head of the OPD will monitor and implement with a regular evaluation.
- Improvement need to be made in terms of checking properly the medical booklet of the patient and make sure that suitable medications are prescribed according to associate medical conditions. The department made available the guideline in the consulting room in hard and soft copy.

- Doctors and nurses to ensure that HbA1C is collected yearly. If investigations cannot be done at the hospital laboratory due lack of reagent, the head of the laboratory need to make sure that the sample is taken to the central laboratory.
- Doctors and nurses should ensure that the BMI is calculated at each visit when the patient is consulted at the facility. During collection of data nurses were shown to take the BMI and if BMI increased, reinforcement on the lifestyle of patients need to be discussed with the patient and reinforced with a possible referral to the dietician.
- Doctors and nurses need to ensure that blood sugar level continues to be checked at each visit and that all recommendations are followed; this will have an impact on the incidence of complications. All actions are very important for the outcome of patient's condition.

6. CONCLUSION

The quality of care in obese DM patients was poor at baseline. After an intervention, there were considerable and average achievements in the structure and process criteria, respectively. Although the outcome was not very satisfactory due to the allocated time for implementing the intervention, there was a reduction in BMI. The quality improvement of the health system is a process which needs maintenance of the reached targets and improvement of the unreached targets. The quality improvement team needs to continue monitoring and evaluating the quality of care provided to obese DM patients; these lessons learnt may be applicable to similar institutions.

7. ACKNOWLEDGEMENTS

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8. AUTHORS' CONTRIBUTIONS

P.M.N (University of Stellenbosch) performed the study as part of his MPhil (FamMed) and was supervised by K.B.v.P. (University of Stellenbosch).

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10. APPENDIX

10.1 Approval letter from the ministry of health



Ministry of Health
PO Box 514
Maseru 100

REF: ID30-2017

Date: Mar. 02, 2016

To:

Nkulu Mulongo Patrick
Stellenbosch University
South Africa

Category of Review:

- Initial Review
- Continuing Annual Review
- Amendment/Modification
- Reactivation
- Serious Adverse Event
- Other: For dissemination of results

RE: How to improve the quality of care of obese patients with type 2 diabetes mellitus receiving care at semirural district hospital in Lesotho (ID 30-2017)

This is to inform you that on Mar. 02, 2017 the Ministry of Health Research and Ethics Committee reviewed and **APPROVED** the above mentioned protocol and hereby authorizes you to conduct the study according to the activities and population specified in the protocol. Departure from the approved protocol will constitute a breach of this permission.

This approval includes review of the following attachments:

- Protocol version dated Oct. 02, 2016
- English consent forms
- Sesotho consent forms
- Data collection forms
- Participant materials: Informed consent form
- Other materials:

This approval is **VALID** until Mar. 01, 2018.

Please note that an annual report and request for renewal, if applicable, must be submitted at least 6 weeks before the expiry date.

All serious adverse events associated with this study must be reported promptly to the MOH Research and Ethics Committee. Any modifications to the approved protocol or consent forms must be submitted to the committee prior to implementation of any changes.

We look forward to receiving your progress reports and a final report at the end of the study. If you have any questions, please contact the Research and Ethics Committee at

Sincerely,

[Redacted Signature]
Director General Health Services

[Redacted Signature]
Co-Chairperson NH-IRB

10.2 Participant information leaflet and consent forms in Sesotho and English

LINTLHA TSA MOKULI LE FOROMO EA TUMELLANO

SEHLOOHO SA BOITHUTO: MEKHOA EA HO NTLAFATSA BOLENG BA LITŠEBELETSO TSA TLHOKOMELO EA BAKULI BA MOKHAHLELO OA BOBELI OA TSOEKERE BA FUMANANG KALAFO LIPETLELENG TSE LITEREKENG NAHENG EA LESOTHO.

MOFUPUTSI E MOHOLO: Dr Patrick Nkulu Mulongo

ATERESE: Seterata sa Koro-Koro, Maseru/Lesotho

NOMORO EA MOHALA: (00266) 63160765

U memeloa ho kenya letsoho boithutong bona. Ke kopa u nke nako ho bala litaba tse ngotsoeng mona tse hlahosang boithuto bona ka botlalo. U ka botsa bafuputsi kapa ngaka lipotso mabapi le boithuto bona moo ebang ha u utloisise. Ho bohlokoa hore utloisise hantle ka boithuto bona le hore na u tl'o kenya letsoho joang. Hape ho kenya letsoho hoa hau, u ho etsaka **boithaopo bohle** ebile u lokolohile ho ka hana ho kenya letsoho. Haeba u hana, hona ho ka se u ame hampe hohang. Hape u lokolohile ho ikhula boithutong bona ka nako efe kapa le haeba u no lumetse ho kenya letsoho.

Boithuto bona bo anantsoe ke **Komiti ea Liphuputso tsa Litaba tsa Bophelo ea Stellenbosch University** 'me bo tla etsoa ho ipapisitsoe le melao le melaoana e tsamaisang boithuto ea Boitlamo ba machababa Helsinki ka tumello ea Lekala la Bophelo Lesotho.

Boithuto boo bo holim'a eng?

- Re rerile ho ntlafatsa boemo ba bophelo ba bakuli bohle ba sepetlele sa St Joseph ba batenya ebile ba e-na le tsoekere.
- Boithuto bona bo tla etsetsoa sepetlele sa St Joseph Maseru/Lesotho ho bakuli ba tlang ngakeng ebile ba khutlela hae; ho tla hloauoa bakuli ba 180 ba batenya.
- Re tla sheba boima ba hao, bolele, boemo ba tsoekere, mofuta oa litlhare oo u phakang le mofuta oa lijo tseo u li jang kapa boikoetliso bo u bo etsang.
- Re tla u hlahloba e le ho laola mathata oohle a bakoang ke tsoekere.
- Kamor'a ho hlahloba lintlha tse boletsoeng kaholimo mona, re tla shebisisa mekhoa e ka fetolang boemo ba hao joaloka ho ntlafatsa litlhare tsa hao le bophelo ba hao ka kakaretso ka thuso ea setsebi sa phepo e nepahetseng. Methati ena e tla nka likhoeli tse tharo ho ntse ho hlahlojoa khafetsa.
- Re tla latela melaoana feela; ha ho tl'o ba le litlhare tse behoang tekong.

Hobaneng u memetsoe hore u kenye letsoho?

- *Re u memela ho kenya letsoho hobane u mokuli oa tsoekere e motenya ea alafshoang setsing sa rona sa bophelo, ea ka holim'a lilemo tse 18 'me a khona ho fana ka tumello. Re lakatsa ho ntlafatsa boemo ba hao ba tsoekere.*

Boikarabelo ba hao e tla ba bofe?

- *Boikarabelo ba hau boithutong bona ke holula u ea setsing ka nako eo u e behetsoeng le ho latela kalafo e khothalelitsoeng.*

Na u tla una molemo ka ho kenya letsoho boithutong boo?

Ha hona chelete e fanoang ho batho ba kenyang letsoho; molemo ke hore bophelo ba hao bo tla ntlafala ka ho laola boemo ba tsoekere ea hau le boima ba 'mele oa hao 'me hona ho tla thusa ho thibela mathata a bakoang ke lefu la tsoekere le botenya. Hona ho tla thusa hape hontlafatsa tlhokomelo ea bakuli ba tsoekere ba batenya ba tlang sepetleleng sa rona.

Na ho na le kotsi e ka bang teng ha u kenya letsoho boithutong boo?

- *Ha ho na kotsi e tla bang teng boithutong bona, ha ho na le litlhare tse ncha tse tla fanoa kapa mekhoa e mecha ea kalafo e tla etsoa. Re tla latela melaoana ea tsamaiso e nepahetseng. Boithuto bona ha se bo tl'o sheba hore na litlhare kapa mekhoa e mecha ea ho alafa bakuli ba tsoekere na eka sebetsa empa ke boithuto bo reretsoeng ho tla ntlafatsa boleng ba litšebeliso setsing sa rona (bo reretsoe ho ntlafatsa tlhokomelo ea bakuli ba tsoekere).*

Ha u sa lumele ho kenya letsoho, u na le boikhetlo bofe?

- *U tla nne u tsoele pele ka ho phaka litlhare tsa hao joalokaha ho tloaelehile sepetleleng sa rona ho latela litokelo tsa hao u le mokuli.*

Ke mang ea tla tseba ka pale ea bokulo ba hao?

- *Litaba tsohle tse bokelelitsoeng ka uena li tla bolokoa ele lekunutu hape li sireletsehile hantle: ha hona motho ea tla phenyaphenyana le litaba tsa bokulo ba hao ntle le mofuputsi le sehlopha se sebetsanang le ho ntlafatsa litšebeliso tsa bakuli ba tsoekere; lebitso la hau ha le tl'o hlaha khatisona efe kapa efe empa litaba tse fumanoeng ke tsona feela tse tla sebelisoa khatisona ea rona ea boithuto bona.*

Na u tla fumana litsieane ha u kentse letsoho boithutong boo hape na ho na le litšenyehelo tse teng?

- *Che, ha u ke ke ua lefelloa ho kenya letsoho boithutong bona le litšenyehelo tsa ho lefella koloi le ho reka lijo ha li tl'o fanoa. Ha ho na litšenyehelo tseo utla lokela ho li lefella ha u kenya letsoho boithutong bona. Sepheo sa boithuto bona ke ho ntlafatsa litšebeliso tsa bakuli ba tsoekere ba batenya. Boithuto bona bo tla etsoa ha mokuli a ntse ea sepetlele ho bona ngaka.*

Na ho na le seo u lokelang ho setseba?

- U ka letsetsa Dr Patrick Nkulu Mulungo nomorong ea mohala ea 63160765 ha u na le lipotso kapa ha u kopana le mathata.
- U tla fuoa foromo e ngotseng litaba tsena le foromo ea boitlamo molemong oa ho ipolokela tsona.

Boitlamo ba mokuli ea kenyang letsoho

Boitlamo ba toloko

'Na (*lebitso*) ke itlama hore:

- Ke thusitse mofuputsi (*lebitso*) ho hlalosa litaba tsohle tse kahar'a tokomane ena ho (*lebitso la mokuli*)..... Ka puo ea Sesotho.
- Re mo kothalelitse ho botsa lipotso le ho nka nako e lekaneng ho li araba.
- Ke fetisitse molaetsa o nepahetseng oa seo ke neng ke se toloka.
- Ke khotsofetse hore mokuli o utloisisa ka botlalo litaba tse hlahang tokomaneng ea tumello le lipotso tsa hae li arabetsoe hantle.

E tekenetsoe (*sebaka*)..... ka la (*letsatsi*).....

.....

Tekeno ea toloko

.....

Tekeno ea paki

PARTICIPANT INFORMATION LEAFLET AND CONSENT FORM

TITLE OF THE RESEARCH PROJECT: HOW TO IMPROVE THE QUALITY OF CARE OF PATIENT WITH TYPE 2 DIABETES MELLITUS RECEIVING CARE AT SEMIRURAL DISTRICT HOSPITAL IN LESOTHO.

REFERENCE NUMBER: 18686133

PRINCIPAL INVESTIGATOR: Dr Patrick Nkulu Mulongo

ADDRESS: Koro Koro Street /Maseru/Lesotho

CONTACT NUMBER:

You are being invited to take part in a research project. Please take some time to read the information presented here, which will explain the details of this project. Please ask the study staff or doctor any questions about any part of this project that you do not fully understand. It is very important that you are fully satisfied that you clearly understand what this research entails and how you could be involved. Also, your participation is **entirely voluntary** and you are free to decline to participate. If you say no, this will not affect you negatively in any way whatsoever. You are also free to withdraw from the study at any point, even if you do agree to take part.

This study has been approved by the **Health Research Ethics Committee at Stellenbosch University** and will be conducted according to the ethical guidelines and principles of the international Declaration of Helsinki with the approval of the Lesotho ministry of health.

What is this research study all about?

- *The study will be conducted at St Joseph Hospital Maseru/Lesotho at outpatient department; 180 overweight patients will be selected.*
- *We are intending to improve the quality of care of all patients with DM associated with overweight at St Joseph Hospital.*
- *We will assess your current weight, height, blood sugar level, checking your medication for diabetes and your lifestyle meaning what you are eating, kind of exercise that you are doing. We will examine you to see and rule out all complications due to diabetes mellitus. After checking all things elaborated just above, we will try ways to change your condition in better ways by improving your medications, your lifestyle with the help of your dietician. This process will take a period of 3 months with a regular assessment.*
- *We will follow only the guidelines; they will not be an experimental medication to be tested.*

Why have you been invited to participate?

- *We invite you to participate because you are overweight Diabetic patient, attending care at our institution, over 18 year-old who can give consent alone. We would like to improve your condition of diabetes and we will try to reduce your weight to normal range according to your height.*

What will your responsibilities be?

- *Your responsibilities in this research are to be committed to our appointment and the treatment changes which may occur to your actual management.*

Will you benefit from taking part in this research?

There is no financial benefit to the researcher or the participants, your benefit is to help you improve your medical condition by controlling your fasting blood glucose level, your body mass index and this will avoid complication related to diabetes and overweight. This will strengthen the hospital management of overweight patient associated with diabetes after this research.

Are there any risks involved in you taking part in this research?

- *No risk will be part of this research, no new medication or methods will be applied to you. We will follow a guideline well established. This is not an experimental research but a quality improvement research at our institution.*

If you do not agree to take part, what alternatives do you have?

- *You will still continue with your care as usual with our facility with all your right to your care.*

Who will have access to your medical records?

- *Your information collected through your record will remain confidential and protected, no one will have access to your record except the researcher and the team for quality improvement; in our publications, your name will not appear, only data will be used in the publication of our research.*

Will you be paid to take part in this study and are there any costs involved?

No, you will not be paid to take part in the study, your transport and meal costs will not be covered for each study visit. There will be no costs involved for you, if you do take part. The purpose of this research is to improve the quality of care of overweight patient living with diabetes. The research will be conducted at the time of consultation of diabetes patients within the hospital. No payment, transport or meal will be covered during this period of the research.

Is there anything else that you should know or do?

- You should inform your family practitioner or usual doctor that you are taking part in a research study. *(Include if applicable)*
- You should also inform your medical insurance company that you are participating in a research study. *(Include if applicable)*
- You can contact Dr Patrick Nkulu Mulongo at Cell no 63160765 if you have any further queries or encounter any problems.
- You will receive a copy of this information and consent form for your own records.

Declaration by participant

By signing below, I agree to take part in a research study entitled *(insert title of study)*.

I declare that:

- I have read or had read to me this information and consent form and it is written in a language with which I am fluent and comfortable.
- I have had a chance to ask questions and all my questions have been adequately answered.
- I understand that taking part in this study is **voluntary** and I have not been pressurised to take part.
- I may choose to leave the study at any time and will not be penalised or prejudiced in any way.
- I may be asked to leave the study before it has finished, if the study doctor or researcher feels it is in my best interests, or if I do not follow the study plan, as agreed to.

Signed at *(place)* on *(date)* 2016.

.....
Signature of participant

.....
Signature of witness

Declaration by investigator

I declare that:

- I explained the information in this document to
- I encouraged him/her to ask questions and took adequate time to answer them.
- I am satisfied that he/she adequately understands all aspects of the research, as discussed above
- I did/did not use an interpreter. *(If an interpreter is used then the interpreter must sign the declaration below.*

Signed at St Joseph Hospital ... on *(date)* 2016.

.....
Signature of investigator

.....
Signature of witness

Declaration by interpreter

I *(name)* declare that:

- I assisted the investigator *(name)* to explain the information in this document to *(name of participant)* Using the language medium of Sesotho...
- We encouraged him/her to ask questions and took adequate time to answer them.
- I conveyed a factually correct version of what was related to me.
- I am satisfied that the participant fully understands the content of this informed consent document and has had all his/her question satisfactorily answered.

Signed at *(place)* On *(date)*

.....
Signature of interpreter

.....
Signature of witness

10.3 Diabetes type 2 lifestyle advice leaflet in English and Sesotho

DIET

Size Matters!

The Diabetic plate should be of a maximum of 22 cm as a normal plate. Also, don't pile too much food on each section. If food overflows the rim of your plate, you're probably going to eat more calories than your body needs.

Fill Your Plate

1/2 Non-starchy Vegetables: Fill half your plate with non-starchy vegetables, such as Sesotho green veggies, cabbage, carrots, cauliflower, green beans, salad,...

1/4 Grain Foods/Starchy Vegetables: Fill one-quarter of your plate with whole grain or starchy foods, such as brown rice, bulgur, green peas, sweet potatoes, and whole wheat bread. Beans, which are both starchy and a good source of protein and fibre, can fit here, as well.

1/4 Lean Protein: Fill the remaining one-quarter of your plate with lean protein foods, such as fish, chicken, eggs, and lean beef or pork (with no fat), and soy products.

Fruit and/or Dairy on the Side

Add fruit, such as a small apple, or small cup of low-fat yogurt, or both as your meal plan allows.

PHYSICAL ACTIVITY

Benefits: Moderate to high levels of physical activity and cardio-respiratory fitness is associated with substantial reductions in morbidity and mortality in both in Diabetes.

Other benefits: Improved glycaemic control, Decreased insulin resistance, improved blood lipid profile, improved blood pressure, Maintenance of weight loss, Reduced abdominal and overall fat percentage, improved well-being, Decreased stress and anxiety.

What to do: People with type 2 diabetes should perform per week at least 1H30 of moderate intensity aerobic physical activity (50-70% of maximum heart rate) and, in the absence of contraindications, they should perform resistance training three times per week.

Diabetes type 2 Lifestyle leaflet



MOKHOA O NEPAHETSENG OA HO JA**Bongata ba lijo boa hua!**

Lijo tsa motho ea nang le lefu la tsoekere li lokela ho fella ka seianeng se tloaelehileng sa bohola ba 22cm. Hape, seke ua tšela lijo tse ngata haholo mofuteng o mong le o mong. Haeba seiana sa hao se tletse haholo, ho hlakile hora u tlo ja hofeta kamoo 'mele oa hao o hlokanang kateng.

Tšela seianeng sa hao

Haloho (1/2) ea meroho: Tšela meroho seianeng sa hao, joaloka meroho e metala ea Sesotho, k'habeche, lihoete, cabbage, lier ekisi tsa lehoetla, salate....

Kotara (1/4) ea Lijo-thollo /Meroho: Tšela kotare e le 'ngoe ea lijo-thollo kapa lijo tse nang le starche seianeng sa hao, joaloka rice e sootho, lierekisi tsa lehoetla, *sweet potatoes* (litapole tse tsoekere) le bohobe ba koro. Linaoa, kaha li na le starche hape li fana ka limatlafatsi tse hlokalahalang le litlheberetsi li ka kenella mona le tšona.

kotara (1/4) ea Limatlafatsi tse tihotliloeng (Lean Protein): Tšela limatlafatsi tse tihotliloeng kotareng, e setseng ea seiana sa hao, joaloka tlhapi, nama ea khoho, mahe,

nama ea khomo kapa ea fariki e tihotliloeng (tse se nang mafura) le lihlahisoa tsa soy.

Tholoana le/ kapa sehlahisoa se entsoeng ka lebesa

Kenveletsa tholoana, joaloka apple e nyane, kapa kopi e nyane ea yokate e se nang mafura a mangata kapa li le peli joalokaha ho lumelleha.

BOIKOETLISO

Melemo: Boikoetliso bo lekaneng hantle le bo boholo le bophelo bo botle ba pelo le matšoafu li amahanngoa le ho fokotsa sekhahla sa lefu le ho shoa ha batho mofuteng e 'meli ea lefu la tsoekere.

Melemo e meng: Taolo e ntlafetseng ea tsoekere e lekaneng, phokotseho ea ho hana tsoekere hoa 'mele, mafura a lekaneng maling phallo ea mali e ntlafetseng, e thusa ho fokotsa 'mele. Phokotseho ea mpa le lefura ka kakaretso, bophelo bo botle bo ntlafetseng, Phokotseho ea khatello ea maikutlo le letsoalo.

Seo u ka se etsang: Batho ba nang le mofuta oa bobeli oa lefu la tsoekere ba lokela ho etsa boikoetliso bo matla ka tsela e lekaneng bonvane hora le haloho ka beke (50-70% ea ho

otla ha pelo) hape, haeba ho keke ha baka bothata, ba ka etsa boikoetliso bo matla ba nako e teletsana hararo ka beke.