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QUALITY OF CARE AND OUTCOMES OF DIABETIC EXTREMITY PATIENTS AFTER THE IMPLEMENTATION OF THE REVISED DIABETES EXTREMITY CARE TEAM PROTOCOL OF THE PHILIPPINE GENERAL HOSPITAL

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ABSTRACT

***Background*: It has been 10 years since the implementation of the diabetes extremity care team (DECT) of the Philippine General Hospital (PGH). Since the report of Isip-Tan in 1999 where a suboptimal quality of care of the services of the DECT was evident, there had been no subsequent studies done to audit the Services of the team.**

***Objectives*: The primary objective of this study is to assess the quality of care given by the Diabetes Extremity Care Team (DECT) to patients admitted to the PGH medical wards for diabetic foot using the Structure-Process-Outcome Model.**

***Study Design*: Retrospective review of charts from 2004-2007 with a diagnosis of diabetic foot ulcer.**

***Population*: All patients admitted at the Philippine General Hospital from 2004-2007 with a primary diagnosis of an infected diabetic foot as recorded in the DECT logbook.**

***Quality of Care Indicators*: 1) Structure – DECT and liason services response rates; 2) Process- Adequacy of diagnostics, appropriateness of antibiotics, adequacy of foot examination, documentation of the body mass index, dietary advice, fundoscopy**

***Outcome*: Morbidity, mortality, functional impairment and patient satisfaction.**

***Results*: Using the Structure-Process-Outcome Model, major improvements were needed at the level of the structure and process. These observations were not different from the earlier findings of Isip-Tan.**

***Conclusion*: The study showed that the quality of care by the DECT to the admitted diabetic foot ulcer patients remained suboptimal and can still be improved.**

***Keywords*: Diabetes mellitus, infected diabetic foot, quality of care**

INTRODUCTION

Diabetic foot syndrome affects up to 20% of patients with diabetes at least once in their lifetime.[1] In other words, it affects 1 out of 5 diabetics once in his lifetime with relevant consequences both on lower limb survival and general morbidity. Diabetes is the most frequent determined of lower limb amputations in developed countries. Lower limb complications are the major contributors to hospitalization of patients with diabetes and they account for the vast majority of in-hospital stay and resource consumption among these patient population.

Diabetic lower extremity ulcers are responsible for 92,000 amputations annually.[2,3] The 10 year cumulative incidence of lower extremity amputation is 5% in younger onset diabetes (diagnosed before 30 years old) and 7% in the older onset diabetes (diagnosed at age 30 or older).[3,4] Within 5 years after its amputation, 28-51% of patients with diabetes require a second leg amputation.[2] Survival after amputation is bleak. The 5 year survival rate after amputation is only 27% translating to a fourfold increase compared to age and sex matched population.[2]

In addition, lower extremity ulcers are costly to manage. The total ulcer related costs average $13,179 per episode and increase with the severity level, ranging from $1,892 (level 1) to $27,721 (level 4/5).[3] Inpatient hospital charges accounted for 77% of the over-all cost.[3] Therefore, efficiency of the multidisciplinary team addressing the diabetic foot management can cut the costs of treatment by decreasing the hospital stay.

According to the international consensus guidelines, such complex pathology necessities the participation of the multidisciplinary team including an endocrinologist, podologist, vascular surgeon, radiologist, and infectious disease specialist, to

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manage and address all the various aspects and presentations of the pathology.

It has been 10 years since the implementation of the diabetes extremity care team (DECT) of the Philippine General Hospital (PGH). During the pre-DECT,[5] diabetic foot ulcers accounted for 16.8% of annual admissions. The average hospital stay was 22 days. Readmission rate was 23%. Mortality was at 14% primarily attributed to sepsis and cardiac related causes. Amputation rate was 70%, predominantly below the knee at 44%.[5] To address the different concerns of diabetic foot management and in line with international consensus guidelines, the DECT of PGH was created in 1996. The team met quarterly to discuss problems encountered. The initial protocol was devised in 1996 (see Figure 1). Two years after its implementation, the average hospital stay decreased to 13 days with readmission at 9%. Amputation rate showed a decreasing trend at 66%. Mortality rate was decreased to 8% and still was attributed to sepsis and cardiac related etiologies.[6] To further improve the patient outcomes, a revision was done in 1998 (see Figure 2). This revised DECT protocol is utilized up to present. The revised protocol was designed to improve the quality of patient care by decreasing the lag time in interdepartmental referrals. A logbook is present at the emergency room where patients for evaluation by the DECT were listed. A year after the revised protocol was established, mortality rate significantly decreased however, it might be falsely low because the home against medical advice rate was 11% which could be considered as mortalities as well. (Table I). Since then, there has been no reassessment of the effectiveness of the DECT in the delivery of quality service. We review the data we have from 2004-2007 to evaluate and benchmark as audit to the services of the DECT.

To improve patient outcomes, protocol adherence should be further elucidated. One approached is to use the Donabedian Structure-Process-Outcome Model. He linked three elements by stating that "good structure increases the likelihood of good process and good process increases the likelihood of good outcome." This model can be used to identify specific factors that are associated with protocol non-adherence and theses factors can serve as focus areas for quality improvement interventions.

Structure is that aspect of health care that is perhaps best represented by things like your guidelines and standards that define what is or what should be. Process is what practitioners do. Table I.

Table I. Structure-Process-Outcome Model for Population, Health and Nutrition Project and the Quality of Care Utilized in this Study.

Structure		Quality of Care Indicators
1.	Organizational arrangements	DECT referral response rates
2.	Personnel	dietary and ophthalmology response rates
3.	Financial resources	Ward admission, compliance to antibiotics
Process		Quality of Care Indicators
4.	Function	Adequacy of diagnostics, appropriateness of antibiotics
5.	Program	Adequacy of foot examination
6.	Support tasks	Documentation of the body mass index, dietary advice, fundoscopy
Measured Outcomes		
7.	Morbidity	Readmission and repeat surgery
8.	Mortality	All-cause mortality
9.	Functional impairment	Amputation rate
10.	Patient satisfaction	Length of hospital stay, home against advice rate

OBJECTIVES

The objectives of this study are as follows:

1. To assess the quality of care given by the DECT to patients admitted to the PGH medical wards for diabetic foot using the Structure-Process-Outcome Model.
2. To compare the quality of care given by the DECT to patients admitted to PGH in 1998-1999 and 2004-2007.
3. To make recommendations using the Structure-Process-Outcome Model.

MATERIALS AND METHODS

Study Design

Cross-sectional, analytical

Study Setting

Philippine General Hospital, Medical Wards

Study Population

All patients admitted at the Philippine General Hospital from 2004-2007 with a primary diagnosis of an infected diabetic foot as recorded in the DECT logbook.

The proposal was technically and ethically reviewed by the Research Implementations and Development Office (RIDO). After a letter addressed to the Director on Research was approved, charts of patient covering the study period were retrieved. Only charts from 2004 onwards were still available at the records section for review. A total of 501 charts were retrieved from 2004-2007. Nine were excluded because of lost pages and therapeutic sheets. There were 492 charts eligible for review. Demographic data were extracted. In the date collection form, a patient was labeled as having:

1. Diabetes – if a patient had a FBS > 126mg% on 2 determinations, RBS > 200mg% with symptoms, 2 hour blood sugar after a 74 grams oral glucose tolerance test of > 200mg% (based on the WHO criteria), or had been taking medications for diabetes.

2. Neuropathy – if a patient had any evidence of loss of sensation using the monofilament test, tuning fork test for vibration; or physician-diagnosed based on patients' symptoms.

3. Peripheral arterial disease (PAD) – if a patient had an ankle brachial pressure index (ABPI) < 0.9 with intermittent claudication, significant occlusion on arterial Doppler, or physician-diagnosed based on patients' symptoms.

4. Hypertension – if a patient had a blood pressure of > 140/90, or had been taking medications for hypertension.

5. Current smoker – if a patient had been actively smoking within 1-2 years.

6. Significant alcohol intake – if a patient had taken $\geq$24 ounces of beer or $\geq$10 ounces of wine, or $\geq$3 ounces of 80 proof whiskey a day for men; $\geq$12 ounces of beer or 5 ounces of wine, or $\geq$1.5 ounces of 80 proof whiskey a day for women based on the Joint National Committee on Hypertension VII or physician diagnosed as indicated in the chart.

Data on the quality of care indicators as pre-determined by the study of Isip-Tan[7] and patient outcomes were extracted from the charts using the standard data collection form. Quality of care indicators were as follows:

1. DECT response time – good quality of care was defined as a referral response time of < 24 hours from the day of admission.

2. Opthalmology response rate – a complete ophthalmologic exam should be part of the initial visit and annually then after for type 2 diabetics as per recommendation of the American Diabetes Association (ADA).

3. Dietary department referral – dietary advice should be part of the diabetes education and management based on the position statement on the standards of care for diabetic patients.

4. Documentation of the height and weight per patient visit as per recommendation of the American Diabetes Association (ADA).

5. Adequacy of foot assessment based on Wound scoring system

    a. Size, depth and complete description of the wound

    b. Staging of the wound by the University of Texas

Table II. The University of Texas Diabetic Foot Classification

Stage	0	1	2	3
A	No. open lesions	Superficial ulcer	Deep to fascia, tendon, joint	Penetrate joint or bone involvement
B	Infection	Infection	Infection	Infection
C	Ischemia	Ischemia	Ischemia	Ischemia
D	Infection & Ischemia	Infection & Ischemia	Infection & Ischemia	Infection & Ischemia

6. Adequacy of the laboratory tests/examinations for the diabetic foot – based on the ADA position statement on foot care for diabetics,[8] the following laboratories were recommended, namely: foot X-ray to exclude subcutaneous gas, presence of a foreign body, osteomyelitis and Charcot's foot; culture specimens from the curettage of the wound base; evaluation of somato-sensory threshold using the Semmes-Weinstein 5.07 (10-g) monofilament and screening for peripheral vascular disease.

7. Appropriateness of the antibiotic. Due to the polymicrobial nature of diabetic foot ulcers, combination antibiotics are ideal and should be started as soon as possible.

    a. Empiric antibiotic should be started at the emergency room as soon as possible and the missed doses received by the patient should not be more than 25% of the required total number of doses. A local study by Raymundo[9] suggested specific empiric antibiotics for each of the Wagner stage; however, the University of Texas wound classification was already used in the specific time frame.

    b. Shifting of the antibiotics at wards based on the culture results.

8. Delayed surgical intervention – during one of the consensus meetings of the DECT, a surgical procedure is considered delayed if it was done >7 days from admission.

Statistical Analysis

Demographic data, patient outcomes and quality of care indicators were expressed as means and percentages. The differences between 2 means were tested for significance by the T-test and the differences between two proportions are tested for significance by the Chi square test. Statistical significance was defined as p value 0.05.

RESULTS

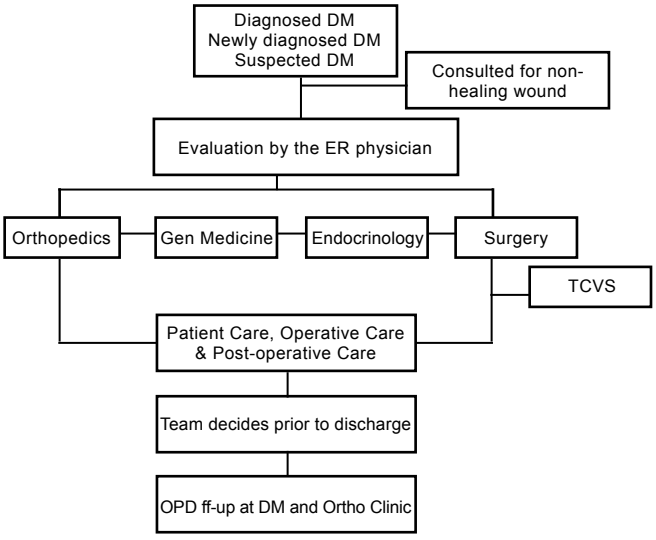

Fig. 1. The 1996 DECT Protocol of Philippine General Hospital [6]

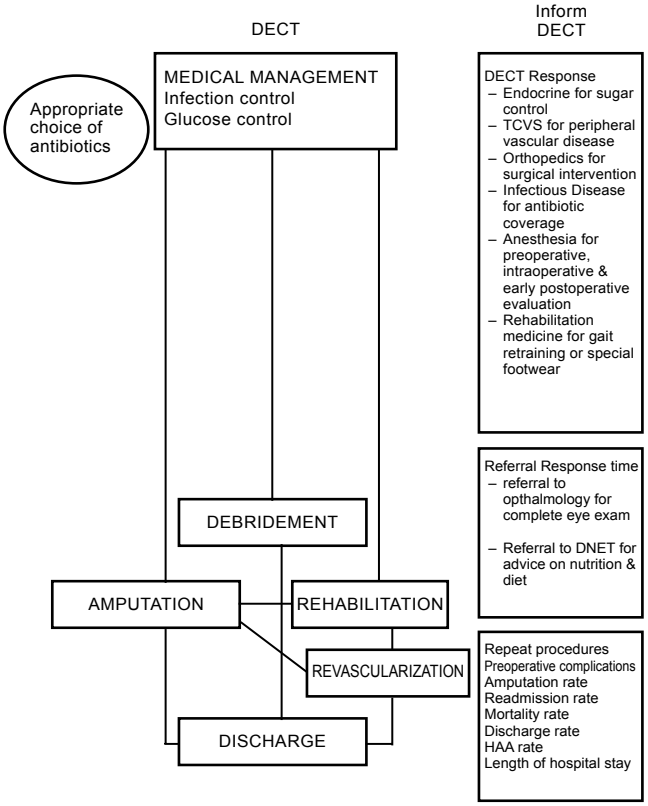

Fig. 2. The 1998 Revised DECT Protocol of the Philippine General Hospital[6]

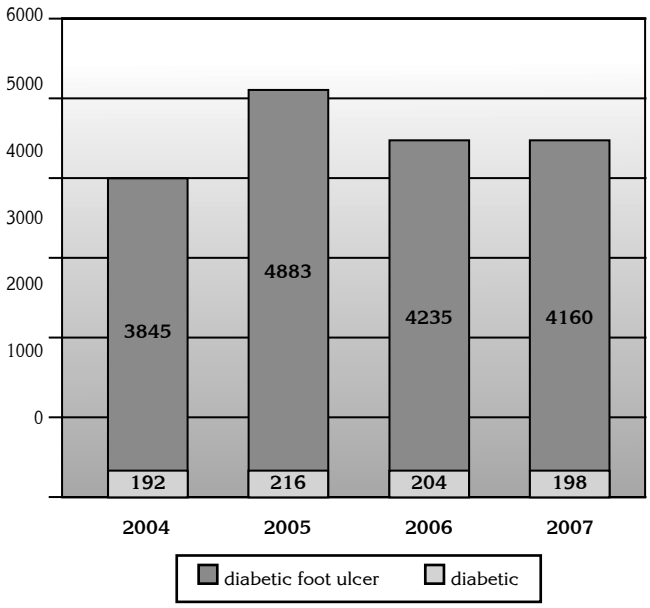

Fig. 3. Diabetic Patients Admitted for Foot Lesions 2004-2007

There was no significant change in the diabetic foot admissions from 2004-2007 as seen in the figure above.

Table III. Demographic Profile of Diabetic Foot Ulcer Patients at the UP-PGH from 2004-2007

Characteristics	1999 N=64	2004 N=103	2005 N=115	2006 N=144	2007 N=129
**No. of patients previously seen at the OPD	–	17	28	56	50
Age, mean + SD	55.6±10.7	55.3±1.5	52.7±1.4	55±9.5	55±11
** Male	24	59	78	96	75
** Duration of diabetes (years), mean ± SD	5.1+5.2	8.9±1	8.8±1	13.1±15.9	7.4±6.8
** Current smokers	30	47	68	100	86
** Alcoholic	17	54	54	62	51
** BMI, mean + SD	20.5±5.7	23±0.65	22±0.67	24.1±2.9	24±3.64
Without Treatment	17	17	26	14	25
With neuropathy	53	75	92	105	99
** With peripheral vascular disease	4	21	26	16	22

Tested for difference in proportions and means from 1999 (or 2004 in the absence of 1999 data) to indicated year
**Statistically significant increase in proportion ($p<0.05$)

There was an increase in the proportion of patients admitted for diabetic foot ulcer who were previously seen at the outpatient department as seen in table II. Majority of these patients were obese males, smoker, with significant alcohol beverage intake and a long standing history of diabetes mellitus. Mean age, percentage of patients without treatment, percentage of patients with neuropathy were not different from the profiles of patients admitted in 1999 compared to 2004-2007. There was an increases in peripheral arterial disease however only 34% (30 out 89) of these patients were diagnosed using either an ankle brachial pressure index or an arterial doppler studies. Majority of these patients were labeled as having PAD based on pulse palpation only.

Table IV. Comparison of the Quality of Care Related to Process: 1998-1999, 2004-2007

II. Process: Quality of Care Indicators	1999 N=64	2004 N=104	2005 N=115	2006 N=144	2007 N=129
**No. of patients with X-ray of foot	42	72	97	125	117
**No. of patients with wound cultures	49	74	86	110	107
**No. of patients with wound staging and description	16	40	49	60	68
No. of patients with monofilament testing	–	5	9	10	15
No. of patients with ABI	–	5	8	6	11
No. of patients with complete documentation of height, weight, BMI	31	42	58	30	43
**Mean time the first dose antibiotic was given, hours (mean+SD)	–	15.1±3.9	7.5±2	9.8±1.4	16.7±20.7
**No. of patients with appropriate empiric antibiotic coverage	16	87	98	130	111
Missed doses of antibiotics ≤25%	–	51	63	75	69

Tested for difference in proportions and means from 1999 (or 2004 in the absence of 1999 data) to indicated year
**Statistically significant increase in proportion ($p<0.05$)

The proportion of patients with foot x-ray and wound cultures increased compared to the data in 1998-1999 as seen in the table IV. However, the adequacy of the wound staging was questionable because of low utility of monofilament testing and ankle brachial pressure index for assessment of neuropathy and vascular insufficiency.

Majority of patients were started on combination antibiotics because of the polymicrobial nature of the disease. The most common combination was Metronidazole and Ceftriaxone. However, the mean time antibiotics were started increased and compliance remained poor.

Table V. Comparison of the Outcomes: 1998-1999, 2004-2007

III. Outcomes	1999 N=64	2004 N=104	2005 N=115	2006 N=144	2007 N=129
Mortality Rate	3	2	3	13	11
***Major Amputation Rate	20	37	62	78	56
-BKA	16	34	60	70	46
-AKA	4	3	2	8	10
Readmission Rate	8	6	4	12	17
Discharge Rate	53	94	103	125	107
Home Against Advice	7	7	9	6	11
Length of Hospital Stay	16±8.6	18.3±11.4	18.1±11.5	16±11	18.5±10
a. Stay at ER	1.6±1.1	1±1.1	1.39±1	2.1±2.9	2.3±1.5
b. Admission of Clearance	4.4±2.5	3±3.6	4.4±4.5	3.9±3.2	5.2±4.6
c. Clearance to surgery	4.7±2.3	4.4±3.8	4.5±3.5	4.6±3.5	4.2±2.6
d. Surgery 1 to Surgery 2	–	11.9±9.1	11.5±8.9	11.3±6.5	7.7±6.0
e. Surgery 2 to Surgery 3	–	8±4.4	7.6±3.8	6.3±0.5	11±3.8
f. Admission to surgery	10.9±6	8.1±4.8	9.5±5.3	9.6±5.4	9.8±5.32
g. Surgery to Discharge	10±8.6	8.45±7.6	7.5±6.8	6.6±5.4	7.16±4.6

Tested for difference in proportions and means from 1999 (or 2004 in the absence of data) to indicated year
***Statistically significant increase in proportion ($p<0.05$)

There was a non-significant trend towards an increase in the mortality rates from 2004-2007 compared to 1999 as seen in table V. No. significant change in the home against advice, readmission, and discharge rates of patients. However, there was a significant increase in major amputation rates.

There was no significant change in the duration of hospital stay. Specifically, the duration of stay at the emergency room, admission to clearance, clearance to surgery and admission to surgery remained the same.

Table VI. Reasons for Delay in Surgery

Reasons for delay in Surgery	1999	2004	2005	2006	2007
Peri-operative clearance	15	16	30	26	26
Blood for surgery	7	11	31	20	29
Electrolyte imbalance	–	6	7	10	16
Consent	–	1	4	12	12
***OR schedule	28	27	39	64	51

Tested for difference in proportions and means from 1999 (or 2004 in the absence of data) to indicated year
***Statistically significant increase in proportion ($p<0.05$)

No available operating room remained to be the most common cause of delay in surgery. An increasing trend on the number of cases with delayed surgery due to unavailability of operating rooms was evident in 2004 to 2007. There was also an increasing trend on the number of cases with delayed perioperative clearance. The increase in blood transfusion prior to surgery was associated with the increase in major amputation ($p<0.01$).

DISCUSSION

The DECT was established with the objectives of **decreasing major amputations** and **mortality rates**. The American Diabetes Association has targeted to decrease the amputation rate by <40% in 2000. [2,10,11] Western countries have reached as much as 90% in decreasing the amputation rates.[10] Earlier study by Chang reported a 55% amputation rate before the DECT was established. Two years after the DECT was created, Balderas reported a decrease by 9%. The study by Isip-Tan reported 31%. Our study showed as high 54% in 2006, similar to the reported rate by Chang.

It has been 10 years since the DECT was created and our objectives have not yet been fulfilled. Using the Structure-Process-Outcome Model, we have observed that major improvements are needed at the level of the structure and process. These observations were not different from the earlier findings of Isip-Tan.

Structure

The set-up had been designed to limit interdepartmental referral however; the response rates of the members remained sub-optimal. Response rate of 80-100% within the first 24 hours from admission among the core group is considered optimal. Response rates of the infectious disease, thoracovascular surgery and rehabilitation medicine can be improved. The quality of patients we received had a more severe stage to start with. They have a longer duration of diabetes with significant smoking and alcohol intake complicated with neuropathies and vascular insufficiency. The findings were consistent with the ADA position statement that the risks for diabetic foot ulcers were higher among patients who had diabetes >10 years, with poor glucose control, and with cardiovascular, retinal, or renal complications. Absence of resources caused significant delay in the admission of patient, administration of antibiotics and performance of the necessary surgical procedures. The current protocol covered only in-hospital management. As we shall see, we had an increasing proportion of patients seen at the OPD that were admitted.

Process

Foot assessment had been inadequate as majority of the tests done were only x-ray and cultures. There were no objective evaluation for neuropathy and vascular insufficiency. Compliance to antibiotics remained poor with >25% missed doses as high as 75%.

Outcome

Over-all, we had a good discharge rates. This showed the effectiveness of the team management of diabetic foot ulcer patients. However, the home against advice rates remained the same, which may indicate patient dissatisfaction of the quality of care, and may be considered as mortalities as well. There had been no change in the duration of hospital stay.

CONCLUSION

The study showed that the quality of care by the DECT to the admitted diabetic foot ulcer patients remained suboptimal, comparable to the findings of Isip-Tan and can still be improved.

RECOMMENDATION

A. Clinical Implications

1. The DECT should also encompass the outpatient management. The 1996 protocol reflected OPD follow up at orthopedic and diabetes clinics only. This was not evident in the 1998 protocol.

2. A unified DECT form be created that will include all vital information needed for high quality of care. A protocolized surgical approach based on the following: extent of involvement of the ulcer using foot x-rays, presence of neuropathy using a monofilament 10g, presence of vascular insufficiency using an ankle brachial pressure index and/or arterial doppler and venous duplex scan if warranted. This is to circumvent prolonged hospital stay due to repeated debridement in the absence of objective evidence of good vascular supply or conversely doing unnecessary amputation on wounds with intact biomechanics and vascular status.

3. Creation of a separate OR slot for patients with diabetic foot

4. Government subsidized antibiotics dedicated for diabetic foot ulcer patients. These antibiotics shall be determined on the quarterly report of the Infectious Disease on the sensitivity testing of common isolates on wound aspirates.

5. Procure a new arterial doppler ultrasound.

B. Research Implications

1. Quality of care studies should be done every 3 years to evaluate the services of the Diabetes Extremity Care Team.

2. Effectiveness of outpatient management should be included in the subsequent quality of care studies.

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