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Management of diabetes and associated costs in a complex humanitarian setting in the Democratic Republic of Congo

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Abstract

Objective: We aimed to evaluate an Integrated Diabetic Clinic within a Hospital Outpatient Department (IDC-OPD) in a complex humanitarian setting. Specific objectives were to: (i) analyse diabetes management outcomes; (ii) examine the association of key insecurity and related programmatic events with diabetes outcomes; and (iii) analyse IDC-OPD programme costs.

Design: A cohort analysis of routine outcome data collected between January 2014 and February 2017; and analysis of programme costs for 2014/15.

Setting: An outpatient diabetes programme (IDC-OPD) in Mweso hospital, supported by Médecins sans Frontières, located in an insecure and impoverished rural area in North Kivu, Demographic Republic of Congo.

Participants: Diabetes patients using the IDC-OPD.

Outcome measures: Clinical outcome trends (glycaemic, blood pressure control); association of key security and related programmatic events with clinical outcomes; and incremental programme costs.

Results: Of 243 enrolled diabetes patients, 44.6% were women, median age was 45 (IQR 32-56); 51.4% were classified Type 2. Visit numbers and visit interval increased on introduction of IDC-OPD but decreased when insecurity led to service scale-back and subsequent suspension. Clinical control rates during initial service scale-back were similar to the preceding period of full implementation. Later, patients were less likely to achieve control due to exhaustion of medications but this improved again on service resumption. Total costs decreased by 20% from 2014 (€32,121) to 2015 (€26,410). Annual cost per patient dropped from €417 in 2014 to €183 in 2015 due to reduced supply costs and increased patient throughput.

Conclusions: Diabetes care for stable patients in humanitarian settings is possible. Costs were less than those for chronic HIV care in low-income settings. Findings indicate the programme could be

simplified to involve drug collection with nurse-led, algorithm-guided treatment adjustment and strengthened emergency preparedness. Further research is required to define a minimum effective treatment package for diabetes in complex humanitarian settings.

Article Summary

- This is the first study of its kind to examine diabetes outcomes and programme costs in a complex humanitarian setting in sub-Saharan Africa.
- Logistic regression was used to estimate the effect of insecurity and related programmatic changes on clinical outcomes.
- The study was limited by the relatively small sample size and lack of control group for comparison.
- The costing analysis was descriptive only and so cost-effectiveness of the programme could not be assessed.

Title: Management of diabetes and associated costs in a complex humanitarian setting in the Democratic Republic of Congo

Background

Over the past 40 years, the prevalence of diabetes has increased sharply worldwide, particularly in low and middle income countries.[1] However, data are scarce from conflict-affected countries, particularly those in Central, West and East Africa.[1] Humanitarian actors have been slow to prioritise diabetes treatment in disaster and post-conflict settings despite reporting increasing presentations of patients within their programmes.[2–4] This is due to lack of knowledge on local diabetes prevalence and needs, limited research on diabetes management or outcomes in emergency settings; and a lack of programmatic and policy guidance to support diabetes care in humanitarian settings.[2,5–7] North Kivu in the Democratic Republic of Congo (DRC) is one such complex humanitarian setting, where diabetes prevalence (estimated at between 4 and 5.4%) is increasing in the context of a health system weakened by prolonged conflict.[8–10]

Since 2008, Médecins sans Frontières (MSF) has supported healthcare delivery in Mweso, North Kivu, DRC, in collaboration with the Ministry of Health. North Kivu, with an estimated population of 365,000, is a rural, impoverished area bordering Rwanda. It remains a flash point in the on-going conflict in the DRC and hosts 17 internally displaced person camps. MSF supports health services in 4 out of 23 Primary Health Care clinics and in Mweso hospital within Masisi District. Mweso hospital serves a catchment area of approximately 145,000 people, with about 65,000 beneficiaries living in the immediate vicinity of the hospital.

In response to growing patient and provider needs, MSF implemented a context-adapted, hospital-based diabetes programme in March 2015, the Integrated Diabetic Clinic within Hospital Outpatient

Department (IDC-OPD) in place of the ad hoc care previously undertaken. Intermittent deteriorations in security led to temporary scaling back or suspension of the programme and restricted patients' movement.

The IDC-OPD was a nurse-led, multi-disciplinary model, based on locally adapted clinical guidelines, patient counselling materials and data collection tools, accompanied by 3 days of specialist training.[11] The clinic team included: a nurse supervisor, nursing assistant, two doctors, a nutritionist, and education and psychosocial support officers. Diabetes was diagnosed according to World Health Organization (WHO) guidelines using repeated fasting capillary glucose. Most patients were identified as diabetic and enrolled after acute hospital presentation, while some were identified via the Mweso outpatient department or referring primary care clinics.

Patients received a detailed enrolment assessment, monthly nurse-led follow-up and 6-monthly medical review, with nutrition and psychosocial support. Each patient was given a clinic-held patient file and patient-held passport to facilitate safe passage. Clinical guidelines were adapted from MSF, WHO and other international guidance. Patient educational tools were adapted from Santé Diabète,[12] a Malian Non-Governmental Organisation, and medications were those included on MSF's Essential Drugs List. Insulin doses were adjusted using single fasting capillary blood glucose readings and patients' reported symptoms of hypo- or hyperglycaemia in the absence of home glucose monitoring.

A mixed methods evaluation of the Mweso IDC-OPD programme was undertaken by MSF (with qualitative component of the evaluation exploring patient and provider challenges, presented elsewhere [13]). Here, we report quantitative data on programmatic and clinical outcomes and programme costs. The overall objective of this study was evaluate the MSF IDC-OPD Programme in the complex humanitarian setting of North Kivu, DRC. The specific objectives were to: (i) analyse

diabetes management outcomes; (ii) examine the association of key insecurity and related programmatic events with diabetes outcomes; and (iii) analyse IDC-OPD programme costs.

Methods

For the outcome analysis, we conducted a retrospective analysis of routine data of enrolled adults aged ≥18 years from January 2014 to February 2017, examining trends in diabetes outcomes and their association with key programmatic events. The study period was divided into five phases, defined by programmatic changes or periods of heightened insecurity (which impacted service delivery due to staff evacuation, supply chain interruption and reduced patient access). Period T1 refers to ad-hoc care delivered before introduction of the IDC-OPD programme (T2). Security incidents in December 2015 prompted a period of service suspension (nurse-only care, with drug pick-ups, glucose testing and minimal treatment adjustments) (S1). Complete suspension followed once drug stocks were exhausted (S2). Limited service resumed in April (R1) until full service recommenced from September 2016 (R2) (Table 1).

Table 1. Study Periods for Evaluation of IDC-OPD Programme, Mweso, DRC

Study Period	Description	Dates
Training 1 (T1)	Ad hoc diabetes service following basic staff training	01/01/2014 – 14/03/2015
Training 2 (T2)	IDC-OPD implemented following formal staff training	15/03/2015 – 14/12/2015
Suspend 1 (S1)	Reduction of clinical supervision but monthly drug refills were provided until buffer stocks were exhausted	15/12/2015 – 31/01/2016
Suspend 2 (S2)	No clinical supervision or drugs were provided	01/02/2016 – 14/04/2016
Resume 1 (R1)	The service was resumed without medical	15/04/2016 –

	supervision or quality control	31/08/2016
Resume 2 (R2)	Full service resumed until end of data collection period	01/09/2016 – 09/02/2017

Data

Patients were given a unique identification number on enrolment. Data were recorded in paper-based clinic-held files by clinical staff and transferred to an electronic database by a trained data entry operator on a weekly basis. Missing data were discussed with the nurse manager and gaps were filled during follow-up clinical visits. Single data entry was performed on a password-protected Microsoft Excel software application specifically developed by MSF for this programme. Anonymised exports were transferred to the study team on a monthly basis.

Demographic data on patients' age, gender, occupation, and village of residence were recorded on enrolment. Cardiovascular risk factors (smoking status, current alcohol use), family history of diabetes and year of diabetes diagnosis were recorded. Clinical parameters: body mass index (BMI), blood pressure (BP) measured by manual sphygmomanometer according to local MSF protocols [11], fasting capillary blood glucose (FBG); prescribed diabetes drugs [insulin and/or oral hypoglycaemic drugs (OHGs)]; and diabetes classification (Type I, Type II or other) were recorded at each clinical encounter. Medical review at enrolment and six monthly thereafter was recorded, including biochemical markers (serum creatinine) and examination for complications (visual acuity, cataract, proteinuria, foot check). Numbers of deaths, transfers out of the area and delays in attendance were also documented. The key programme and clinical outcome measured used in the analysis are shown in Table 2.

Table 2: Outcome measures used to determine effect of different programme periods on programme delivery and intermediate clinical outcomes

Category	Variable
Frequency of Visits	Number of visits per month Number of patients seen per month Average visits per patient per month Average days from previous visit Missing data for BP / glycaemia per visit
Clinical Effectiveness	Proportion of visits per month where patients' BP is at target (< 140/90 mmHg) Proportion of visits per month were patients' glycaemia is at target (> 4.2 and ≤ 8.3 mmol/L)
Effect of insulin prescription	Proportion of visits per month where BP of patients prescribed* OHG only is at target Proportion of visits per month where BP of patients prescribed* insulin (+/- OHG) is at target Proportion of visits per month where glycaemia of patients prescribed* OHG only is at target Proportion of visits per month where glycaemia of patients prescribed* insulin (+/-OHG) is at target

*Note: "Prescribed" refers to the prescription record from the previous visit.

Analysis

Basic demographics were analysed using mean and median and were presented with inter-quartile ranges. We assessed the relationship of different study periods with the frequency of visits and the

impact of study periods on intermediate clinical outcomes i.e. per visit attainment of blood pressure (< 140/90 mmHg) and glycaemic (> 4.2 and ≤ 8.3 mmol/L) targets.

To estimate the effect of a period change we calculated the odds ratio (OR) of the odds of having the biomarker under control in a visit in the new period (t) over the odds of having the biomarker controlled in a visit in the previous period (t-1): $OR_t = Odds_t / Odds_{t-1}$. If $OR_t > 1$, this meant that the chances of the biomarker being under control in a visit in period *t* was greater than the chances of the biomarker being under control in a visit in the previous period (*t-1*) (but not necessarily than other periods, *t-2*, *t-3*, etc.). Likewise, $OR_t < 1$ implied a reduction in the chances of having the biomarker under control in a visit during period *t* compared to a visit during the previous period (*t-1*). To estimate these OR we ran a logistic model with period as a categorical variable, suitably coded, and adjusted for sex, age (and square and cube terms) and number of visits of the patient (and square term).

Missing data: Our main analysis used only complete data. Few outcome variable data were missing: less than 3% in BP control (most of it in the pre-training period) and less than 0.3% for glycaemic control (Supplement SM1). There were no missing data for date of visit, sex or age.

Costing data and analysis

For the descriptive cost analysis we took a health services perspective. Key cost items identified from a field visit were grouped into: (a) medicine, (b) supplies, and (c) staff time. Monthly resource use and unit cost data were collected from clinic records (Supplement SM3). Monthly costs for each item were annualised; total cost, cost per visit and cost per patient were reported in Euro (€) for 2014 and 2015.

The study was approved by the Ministry of Health of North Kivu Province and the MSF and London School of Hygiene and Tropical Medicine Ethics Review Boards.

Patient and Public Involvement

Patients were not involved in the design or conduct of this study.

Results

Between January 1st 2014 and February 9th 2017, 243 patients were enrolled in the IDC-OPD programme (Supplement SM2). Median age was 45 years (IQR 32 – 56); 44.6% of the cohort was female. For adults ≥ 18 years (n=219), mean BMI was 21.3 kg/m^2 and 31.1% were underweight (BMI < 18.5 kg/m^2). On enrolment, 8.2% were current smokers; 24.4% reported recent alcohol intake; self-reported medical history included: 9.1% hypertension, 2.2 % CVD, 2.7% tuberculosis (TB) and 8.7% malnutrition. Half were classified clinically as Type 2 diabetic (51%; n=125); 26% (n=62) as Type 1; and 23% (n=56) were either unclassified or classed as "other" (Supplement SM2).

Trends in outcomes and impact of programmatic events

Numbers of visits and appointment intervals increased after the introduction of the systematic approach to diabetes care, which included monthly review appointments for stable patients (T2) (Figure 1; Supplement SM4). During the period of scaled back service (S1), visit numbers initially climbed while the visit interval decreased, which may reflect increased visit frequency due to short-term drug supplies. Once drug buffer stock was exhausted, visit numbers dropped off sharply. Patients may have avoided or were prevented from attending due to security conditions.

Figure 1: Average number of days from previous visit per month for Mweso IDC-OPD service

BP control was consistently better than glycaemic control (of note, patients without diagnosed hypertension were included in the analysis) (Figure 2). By period T2, approximately 80% of visits achieved BP and 60% achieved glycaemic control. There was a notable drop in control of both

parameters during programme suspension with a gradual improvement on resumption. Blood pressure control was consistently better, while glycaemic control was consistently worse, in patients prescribed insulin (+/- OHGs) compared with those prescribed OHGs alone (Supplement SM5), which may be because the former group contained relatively young Type 1 and malnutrition-related diabetics.

Figure 2: Proportion of visits with BP or glycaemia at target by month, Mweso IDC-OPD service

The results of the odds ratio (OR) calculations were unexpected. Odds of attaining BP control appeared to worsen following implementation of the formal IDC-OPD programme (T2 vs. T1), while odds of attaining glucose control improved, perhaps because care was initially focussed on glucose control (Supplement SM6). On scaling back the service (S1), control of both parameters seemed to improve, possibly because the service itself or the subset of patients reaching it during the insecure period were somehow different. Once medications supplies were exhausted (S2), control of both parameters seemed to worsen, but control was regained on service resumption. Stratifying by insulin prescription showed similar results (Supplement SM5).

Costs of providing diabetes care

The total costs of diabetes care in 2014 and 2015 were approximately €32,000 and €26,000 respectively (Table 3). Supplies were the major driver of costs. The main costs in 2014 were for latex gloves, glucometers and glucometer strips, and in 2015 were glucometers, strips and lancets (Supplement SM3). While medication costs increased in 2015 relative to 2014, total costs decreased, largely driven by reduced excess consumption of latex gloves post-training. The cost per-patient per-year dropped from €417 to €183 and the cost per-visit halved from €51 to €24. This was due to the combined effect of increased patient throughput and lower costs in 2015.

Table 3. Costs (€) of diabetes care in 2014 and 2015, Mweso IDC-OPD service

Cost category	2014	% 2014 costs	2015	% 2015 costs
Medicine costs	5,202	16%	7,746	29%
Supply costs	25,435	79%	17,180	65%
Staff costs	1,484	5%	1,484	6%
Total costs	**32,121**	100%	**26,410**	100%
Costs per visit	**51**		**24**	
Costs per patient	**417**		**183**	

Discussion

The programme encountered challenges related to insecurity impeding patient access and continuity of care; patient and provider difficulties with insulin management; and lack of evidence or guidance in managing what we believed to be malnutrition-related diabetes. Despite this, the findings show that glycaemic control was similar or better to that documented in other humanitarian or low-income settings (although different targets were used) and, while it was positively impacted by programmatic changes, control clearly deteriorated during periods of heightened insecurity.[14] Our findings indicate that, in a population previously undergoing regular supervision, a simplified nurse-provided, algorithm-driven service with consistent medication supply may be as effective as close medical supervision in maintaining disease control, particularly during periods of service interruption. Medical input could thus be focused on achieving glycaemic control in patients prescribed insulin, who appeared most affected by service interruption.

We suggest that chronic disease programmes in unstable settings should engage in emergency preparedness, learning from the experience of HIV programmes in similar settings.[20] Preparation may include: emergency response planning; patient triage by vulnerability; provision of patient-held treatment plans and emergency kits; building staff capacity to allow flexibility of roles in crises; establishing alternative communication networks, including technology-facilitated patient support; and medication stockpiling and secure storage.[4,20,21]

The relatively poorer glycaemic control in insulin-prescribed patients may reflect either disease severity or the challenges associated with insulin therapy. Adherence to daily insulin injections is difficult anywhere; in Mweso, patients are challenged by the security, financial and geographical barriers to accessing medications and the recommended diabetes diet.[13] Adjusting insulin doses based on single fasting glucose readings and patients' reported symptoms proved challenging for clinicians.

There is limited, although growing, evidence on the incidence, prevalence and characterisation of diabetes in Sub-Saharan Africa, which our findings broadly reflect.[15] Several reviews have described controversial "atypical" forms of diabetes, including *"malnutrition-related diabetes"* in Sub-Saharan Africa. [9,16] Local prevalence studies support its existence in the DRC, which is in keeping with the high proportion of underweight adults and "unclassified" diabetics in our cohort.[10,17] Little evidence exists to guide either malnutrition-related diabetes care or the effective management of insulin in humanitarian settings, particularly in the absence of home or community-based glycaemia testing.[2,5]

The introduction of the IDC-OPD programme, and associated training, contributed to reducing total costs of care by approximately 20% and per patient per year (PPPY) costs by 44% from 2014 to 2015. To our knowledge, there is no available literature to compare costs of diabetes care delivered in a similar setting. However, the 2015 PPPY cost reported here is far lower than that reported by

PEPFAR and others to deliver chronic HIV care programmes in low and middle income Sub-Saharan Africa countries.[18,19]

Future research is needed in complex humanitarian settings to evaluate simplified, task-shared models of diabetes care; to optimise insulin management without regular finger-stick glycaemia testing; and to evaluate emergency preparedness plans and technology-facilitated remote patient support.[2,4,7,9,21] This should include the cost-effectiveness of different models of diabetes care.

Limitations

Our study was limited by the relatively small sample size and lack of control group for comparison. We did not explore per patient control of clinical parameters over time, control by type of diabetes (or by age), or appropriateness of insulin prescribing. Care for gestational diabetes was not addressed since this took place within antenatal care. Our costing analysis was descriptive and thus we cannot comment on the cost-effectiveness of the programme. Costing data are presented as average annual costs and did not explore the impact of the various programme periods on costs or patient-level costs. While our findings may not be generalizable to other complex humanitarian settings or to other providers' diabetes programmes in the DRC, our study contributes knowledge on key challenges and suggests solutions, which may be more broadly applicable.

Conclusion

Our results help develop the sparse knowledge on prevalence and characterisation of diabetes in Sub-Saharan Africa. They demonstrate that diabetes care is feasible even in complex humanitarian emergencies, and at a cost that is lower than chronic HIV care. The results also indicate that the Mweso IDC-OPD programme could be further simplified to involve drug collection along with nurse-led, algorithm-guided treatment adjustment. We suggest that chronic disease programmes in unstable settings should engage in emergency preparedness, learning from the experience of HIV programmes in similar settings. Future research is needed to evaluate simplified, task-shared models

of diabetes care and management; and to evaluate emergency preparedness plans and technology-facilitated remote patient support.

List of Abbreviations

BMI	Body Mass Index
BP	Blood Pressure
DM	Diabetes Mellitus
DRC	Democratic Republic of Congo
HIV	Human Immunodeficiency Virus
IDC-OPD	Integrated Diabetic Clinic within Hospital Outpatient Department
MSF	Médecins sans Frontières
OHG	Oral Hypoglycaemic Drugs
OR	Odds Ratio
PPPY	Per Patient Per Year

Declarations

Ethics approval and consent to participate

This study was approved by the Ministry of Health of North Kivu Province, DRC, by the MSF Ethics Review Board, and the Ethics Committee of the London School of Hygiene and Tropical Medicine. Information sheets on the clinic walls provided details of the evaluation; no specific consent was sought from patients for use of their routine clinical data.

Authors' contributions

KJ and BR were involved in study conception; EA, GC, KJ, DPM, PP and BR contributed to study design and interpretation of data. DPM and ZS analysed the data. MB contributed to data collection. EA drafted the manuscript and all authors reviewed drafts and approved the final version.

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Competing Interests

The authors declare that they have no competing interests.

Data Sharing

The datasets are available from MSF on request by researchers who fulfil certain criteria and under the auspices of a data sharing agreement.

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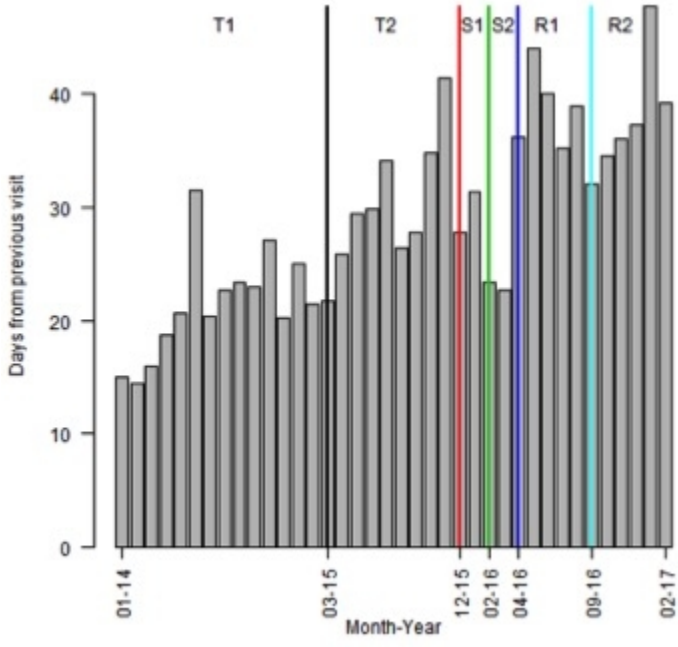

Figure 1: Average number of days from previous visit per month for Mweso IDC-OPD service

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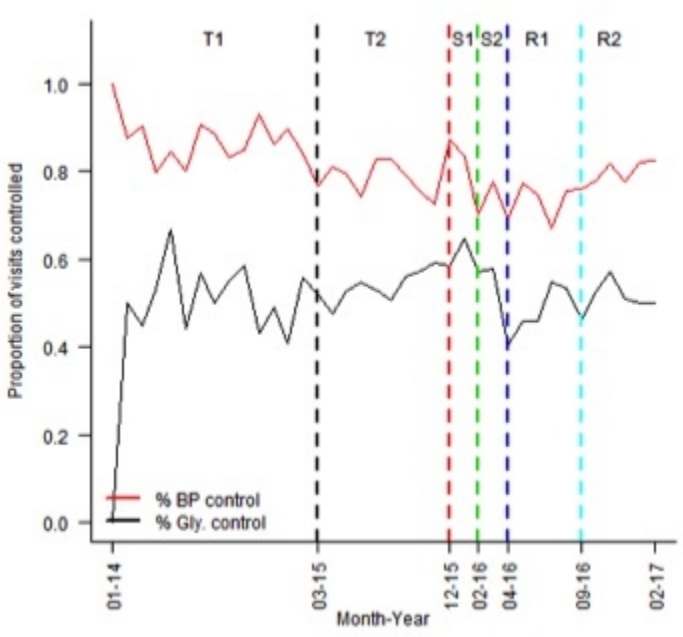
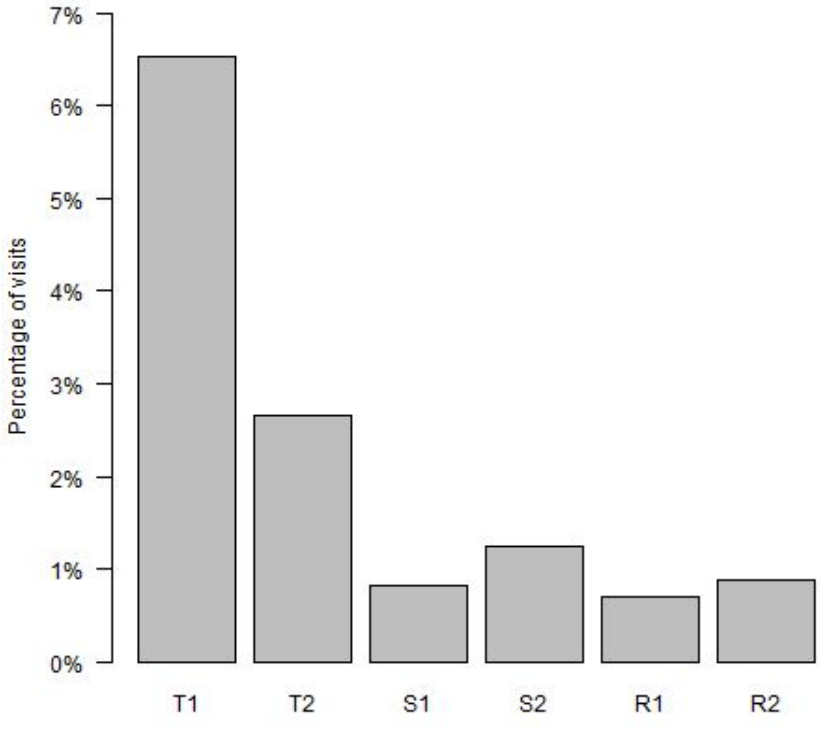


Figure 2: Proportion of visits with BP or glycaemia at target by month, Mweso IDC-OPD service

127x113mm (72 x 72 DPI)

SM1. Proportion of visits with missing data for either blood pressure or glycaemia measurements, IDC-OPD Programme, Mweso, DRC



Note: Definitions of study periods T1 – R2 are described in Supplementary Data S1

S2. Baseline characteristics of 243 patients on enrolment into Mweso IDC-OPD service

Variable	Total	(%)	DM-1	(%)	DM-2	(%)	Other/NA	(%)
Patients (N)	243		62		125		56	
Age								
<18	24	(9.9%)	19	(30.6%)	0	(0.0%)	5	**(8.9%)**
18-40	74	(30.5%)	39	(62.9%)	20	(16.0%)	15	**(26.8%)**
41-60	112	(46.1%)	3	(4.8%)	80	(64.0%)	29	**(51.8%)**
>60	33	(13.6%)	1	(1.6%)	25	(20.0%)	7	**(12.5%)**
Sex								
Male	134	(55.1%)	34	(54.8%)	70	(56.0%)	30	**(53.6%)**
Female	108	(44.4%)	28	(45.2%)	55	(44.0%)	25	**(44.6%)**
No data	1	(0.4%)	0	(0.0%)	0	(0.0%)	1	**(1.8%)**
Occupation								
Labourer	121	(49.8%)	29	(46.8%)	85	(68.0%)	7	**(12.5%)**
Office worker	19	(7.8%)	2	(3.2%)	11	(8.8%)	6	**(10.7%)**
Student	8	(3.3%)	8	(12.9%)	0	(0.0%)	0	**(0.0%)**
Unable to work	11	(4.5%)	7	(11.3%)	3	(2.4%)	1	**(1.8%)**
Other	48	(19.8%)	15	(24.2%)	26	(20.8%)	7	**(12.5%)**
No data	36	(14.8%)	1	(1.6%)	0	(0.0%)	35	**(62.5%)**
Medical History								
CVD								
Yes	5	(2.1%)	1	(1.6%)	3	(2.4%)	1	**(1.8%)**
No data	24	(9.9%)	0	(0.0%)	0	(0.0%)	24	**(42.9%)**
Hypertension								
Yes	20	(8.2%)	0	(0.0%)	18	(14.4%)	2	**(3.6%)**
No data	25	(10.3%)	0	(0.0%)	1	(0.8%)	24	**(42.9%)**
Tuberculosis								
Yes	6	(2.5%)	1	(1.6%)	5	(4.0%)	0	**(0.0%)**
No data	24	(9.9%)	0	(0.0%)	0	(0.0%)	24	**(42.9%)**
Malnutrition								
Yes	19	(7.8%)	15	(24.2%)	2	(1.6%)	2	**(3.6%)**
No data	24	(9.9%)	0	(0.0%)	0	(0.0%)	24	**(42.9%)**
Family Hx of DM								
Yes	35	(14.4%)	6	(9.7%)	23	(18.4%)	6	**(10.7%)**
No data	24	(9.9%)	0	(0.0%)	0	(0.0%)	24	**(42.9%)**

Patients >=18 years(N)*	219		43		125		51	
Smoking								
Yes	18	(8.2%)	1	(2.3%)	16	(12.8%)	1	**(2.0%)**
No data	21	(9.6%)	0	(0.0%)	0	(0.0%)	21	**(41.2%)**
Alcohol								
Yes	50	(22.8%)	12	(27.9%)	32	(25.6%)	6	**(11.8%)**
No data	33	(15.1%)	0	(0.0%)	1	(0.8%)	32	**(62.7%)**
BMI								
<18.5	68	(31.1%)	23	(53.5%)	34	(27.2%)	11	**(21.6%)**
18.5-24.9	96	(43.8%)	15	(34.9%)	59	(47.2%)	22	**(43.1%)**
25.0-29.9	41	(18.7%)	5	(11.6%)	27	(21.6%)	9	**(17.6%)**
>=30	7	(3.2%)	0	(0.0%)	5	(4.0%)	2	**(3.9%)**
No data	7	(3.2%)	0	(0.0%)	0	(0.0%)	7	(13.7%)

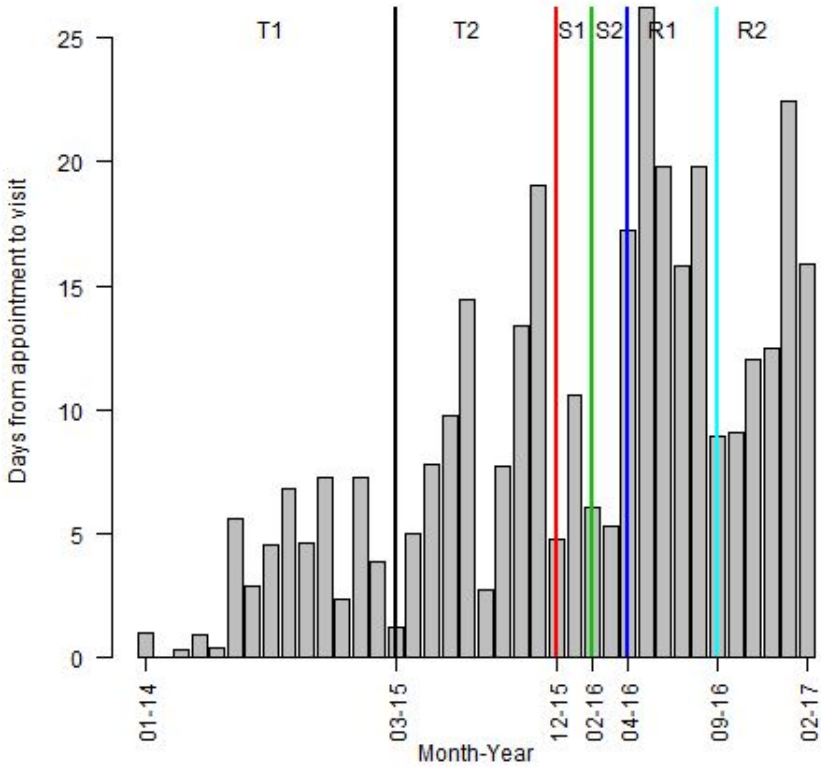
Note: For smoking, alcohol and BMI, denominators included only patients aged 18 years or above.

SM3. Monthly resource use associated with IDC-OPD in Mweso Hospital, North Kivu, DRC

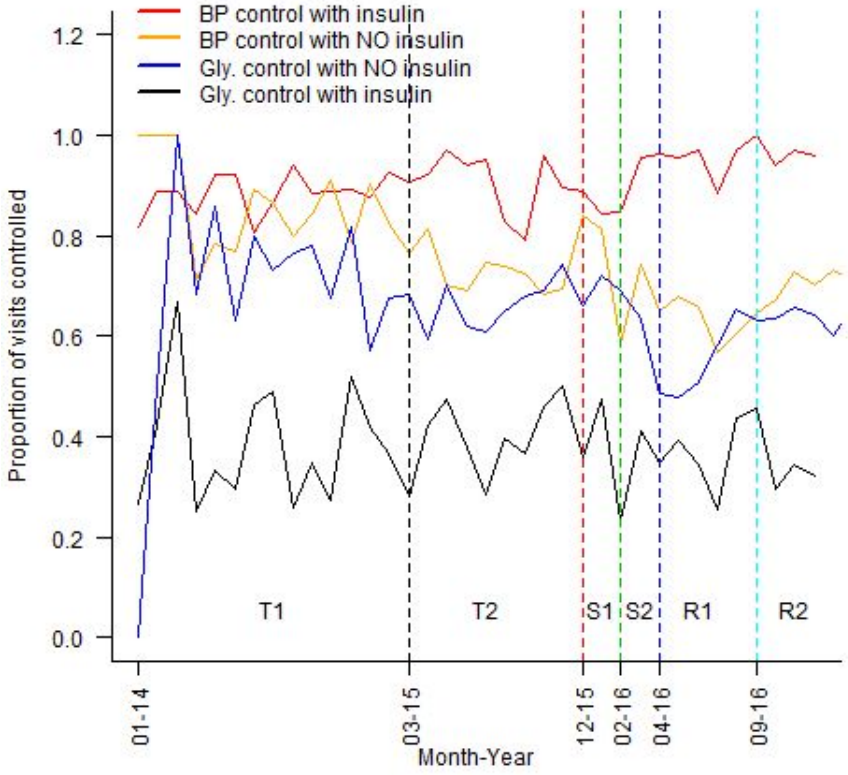
Items	Unit	2014	2015
Medicine			
INSULIN ISOPHANE (NPH), human, 100 UI/ml, 10 ml, vial	6.300	40	40
INSULIN RAPID, human, 100 IU/ml, 10 ml, vial	6.300	8	8
INSULIN, 100IU/ml, BIPHASIC 30, human, 10ml, vial	13.610	10	10
METFORMIN hydrochloride, 500 mg, tab.	0.014	5,300	12,000
GLIBENCLAMIDE, 5 mg, tab.	0.005	750	3,600
HYDROCHLOROTHIAZIDE, 50 mg, tab.	0.003	0	300
GLUCOSE HYPERTONIC, 50%, 50 ml, vial	0.556	75	6
AMITRIPTYLINE hydrochloride, 25 mg, tab.	0.006	200	750
ACETYLSALICYLIC acid (aspirin), 75 mg, tab.	0.005	0	2,000
AMLODIPINE 5mg, tabs.	0.018	0	300
Supplies			
GLUCOMETER, blood glucose monitor (Nova StatStrip) + strips	96.705	5	10
(glucometer Nova StatStrip) STRIP ref. 42214	0.230	2,000	4,000
SYRINGE, s.u., Luer, insulin, 100 IU/1 ml + fixed needle	0.079	2,000	4,000
(spectrophotometer) KIT, DOSAGE CREATININE, Liquicolor 200ml	4.830	3.5	3.5
THERMOMETER, ELECTRONIC, accuracy 0.1§ C + case	1.110	20	3
SPHYGMOMANOMETER, one-hand manometer, Velcro, adult	26.000	0	1
TEST, URINE, pH,dens,prot,gluc,ket,blood,nit,leuc, 1 strip	0.197	100	200
REUSABLE SHARPS CONTAINER (RSC), 1.2 litre	44.750	1	1
CONTAINER, SAMPLE, plast., 60ml, non sterile, urine	0.083	1,700	200
LANCET, s.u., sterile, standard point	0.006	900	4,000
GLOVE, EXAMINATION, latex, s.u. non sterile, medium	0.025	50,000	500
Staff time (days allocated to diabetes care)*			
MSF Medical doctor	1,350	1	1
MSF Nurse	900	1	1
BCZ Nurse	239	1	1
MSF psychosocial worker	1,422	0.125	0.125
1 Nutritionist (MSF)	864	0.0625	0.0625

*Note: Staff time costs assumed 22 full-time working days per month.

SM4. Average days' delay in attendance since planned appointment per month of IDC-OPD service, Mweso, DRC



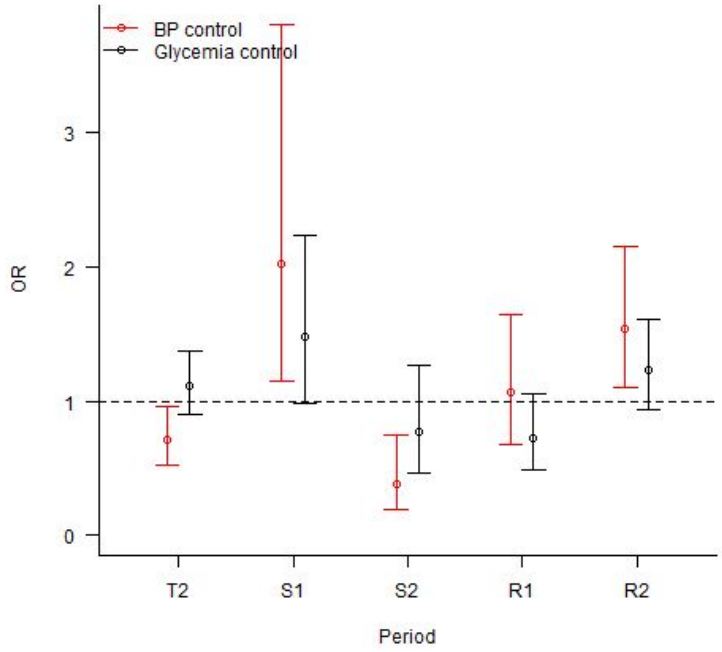
SM5. Proportion of visits at target for BP and glycaemic control, stratified by insulin prescription per month of IDC-OPD service, Mweso, DRC



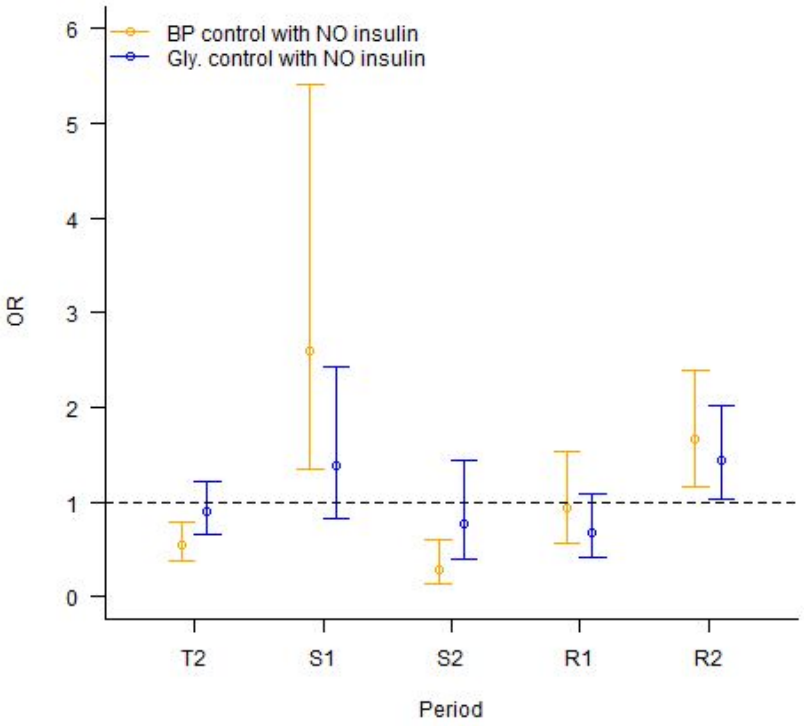
Note: Patients were categorised by whether they were prescribed insulin [+/- oral hypoglycaemic (OHG) drugs]) or OHG drugs alone at their last recorded visit. The former group would have included Type 1 diabetics, Type 2 diabetics with more advance illness requiring a combination of OHG and insulin, and those with an intermediate type of diabetes, presenting with high insulin requirements in the absence of diabetic ketoacidosis, which we postulated represented "malnutrition-related diabetes". The latter group were likely to include Type 2 diabetics.

SM6. Impact (OR) on BP and glycaemic control of study period over previous period, unstratified (A) and stratified by insulin prescription (B and C) per month of IDC-OPD service, Mweso, DRC

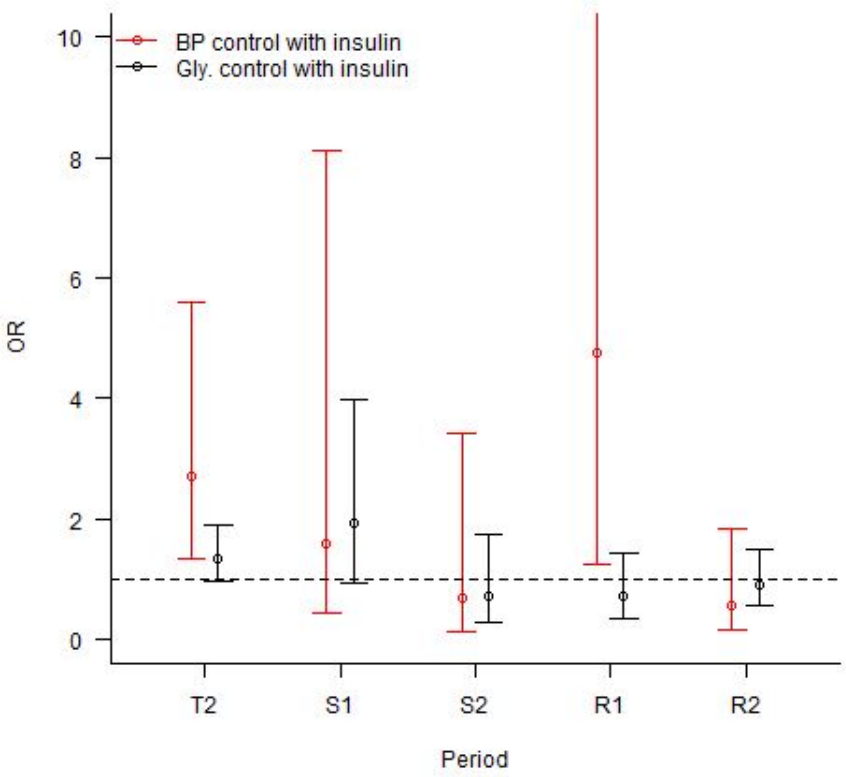
A. Impact (OR) on BP and glycaemia in all patients (not stratified by insulin prescription)



B. Impact (OR) on BP and glycaemia in patients on oral hypoglycaemic drugs only



C. Impact (OR) on BP and glycaemia in patients prescribed insulin (+/- OHG)



STROBE Statement—Checklist of items that should be included in reports of ***cross-sectional studies***

Study Title: Management of diabetes and associated costs in a complex humanitarian setting in the Democratic Republic of Congo.

	Item No	Recommendation	Page No
Title and abstract	1	(*a*) Indicate the study's design with a commonly used term in the title or the abstract	
		(*b*) Provide in the abstract an informative and balanced summary of what was done and what was found	2
Introduction			
Background/rationale	2	Explain the scientific background and rationale for the investigation being reported	4
Objectives	3	State specific objectives, including any prespecified hypotheses	5,6
Methods			
Study design	4	Present key elements of study design early in the paper	5,7,8
Setting	5	Describe the setting, locations, and relevant dates, including periods of recruitment, exposure, follow-up, and data collection	4 -7
Participants	6	(*a*) Give the eligibility criteria, and the sources and methods of selection of participants	5,7,8
Variables	7	Clearly define all outcomes, exposures, predictors, potential confounders, and effect modifiers. Give diagnostic criteria, if applicable	7
Data sources/ measurement	8*	For each variable of interest, give sources of data and details of methods of assessment (measurement). Describe comparability of assessment methods if there is more than one group	*7,9*
Bias	9	Describe any efforts to address potential sources of bias	8
Study size	10	Explain how the study size was arrived at	6
Quantitative variables	11	Explain how quantitative variables were handled in the analyses. If applicable, describe which groupings were chosen and why	8, 9
Statistical methods	12	(*a*) Describe all statistical methods, including those used to control for confounding	8
		(*b*) Describe any methods used to examine subgroups and interactions	n/a
		(*c*) Explain how missing data were addressed	9; Supp Mat1
		(*d*) If applicable, describe analytical methods taking account of sampling strategy	8
		(*e*) Describe any sensitivity analyses	n/a
Results			
Participants	13*	(a) Report numbers of individuals at each stage of study—eg numbers potentially eligible, examined for eligibility, confirmed eligible, included in the study, completing follow-up, and analysed	10
		(b) Give reasons for non-participation at each stage	n/a
		(c) Consider use of a flow diagram	n/a
Descriptive data	14*	(a) Give characteristics of study participants (eg demographic, clinical, social) and information on exposures and potential confounders	Supp Mat 2
		(b) Indicate number of participants with missing data for each variable of interest	Supp Mat 1

Outcome data	15*	Report numbers of outcome events or summary measures	n/a
Main results	16	(*a*) Give unadjusted estimates and, if applicable, confounder-adjusted estimates and their precision (eg, 95% confidence interval). Make clear which confounders were adjusted for and why they were included	8
		(*b*) Report category boundaries when continuous variables were categorized	Supp Mat 2
		(*c*) If relevant, consider translating estimates of relative risk into absolute risk for a meaningful time period	n/a
Other analyses	17	Report other analyses done—eg analyses of subgroups and interactions, and sensitivity analyses	n/a
Discussion			
Key results	18	Summarise key results with reference to study objectives	10-12
Limitations	19	Discuss limitations of the study, taking into account sources of potential bias or imprecision. Discuss both direction and magnitude of any potential bias	14
Interpretation	20	Give a cautious overall interpretation of results considering objectives, limitations, multiplicity of analyses, results from similar studies, and other relevant evidence	12-14
Generalisability	21	Discuss the generalisability (external validity) of the study results	14
Other information			
Funding	22	Give the source of funding and the role of the funders for the present study and, if applicable, for the original study on which the present article is based	16

*Give information separately for exposed and unexposed groups.

Note: An Explanation and Elaboration article discusses each checklist item and gives methodological background and published examples of transparent reporting. The STROBE checklist is best used in conjunction with this article (freely available on the Web sites of PLoS Medicine at http://www.plosmedicine.org/, Annals of Internal Medicine at http://www.annals.org/, and Epidemiology at http://www.epidem.com/). Information on the STROBE Initiative is available at www.strobe-statement.org.

BMJ Open

Management of diabetes and associated costs in a complex humanitarian setting in the Democratic Republic of Congo: a retrospective cohort study

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Title: Management of diabetes and associated costs in a complex humanitarian setting in the Democratic Republic of Congo: a retrospective cohort study.

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Word Count: 4000

Keywords: Democratic Republic of Congo, Subsaharan Africa, diabetes, hypertension, noncommunicable disease, humanitarian, conflict, care model, management, programme, chronic care, outpatient, hospital care, task shifting, cost, economic.

Abstract

Objective: We aimed to evaluate an Integrated Diabetic Clinic within a Hospital Outpatient Department (IDC-OPD) in a complex humanitarian setting in North Kivu, Democratic Republic of Congo. Specific objectives were to: (i) analyse diabetes intermediate clinical and programmatic outcomes (blood pressure/glycaemic control, visit volume and frequency); (ii) explore the association of key insecurity and related programmatic events with these outcomes; and (iii) describe incremental IDC OPD programme costs.

Design: Retrospective cohort analysis of routine programmatic data collected from January 2014 - February 2017; analysis of programme costs for 2014/2015.

Setting: Outpatient diabetes programme in Mweso hospital, supported by Médecins sans Frontières, in North Kivu, Demographic Republic of Congo.

Participants: Diabetes patients attending IDC-OPD.

Outcome measures: Intermediate clinical and programmatic outcome trends (blood pressure/ glycaemic control; visit volume/frequency); incremental programme costs.

Results: Of 243 diabetes patients, 44.6% were women, median age was 45 (IQR 32-56); 51.4% were classified Type 2. On introduction of IDC-OPD, glucose control improved and patient volume and visit interval increased. During insecurity, control rates were initially maintained by a nurse-provided, scaled-back service, while patient volume and visit interval decreased. Following service suspension due to drug stock-outs, patients were less likely to achieve control;, improving on service resumption. Total costs decreased 20% from 2014 (€32,121) to 2015 (€26,410). Annual cost per patient dropped from €417 in 2014 to €183 in 2015 due to reduced supply costs and increased patient numbers.

Conclusions: In a chronic conflict setting, we documented that control of diabetes intermediate outcomes was achievable during stable periods. During insecure periods, a simplified, nurse-led model maintained control rates until drug stock-outs occurred. Incremental per patient annual costs were lower than chronic HIV care costs in low-income settings. Future operational research should define a simplified diabetes care package including emergency preparedness.

Strengths and Limitations

- This is the first study of its kind to examine diabetes intermediate clinical outcomes and programme costs in a complex humanitarian setting in sub-Saharan Africa.
- Using routine clinical and programmatic data collected in a protracted conflict setting, we estimated the effect of insecurity and related programmatic changes on diabetes intermediate clinical outcomes, which to our knowledge, has not been addressed in the literature to date.
- The study was limited by the relatively small sample size and lack of control group for comparison.
- The costing analysis was descriptive and based on aggregate data and so neither the cost-effectiveness of the programme nor patient-level costs could be determined.

Title: Management of diabetes and associated costs in a complex humanitarian setting in the Democratic Republic of Congo: a retrospective cohort study.

Background

Over the past 40 years, diabetes prevalence has increased sharply worldwide, particularly in low and middle income countries (LMICs).[1] However, data on the burden and needs related to diabetes and other non-communicable diseases (NCDs) are scarce from conflict-affected countries, particularly those in Sub-Saharan Africa.[1,2] Humanitarian actors have been slow to prioritise diabetes treatment in disaster and post-conflict settings despite reporting increasing presentations of diabetic patients within their programmes.[3–6] This is due to lack of knowledge on local diabetes epidemiology, limited research on diabetes management or outcomes in crisis settings; a lack of programmatic and policy guidance or tools to support diabetes care in such settings; prioritisation of other health needs; and also a perception that diabetes care is complex and expensive. [2,3,6–8]

The humanitarian situation in Democratic Republic of Congo (DRC) is considered one of the most complex and challenging worldwide. Prolonged conflict over two decades has resulted in over 5 million deaths, over 4.5 million internally displaced people, the exodus of over 800,000 refugees, and ongoing political and social instability. [9,10] The health system, weakened by prolonged conflict, is challenged by competing health needs in a country ranked 176 of 189 on the human development index despite holding rich natural resources. [11]

On this backdrop, diabetes prevalence is increasing, currently estimated at 4.0 - 5.4%. [12–14] While some factors implicated in the global rise in diabetes prevalence hold true in DRC (demographic change, urbanisation, changing diets etc.) chronic conflict and political instability add additional

complexity. Recent reviews and ethnographic evidence point to a link between chronic food insecurity, childhood malnutrition and diabetes. [13,15,16] In DRC, 43% of children under 5 years are chronically malnourished and levels of food insecurity have risen sharply, with millions subsisting on World Food Programme rations. [17] Recent evidence also supports an association between chronic perceived stress and diabetes onset, while patients with diabetes in humanitarian settings focus on suffering and loss as a cause of their illness. [16,18] Furthermore, in humanitarian crises, people with diabetes are at increased risk of complications and death due to treatment interruption and precarious access to food and water. [2,6]

Médecins sans Frontières (MSF), a medical humanitarian organisation, has supported healthcare delivery in Mweso, North Kivu, in collaboration with the Ministry of Health since 2008. North Kivu is a rural, impoverished area bordering Rwanda with an estimated population of 365,000. It remains a flash point in the on-going conflict between shifting rebel groups and government forces, which has been characterised by brutal violence against civilians and destruction of lives and livelihoods. Outbreaks of violence since 2016 have resulted in recurrent waves of population displacement; North Kivu alone hosts 17 internally displaced person camps. MSF supports health services in 4 out of 23 Primary Health Care clinics and in Mweso hospital within Masisi District. Mweso hospital serves a catchment area of approximately 145,000 people, with about 65,000 recipients of care living in the immediate vicinity of the hospital.

While a national diabetes programme exists in DRC, available diabetes care is concentrated at hospital level in major cities. [19] In response to growing patient and provider needs in Mweso, MSF implemented a hospital-outpatient based diabetes programme in March 2015, the Integrated Diabetic Clinic within Hospital Outpatient Department (IDC-OPD) in place of the ad hoc care previously undertaken. The IDC-OPD was integrated at the clinical level into usual outpatient activities, with pre-existing staff trained to provide this additional service. [20] The programme comprised a nurse-led, multi-disciplinary model, using locally adapted clinical guidelines, patient

counselling materials and data collection tools, accompanied by three days of specialist training.[21] The clinic team included: a nurse supervisor, nursing assistant, two doctors, a nutritionist, and education and psychosocial support officers. Diabetes was diagnosed according to World Health Organization (WHO) guidelines using repeated fasting capillary glucose. Most patients were identified as diabetic and enrolled after acute hospital presentation, while some were identified via the Mweso outpatient department or referring primary care clinics.

Patients received a detailed enrolment assessment, monthly nurse-led follow-up and 6-monthly medical review. The programme included context-adapted dietary advice (accounting for locally available and affordable foods and customs) and psychosocial support, including clinician-moderated peer support groups and involvement of family or friends as treatment supporters. The psychosocial aspects of patients and providers managing diabetes are discussed in a related paper, with major themes from the patient perspective including the difficulty adhering to the recommended diet and barriers to clinic access during outbreaks of violence. [22] Each patient was given a clinic-held patient file and patient-held passport to facilitate safe passage when armed groups impeded their travel. Clinical guidelines were adapted from MSF, WHO and other international guidance. [23] Patient educational tools (disease and diet education leaflets) were adapted from Santé Diabète [24], a Malian Non-Governmental Organisation, and generic medications, included on MSF's Essential Drugs List, were prescribed. Insulin doses were adjusted using single fasting capillary blood glucose readings and patients' reported symptoms of hypo- or hyperglycaemia in the absence of home glucose monitoring. Insulin-dependent patients were prescribed human insulin, delivered via needle and syringe, and advised to store this at home in a clay pot (refrigeration was unavailable), recommended as a safe alternative in similar contexts. [25]

In early 2016, outbreaks of armed violence restricted movement of patients and supplies. Direct attacks on MSF staff and facilities, including an armed robbery and abductions, led to withdrawal of the international staff from Mweso and temporary scaling back of the programme, with local nursing

staff dispensing medications to any patients reaching the clinic. Later, the programme was suspended for a period of six weeks when supply routes were entirely blocked and drug supplies were exhausted.

A mixed methods evaluation of the Mweso IDC-OPD programme was undertaken by MSF and included a qualitative evaluation exploring patient and provider clinical and psychosocial challenges, presented elsewhere [22]; and a retrospective review of quantitative programmatic data and cost data collected as part of routine care in a chronic conflict zone, reported here. The overall objective of this paper is to evaluate an Integrated Diabetic Clinic within a Hospital Outpatient Department (IDC-OPD) in a complex humanitarian setting in North Kivu in Democratic Republic of Congo. The specific objectives are to: (i) analyse diabetes intermediate clinical and programmatic outcomes (blood pressure/glycaemic control, visit frequency and volume); (ii) explore the association of key insecurity and related programmatic events with these outcomes; and (iii) describe incremental IDC OPD programme costs.

Methods

It has been acknowledged that traditional experimental and evaluation methods may be unfeasible, inappropriate or even unethical to apply in humanitarian settings [26]. Therefore, we have used a pragmatic approach to utilising programmatic data, with an open cohort design. For the outcome analysis, we conducted a retrospective analysis of routine data of enrolled adults aged ≥18 years from January 2014 to February 2017, examining trends in diabetes outcomes and their association with key programmatic events. The study period was divided into five phases, defined by programmatic changes or periods of heightened insecurity (which impacted service delivery due to staff evacuation, supply chain interruption and reduced patient access). Period T1 refers to ad-hoc care delivered before introduction of the IDC-OPD programme (T2). Security incidents in December 2015 prompted a period of service suspension (nurse-only care, with drug pick-ups, glucose testing

and minimal treatment adjustments) (S1). Complete suspension followed once drug stocks were exhausted (S2). Limited service resumed in April (R1) until full service recommenced from September 2016 (R2) (Table 1).

Table 1. Study Periods for Evaluation of IDC-OPD Programme, Mweso, DRC

Study Period	Description	Dates
Training 1 (T1)	Ad hoc diabetes service following basic staff training	01/01/2014 – 14/03/2015
Training 2 (T2)	IDC-OPD implemented following formal staff training	15/03/2015 – 14/12/2015
Suspend 1 (S1)	Nurse-provided care without medical supervision; monthly drug refills provided until buffer stocks were exhausted	15/12/2015 – 31/01/2016
Suspend 2 (S2)	No clinical supervision or drugs were provided	01/02/2016 – 14/04/2016
Resume 1 (R1)	The service was resumed without medical supervision or quality control	15/04/2016 – 31/08/2016
Resume 2 (R2)	Full service resumed until end of data collection period	01/09/2016 – 09/02/2017

Data

Patients were given a unique identification number on enrolment. Data were recorded in paper-based clinic-held files by clinical staff and transferred to an electronic database by a trained data entry operator on a weekly basis. Missing data were discussed with the nurse manager and gaps were filled during follow-up clinical visits. Single data entry was performed on a password-protected

Microsoft Excel software application specifically developed by MSF for this programme. Anonymised exports were transferred to the study team on a monthly basis.

Demographic data on patients' age, gender, occupation, and village of residence were recorded on enrolment. Cardiovascular risk factors (smoking status, current alcohol use), family history of diabetes, year of diabetes diagnosis and self-reported history of childhood malnutrition and/or tuberculosis were recorded. Clinical parameters: body mass index (BMI), blood pressure (BP) measured by manual sphygmomanometer according to local MSF protocols [21], fasting capillary blood glucose (FBG); prescribed diabetes drugs [insulin and/or oral hypoglycaemic drugs (OHGs)]; and diabetes classification (Type I, Type II or other) were recorded at each clinical encounter. Medical review at enrolment and six monthly thereafter was recorded, including biochemical markers (serum creatinine) and examination for complications (visual acuity, cataract, proteinuria, foot check). Numbers of deaths, transfers out of the area and delays in attendance were also documented. The key intermediate clinical outcome and programme measures used in the analysis are shown in Table 2.

Table 2: Outcome measures used to determine effect of different programme periods on programme delivery and intermediate clinical outcomes

Category	Variable
Intermediate Clinical Outcomes	Proportion of visits per month where patients' BP is at target (< 140/90 mmHg) Proportion of visits per month were patients' blood glucose is at target (> 4.2 and ≤ 8.3 mmol/L)
Number and frequency of visits	Number of visits per month Number of patients seen per month

	Average visits per patient per month Average days from previous visit Missing data for BP / glycaemia per visit

Analysis

Basic demographics were analysed using mean and median and were presented with inter-quartile ranges. We assessed the relationship of different study periods with the frequency of visits and the impact of study periods on intermediate clinical outcomes i.e. per visit attainment of blood pressure (< 140/90 mmHg) and glycaemic (> 4.2 and ≤ 8.3 mmol/L) targets.

To estimate the effect of a period change we calculated the odds ratio (OR) of the odds of having the biomarker under control in a visit in the new period (t) over the odds of having the biomarker controlled in a visit in the previous period (t-1): $OR_t = Odds_t / Odds_{t-1}$. If $OR_t > 1$, this meant that the chances of the biomarker being under control in a visit in period *t* was greater than the chances of the biomarker being under control in a visit in the previous period (*t-1*) (but not necessarily than other periods, *t-2*, *t-3*, etc.). Likewise, $OR_t < 1$ implied a reduction in the chances of having the biomarker under control in a visit during period *t* compared to a visit during the previous period (*t-1*). To estimate these OR we ran a logistic model with period as a categorical variable, suitably coded, and adjusted for sex, age (and square and cube terms) and number of visits of the patient (and square term). The models were stratified by whether the patient was prescribed insulin (+/- oral hypoglycaemic agents) at the previous visit.

Missing data: Our main analysis used only complete data; records with missing data were excluded. Few outcome variable data were missing: less than 3% in BP control (most of it in the pre-training

period) and less than 0.3% for glycaemic control (Supplement SM1). There were no missing data for date of visit, sex or age.

Costing data and analysis

For the descriptive, incremental cost analysis we took a health services perspective. Information related to the nature, location and mode of delivery of the NCD services was collected during a field visit in December 2015 by the study team and was supplemented by informal interviews with clinical and administrative staff. A data analysis tool was designed to collate the relevant financial costs for the study period 2014 -2015 from routine programme documents and standard MSF tools including budget, human resources, drug consumption monitoring, logistics/supply tools, clinic records and programme reports. For salary costs, we included the incremental costs of an MSF-employed medical doctor and nurse and an MOH-employed nurse (with salary supplement paid by MSF) dedicating one day, two psychosocial workers dedicating one hour and a nutritionist dedicating 30 minutes per month to the IDC-OPD service (based on 22 working days per month). Hence, most costs were related to drugs, equipment, disposables and stationary costs. Key cost items were grouped into: (a) medicine, (b) supplies, and (c) staff time. Monthly resource use and unit cost data were recorded and annualised (Supplement SM2); annual total cost, cost per visit and cost per patient were reported in Euro (€) for 2014 before formal implementation of the IDC-OPD programme and 2015 during full implementation.

The study was approved by the Ministry of Health of North Kivu Province, DRC, and the Médecins sans Frontières Ethics Review Board (ID 1542).

Patient and Public Involvement

Patients were not involved in the design or conduct of this study.

Results

Between January 1st 2014 and February 9th 2017, 243 patients were enrolled in the IDC-OPD programme (Supplement SM3). Median age was 45 years (IQR 32 – 56); 44.6% of the cohort was female. For adults ≥ 18 years (n=219), mean BMI was 21.3 kg/m^2 and 31.1% were underweight (BMI < 18.5 kg/m^2). On enrolment, 8.2% were current smokers; 24.4% reported recent alcohol intake; self-reported medical history included: 9.1% hypertension, 2.2 % CVD, 2.7% tuberculosis (TB) and 8.7% malnutrition. Half were classified clinically as Type 2 diabetic (51%; n=125); 26% (n=62) as Type 1; and 23% (n=56) were either unclassified or classed as "other" (Supplement SM3).

Trends in outcomes and impact of programmatic events

Numbers of visits and appointment intervals increased after the introduction of the systematic approach to diabetes care, which included monthly review appointments for stable patients (T2) (Figure 1; Supplement SM4). During the period of scaled back service (S1), visit numbers initially climbed while the visit interval decreased, which may reflect increased visit frequency due to short-term drug supplies. Once drug buffer stock was exhausted, visit numbers dropped off sharply. Patients may have avoided or were prevented from attending due to security conditions.

Figure 1: Average number of days from previous visit per month for Mweso IDC-OPD service

BP control was consistently better than glycaemic control (of note, patients without diagnosed hypertension were included in the analysis) (Figure 2). By period T2, approximately 80% of visits achieved BP and 60% achieved glycaemic control. There was a notable drop in control of both parameters during programme suspension with a gradual improvement on resumption. Blood pressure control was consistently better, while glycaemic control was consistently worse, in patients prescribed insulin (+/- OHGs) compared with those prescribed OHGs alone (Supplement SM5), which

may be because the former group contained relatively young Type 1 and malnutrition-related diabetics.

Figure 2: Proportion of visits with BP or glycaemia at target by month, Mweso IDC-OPD service

The results of the odds ratio (OR) calculations were unexpected. Odds of attaining BP control appeared to worsen following implementation of the formal IDC-OPD programme (T2 vs. T1), while odds of attaining glucose control improved, perhaps because care was initially focussed on glucose control (Supplement SM6). On scaling back the service (S1), control of both parameters seemed to improve, possibly because the service itself or the subset of patients reaching it during the insecure period were somehow different. Once medications supplies were exhausted (S2), control of both parameters seemed to worsen, but control was regained on service resumption. Stratifying by insulin prescription showed similar results (Supplement SM5).

Costs of providing diabetes care

The total costs of diabetes care in 2014 and 2015 were approximately €32,000 and €26,000 respectively (Table 3). Supplies were the major driver of costs each year. The greatest costs in 2014 were for latex gloves, glucometers and glucometer strips; in 2015 they were for glucometers, strips and lancets (Supplement SM3). While medication costs increased in 2015 relative to 2014, staff costs remained unchanged, and total costs decreased, largely driven by reduced excess consumption of latex gloves after it was identified during the IDP-OPD training sessions. The total number of patients and number of visits increased significantly from 2014 to 2015, rising from 77 and 626 to 144 and 1033, respectively. Thus, cost per-patient per-year (PPPY) dropped from €417 to €183 and cost per-visit was halved from €51 to €24. This was due to the combined effect of higher patient numbers, greater total number of visits and lower supply costs in 2015 compared to 2014 (Supplement SM3).

Table 3. Costs (€) of diabetes care in 2014 and 2015, Mweso IDC-OPD service

Cost category	2014	% 2014 costs	2015	% 2015 costs
Medicine costs	5,202	16%	7,746	29%
Supply costs	25,435	79%	17,180	65%
Staff costs	1,484	5%	1,484	6%
Total costs	**32,121**	100%	**26,410**	100%
Costs per visit	**51**		**24**	
Costs per patient	**417**		**183**	

Discussion

This evaluation of a chronic disease programme in a complex conflict setting, using routine programmatic and cost data, provided lessons, which may improve clinical care and programme design. To the best of our knowledge, the influence of treatment interruption and insecurity on diabetes management in humanitarian settings has not been addressed in the literature. Similarly, we are not aware of studies providing data on costs of diabetes care in crisis settings.

Our results show that glycaemic control was similar or better to that documented in other humanitarian or low-income settings (although different targets were used) and, while it was positively impacted by programmatic changes, control clearly deteriorated during periods of heightened insecurity.[27] Our findings also indicate that, in a population previously undergoing

regular supervision, a simplified nurse-provided, algorithm-driven service with consistent medication supply may be as effective as close medical supervision in maintaining disease control, particularly during periods of service interruption. Medical input could thus be focused on achieving glycaemic control in patients prescribed insulin, who appeared most affected by service interruption. We also note lack of evidence supporting the management of what we believed to be malnutrition-related diabetes.

Intermittent outbreaks of armed conflict limited patient access and disrupted supply chains, impeding continuity of care. We suggest, therefore, that in high-insecurity settings, chronic disease programmes should focus on preparing patients, staff and supply chains to pre-empt treatment interruption during insecure periods, learning from HIV programme experiences in similar settings.[28] Preparation could include: patient triage by vulnerability (e.g. prioritising insulin-dependent diabetic patients, those with established complications and/or living far from the facility); provision of patient-held personal treatment plans and emergency kits (including several months' supply of medications, such as insulin, delivery devices and guidance as appropriate); building staff capacity to allow for flexibility of roles in crises; establishing networks with other chronic disease programmes; and medication stockpiling and secure storage.[5,28,29] Technology could facilitate continued patient treatment support when access to facilities is impossible e.g. via mobile phone SMS messaging or decentralisation of care to community-based health workers furnished with clinical decision support tools or support via telemedicine.

The relatively poorer glycaemic control in insulin-prescribed patients may reflect either disease severity or the challenges associated with insulin therapy. Adherence to daily insulin injections is difficult anywhere; in Mweso, the security, financial and geographical barriers to accessing insulin and the unavailability, unaffordability and burden for families brought by the recommended diabetes diet, may additionally contribute to poor adherence.[22] In this programme, clinicians adjusted insulin doses, based on a single fasting glucose reading taken in clinic and on patients'

reported symptoms in the absence of home glucose monitoring and, therefore, dose adjustment was cautious and treatment targets were conservative.

There is limited, although growing, evidence on the incidence, prevalence and characterisation of diabetes in Sub-Saharan Africa, which our findings broadly reflect.[30] Several reviews and recent ethnographic evidence describe "atypical" forms of diabetes, which may complicate diagnosis, classification and management. These include "*ketosis-prone atypical diabetes mellitus"* and *"malnutrition-related diabetes"*. [13,16,31] Local prevalence studies support the existence of the latter in the DRC, which is in keeping with the high proportion of underweight adults and "unclassified" diabetics in our cohort.[14,32] It is unclear whether malnutrition is causative, associated with hyperglycaemia or with pancreatic insufficiency and further study of diabetes epidemiology in DRC is needed, exploring factors such as childhood malnutrition, food insecurity and underweight and use of calorie-dense therapeutic foods. [31] Moreover, little evidence exists to guide either malnutrition-related diabetes care or the effective management of insulin in humanitarian settings, particularly in the absence of home or community-based glucose testing.[3,7]

The total cost of care delivery decreased by approximately 20% from 2014 to 2015 despite increased visit and patient numbers. This was largely due to decreased supply costs, driven by the 100-fold reduction in consumption of latex gloves following IDC-OPD training. Efficiencies of supply consumption and patient throughput (more visits and more patients seen by the same number of staff) contributed to reducing PPPY costs by 44% from €417 in 2014 to €183 in 2015.

To our knowledge, there is no available literature to compare cost per patient or per visit for diabetes care (or NCD care generally) delivered in an unstable humanitarian setting. A study from Ghana reported a per patient annual direct cost of US$372.65 for hospital-delivered diabetes care in 2005. For a potential comparator, we looked at the cost of delivering chronic care for HIV, the main life-long condition with which humanitarian actors have traditionally engaged. The 2015 PPPY cost reported in this study is far lower than that reported by PEPFAR and others to deliver chronic HIV

care programmes in low and middle income countries in SSA [33,34]. In terms of cost structure, supplies were the major cost driver in the Ghanaian study (syringes, lancets and strips), whereas other analyses of diabetes care in SSA identified medications, and specifically insulin, as the main cost contributor [35,36].

Strengths and Limitations

Using routine clinical and programmatic data, with minimal service disruption, we have explored clinical outcomes of a chronic disease programme in a protracted conflict setting and the influence of periods of heightened insecurity on intermediate clinical outcomes and on service delivery. Each patient who attended in a given month contributed data, irrespective of whether they ever experienced a treatment interruption. Our study provides new costing information for humanitarian actors to support the initiation or adaptation of specific NCD programmes and may potentially support scale up of similar services in DRC (and other conflict-affected settings). We concluded that the incremental cost of adding an outpatient diabetes service to a humanitarian health programme in a rural hospital setting may be achieved at a cost similar to that of delivering chronic HIV programmes. While we cannot confirm whether an external audit of cost data had taken place, we are confident in the quality of these data due to MSF's robust systems and oversight by strong in-country and international teams.

Given the logistical and ethical challenges of undertaking research in conflict settings, we acknowledge that there are a number of limitations to our study. We had a relatively small sample size and no control group for comparison. We did not explore per patient control of clinical parameters over time, control by diabetes type (or age), appropriateness of prescribing, patient-reported outcomes or the influence of psychosocial factors, diet, or adherence in each study phase since these data were unavailable. Gestational diabetes was not addressed since this took place within antenatal services. Our costing analysis was descriptive so we could not comment on programme cost-effectiveness. Costing data were presented as average annual costs and did not

explore the impact of various programme periods on costs. Since our cost data were aggregate, we could not explore patient-level costs or account for patient heterogeneity. While our findings may not be generalizable to other complex humanitarian settings or to other providers' diabetes programmes in the DRC, our study contributes knowledge on key challenges and suggests solutions, which may be more broadly applicable.

Future research is needed in complex humanitarian settings to evaluate simplified, task-shared models of diabetes care, including culturally- and contextually-relevant psychosocial support and dietary advice; to optimise insulin management; and to evaluate emergency preparedness plans and technology-facilitated remote patient support.[3,5,8,13,29] We recommend that future prospective studies should explore per-patient outcomes (as well as exploring programme-level outcomes as done in this study). We suggest including a control group, collection of additional outcome variables, such as complication rates and patient-reported outcomes e.g. related to quality-of-life, including functionality and mental health, and exploration of the impact of psychosocial stressors and treatment interruption on clinical outcomes. We also suggest that the cost-effectiveness of different models of diabetes care, including use of technology-facilitated remote support, and patient level costing studies from both provider and patient perspectives should be undertaken, exploring patient heterogeneity and direct and indirect patient costs.

Conclusion

Our results help develop the sparse knowledge on the prevalence and characterisation of diabetes in Sub-Saharan Africa. They demonstrate that diabetes care is feasible even in complex humanitarian emergencies, and at a cost that is lower than chronic HIV care. The results also indicate that the Mweso IDC-OPD programme could be further simplified to involve drug collection along with nurse-led, algorithm-guided treatment adjustment. We suggest that chronic disease programmes in unstable settings should engage in emergency preparedness, learning from the experience of HIV

programmes in similar settings. Future research is needed to evaluate simplified, task-shared models of diabetes care and management; and to evaluate emergency preparedness plans and technology-facilitated remote patient support.

List of Abbreviations

BMI	Body Mass Index
BP	Blood Pressure
DM	Diabetes Mellitus
DRC	Democratic Republic of Congo
HIV	Human Immunodeficiency Virus
IDC-OPD	Integrated Diabetic Clinic within Hospital Outpatient Department
LMICs	Low- and Middle-Income Countries
MSF	Médecins sans Frontières
NCD	Noncommunicable Disease
OHG	Oral Hypoglycaemic Drugs
OR	Odds Ratio
PPPY	Per Patient Per Year

Declarations

Ethics approval and consent to participate

This study was approved by the Ministry of Health of North Kivu Province, DRC, by the MSF Ethics Review Board, and the Ethics Committee of the London School of Hygiene and Tropical Medicine. Information sheets on the clinic walls provided details of the evaluation; no specific consent was sought from patients for use of their routine clinical data.

Authors' contributions

KJ and BR were involved in study conception; EA, GC, KJ, DPM, PP and BR contributed to study design and interpretation of data. DPM and ZS analysed the data. MB contributed to data collection. EA drafted the manuscript and all authors reviewed drafts and approved the final version.

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Competing Interests

The authors declare that they have no competing interests.

Data Sharing

The datasets are available from MSF on request by researchers who fulfil certain criteria and under the auspices of a data sharing agreement.

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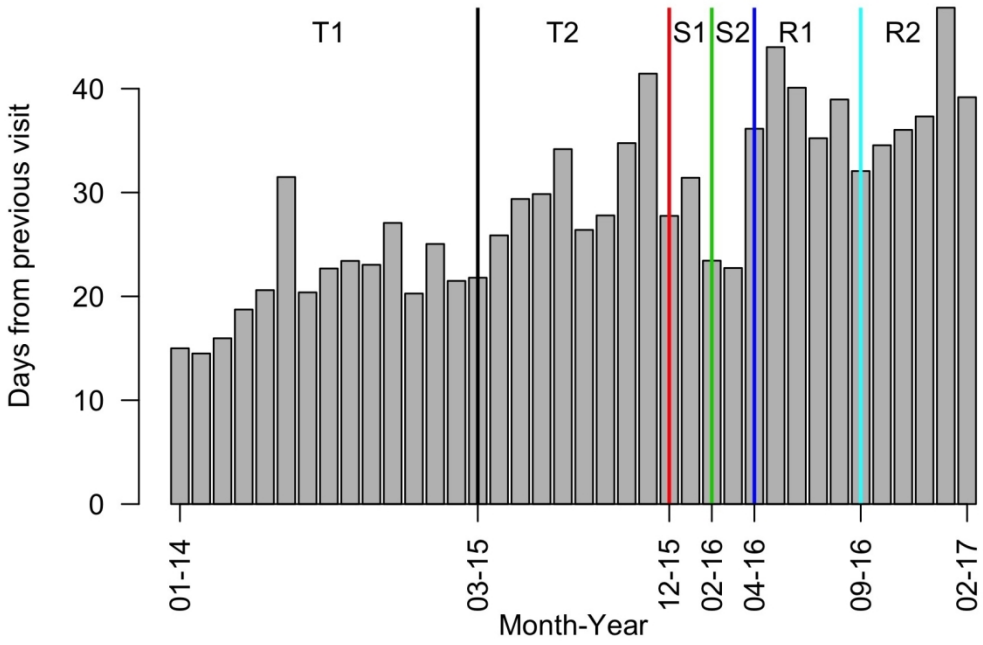


Figure 1: Average number of days from previous visit per month for Mweso IDC-OPD service

615x436mm (72 x 72 DPI)

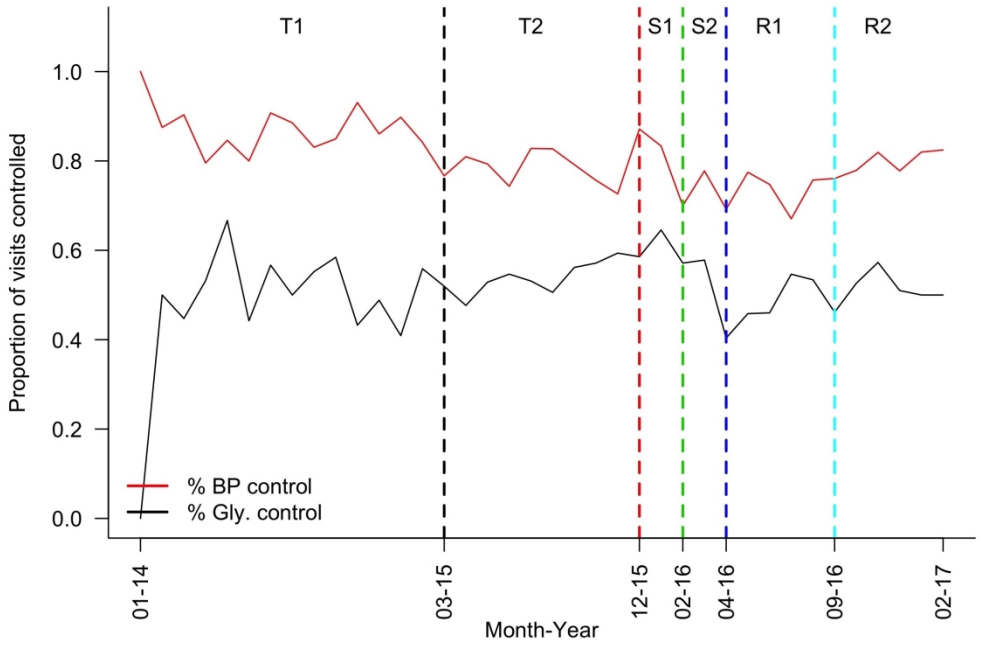
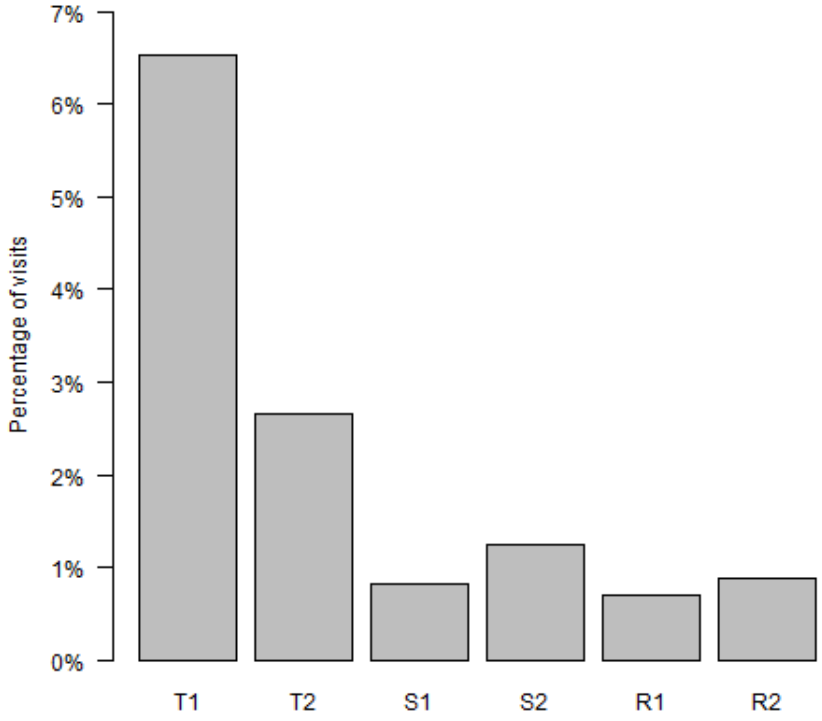


Figure 2: Proportion of visits with BP or glycaemia at target by month, Mweso IDC-OPD service

809x558mm (72 x 72 DPI)

SM1. Proportion of visits with missing data for either blood pressure or glycaemia measurements, IDC-OPD Programme, Mweso, DRC



Note: Definitions of study periods T1 – R2 are described in Supplementary Data S1

SM2. Monthly resource use associated with IDC-OPD in Mweso Hospital, North Kivu, DRC

Items	Unit	2014	2015
Medicine			
INSULIN ISOPHANE (NPH), human, 100 UI/ml, 10 ml, vial	6.300	40	40
INSULIN RAPID, human, 100 IU/ml, 10 ml, vial	6.300	8	8
INSULIN, 100IU/ml, BIPHASIC 30, human, 10ml, vial	13.610	10	10
METFORMIN hydrochloride, 500 mg, tab.	0.014	5,300	12,000
GLIBENCLAMIDE, 5 mg, tab.	0.005	750	3,600
HYDROCHLOROTHIAZIDE, 50 mg, tab.	0.003	0	300
GLUCOSE HYPERTONIC, 50%, 50 ml, vial	0.556	75	6
AMITRIPTYLINE hydrochloride, 25 mg, tab.	0.006	200	750
ACETYLSALICYLIC acid (aspirin), 75 mg, tab.	0.005	0	2,000
AMLODIPINE 5mg, tabs.	0.018	0	300
Supplies			
GLUCOMETER, blood glucose monitor (Nova StatStrip) + strips	96.705	5	10
(glucometer Nova StatStrip) STRIP ref. 42214	0.230	2,000	4,000
SYRINGE, s.u., Luer, insulin, 100 IU/1 ml + fixed needle	0.079	2,000	4,000
(spectrophotometer) KIT, DOSAGE CREATININE, Liquicolor 200ml	4.830	3.5	3.5
THERMOMETER, ELECTRONIC, accuracy 0.1§ C + case	1.110	20	3
SPHYGMOMANOMETER, one-hand manometer, Velcro, adult	26.000	0	1
TEST, URINE, pH,dens,prot,gluc,ket,blood,nit,leuc, 1 strip	0.197	100	200
REUSABLE SHARPS CONTAINER (RSC), 1.2 litre	44.750	1	1
CONTAINER, SAMPLE, plast., 60ml, non sterile, urine	0.083	1,700	200
LANCET, s.u., sterile, standard point	0.006	900	4,000
GLOVE, EXAMINATION, latex, s.u. non sterile, medium	0.025	50,000	500
Staff time (days allocated to diabetes care)*			
MSF Medical doctor	1,350	1	1
MSF Nurse	900	1	1
BCZ Nurse	239	1	1
MSF psychosocial worker	1,422	0.125	0.125
1 Nutritionist (MSF)	864	0.0625	0.0625

*Note: Staff time costs assumed 22 full-time working days per month.

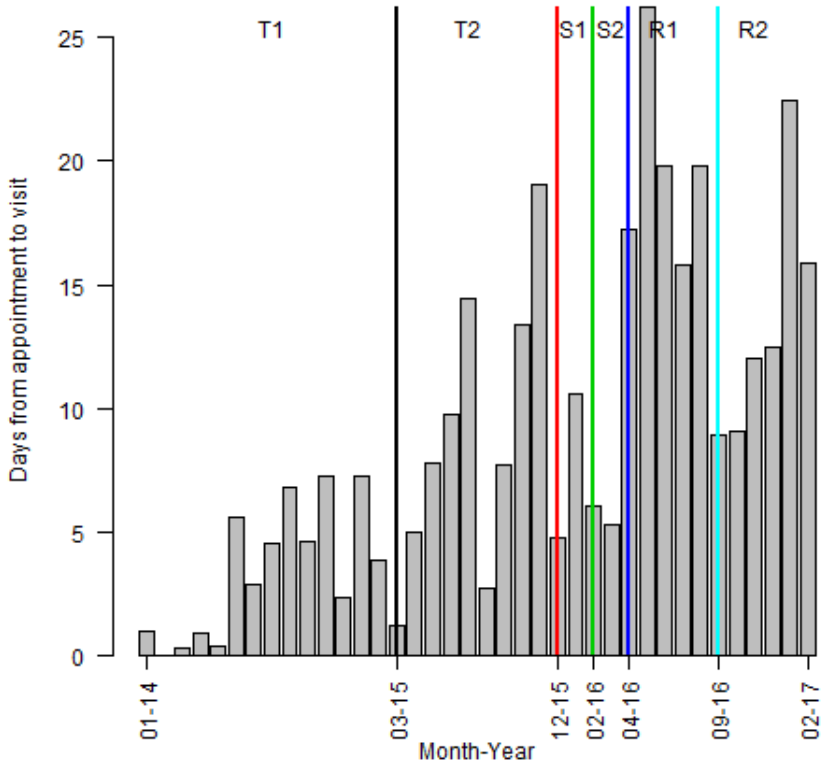
S3. Baseline characteristics of 243 patients on enrolment into Mweso IDC-OPD service

Variable	Total	(%)	DM-1	(%)	DM-2	(%)	Other/NA	(%)
Patients (N)	243		62		125		56	
Age								
<18	24	(9.9%)	19	(30.6%)	0	(0.0%)	5	**(8.9%)**
18-40	74	(30.5%)	39	(62.9%)	20	(16.0%)	15	**(26.8%)**
41-60	112	(46.1%)	3	(4.8%)	80	(64.0%)	29	**(51.8%)**
>60	33	(13.6%)	1	(1.6%)	25	(20.0%)	7	**(12.5%)**
Sex								
Male	134	(55.1%)	34	(54.8%)	70	(56.0%)	30	**(53.6%)**
Female	108	(44.4%)	28	(45.2%)	55	(44.0%)	25	**(44.6%)**
No data	1	(0.4%)	0	(0.0%)	0	(0.0%)	1	**(1.8%)**
Occupation								
Labourer	121	(49.8%)	29	(46.8%)	85	(68.0%)	7	**(12.5%)**
Office worker	19	(7.8%)	2	(3.2%)	11	(8.8%)	6	**(10.7%)**
Student	8	(3.3%)	8	(12.9%)	0	(0.0%)	0	**(0.0%)**
Unable to work	11	(4.5%)	7	(11.3%)	3	(2.4%)	1	**(1.8%)**
Other	48	(19.8%)	15	(24.2%)	26	(20.8%)	7	**(12.5%)**
No data	36	(14.8%)	1	(1.6%)	0	(0.0%)	35	**(62.5%)**
Medical History								
CVD								
Yes	5	(2.1%)	1	(1.6%)	3	(2.4%)	1	**(1.8%)**
No data	24	(9.9%)	0	(0.0%)	0	(0.0%)	24	**(42.9%)**
Hypertension								
Yes	20	(8.2%)	0	(0.0%)	18	(14.4%)	2	**(3.6%)**
No data	25	(10.3%)	0	(0.0%)	1	(0.8%)	24	**(42.9%)**
Tuberculosis								
Yes	6	(2.5%)	1	(1.6%)	5	(4.0%)	0	**(0.0%)**
No data	24	(9.9%)	0	(0.0%)	0	(0.0%)	24	**(42.9%)**
Malnutrition								
Yes	19	(7.8%)	15	(24.2%)	2	(1.6%)	2	**(3.6%)**
No data	24	(9.9%)	0	(0.0%)	0	(0.0%)	24	**(42.9%)**
Family Hx of DM								
Yes	35	(14.4%)	6	(9.7%)	23	(18.4%)	6	**(10.7%)**
No data	24	(9.9%)	0	(0.0%)	0	(0.0%)	24	**(42.9%)**

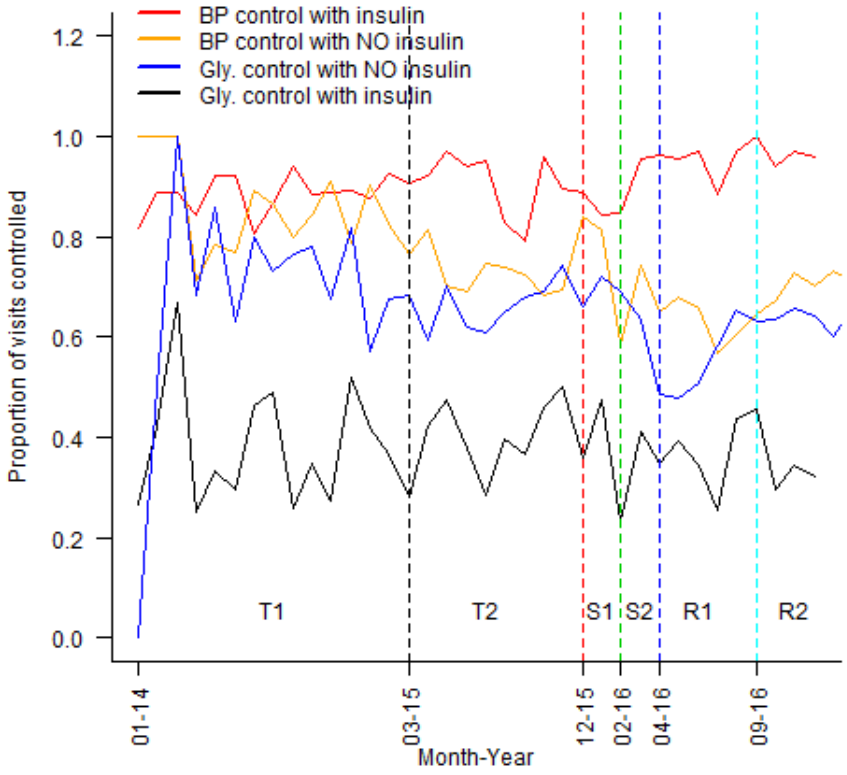
Patients >=18 years(N)*	219		43		125		51	
Smoking								
Yes	18	(8.2%)	1	(2.3%)	16	(12.8%)	1	**(2.0%)**
No data	21	(9.6%)	0	(0.0%)	0	(0.0%)	21	**(41.2%)**
Alcohol								
Yes	50	(22.8%)	12	(27.9%)	32	(25.6%)	6	**(11.8%)**
No data	33	(15.1%)	0	(0.0%)	1	(0.8%)	32	**(62.7%)**
BMI								
<18.5	68	(31.1%)	23	(53.5%)	34	(27.2%)	11	**(21.6%)**
18.5-24.9	96	(43.8%)	15	(34.9%)	59	(47.2%)	22	**(43.1%)**
25.0-29.9	41	(18.7%)	5	(11.6%)	27	(21.6%)	9	**(17.6%)**
>=30	7	(3.2%)	0	(0.0%)	5	(4.0%)	2	**(3.9%)**
No data	7	(3.2%)	0	(0.0%)	0	(0.0%)	7	(13.7%)

Note: For smoking, alcohol and BMI, denominators included only patients aged 18 years or above.

SM4. Average days' delay in attendance since planned appointment per month of IDC-OPD service, Mweso, DRC



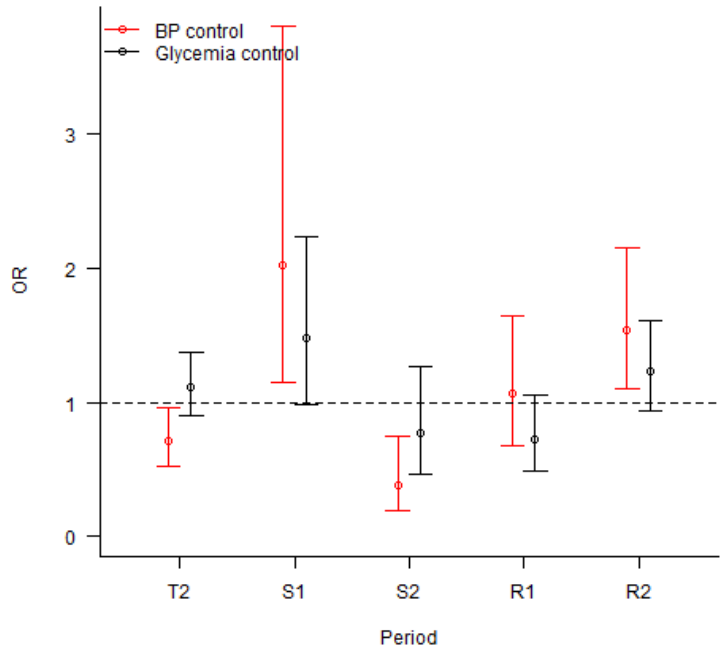
SM5. Proportion of visits at target for BP and glycaemic control, stratified by insulin prescription per month of IDC-OPD service, Mweso, DRC



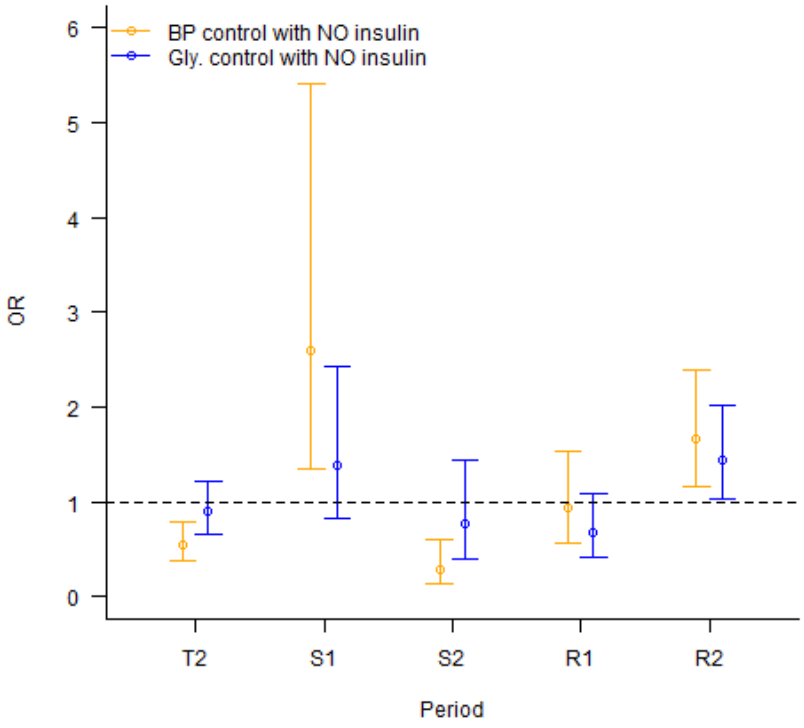
Note: Patients were categorised by whether they were prescribed insulin [+/- oral hypoglycaemic (OHG) drugs]) or OHG drugs alone at their last recorded visit. The former group would have included Type 1 diabetics, Type 2 diabetics with more advance illness requiring a combination of OHG and insulin, and those with an intermediate type of diabetes, presenting with high insulin requirements in the absence of diabetic ketoacidosis, which we postulated represented "malnutrition-related diabetes". The latter group were likely to include Type 2 diabetics.

SM6. Impact (OR) on BP and glycaemic control of study period over previous period, unstratified (A) and stratified by insulin prescription (B and C) per month of IDC-OPD service, Mweso, DRC

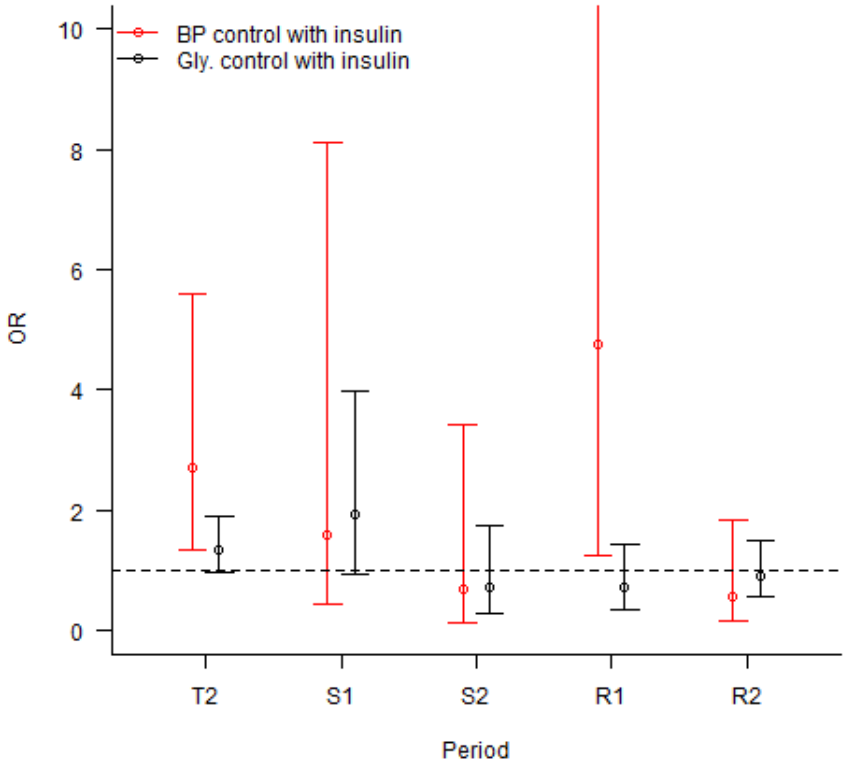
A. Impact (OR) on BP and glycaemia in all patients (not stratified by insulin prescription)



B. Impact (OR) on BP and glycaemia in patients on oral hypoglycaemic drugs only



C. Impact (OR) on BP and glycaemia in patients prescribed insulin (+/- OHG)



STROBE Statement—Checklist of items that should be included in reports of ***cross-sectional studies***

Study Title: Management of diabetes and associated costs in a complex humanitarian setting in the Democratic Republic of Congo: a retrospective cohort study.

	Item No	Recommendation	Page No
Title and abstract	1	(*a*) Indicate the study's design with a commonly used term in the title or the abstract	1,4
		(*b*) Provide in the abstract an informative and balanced summary of what was done and what was found	2-3
Introduction			
Background/rationale	2	Explain the scientific background and rationale for the investigation being reported	4-7
Objectives	3	State specific objectives, including any prespecified hypotheses	7
Methods			
Study design	4	Present key elements of study design early in the paper	7-11
Setting	5	Describe the setting, locations, and relevant dates, including periods of recruitment, exposure, follow-up, and data collection	4,5,7, 8, 11
Participants	6	(*a*) Give the eligibility criteria, and the sources and methods of selection of participants	7
Variables	7	Clearly define all outcomes, exposures, predictors, potential confounders, and effect modifiers. Give diagnostic criteria, if applicable	6,9,10
Data sources/ measurement	8*	For each variable of interest, give sources of data and details of methods of assessment (measurement). Describe comparability of assessment methods if there is more than one group	6
Bias	9	Describe any efforts to address potential sources of bias	n/a
Study size	10	Explain how the study size was arrived at	7
Quantitative variables	11	Explain how quantitative variables were handled in the analyses. If applicable, describe which groupings were chosen and why	10
Statistical methods	12	(*a*) Describe all statistical methods, including those used to control for confounding	10
		(*b*) Describe any methods used to examine subgroups and interactions	10
		(*c*) Explain how missing data were addressed	10,11
		(*d*) If applicable, describe analytical methods taking account of sampling strategy	10
		(*e*) Describe any sensitivity analyses	n/a
Results			
Participants	13*	(a) Report numbers of individuals at each stage of study—eg numbers potentially eligible, examined for eligibility, confirmed eligible, included in the study, completing follow-up, and analysed	10
		(b) Give reasons for non-participation at each stage	n/a
		(c) Consider use of a flow diagram	n/a
Descriptive data	14*	(a) Give characteristics of study participants (eg demographic, clinical, social) and information on exposures and potential confounders	Supp Mat 3
		(b) Indicate number of participants with missing data for each variable of interest	Supp Mat 1
Outcome data	15*	Report numbers of outcome events or summary measures	9,10

Main results	16	(*a*) Give unadjusted estimates and, if applicable, confounder-adjusted estimates and their precision (eg, 95% confidence interval). Make clear which confounders were adjusted for and why they were included	n/a
		(*b*) Report category boundaries when continuous variables were categorized	Supp Mat 3
		(*c*) If relevant, consider translating estimates of relative risk into absolute risk for a meaningful time period	n/a
Other analyses	17	Report other analyses done—eg analyses of subgroups and interactions, and sensitivity analyses	n/a
Discussion			
Key results	18	Summarise key results with reference to study objectives	12-14
Limitations	19	Discuss limitations of the study, taking into account sources of potential bias or imprecision. Discuss both direction and magnitude of any potential bias	17,18
Interpretation	20	Give a cautious overall interpretation of results considering objectives, limitations, multiplicity of analyses, results from similar studies, and other relevant evidence	14-16
Generalisability	21	Discuss the generalisability (external validity) of the study results	18
Other information			
Funding	22	Give the source of funding and the role of the funders for the present study and, if applicable, for the original study on which the present article is based	20

*Give information separately for exposed and unexposed groups.

Note: An Explanation and Elaboration article discusses each checklist item and gives methodological background and published examples of transparent reporting. The STROBE checklist is best used in conjunction with this article (freely available on the Web sites of PLoS Medicine at http://www.plosmedicine.org/, Annals of Internal Medicine at http://www.annals.org/, and Epidemiology at http://www.epidem.com/). Information on the STROBE Initiative is available at www.strobe-statement.org.

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Management of diabetes and associated costs in a complex humanitarian setting in the Democratic Republic of Congo: a retrospective cohort study

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Title: Management of diabetes and associated costs in a complex humanitarian setting in the Democratic Republic of Congo: a retrospective cohort study.

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Word Count: 3999

Keywords: Democratic Republic of Congo, Subsaharan Africa, diabetes, hypertension, noncommunicable disease, humanitarian, conflict, care model, management, programme, chronic care, outpatient, hospital care, task shifting, cost, economic.

Abstract

Objective: We aimed to evaluate an Integrated Diabetic Clinic within a Hospital Outpatient Department (IDC-OPD) in a complex humanitarian setting in North Kivu, Democratic Republic of Congo. Specific objectives were to: (i) analyse diabetes intermediate clinical and programmatic outcomes (blood pressure/glycaemic control, visit volume and frequency); (ii) explore the association of key insecurity and related programmatic events with these outcomes; and (iii) describe incremental IDC OPD programme costs.

Design: Retrospective cohort analysis of routine programmatic data collected from January 2014 - February 2017; analysis of programme costs for 2014/2015.

Setting: Outpatient diabetes programme in Mweso hospital, supported by Médecins sans Frontières, in North Kivu, Demographic Republic of Congo.

Participants: Diabetes patients attending IDC-OPD.

Outcome measures: Intermediate clinical and programmatic outcome trends (blood pressure/ glycaemic control; visit volume/frequency); incremental programme costs.

Results: Of 243 diabetes patients, 44.6% were women, median age was 45 (IQR 32-56); 51.4% were classified Type 2. On introduction of IDC-OPD, glucose control improved and patient volume and visit interval increased. During insecurity, control rates were initially maintained by a nurse-provided, scaled-back service, while patient volume and visit interval decreased. Following service suspension due to drug stock-outs, patients were less likely to achieve control, improving on service resumption. Total costs decreased 16% from 2014 (€36,573) to 2015 (€30,861). Annual cost per patient dropped from €475 in 2014 to €214 in 2015 due to reduced supply costs and increased patient numbers.

Conclusions: In a chronic conflict setting, we documented that control of diabetes intermediate outcomes was achievable during stable periods. During insecure periods, a simplified, nurse-led

model maintained control rates until drug stock-outs occurred. Incremental per patient annual costs were lower than chronic HIV care costs in low-income settings. Future operational research should define a simplified diabetes care package including emergency preparedness.

Strengths and Limitations

- This is the first study of its kind to examine diabetes intermediate clinical outcomes and programme costs in a complex humanitarian setting in sub-Saharan Africa.
- Using routine clinical and programmatic data collected in a protracted conflict setting, we estimated the effect of insecurity and related programmatic changes on diabetes intermediate clinical outcomes, which to our knowledge, has not been addressed in the literature to date.
- The study was limited by the relatively small sample size and lack of control group for comparison.
- The costing analysis was descriptive and based on aggregate data and so neither the cost-effectiveness of the programme nor patient-level costs could be determined.

Title: Management of diabetes and associated costs in a complex humanitarian setting in the Democratic Republic of Congo: a retrospective cohort study.

Background

Over the past 40 years, diabetes prevalence has increased sharply worldwide, particularly in low and middle income countries (LMICs).[1] However, data on the burden and needs related to diabetes and other non-communicable diseases (NCDs) are scarce from conflict-affected countries, particularly those in Sub-Saharan Africa.[1,2] Humanitarian actors have been slow to prioritise diabetes treatment in disaster and post-conflict settings despite reporting increasing presentations of diabetic patients within their programmes.[3–6] This is due to lack of knowledge on local diabetes epidemiology, limited research on diabetes management or outcomes in crisis settings; a lack of programmatic and policy guidance or tools to support diabetes care in such settings; prioritisation of other health needs; and also a perception that diabetes care is complex and expensive. [2,3,6–8]

The humanitarian situation in Democratic Republic of Congo (DRC) is considered one of the most complex and challenging worldwide. Prolonged conflict over two decades has resulted in over 5 million deaths, over 4.5 million internally displaced people, the exodus of over 800,000 refugees, and ongoing political and social instability. [9,10] The health system, weakened by prolonged conflict, is challenged by competing health needs in a country ranked 176 of 189 on the human development index despite holding rich natural resources. [11]

On this backdrop, diabetes prevalence is increasing, currently estimated at 4.0 - 5.4%. [12–14] While some factors implicated in the global rise in diabetes prevalence hold true in DRC (demographic change, urbanisation, changing diets etc.) chronic conflict and political instability add additional

complexity. Recent reviews and ethnographic evidence point to a link between chronic food insecurity, childhood malnutrition and diabetes. [13,15,16] In DRC, 43% of children under 5 years are chronically malnourished and levels of food insecurity have risen sharply, with millions subsisting on World Food Programme rations. [17] Recent evidence also supports an association between chronic perceived stress and diabetes onset, while patients with diabetes in humanitarian settings focus on suffering and loss as a cause of their illness. [16,18] Furthermore, in humanitarian crises, people with diabetes are at increased risk of complications and death due to treatment interruption and precarious access to food and water. [2,6]

Médecins sans Frontières (MSF), a medical humanitarian organisation, has supported healthcare delivery in Mweso, North Kivu, in collaboration with the Ministry of Health since 2008. North Kivu is a rural, impoverished area bordering Rwanda with an estimated population of 365,000. It remains a flash point in the on-going conflict between shifting rebel groups and government forces, which has been characterised by brutal violence against civilians and destruction of lives and livelihoods. Outbreaks of violence since 2016 have resulted in recurrent waves of population displacement; North Kivu alone hosts 17 internally displaced person camps. MSF supports health services in 4 out of 23 Primary Health Care clinics and in Mweso hospital within Masisi District. Mweso hospital serves a catchment area of approximately 145,000 people, with about 65,000 recipients of care living in the immediate vicinity of the hospital.

While a national diabetes programme exists in DRC, available diabetes care is concentrated at hospital level in major cities. [19] In response to growing patient and provider needs in Mweso, MSF implemented a hospital-outpatient based diabetes programme in March 2015, the Integrated Diabetic Clinic within Hospital Outpatient Department (IDC-OPD) in place of the ad hoc care previously undertaken. The IDC-OPD was integrated at the clinical level into usual outpatient activities, with pre-existing staff trained to provide this additional service. [20] The programme comprised a nurse-led, multi-disciplinary model, using locally adapted clinical guidelines, patient

counselling materials and data collection tools, accompanied by three days of specialist training.[21] The clinic team included: a nurse supervisor, nursing assistant, two doctors, a nutritionist, and education and psychosocial support officers. Diabetes was diagnosed according to World Health Organization (WHO) guidelines using repeated fasting capillary glucose. Most patients were identified as diabetic and enrolled after acute hospital presentation, while some were identified via the Mweso outpatient department or referring primary care clinics.

Patients received a detailed enrolment assessment, monthly nurse-led follow-up and 6-monthly medical review. The programme included context-adapted dietary advice (accounting for locally available and affordable foods and customs) and psychosocial support, including clinician-moderated peer support groups and involvement of family or friends as treatment supporters. The psychosocial aspects of patients and providers managing diabetes are discussed in a related paper, with major themes from the patient perspective including the difficulty adhering to the recommended diet and barriers to clinic access during outbreaks of violence. [22] Each patient was given a clinic-held patient file and patient-held passport to facilitate safe passage when armed groups impeded their travel. Clinical guidelines were adapted from MSF, WHO and other international guidance. [23] Patient educational tools (disease and diet education leaflets) were adapted from Santé Diabète [24], a Malian Non-Governmental Organisation, and generic medications, included on MSF's Essential Drugs List, were prescribed. Insulin doses were adjusted using single fasting capillary blood glucose readings and patients' reported symptoms of hypo- or hyperglycaemia in the absence of home glucose monitoring. Insulin-dependent patients were prescribed human insulin, delivered via needle and syringe, and advised to store this at home in a clay pot, recommended as a safe alternative to refrigeration in similar contexts. [25]

In early 2016, outbreaks of armed violence restricted movement of patients and supplies. Direct attacks on MSF staff and facilities, including an armed robbery and abductions, led to withdrawal of the international staff from Mweso and temporary scaling back of the programme, with local nursing

staff dispensing medications to any patients reaching the clinic. Later, the programme was suspended for a period of six weeks when supply routes were entirely blocked and drug stocks were exhausted.

A mixed methods evaluation of the Mweso IDC-OPD programme was undertaken by MSF and included a qualitative evaluation exploring patient and provider clinical and psychosocial challenges, presented elsewhere [22]; and a retrospective review of quantitative programmatic data and cost data collected as part of routine care in a chronic conflict zone, reported here. The overall aim of this paper was to evaluate an Integrated Diabetic Clinic within a Hospital Outpatient Department (IDC-OPD) in a complex humanitarian setting in North Kivu in Democratic Republic of Congo. The specific objectives were to: (i) analyse diabetes intermediate clinical and programmatic outcomes (blood pressure/glycaemic control, visit frequency and volume); (ii) explore the association of key insecurity and related programmatic events with these outcomes; and (iii) describe incremental IDC OPD programme costs.

Methods

It has been acknowledged that traditional experimental and evaluation methods may be unfeasible, inappropriate or even unethical to apply in humanitarian settings [26]. Therefore, we have used a pragmatic approach to utilising programmatic data, with an open cohort design. For the outcome analysis, we conducted a retrospective analysis of routine data of enrolled adults aged ≥18 years from January 2014 to February 2017, examining trends in diabetes outcomes and their association with key programmatic events. The study period was divided into five phases, defined by programmatic changes or periods of heightened insecurity (which impacted service delivery due to staff evacuation, supply chain interruption and reduced patient access). Period T1 refers to ad-hoc care delivered before introduction of the IDC-OPD programme (T2). Security incidents in December 2015 prompted a period of service suspension (nurse-only care, with drug pick-ups, glucose testing

and minimal treatment adjustments) (S1). Complete suspension followed once drug stocks were exhausted (S2). Limited service resumed in April (R1) until full service recommenced from September 2016 (R2) (Table 1).

Table 1. Study Periods for Evaluation of IDC-OPD Programme, Mweso, DRC

Study Period	Description	Dates
Training 1 (T1)	Ad hoc diabetes service following basic staff training	01/01/2014 – 14/03/2015
Training 2 (T2)	IDC-OPD implemented following formal staff training	15/03/2015 – 14/12/2015
Suspend 1 (S1)	Nurse-provided care without medical supervision; monthly drug refills provided until buffer stocks were exhausted	15/12/2015 – 31/01/2016
Suspend 2 (S2)	No clinical supervision or drugs were provided	01/02/2016 – 14/04/2016
Resume 1 (R1)	The service was resumed without medical supervision or quality control	15/04/2016 – 31/08/2016
Resume 2 (R2)	Full service resumed until end of data collection period	01/09/2016 – 09/02/2017

Data

Patients were given a unique identification number on enrolment. Data were recorded in paper-based clinic-held files by clinical staff and transferred to an electronic database by a trained data entry operator on a weekly basis. Missing data were discussed with the nurse manager and gaps were filled during follow-up clinical visits. Single data entry was performed on a password-protected

Microsoft Excel software application specifically developed by MSF for this programme. Anonymised exports were transferred to the study team on a monthly basis.

Demographic data on patients' age, gender, occupation, and village of residence were recorded on enrolment. Cardiovascular risk factors (smoking status, current alcohol use), family history of diabetes, year of diabetes diagnosis and self-reported history of childhood malnutrition and/or tuberculosis were recorded. Clinical parameters: body mass index (BMI), blood pressure (BP) measured by manual sphygmomanometer according to local MSF protocols [21], fasting capillary blood glucose (FBG); prescribed diabetes drugs [insulin and/or oral hypoglycaemic drugs (OHGs)]; and diabetes classification (Type I, Type II or other) were recorded at each clinical encounter. Medical review at enrolment and six monthly thereafter was recorded, including biochemical markers (serum creatinine) and examination for complications (visual acuity, cataract, proteinuria, foot check). Numbers of deaths, transfers out of the area and delays in attendance were also documented. The key intermediate clinical outcome and programme measures used in the analysis are shown in Table 2.

Table 2: Outcome measures used to determine effect of different programme periods on programme delivery and intermediate clinical outcomes

Category	Variable
Intermediate Clinical Outcomes	Proportion of visits per month where patients' BP is at target (< 140/90 mmHg) Proportion of visits per month where patients' blood glucose is at target (> 4.2 and ≤ 8.3 mmol/L)
Number and frequency of visits	Number of visits per month Number of patients seen per month

	Average visits per patient per month Average days from previous visit Missing data for BP / glycaemia per visit

Analysis

Basic demographics were analysed using mean and median and were presented with inter-quartile ranges. We assessed the relationship of different study periods with the frequency of visits and the impact of study periods on intermediate clinical outcomes i.e. per visit attainment of blood pressure (< 140/90 mmHg) and glycaemic (> 4.2 and ≤ 8.3 mmol/L) targets.

To estimate the effect of a period change we calculated the odds ratio (OR) of the odds of having the biomarker under control in a visit in the new period (t) over the odds of having the biomarker controlled in a visit in the previous period (t-1): $OR_t = Odds_t / Odds_{t-1}$. If $OR_t > 1$, this meant that the chances of the biomarker being under control in a visit in period *t* was greater than the chances of the biomarker being under control in a visit in the previous period (*t-1*) (but not necessarily than other periods, *t-2*, *t-3*, etc.). Likewise, $OR_t < 1$ implied a reduction in the chances of having the biomarker under control in a visit during period *t* compared to a visit during the previous period (*t-1*). To estimate these OR we ran a logistic model with period as a categorical variable, suitably coded, and adjusted for sex, age (and square and cube terms) and number of visits of the patient (and square term). The models were stratified by whether the patient was prescribed insulin (+/- oral hypoglycaemic agents) at the previous visit.

Missing data: Our main analysis used only complete data; records with missing data were excluded. Few outcome variable data were missing: less than 3% in BP control (most of it in the pre-training

period) and less than 0.3% for glycaemic control (Supplement SM1). There were no missing data for date of visit, sex or age.

Costing data and analysis

For the descriptive, incremental cost analysis we took a health services perspective. Information related to the nature, location and mode of delivery of the NCD services was collected during a field visit in December 2015 by the study team and was supplemented by informal interviews with clinical and administrative staff. A data analysis tool was designed to collate the relevant financial costs for the study period 2014 -2015 from routine programme documents and standard MSF tools including budget, human resources, drug consumption monitoring, logistics/supply tools, clinic records and programme reports. For salary costs, we included the incremental costs of an MSF-employed medical doctor and nurse and an MOH-employed nurse (with salary supplement paid by MSF) dedicating one day, two psychosocial workers dedicating one hour and a nutritionist dedicating 30 minutes per week to the IDC-OPD service (based on 22 working days per month). Hence, most costs were related to drugs, equipment, disposables and stationary. Key cost items were grouped into: (a) medicine, (b) supplies, and (c) staff time. Monthly resource use and unit cost data were recorded and annualised (Supplement SM2); annual total cost, cost per visit and cost per patient were reported in Euro (€) for 2014 before formal implementation of the IDC-OPD programme and for 2015 during full implementation.

The study was approved by the Ministry of Health of North Kivu Province, DRC, and the Médecins sans Frontières Ethics Review Board (ID 1542).

Patient and Public Involvement

Patients were not involved in the design or conduct of this study.

Results

Between January 1st 2014 and February 9th 2017, 243 patients were enrolled in the IDC-OPD programme (Supplement SM3). Median age was 45 years (IQR 32 – 56); 44.6% of the cohort was female. For adults ≥ 18 years (n=219), mean BMI was 21.3 kg/m^2 and 31.1% were underweight (BMI < 18.5 kg/m^2). On enrolment, 8.2% were current smokers; 24.4% reported recent alcohol intake; self-reported medical history included: 9.1% hypertension, 2.2 % CVD, 2.7% tuberculosis and 8.7% malnutrition. Half were classified clinically as Type 2 diabetic (51%; n=125); 26% (n=62) as Type 1; and 23% (n=56) were either unclassified or classed as "other" (Supplement SM3).

Trends in outcomes and impact of programmatic events

Numbers of visits and appointment intervals increased after the introduction of the systematic approach to diabetes care, which included monthly review appointments for stable patients (T2) (Figure 1; Supplement SM4). During the period of scaled back service (S1), visit numbers initially climbed while the visit interval decreased, which may reflect increased visit frequency due to short-term drug supplies. Once drug buffer stock was exhausted, visit numbers dropped off sharply. Patients may have avoided or were prevented from attending due to security conditions.

Figure 1: Average number of days from previous visit per month for Mweso IDC-OPD service

BP control was consistently better than glycaemic control (of note, patients without diagnosed hypertension were included in the analysis) (Figure 2). By period T2, approximately 80% of visits achieved BP and 60% achieved glycaemic control. There was a notable drop in control of both parameters during programme suspension with a gradual improvement on resumption. Blood pressure control was consistently better, while glycaemic control was consistently worse, in patients prescribed insulin (+/- OHGs) compared with those prescribed OHGs alone (Supplement SM5), which

may be because the former group contained relatively young Type 1 and malnutrition-related diabetics.

Figure 2: Proportion of visits with BP or glycaemia at target by month, Mweso IDC-OPD service

The results of the odds ratio (OR) calculations were unexpected. Odds of attaining BP control appeared to worsen following implementation of the formal IDC-OPD programme (T2 vs. T1), while odds of attaining glucose control improved, perhaps because care was initially focussed on glucose control (Supplement SM6). On scaling back the service (S1), control of both parameters seemed to improve, possibly because the service itself or the subset of patients reaching it during the insecure period were somehow different. Once medications supplies were exhausted (S2), control of both parameters seemed to worsen, but control was regained on service resumption. Stratifying by insulin prescription showed similar results (Supplement SM5).

Costs of providing diabetes care

The total costs of diabetes care in 2014 and 2015 were approximately €37,000 and €31,000 respectively (Table 3). Supplies were the major driver of costs each year. The greatest costs in 2014 were for latex gloves, glucometers and glucometer strips; in 2015 they were for glucometers, strips and lancets (Supplement SM2). While medication costs increased in 2015 relative to 2014, staff costs remained unchanged, and total costs decreased, largely driven by reduced excess consumption of latex gloves after it was identified during the IDP-OPD training sessions. The total number of patients and number of visits increased significantly from 2014 to 2015, rising from 77 and 626 to 144 and 1103, respectively. Thus, cost per-patient per-year (PPPY) dropped from €475 to €214 and cost per-visit was halved from €58 to €28. This was due to the combined effect of higher patient numbers, greater total number of visits and lower supply costs in 2015 compared to 2014 (Supplement SM2).

Table 3. Costs (€) of diabetes care in 2014 and 2015, Mweso IDC-OPD service

Cost category	2014	% 2014 costs	2015	% 2015 costs
Medicine costs	5,202	14%	7,746	25%
Supply costs	25,435	70%	17,180	56%
Staff costs	5,935	16%	5,935	19%
Total costs	**36,573**	100%	**30,861**	100%
Costs per visit	**58**		**28**	
Costs per patient	**475**		**214**	

Discussion

This evaluation of a chronic disease programme in a complex conflict setting, using routine programmatic and cost data, provided lessons, which may improve clinical care and programme design. To the best of our knowledge, the influence of treatment interruption and insecurity on diabetes management in humanitarian settings has not been addressed in the literature. Similarly, we are not aware of costing studies of diabetes care in crisis settings.

Our results show that glycaemic control was similar or better to that documented in other humanitarian or low-income settings (using different targets) and, while it was positively impacted by programmatic changes, control clearly deteriorated during periods of heightened insecurity.[27] Our findings also indicate that, in a population previously undergoing regular supervision, a simplified nurse-provided, algorithm-driven service with consistent medication supply may be as

effective as close medical supervision in maintaining disease control, particularly during periods of service interruption. Medical input could thus be focused on achieving glycaemic control in patients prescribed insulin, who appeared most affected by service interruption. We also note the lack of evidence supporting management of what we believed to be malnutrition-related diabetes.

Intermittent outbreaks of armed conflict limited patient access and disrupted supply chains, impeding continuity of care. We suggest that in high-insecurity settings, chronic disease programmes should focus on preparing patients, staff and supply chains to pre-empt treatment interruption during insecure periods, learning from HIV programme experiences in similar settings.[28] Preparation could include: triaging patients by vulnerability (e.g. prioritising insulin-dependent diabetic patients, those with established complications and/or living far from the facility); enhancing patients' health literacy and self-management education and provision of patient-held personal treatment plans and emergency kits (including several months' supply of medications, such as insulin, delivery devices and guidance as appropriate) to facilitate self-care during insecure periods; building staff capacity to allow for flexibility of roles in crises; establishing networks with other chronic disease programmes; and stockpiling and secure storage of medications.[5,28,29] Technology could facilitate continued patient treatment support when access to facilities is impossible e.g. via mobile phone SMS messaging or decentralisation of care to community-based health workers furnished with clinical decision support tools or supported via telemedicine.

The relatively poorer glycaemic control in insulin-prescribed patients may reflect either disease severity or the challenges associated with insulin therapy. Adherence to daily insulin injections is difficult anywhere; in Mweso, the security, financial and geographical barriers to accessing insulin and the unavailability, unaffordability and burden for families of the recommended diabetes diet, may additionally contribute to poor adherence.[22] In this programme, clinicians adjusted insulin doses based on a single fasting glucose reading taken in clinic and on patients' reported symptoms in

the absence of home glucose monitoring and, therefore, dose adjustment was cautious and treatment targets were conservative.

There is limited, although growing, evidence on the incidence, prevalence and characterisation of diabetes in Sub-Saharan Africa, which our findings broadly reflect.[30] Several reviews and recent ethnographic evidence describe "atypical" forms of diabetes, which may complicate diagnosis, classification and management. These include "*ketosis-prone atypical diabetes mellitus"* and *"malnutrition-related diabetes"*. [13,16,31] Local prevalence studies support the existence of the latter in the DRC, which is in keeping with the high proportion of underweight adults and "unclassified" diabetics in our cohort.[14,32] It is unclear whether malnutrition is causative, associated with hyperglycaemia or with pancreatic insufficiency and further study of diabetes epidemiology in DRC is needed, exploring factors such as childhood malnutrition, food insecurity and underweight and use of calorie-dense therapeutic foods. [31] Moreover, little evidence exists to guide either malnutrition-related diabetes care or the effective management of insulin in humanitarian settings, particularly in the absence of home or community-based glucose testing.[3,7]

The total cost of care delivery decreased by 16% from 2014 to 2015 despite increased visit and patient numbers. This was largely due to decreased supply costs, driven by the 100-fold reduction in consumption of latex gloves following IDC-OPD training. Efficiencies of supply consumption and patient throughput (more visits and more patients seen by the same number of staff) contributed to reducing PPPY costs by 55% from €475 in 2014 to €214 in 2015.

To our knowledge, there is no available literature to compare cost per patient or per visit for diabetes care (or NCD care generally) delivered in unstable humanitarian settings. A study from Ghana reported a per patient annual direct cost of US$372.65 for hospital-delivered diabetes care in 2005. For a potential comparator, we looked at the cost of delivering chronic care for HIV, the main life-long condition with which humanitarian actors have traditionally engaged. The 2015 PPPY cost reported in this study is far lower than that reported by PEPFAR and others to deliver chronic HIV

care programmes in low and middle income countries in SSA [33,34]. In terms of cost structure, supplies were the major cost driver in the Ghanaian study (syringes, lancets and strips), whereas other analyses of diabetes care in SSA identified medications, and specifically insulin, as the main cost contributor [35,36].

Strengths and Limitations

Using routine clinical and programmatic data, with minimal service disruption, we have explored clinical outcomes of a chronic disease programme in a protracted conflict setting and the influence of periods of heightened insecurity on intermediate clinical outcomes and on service delivery. Each patient who attended in a given month contributed data, irrespective of whether they ever experienced a treatment interruption. Our study provides new costing information for humanitarian actors to support the initiation or adaptation of specific NCD programmes and may potentially support scale up of similar services in DRC (and other conflict-affected settings). We concluded that the incremental cost of adding an outpatient diabetes service to a humanitarian health programme in a rural hospital setting may be achieved at a cost similar to that of delivering chronic HIV programmes. While we cannot confirm whether an external audit of cost data had taken place, we are confident in the quality of these data due to MSF's robust systems and oversight by strong in-country and international teams.

Given the logistical and ethical challenges of undertaking research in conflict settings, we acknowledge that there are a number of study limitations. We had a relatively small sample size and no control group for comparison. We did not explore per patient control of clinical parameters over time, control by diabetes type (or age), appropriateness of prescribing, patient-reported outcomes or the influence of psychosocial factors, diet, or adherence in each study phase since these data were unavailable. Gestational diabetes was not addressed since this was managed within antenatal services. Our costing analysis was descriptive so we could not comment on programme cost-effectiveness. Costing data were presented as average annual costs and did not explore the impact

of various programme periods on costs. Since our cost data were aggregate, we could not explore patient-level costs or account for patient heterogeneity. While our findings may not be generalizable to other complex humanitarian settings or to other providers' diabetes programmes in the DRC, our study contributes knowledge on key challenges and suggests solutions, which may be more broadly applicable.

Future research is needed in complex humanitarian settings to evaluate simplified, task-shared models of diabetes care, including culturally- and contextually-relevant psychosocial support and dietary advice; to optimise insulin management; and to evaluate emergency preparedness plans and technology-facilitated remote patient support.[3,5,8,13,29] We recommend that future prospective studies should explore per-patient outcomes (while also exploring programme-level outcomes as done in this study). We suggest including a control group; collecting additional outcome variables, such as complication rates and patient-reported outcomes e.g. related to quality-of-life, including functionality and mental health; and exploring the impact of psychosocial stressors and treatment interruption on clinical outcomes. We also suggest that cost-effectiveness studies of different models of diabetes care, including use of technology-facilitated remote support, and patient level costing studies from both provider and patient perspectives should be undertaken, exploring patient heterogeneity and direct and indirect patient costs.

Conclusion

Our results help develop the sparse knowledge on the prevalence and characterisation of diabetes in Sub-Saharan Africa. They demonstrate that diabetes care is feasible even in complex humanitarian emergencies, and at a cost that is lower than chronic HIV care. The results also indicate that the Mweso IDC-OPD programme could be further simplified to involve drug collection along with nurse-led, algorithm-guided treatment adjustment. We suggest that chronic disease programmes in unstable settings should engage in emergency preparedness, learning from the experience of HIV

programmes in similar settings. Future research is needed to evaluate simplified, task-shared models of diabetes care and management; and to evaluate emergency preparedness plans and technology-facilitated remote patient support.

List of Abbreviations

BMI	Body Mass Index
BP	Blood Pressure
DM	Diabetes Mellitus
DRC	Democratic Republic of Congo
HIV	Human Immunodeficiency Virus
IDC-OPD	Integrated Diabetic Clinic within Hospital Outpatient Department
LMICs	Low- and Middle-Income Countries
MSF	Médecins sans Frontières
NCD	Noncommunicable Disease
OHG	Oral Hypoglycaemic Drugs
OR	Odds Ratio
PPPY	Per Patient Per Year

Declarations

Ethics approval and consent to participate

This study was approved by the Ministry of Health of North Kivu Province, DRC, by the MSF Ethics Review Board, and the Ethics Committee of the London School of Hygiene and Tropical Medicine. Information sheets on the clinic walls provided details of the evaluation; no specific consent was sought from patients for use of their routine clinical data.

Authors' contributions

KJ and BR were involved in study conception; EA, GC, KJ, DPM, PP and BR contributed to study design and interpretation of data. DPM and ZS analysed the data. MB contributed to data collection. EA drafted the manuscript and all authors reviewed drafts and approved the final version.

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Competing Interests

The authors declare that they have no competing interests.

Data Sharing

The datasets are available from MSF on request by researchers who fulfil certain criteria and under the auspices of a data sharing agreement.

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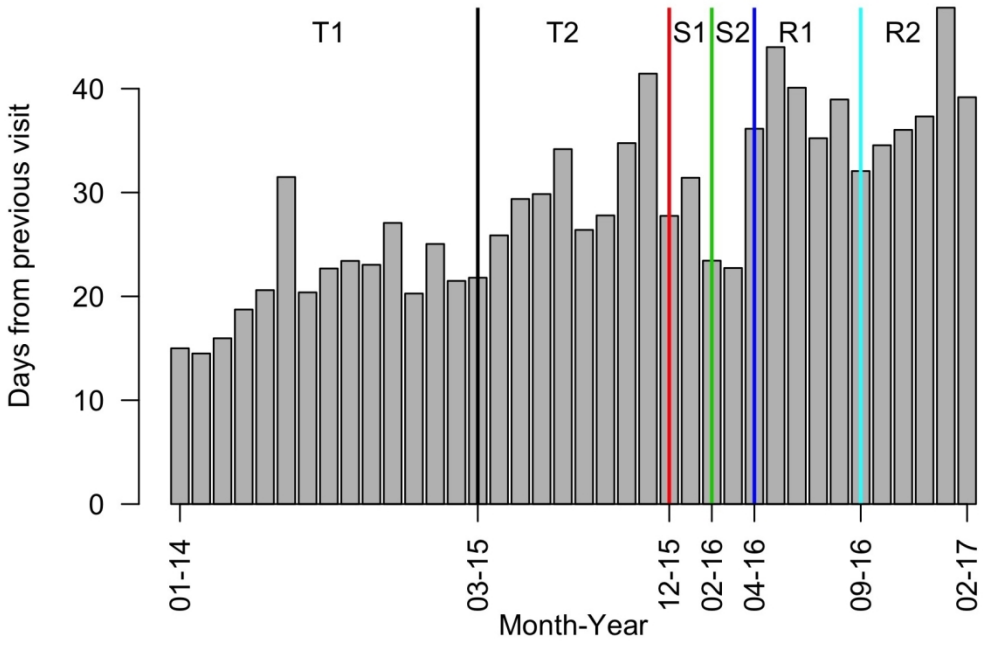

Figure 1: Average number of days from previous visit per month for Mweso IDC-OPD service

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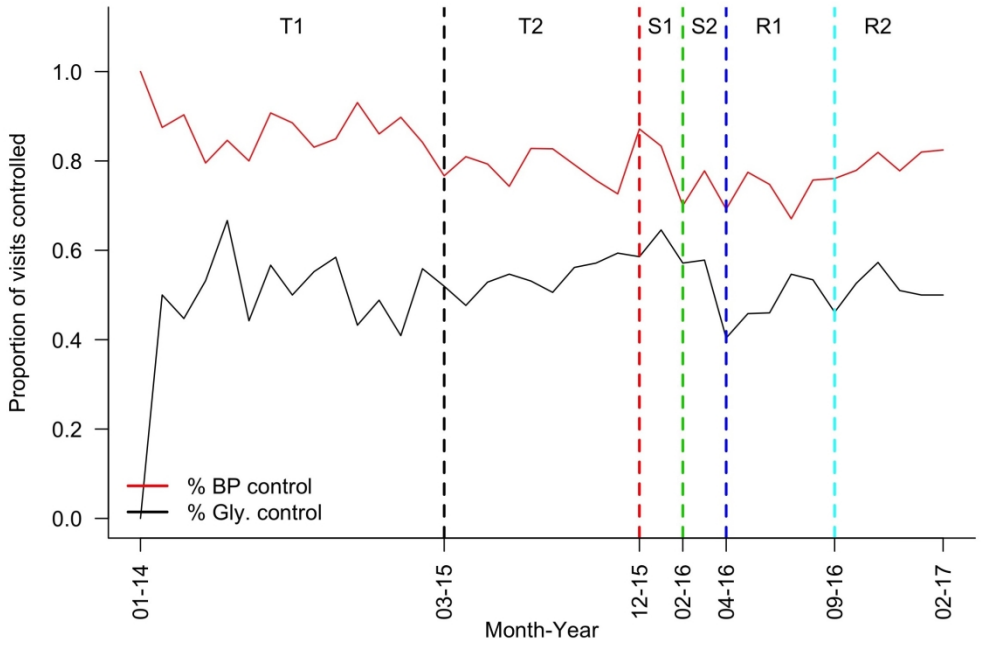

Figure 2: Proportion of visits with BP or glycaemia at target by month, Mweso IDC-OPD service

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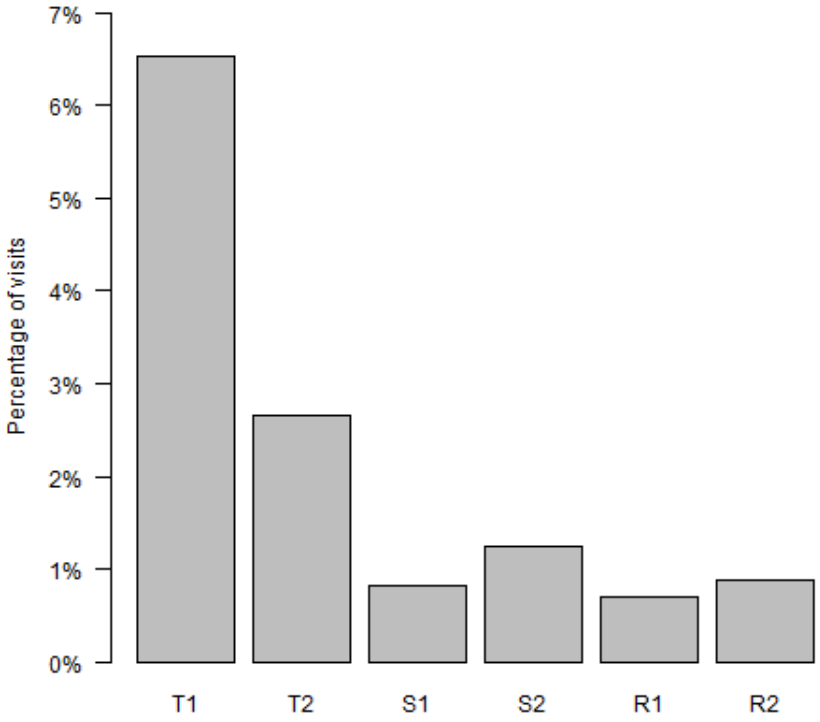
SM1. Proportion of visits with missing data for either blood pressure or glycaemia measurements, IDC-OPD Programme, Mweso, DRC



Note: Definitions of study periods T1 – R2 are described in Table 1

SM2. Monthly resource use associated with IDC-OPD in Mweso Hospital, North Kivu, DRC

Items	Unit cost (€)	Forecast monthly consumption	
		2014	2015
Medicine			
INSULIN ISOPHANE (NPH), human, 100 UI/ml, 10 ml, vial	6.300	40	40
INSULIN RAPID, human, 100 IU/ml, 10 ml, vial	6.300	8	8
INSULIN, 100IU/ml, BIPHASIC 30, human, 10ml, vial	13.610	10	10
METFORMIN hydrochloride, 500 mg, tab.	0.014	5,300	12,000
GLIBENCLAMIDE, 5 mg, tab.	0.005	750	3,600
HYDROCHLOROTHIAZIDE, 50 mg, tab.	0.003	0	300
GLUCOSE HYPERTONIC, 50%, 50 ml, vial	0.556	75	6
AMITRIPTYLINE hydrochloride, 25 mg, tab.	0.006	200	750
ACETYLSALICYLIC acid (aspirin), 75 mg, tab.	0.005	0	2,000
AMLODIPINE 5mg, tabs.	0.018	0	300
Supplies			
GLUCOMETER, blood glucose monitor (Nova StatStrip) + strips	96.705	5	10
(glucometer Nova StatStrip) STRIP ref. 42214	0.230	2,000	4,000
SYRINGE, s.u., Luer, insulin, 100 IU/1 ml + fixed needle	0.079	2,000	4,000
(spectrophotometer) KIT, DOSAGE CREATININE, Liquicolor 200ml	4.830	3.5	3.5
THERMOMETER, ELECTRONIC, accuracy 0.1§ C + case	1.110	20	3
SPHYGMOMANOMETER, one-hand manometer, Velcro, adult	26.000	0	1
TEST, URINE, pH,dens,prot,gluc,ket,blood,nit,leuc, 1 strip	0.197	100	200
REUSABLE SHARPS CONTAINER (RSC), 1.2 litre	44.750	1	1
CONTAINER, SAMPLE, plast., 60ml, non sterile, urine	0.083	1,700	200
LANCET, s.u., sterile, standard point	0.006	900	4,000
GLOVE, EXAMINATION, latex, s.u. non sterile, medium	0.025	50,000	500
Staff time (days allocated to diabetes care)*			
MSF Medical doctor	1,350	4	4
MSF Nurse	900	4	4
BCZ Nurse	239	4	4
MSF psychosocial worker	1,422	0.5	0.5
1 Nutritionist (MSF)	864	0.25	0.25

*Note: Staff time costs assumed 22 full-time working days per month.

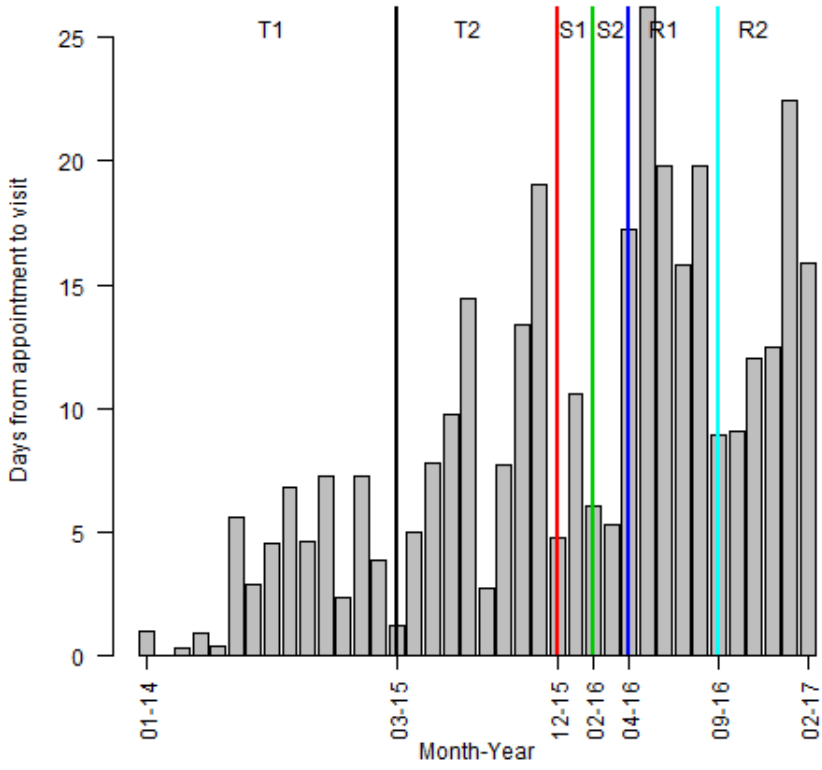
SM3. Baseline characteristics of 243 patients on enrolment into Mweso IDC-OPD service

Variable	Total	(%)	DM-1	(%)	DM-2	(%)	Other/NA	(%)
Patients (N)	243		62		125		56	
Age								
<18	24	(9.9%)	19	(30.6%)	0	(0.0%)	5	**(8.9%)**
18-40	74	(30.5%)	39	(62.9%)	20	(16.0%)	15	**(26.8%)**
41-60	112	(46.1%)	3	(4.8%)	80	(64.0%)	29	**(51.8%)**
>60	33	(13.6%)	1	(1.6%)	25	(20.0%)	7	**(12.5%)**
Sex								
Male	134	(55.1%)	34	(54.8%)	70	(56.0%)	30	**(53.6%)**
Female	108	(44.4%)	28	(45.2%)	55	(44.0%)	25	**(44.6%)**
No data	1	(0.4%)	0	(0.0%)	0	(0.0%)	1	**(1.8%)**
Occupation								
Labourer	121	(49.8%)	29	(46.8%)	85	(68.0%)	7	**(12.5%)**
Office worker	19	(7.8%)	2	(3.2%)	11	(8.8%)	6	**(10.7%)**
Student	8	(3.3%)	8	(12.9%)	0	(0.0%)	0	**(0.0%)**
Unable to work	11	(4.5%)	7	(11.3%)	3	(2.4%)	1	**(1.8%)**
Other	48	(19.8%)	15	(24.2%)	26	(20.8%)	7	**(12.5%)**
No data	36	(14.8%)	1	(1.6%)	0	(0.0%)	35	**(62.5%)**
Medical History								
CVD								
Yes	5	(2.1%)	1	(1.6%)	3	(2.4%)	1	**(1.8%)**
No data	24	(9.9%)	0	(0.0%)	0	(0.0%)	24	**(42.9%)**
Hypertension								
Yes	20	(8.2%)	0	(0.0%)	18	(14.4%)	2	**(3.6%)**
No data	25	(10.3%)	0	(0.0%)	1	(0.8%)	24	**(42.9%)**
Tuberculosis								
Yes	6	(2.5%)	1	(1.6%)	5	(4.0%)	0	**(0.0%)**
No data	24	(9.9%)	0	(0.0%)	0	(0.0%)	24	**(42.9%)**
Malnutrition								
Yes	19	(7.8%)	15	(24.2%)	2	(1.6%)	2	**(3.6%)**
No data	24	(9.9%)	0	(0.0%)	0	(0.0%)	24	**(42.9%)**
Family Hx of DM								
Yes	35	(14.4%)	6	(9.7%)	23	(18.4%)	6	**(10.7%)**
No data	24	(9.9%)	0	(0.0%)	0	(0.0%)	24	**(42.9%)**

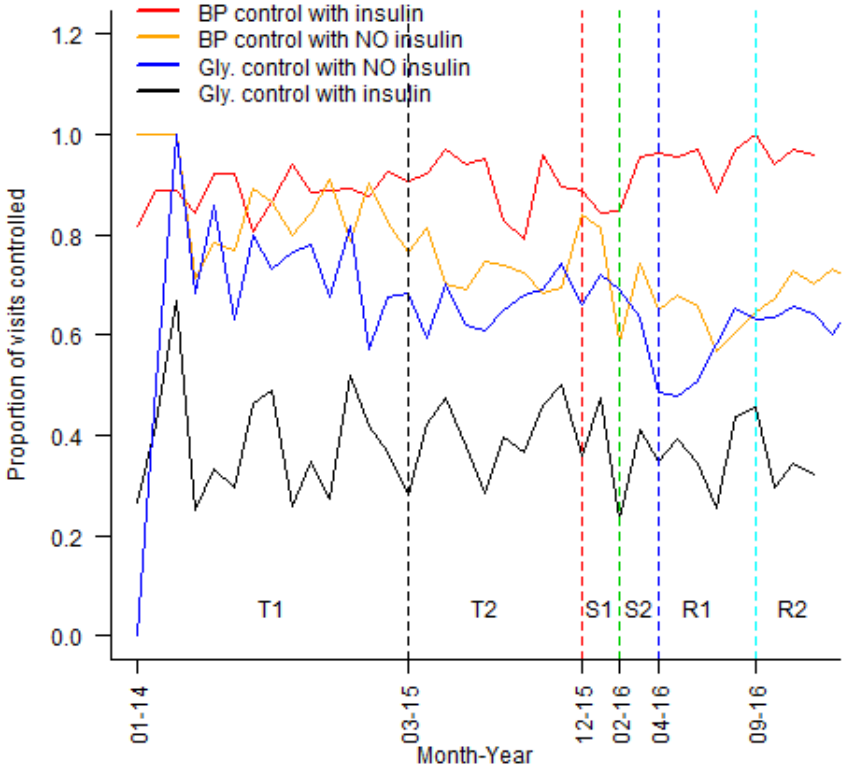
Patients >=18 years(N)*	219		43		125		51	
Smoking								
Yes	18	(8.2%)	1	(2.3%)	16	(12.8%)	1	**(2.0%)**
No data	21	(9.6%)	0	(0.0%)	0	(0.0%)	21	**(41.2%)**
Alcohol								
Yes	50	(22.8%)	12	(27.9%)	32	(25.6%)	6	**(11.8%)**
No data	33	(15.1%)	0	(0.0%)	1	(0.8%)	32	**(62.7%)**
BMI								
<18.5	68	(31.1%)	23	(53.5%)	34	(27.2%)	11	**(21.6%)**
18.5-24.9	96	(43.8%)	15	(34.9%)	59	(47.2%)	22	**(43.1%)**
25.0-29.9	41	(18.7%)	5	(11.6%)	27	(21.6%)	9	**(17.6%)**
>=30	7	(3.2%)	0	(0.0%)	5	(4.0%)	2	**(3.9%)**
No data	7	(3.2%)	0	(0.0%)	0	(0.0%)	7	(13.7%)

Note: For smoking, alcohol and BMI, denominators included only patients aged 18 years or above.

SM4. Average days' delay in attendance since planned appointment per month of IDC-OPD service, Mweso, DRC



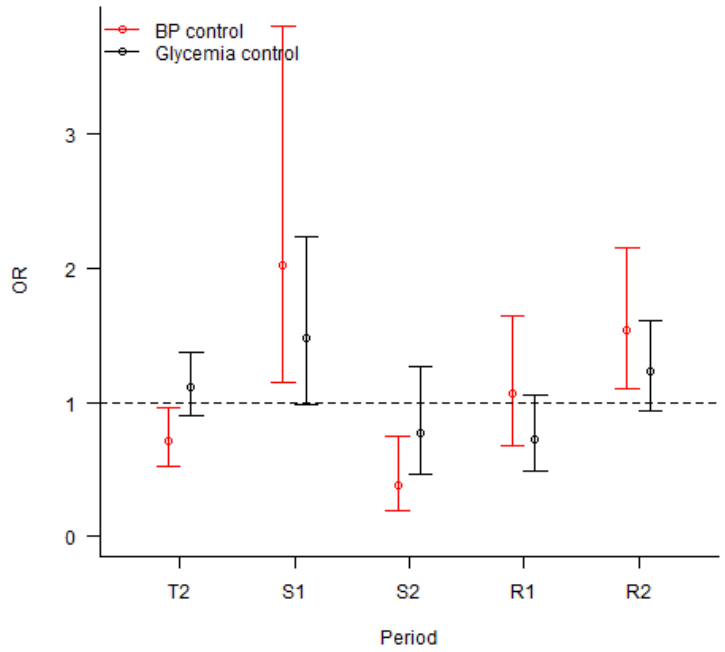
SM5. Proportion of visits at target for BP and glycaemic control, stratified by insulin prescription per month of IDC-OPD service, Mweso, DRC



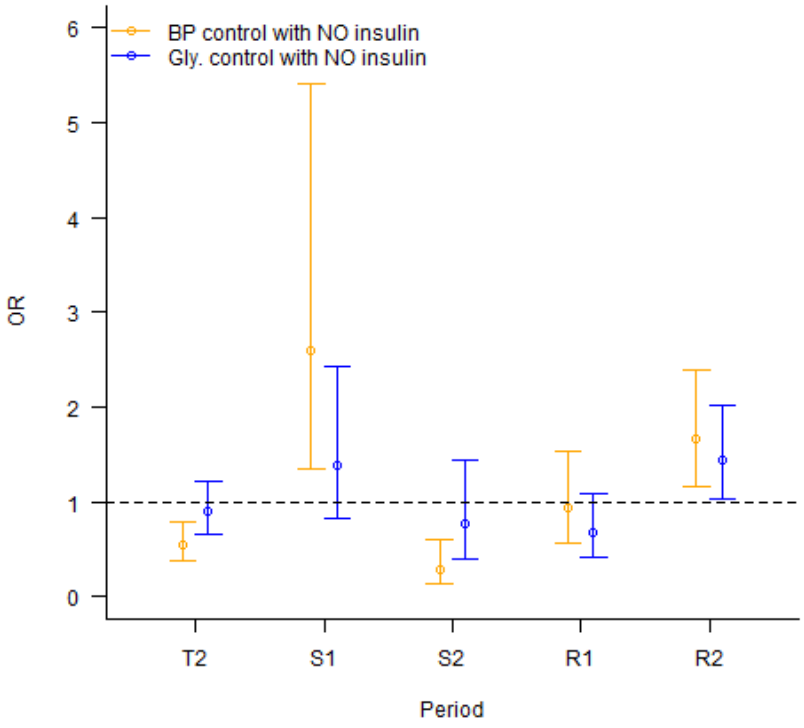
Note: Patients were categorised by whether they were prescribed insulin [+/- oral hypoglycaemic (OHG) drugs]) or OHG drugs alone at their last recorded visit. The former group would have included Type 1 diabetics, Type 2 diabetics with more advanced illness requiring a combination of OHG and insulin, and those with an intermediate type of diabetes, presenting with high insulin requirements in the absence of diabetic ketoacidosis, which we postulated represented "malnutrition-related diabetes". The latter group were likely to include Type 2 diabetics.

SM6. Impact (OR) on BP and glycaemic control of study period over previous period, unstratified (A) and stratified by insulin prescription (B and C) per month of IDC-OPD service, Mweso, DRC

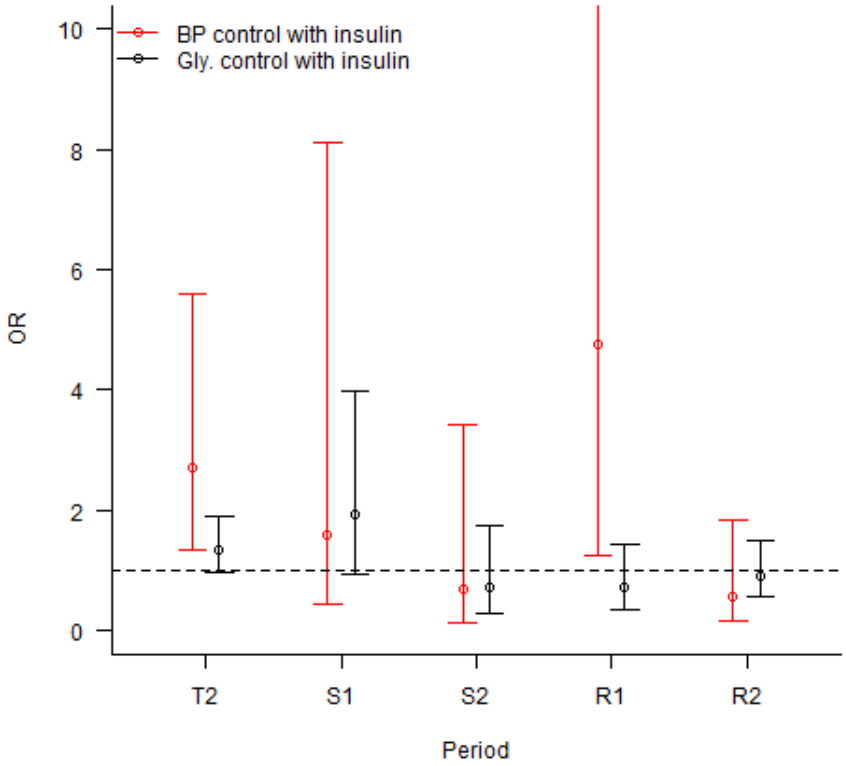
A. Impact (OR) on BP and glycaemia in all patients (not stratified by insulin prescription)



B. Impact (OR) on BP and glycaemia in patients on oral hypoglycaemic drugs only



C. Impact (OR) on BP and glycaemia in patients prescribed insulin (+/- OHG)



STROBE Statement—Checklist of items that should be included in reports of ***cross-sectional studies***

Study Title: Management of diabetes and associated costs in a complex humanitarian setting in the Democratic Republic of Congo: a retrospective cohort study.

	Item No	Recommendation	Page No
Title and abstract	1	(*a*) Indicate the study's design with a commonly used term in the title or the abstract	1,4
		(*b*) Provide in the abstract an informative and balanced summary of what was done and what was found	2-3
Introduction			
Background/rationale	2	Explain the scientific background and rationale for the investigation being reported	4-7
Objectives	3	State specific objectives, including any prespecified hypotheses	7
Methods			
Study design	4	Present key elements of study design early in the paper	7-11
Setting	5	Describe the setting, locations, and relevant dates, including periods of recruitment, exposure, follow-up, and data collection	4,5,7, 8, 11
Participants	6	(*a*) Give the eligibility criteria, and the sources and methods of selection of participants	7
Variables	7	Clearly define all outcomes, exposures, predictors, potential confounders, and effect modifiers. Give diagnostic criteria, if applicable	6,9,10
Data sources/ measurement	8*	For each variable of interest, give sources of data and details of methods of assessment (measurement). Describe comparability of assessment methods if there is more than one group	6
Bias	9	Describe any efforts to address potential sources of bias	n/a
Study size	10	Explain how the study size was arrived at	7
Quantitative variables	11	Explain how quantitative variables were handled in the analyses. If applicable, describe which groupings were chosen and why	10
Statistical methods	12	(*a*) Describe all statistical methods, including those used to control for confounding	10
		(*b*) Describe any methods used to examine subgroups and interactions	10
		(*c*) Explain how missing data were addressed	10,11
		(*d*) If applicable, describe analytical methods taking account of sampling strategy	10
		(*e*) Describe any sensitivity analyses	n/a
Results			
Participants	13*	(a) Report numbers of individuals at each stage of study—eg numbers potentially eligible, examined for eligibility, confirmed eligible, included in the study, completing follow-up, and analysed	10
		(b) Give reasons for non-participation at each stage	n/a
		(c) Consider use of a flow diagram	n/a
Descriptive data	14*	(a) Give characteristics of study participants (eg demographic, clinical, social) and information on exposures and potential confounders	Supp Mat 3
		(b) Indicate number of participants with missing data for each variable of interest	Supp Mat 1
Outcome data	15*	Report numbers of outcome events or summary measures	9,10

Main results	16	(*a*) Give unadjusted estimates and, if applicable, confounder-adjusted estimates and their precision (eg, 95% confidence interval). Make clear which confounders were adjusted for and why they were included	n/a
		(*b*) Report category boundaries when continuous variables were categorized	Supp Mat 3
		(*c*) If relevant, consider translating estimates of relative risk into absolute risk for a meaningful time period	n/a
Other analyses	17	Report other analyses done—eg analyses of subgroups and interactions, and sensitivity analyses	n/a
Discussion			
Key results	18	Summarise key results with reference to study objectives	12-14
Limitations	19	Discuss limitations of the study, taking into account sources of potential bias or imprecision. Discuss both direction and magnitude of any potential bias	17,18
Interpretation	20	Give a cautious overall interpretation of results considering objectives, limitations, multiplicity of analyses, results from similar studies, and other relevant evidence	14-16
Generalisability	21	Discuss the generalisability (external validity) of the study results	18
Other information			
Funding	22	Give the source of funding and the role of the funders for the present study and, if applicable, for the original study on which the present article is based	20

*Give information separately for exposed and unexposed groups.

Note: An Explanation and Elaboration article discusses each checklist item and gives methodological background and published examples of transparent reporting. The STROBE checklist is best used in conjunction with this article (freely available on the Web sites of PLoS Medicine at http://www.plosmedicine.org/, Annals of Internal Medicine at http://www.annals.org/, and Epidemiology at http://www.epidem.com/). Information on the STROBE Initiative is available at www.strobe-statement.org.