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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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3 1 **Title: Management of diabetes and associated costs in a complex humanitarian setting in the**
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5 2 **Democratic Republic of Congo.**
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54 27 noncommunicable disease, humanitarian, conflict, care model, management, programme, chronic
55 28 care, outpatient, hospital care, task shifting, cost, economic.
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30 Abstract

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

35 **Design:** A cohort analysis of routine outcome data collected between January 2014 and February
36 2017; and analysis of programme costs for 2014/15.

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

40 **Participants:** Diabetes patients using the IDC-OPD.

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

43 **Results:** Of 243 enrolled diabetes patients, 44.6% were women, median age was 45 (IQR 32-56);
44 51.4% were classified Type 2. Visit numbers and visit interval increased on introduction of IDC-OPD
45 but decreased when insecurity led to service scale-back and subsequent suspension. Clinical control
46 rates during initial service scale-back were similar to the preceding period of full implementation.
47 Later, patients were less likely to achieve control due to exhaustion of medications but this improved
48 again on service resumption. Total costs decreased by 20% from 2014 (€32,121) to 2015 (€26,410).
49 Annual cost per patient dropped from €417 in 2014 to €183 in 2015 due to reduced supply costs and
50 increased patient throughput.

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

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3 53 simplified to involve drug collection with nurse-led, algorithm-guided treatment adjustment and
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5 54 strengthened emergency preparedness. Further research is required to define a minimum effective
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8 55 treatment package for diabetes in complex humanitarian settings.
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13 57 **Article Summary**

- 16 58 • This is the first study of its kind to examine diabetes outcomes and programme costs in a
17 59 complex humanitarian setting in sub-Saharan Africa.
- 19 60 • Logistic regression was used to estimate the effect of insecurity and related programmatic
20 61 changes on clinical outcomes.
- 22 62 • The study was limited by the relatively small sample size and lack of control group for
23 63 comparison.
- 25 64 • The costing analysis was descriptive only and so cost-effectiveness of the programme could
26 65 not be assessed.

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4 67 **Title: Management of diabetes and associated costs in a complex**
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6 68 **humanitarian setting in the Democratic Republic of Congo**
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13 70 **Background**
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15 71 Over the past 40 years, the prevalence of diabetes has increased sharply worldwide, particularly in
16 72 low and middle income countries.[1] However, data are scarce from conflict-affected countries,
17 73 particularly those in Central, West and East Africa.[1] Humanitarian actors have been slow to
18 74 prioritise diabetes treatment in disaster and post-conflict settings despite reporting increasing
19 75 presentations of patients within their programmes.[2–4] This is due to lack of knowledge on local
20 76 diabetes prevalence and needs, limited research on diabetes management or outcomes in
21 77 emergency settings; and a lack of programmatic and policy guidance to support diabetes care in
22 78 humanitarian settings.[2,5–7] North Kivu in the Democratic Republic of Congo (DRC) is one such
23 79 complex humanitarian setting, where diabetes prevalence (estimated at between 4 and 5.4%) is
24 80 increasing in the context of a health system weakened by prolonged conflict.[8–10]
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29 81 Since 2008, Médecins sans Frontières (MSF) has supported healthcare delivery in Mweso, North
30 82 Kivu, DRC, in collaboration with the Ministry of Health. North Kivu, with an estimated population of
31 83 365,000, is a rural, impoverished area bordering Rwanda. It remains a flash point in the on-going
32 84 conflict in the DRC and hosts 17 internally displaced person camps. MSF supports health services in 4
33 85 out of 23 Primary Health Care clinics and in Mweso hospital within Masisi District. Mweso hospital
34 86 serves a catchment area of approximately 145,000 people, with about 65,000 beneficiaries living in
35 87 the immediate vicinity of the hospital.
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55 88 In response to growing patient and provider needs, MSF implemented a context-adapted, hospital-
56 89 based diabetes programme in March 2015, the Integrated Diabetic Clinic within Hospital Outpatient
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3 90 Department (IDC-OPD) in place of the ad hoc care previously undertaken. Intermittent
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5 91 deteriorations in security led to temporary scaling back or suspension of the programme and
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7 92 restricted patients' movement.
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10 93 The IDC-OPD was a nurse-led, multi-disciplinary model, based on locally adapted clinical guidelines,
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12 94 patient counselling materials and data collection tools, accompanied by 3 days of specialist
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14 95 training.[11] The clinic team included: a nurse supervisor, nursing assistant, two doctors, a
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16 96 nutritionist, and education and psychosocial support officers. Diabetes was diagnosed according to
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18 97 World Health Organization (WHO) guidelines using repeated fasting capillary glucose. Most patients
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20 98 were identified as diabetic and enrolled after acute hospital presentation, while some were
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22 99 identified via the Mweso outpatient department or referring primary care clinics.
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27 100 Patients received a detailed enrolment assessment, monthly nurse-led follow-up and 6-monthly
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29 101 medical review, with nutrition and psychosocial support. Each patient was given a clinic-held patient
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31 102 file and patient-held passport to facilitate safe passage. Clinical guidelines were adapted from MSF,
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33 103 WHO and other international guidance. Patient educational tools were adapted from Santé
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35 104 Diabète,[12] a Malian Non-Governmental Organisation, and medications were those included on
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37 105 MSF's Essential Drugs List. Insulin doses were adjusted using single fasting capillary blood glucose
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39 106 readings and patients' reported symptoms of hypo- or hyperglycaemia in the absence of home
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41 107 glucose monitoring.
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46 108 A mixed methods evaluation of the Mweso IDC-OPD programme was undertaken by MSF (with
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48 109 qualitative component of the evaluation exploring patient and provider challenges, presented
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50 110 elsewhere [13]). Here, we report quantitative data on programmatic and clinical outcomes and
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52 111 programme costs. The overall objective of this study was evaluate the MSF IDC-OPD Programme in
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54 112 the complex humanitarian setting of North Kivu, DRC. The specific objectives were to: (i) analyse
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3 113 diabetes management outcomes; (ii) examine the association of key insecurity and related
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5 114 programmatic events with diabetes outcomes; and (iii) analyse IDC-OPD programme costs.
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8 9 115 **Methods**

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11 116 For the outcome analysis, we conducted a retrospective analysis of routine data of enrolled adults
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13 117 aged ≥ 18 years from January 2014 to February 2017, examining trends in diabetes outcomes and
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15 118 their association with key programmatic events. The study period was divided into five phases,
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17 119 defined by programmatic changes or periods of heightened insecurity (which impacted service
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19 120 delivery due to staff evacuation, supply chain interruption and reduced patient access). Period T1
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21 121 refers to ad-hoc care delivered before introduction of the IDC-OPD programme (T2). Security
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23 122 incidents in December 2015 prompted a period of service suspension (nurse-only care, with drug
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25 123 pick-ups, glucose testing and minimal treatment adjustments) (S1). Complete suspension followed
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27 124 once drug stocks were exhausted (S2). Limited service resumed in April (R1) until full service
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29 125 recommenced from September 2016 (R2) (Table 1).
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33

34 126 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

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128 Data

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

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

146

147 Table 2: Outcome measures used to determine effect of different programme periods on
 148 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 where 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

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

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151 Analysis

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

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3 154 impact of study periods on intermediate clinical outcomes i.e. per visit attainment of blood pressure
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5 155 (< 140/90 mmHg) and glycaemic (> 4.2 and ≤ 8.3 mmol/L) targets.
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8 156 To estimate the effect of a period change we calculated the odds ratio (OR) of the odds of having the
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10 157 biomarker under control in a visit in the new period (t) over the odds of having the biomarker
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12 158 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
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14 159 chances of the biomarker being under control in a visit in period t was greater than the chances of
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16 160 the biomarker being under control in a visit in the previous period ($t-1$) (but not necessarily than
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18 161 other periods, $t-2$, $t-3$, etc.). Likewise, $OR_t < 1$ implied a reduction in the chances of having the
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20 162 biomarker under control in a visit during period t compared to a visit during the previous period ($t-$
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22 163 1). To estimate these OR we ran a logistic model with period as a categorical variable, suitably
23
24 164 coded, and adjusted for sex, age (and square and cube terms) and number of visits of the patient
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26 165 (and square term).
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31 166 Missing data: Our main analysis used only complete data. Few outcome variable data were missing:
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33 167 less than 3% in BP control (most of it in the pre-training period) and less than 0.3% for glycaemic
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35 168 control (Supplement SM1). There were no missing data for date of visit, sex or age.
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40 41 170 **Costing data and analysis**

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43 171 For the descriptive cost analysis we took a health services perspective. Key cost items identified from
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45 172 a field visit were grouped into: (a) medicine, (b) supplies, and (c) staff time. Monthly resource use
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47 173 and unit cost data were collected from clinic records (Supplement SM3). Monthly costs for each item
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49 174 were annualised; total cost, cost per visit and cost per patient were reported in Euro (€) for 2014 and
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51 175 2015.
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53

54 176 The study was approved by the Ministry of Health of North Kivu Province and the MSF and London
55
56 177 School of Hygiene and Tropical Medicine Ethics Review Boards.
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178 Patient and Public Involvement

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

180 Results

181 Between January 1st 2014 and February 9th 2017, 243 patients were enrolled in the IDC-OPD
182 programme (Supplement SM2). Median age was 45 years (IQR 32 – 56); 44.6% of the cohort was
183 female. For adults ≥ 18 years ($n=219$), mean BMI was 21.3 kg/m² and 31.1% were underweight (BMI
184 < 18.5 kg/m²). On enrolment, 8.2% were current smokers; 24.4% reported recent alcohol intake;
185 self-reported medical history included: 9.1% hypertension, 2.2 % CVD, 2.7% tuberculosis (TB) and
186 8.7% malnutrition. Half were classified clinically as Type 2 diabetic (51%; $n=125$); 26% ($n=62$) as Type
187 1; and 23% ($n=56$) were either unclassified or classed as “other” (Supplement SM2).

188 Trends in outcomes and impact of programmatic events

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

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

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

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3 201 parameters during programme suspension with a gradual improvement on resumption. Blood
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5 202 pressure control was consistently better, while glycaemic control was consistently worse, in patients
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7 203 prescribed insulin (+/- OHGs) compared with those prescribed OHGs alone (Supplement SM5), which
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9 204 may be because the former group contained relatively young Type 1 and malnutrition-related
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12 205 diabetics.

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17 207 Figure 2: Proportion of visits with BP or glycaemia at target by month, Mwesio IDC-OPD service18
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23 209 The results of the odds ratio (OR) calculations were unexpected. Odds of attaining BP control
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25 210 appeared to worsen following implementation of the formal IDC-OPD programme (T2 vs. T1), while
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27 211 odds of attaining glucose control improved, perhaps because care was initially focussed on glucose
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29 212 control (Supplement SM6). On scaling back the service (S1), control of both parameters seemed to
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31 213 improve, possibly because the service itself or the subset of patients reaching it during the insecure
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33 214 period were somehow different. Once medications supplies were exhausted (S2), control of both
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35 215 parameters seemed to worsen, but control was regained on service resumption. Stratifying by
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37 216 insulin prescription showed similar results (Supplement SM5).

40 41 217 **Costs of providing diabetes care**

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44 218 The total costs of diabetes care in 2014 and 2015 were approximately €32,000 and €26,000
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46 219 respectively (Table 3). Supplies were the major driver of costs. The main costs in 2014 were for latex
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48 220 gloves, glucometers and glucometer strips, and in 2015 were glucometers, strips and lancets
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50 221 (Supplement SM3). While medication costs increased in 2015 relative to 2014, total costs decreased,
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52 222 largely driven by reduced excess consumption of latex gloves post-training. The cost per-patient per-
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54 223 year dropped from €417 to €183 and the cost per-visit halved from €51 to €24. This was due to the
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56 224 combined effect of increased patient throughput and lower costs in 2015.

225

226 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	

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229 **Discussion**

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

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3 241 We suggest that chronic disease programmes in unstable settings should engage in emergency
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5 242 preparedness, learning from the experience of HIV programmes in similar settings.[20] Preparation
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7 243 may include: emergency response planning; patient triage by vulnerability; provision of patient-held
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9 244 treatment plans and emergency kits; building staff capacity to allow flexibility of roles in crises;
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11 245 establishing alternative communication networks, including technology-facilitated patient support;
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13 246 and medication stockpiling and secure storage.[4,20,21]
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17 247 The relatively poorer glycaemic control in insulin-prescribed patients may reflect either disease
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19 248 severity or the challenges associated with insulin therapy. Adherence to daily insulin injections is
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21 249 difficult anywhere; in Mweso, patients are challenged by the security, financial and geographical
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23 250 barriers to accessing medications and the recommended diabetes diet.[13] Adjusting insulin doses
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25 251 based on single fasting glucose readings and patients' reported symptoms proved challenging for
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27 252 clinicians.
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31 253 There is limited, although growing, evidence on the incidence, prevalence and characterisation of
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33 254 diabetes in Sub-Saharan Africa, which our findings broadly reflect.[15] Several reviews have
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35 255 described controversial "atypical" forms of diabetes, including "*malnutrition-related diabetes*" in
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37 256 Sub-Saharan Africa. [9,16] Local prevalence studies support its existence in the DRC, which is in
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39 257 keeping with the high proportion of underweight adults and "unclassified" diabetics in our
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41 258 cohort.[10,17] Little evidence exists to guide either malnutrition-related diabetes care or the
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43 259 effective management of insulin in humanitarian settings, particularly in the absence of home or
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45 260 community-based glycaemia testing.[2,5]
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50 261 The introduction of the IDC-OPD programme, and associated training, contributed to reducing total
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52 262 costs of care by approximately 20% and per patient per year (PPPY) costs by 44% from 2014 to 2015.
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54 263 To our knowledge, there is no available literature to compare costs of diabetes care delivered in a
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56 264 similar setting. However, the 2015 PPPY cost reported here is far lower than that reported by
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3 265 PEPFAR and others to deliver chronic HIV care programmes in low and middle income Sub-Saharan
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5 266 Africa countries.[18,19]
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8 267 Future research is needed in complex humanitarian settings to evaluate simplified, task-shared
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10 268 models of diabetes care; to optimise insulin management without regular finger-stick glycaemia
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12 269 testing; and to evaluate emergency preparedness plans and technology-facilitated remote patient
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14 270 support.[2,4,7,9,21] This should include the cost-effectiveness of different models of diabetes care.
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271 **Limitations**

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

281 **Conclusion**

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

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3 289 of diabetes care and management; and to evaluate emergency preparedness plans and technology-
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5 290 facilitated remote patient support.
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12 292 **List of Abbreviations**
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15 293	BMI	Body Mass Index
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17 294	BP	Blood Pressure
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19 295	DM	Diabetes Mellitus
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21 296	DRC	Democratic Republic of Congo
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23 297	HIV	Human Immunodeficiency Virus
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25 298	IDC-OPD	Integrated Diabetic Clinic within Hospital Outpatient Department
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27 299	MSF	Médecins sans Frontières
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29 300	OHG	Oral Hypoglycaemic Drugs
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31 301	OR	Odds Ratio
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33 302	PPPY	Per Patient Per Year
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3 306 **Declarations**
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7 307 ***Ethics approval and consent to participate***
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10 308 This study was approved by the Ministry of Health of North Kivu Province, DRC, by the MSF Ethics
11
12 309 Review Board, and the Ethics Committee of the London School of Hygiene and Tropical Medicine.
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14 310 Information sheets on the clinic walls provided details of the evaluation; no specific consent was
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16 311 sought from patients for use of their routine clinical data.
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20 312 ***Authors' contributions***
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24 313 KJ and BR were involved in study conception; EA, GC, KJ, DPM, PP and BR contributed to study
25
26 314 design and interpretation of data. DPM and ZS analysed the data. MB contributed to data collection.
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28 315 EA drafted the manuscript and all authors reviewed drafts and approved the final version.
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30

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38 319 presented at MSF Scientific Days Conference in London, May 2018.
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41 320 **Competing Interests**
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44 321 The authors declare that they have no competing interests.
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47 322 **Data Sharing**
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50 323 The datasets are available from MSF on request by researchers who fulfil certain criteria and under
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52 324 the auspices of a data sharing agreement.
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54

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57

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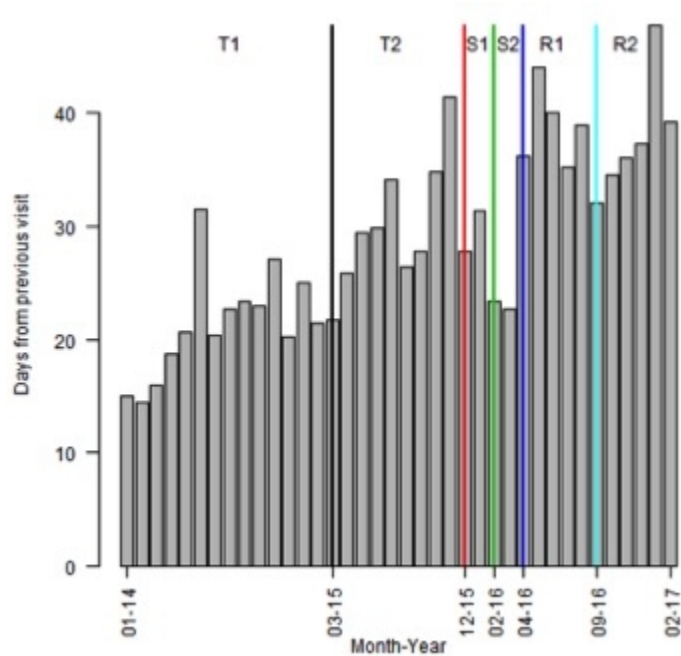


Figure 1: Average number of days from previous visit per month for Mweso IDC-OPD service

130x118mm (72 x 72 DPI)

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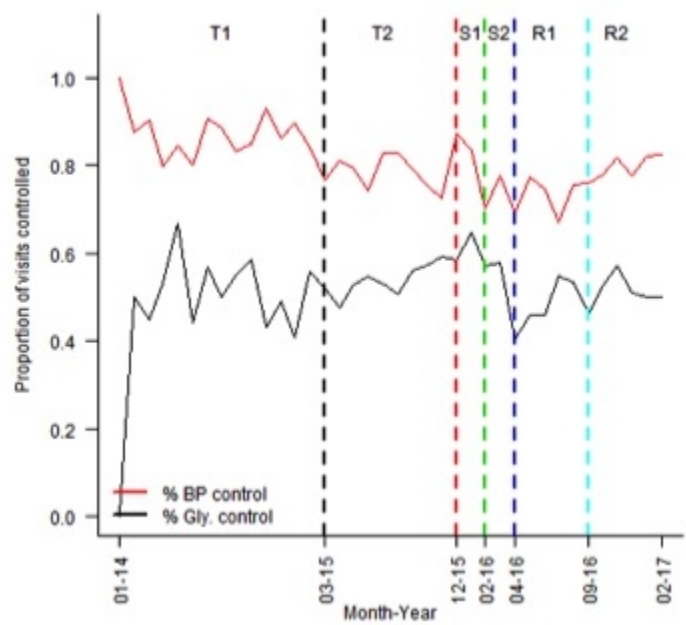
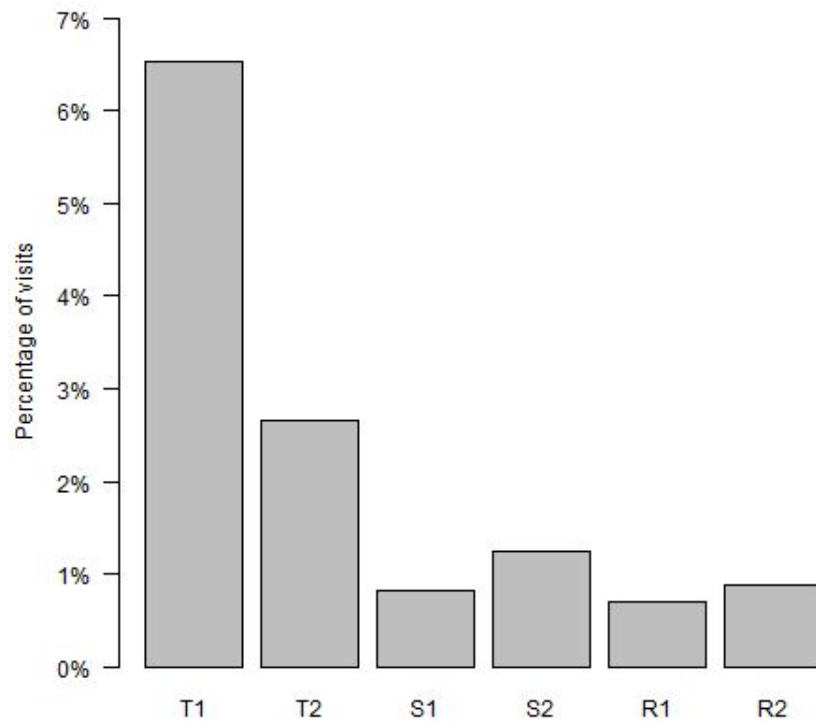


Figure 2: Proportion of visits with BP or glycaemia at target by month, Mweso IDC-OPD service

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 Mwesio 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.

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

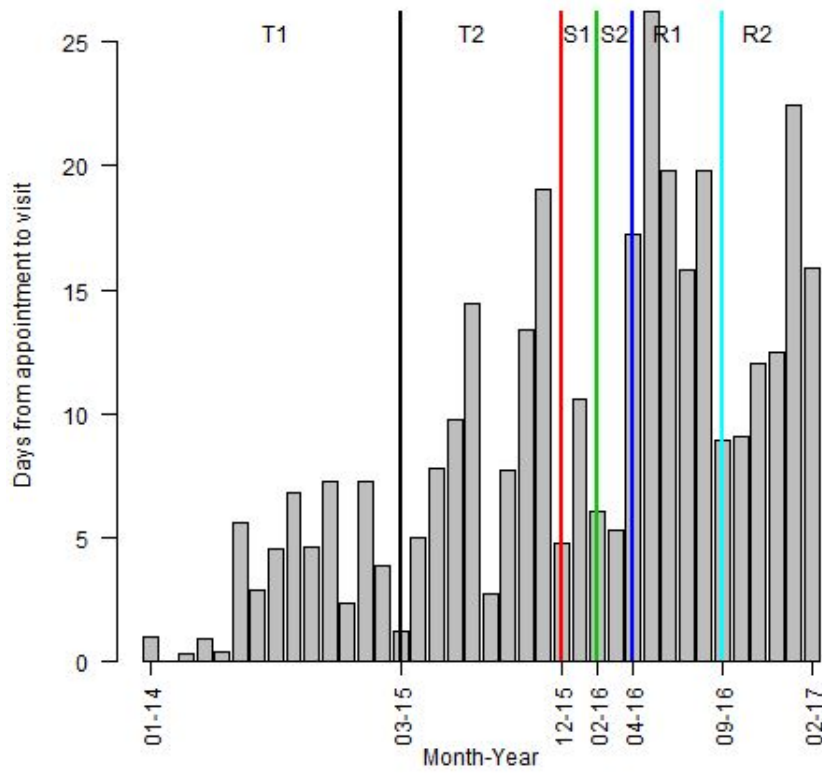
DRC

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 \pm 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.

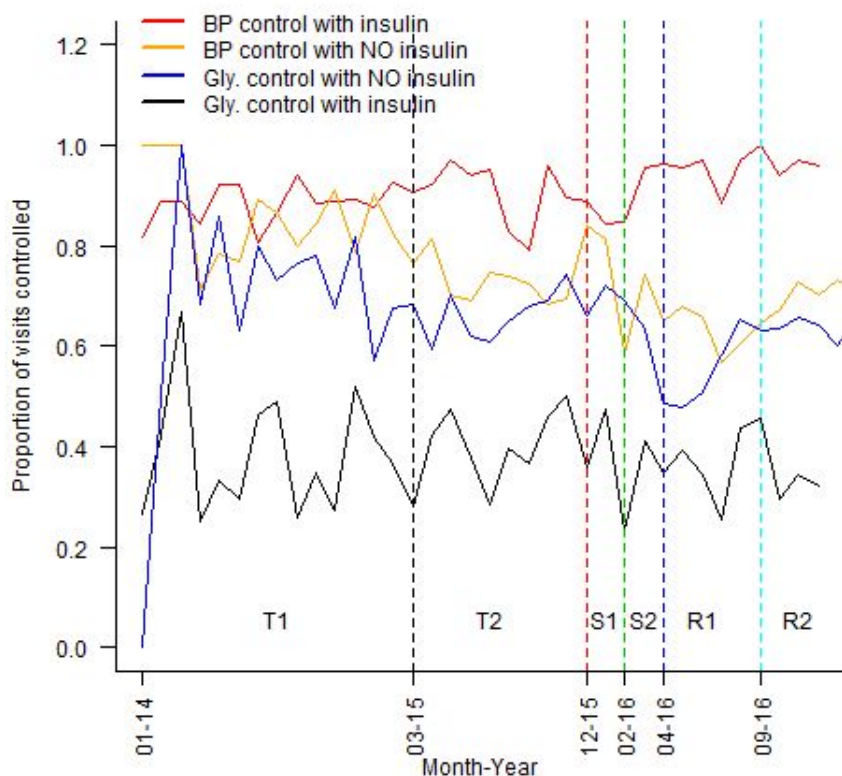
SM4. Average days' delay in attendance since planned appointment per month of

IDC-OPD service, Mweso, DRC



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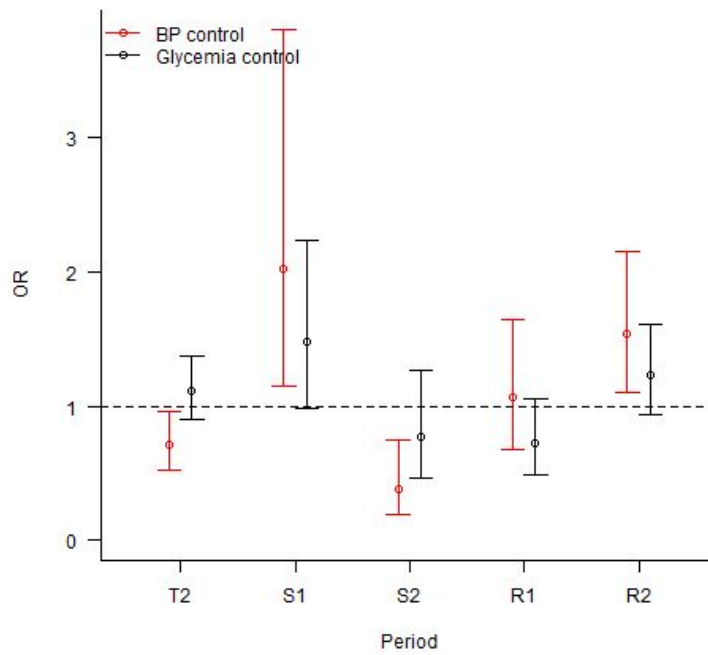
SM5. Proportion of visits at target for BP and glycaemic control, stratified by insulin prescription per month of IDC-OPD service, Mweso, DRC



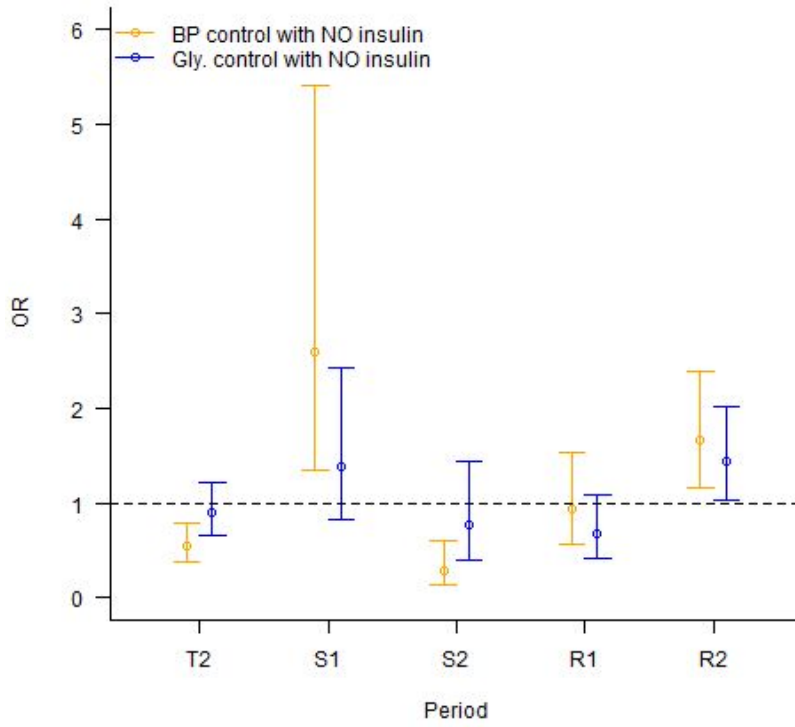
Note: Patients were categorised by whether they were prescribed insulin [+/- oral hypoglycaemic (OHG) drugs] or OHG drugs alone at their last recorded visit. The former group would have included Type 1 diabetics, Type 2 diabetics with more advanced illness requiring a combination of OHG and insulin, 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

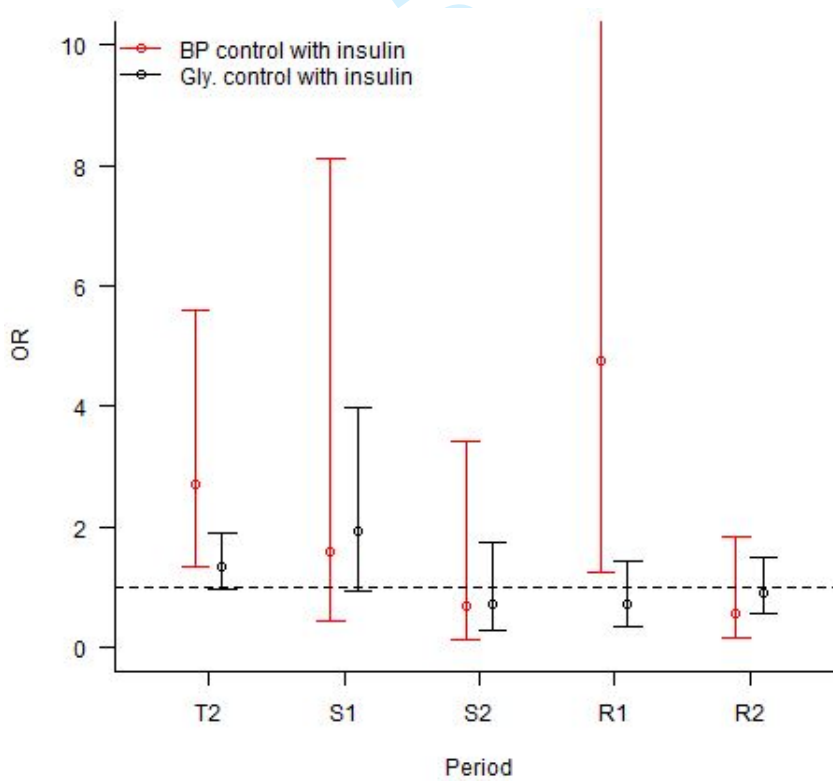
A. Impact (OR) on BP and glycaemia in all patients (not stratified by insulin prescription)



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.

	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

Journal:	<i>BMJ Open</i>
Manuscript ID	bmjopen-2019-030176.R1
Article Type:	Original research
Date Submitted by the Author:	21-Aug-2019
Complete List of Authors:	<p>Ansbro, Éimhín; Médecins sans Frontières, Manson Unit; London School of Hygiene and Tropical Medicine Faculty of Epidemiology and Population Health, Centre for Global Chronic Conditions</p> <p>Biringanine, Michel; Medecins Sans Frontieres Operational Centre Amsterdam, Mweso Hospital</p> <p>Caleo, Grazia; Médecins sans Frontières, Manson Unit</p> <p>Prieto-Merino, David; London School of Hygiene and Tropical Medicine Faculty of Epidemiology and Population Health, Epidemiology of NCDs</p> <p>Sadique, Zia; London School of Hygiene and Tropical Medicine Faculty of Public Health and Policy, Health Services Research and Policy</p> <p>Perel, Pablo; London School of Hygiene and Tropical Medicine Faculty of Epidemiology and Population Health, Centre for Global Chronic Conditions</p> <p>Jobanputra, Kiran; Médecins sans Frontières, Manson Unit</p> <p>Roberts, Bayard; London School of Hygiene and Tropical Medicine Faculty of Public Health and Policy, Centre for Global Chronic Conditions</p>
Primary Subject Heading:	Global health
Secondary Subject Heading:	Diabetes and endocrinology, Epidemiology
Keywords:	Health economics < HEALTH SERVICES ADMINISTRATION & MANAGEMENT, DIABETES & ENDOCRINOLOGY, International health services < HEALTH SERVICES ADMINISTRATION & MANAGEMENT, Epidemiology < TROPICAL MEDICINE, General diabetes < DIABETES & ENDOCRINOLOGY

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Manuscripts

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3 1 **Title: Management of diabetes and associated costs in a complex humanitarian setting in the**
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5 2 **Democratic Republic of Congo: a retrospective cohort study.**
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49 24 **Word Count: 4000**

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52 26 **Keywords:** Democratic Republic of Congo, Sub-Saharan Africa, diabetes, hypertension,
53 27 noncommunicable disease, humanitarian, conflict, care model, management, programme, chronic
54 28 care, outpatient, hospital care, task shifting, cost, economic.
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30 Abstract

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

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

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

41 **Participants:** Diabetes patients attending IDC-OPD.

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

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

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3 52 **Conclusions:** In a chronic conflict setting, we documented that control of diabetes intermediate
4
5 53 outcomes was achievable during stable periods. During insecure periods, a simplified, nurse-led
6
7 54 model maintained control rates until drug stock-outs occurred. Incremental per patient annual costs
8
9 55 were lower than chronic HIV care costs in low-income settings. Future operational research should
10
11 56 define a simplified diabetes care package including emergency preparedness.
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18 58 **Strengths and Limitations**

- 19
20 59 • This is the first study of its kind to examine diabetes intermediate clinical outcomes and
21
22 60 programme costs in a complex humanitarian setting in sub-Saharan Africa.
- 23
24 61 • Using routine clinical and programmatic data collected in a protracted conflict setting, we
25
26 62 estimated the effect of insecurity and related programmatic changes on diabetes
27
28 63 intermediate clinical outcomes, which to our knowledge, has not been addressed in the
29
30 64 literature to date.
- 31
32 65 • The study was limited by the relatively small sample size and lack of control group for
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34 66 comparison.
- 35
36 67 • The costing analysis was descriptive and based on aggregate data and so neither the cost-
37
38 68 effectiveness of the programme nor patient-level costs could be determined.
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4 70 **Title: Management of diabetes and associated costs in a complex**
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6 71 **humanitarian setting in the Democratic Republic of Congo: a retrospective**
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9 72 **cohort study.**
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16 74 **Background**
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21 75 Over the past 40 years, diabetes prevalence has increased sharply worldwide, particularly in low and
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23 76 middle income countries (LMICs).[1] However, data on the burden and needs related to diabetes
24
25 77 and other non-communicable diseases (NCDs) are scarce from conflict-affected countries,
26
27 78 particularly those in Sub-Saharan Africa.[1,2] Humanitarian actors have been slow to prioritise
28
29 79 diabetes treatment in disaster and post-conflict settings despite reporting increasing presentations
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31 80 of diabetic patients within their programmes.[3–6] This is due to lack of knowledge on local diabetes
32
33 81 epidemiology, limited research on diabetes management or outcomes in crisis settings; a lack of
34
35 82 programmatic and policy guidance or tools to support diabetes care in such settings; prioritisation of
36
37 83 other health needs; and also a perception that diabetes care is complex and expensive. [2,3,6–8]
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40
41 84 The humanitarian situation in Democratic Republic of Congo (DRC) is considered one of the most
42
43 85 complex and challenging worldwide. Prolonged conflict over two decades has resulted in over 5
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45 86 million deaths, over 4.5 million internally displaced people, the exodus of over 800,000 refugees,
46
47 87 and ongoing political and social instability. [9,10] The health system, weakened by prolonged
48
49 88 conflict, is challenged by competing health needs in a country ranked 176 of 189 on the human
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51 89 development index despite holding rich natural resources. [11]
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55 90 On this backdrop, diabetes prevalence is increasing, currently estimated at 4.0 - 5.4%. [12–14] While
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57 91 some factors implicated in the global rise in diabetes prevalence hold true in DRC (demographic
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59 92 change, urbanisation, changing diets etc.) chronic conflict and political instability add additional
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3 93 complexity. Recent reviews and ethnographic evidence point to a link between chronic food
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5 94 insecurity, childhood malnutrition and diabetes. [13,15,16] In DRC, 43% of children under 5 years are
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7 95 chronically malnourished and levels of food insecurity have risen sharply, with millions subsisting on
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10 96 World Food Programme rations. [17] Recent evidence also supports an association between chronic
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12 97 perceived stress and diabetes onset, while patients with diabetes in humanitarian settings focus on
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14 98 suffering and loss as a cause of their illness. [16,18] Furthermore, in humanitarian crises, people with
15
16 99 diabetes are at increased risk of complications and death due to treatment interruption and
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19 100 precarious access to food and water. [2,6]
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21
22 101 Médecins sans Frontières (MSF), a medical humanitarian organisation, has supported healthcare
23
24 102 delivery in Mweso, North Kivu, in collaboration with the Ministry of Health since 2008. North Kivu is
25
26 103 a rural, impoverished area bordering Rwanda with an estimated population of 365,000. It remains a
27
28 104 flash point in the on-going conflict between shifting rebel groups and government forces, which has
29
30 105 been characterised by brutal violence against civilians and destruction of lives and livelihoods.
31
32
33 106 Outbreaks of violence since 2016 have resulted in recurrent waves of population displacement;
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35 107 North Kivu alone hosts 17 internally displaced person camps. MSF supports health services in 4 out
36
37 108 of 23 Primary Health Care clinics and in Mweso hospital within Masisi District. Mweso hospital
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39 109 serves a catchment area of approximately 145,000 people, with about 65,000 recipients of care
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41 110 living in the immediate vicinity of the hospital.
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45 111 While a national diabetes programme exists in DRC, available diabetes care is concentrated at
46
47 112 hospital level in major cities. [19] In response to growing patient and provider needs in Mweso, MSF
48
49 113 implemented a hospital-outpatient based diabetes programme in March 2015, the Integrated
50
51 114 Diabetic Clinic within Hospital Outpatient Department (IDC-OPD) in place of the ad hoc care
52
53 115 previously undertaken. The IDC-OPD was integrated at the clinical level into usual outpatient
54
55 116 activities, with pre-existing staff trained to provide this additional service. [20] The programme
56
57
58 117 comprised a nurse-led, multi-disciplinary model, using locally adapted clinical guidelines, patient
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3 118 counselling materials and data collection tools, accompanied by three days of specialist training.[21]
4

5 119 The clinic team included: a nurse supervisor, nursing assistant, two doctors, a nutritionist, and
6
7 120 education and psychosocial support officers. Diabetes was diagnosed according to World Health
8
9 121 Organization (WHO) guidelines using repeated fasting capillary glucose. Most patients were
10
11 122 identified as diabetic and enrolled after acute hospital presentation, while some were identified via
12
13 123 the Mweso outpatient department or referring primary care clinics.
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17 124 Patients received a detailed enrolment assessment, monthly nurse-led follow-up and 6-monthly
18
19 125 medical review. The program included context-adapted dietary advice (accounting for locally
20
21 126 available and affordable foods and customs) and psychosocial support, including clinician-moderated
22
23 127 peer support groups and involvement of family or friends as treatment supporters. The psychosocial
24
25 128 aspects of patients and providers managing diabetes are discussed in a related paper, with major
26
27 129 themes from the patient perspective including the difficulty adhering to the recommended diet and
28
29 130 barriers to clinic access during outbreaks of violence. [22] Each patient was given a clinic-held
30
31 131 patient file and patient-held passport to facilitate safe passage when armed groups impeded their
32
33 132 travel. Clinical guidelines were adapted from MSF, WHO and other international guidance. [23]
34
35 133 Patient educational tools (disease and diet education leaflets) were adapted from Santé Diabète
36
37 134 [24], a Malian Non-Governmental Organisation, and generic medications, included on MSF's
38
39 135 Essential Drugs List, were prescribed. Insulin doses were adjusted using single fasting capillary blood
40
41 136 glucose readings and patients' reported symptoms of hypo- or hyperglycaemia in the absence of
42
43 137 home glucose monitoring. Insulin-dependent patients were prescribed human insulin, delivered via
44
45 138 needle and syringe, and advised to store this at home in a clay pot (refrigeration was unavailable),
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47 139 recommended as a safe alternative in similar contexts. [25]
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54 140 In early 2016, outbreaks of armed violence restricted movement of patients and supplies. Direct
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56 141 attacks on MSF staff and facilities, including an armed robbery and abductions, led to withdrawal of
57
58 142 the international staff from Mweso and temporary scaling back of the programme, with local nursing
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3 143 staff dispensing medications to any patients reaching the clinic. Later, the programme was
4
5 144 suspended for a period of six weeks when supply routes were entirely blocked and drug supplies
6
7 145 were exhausted.
8
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10 146 A mixed methods evaluation of the Mweso IDC-OPD programme was undertaken by MSF and
11
12
13 147 included a qualitative evaluation exploring patient and provider clinical and psychosocial challenges,
14
15 148 presented elsewhere [22]; and a retrospective review of quantitative programmatic data and cost
16
17 149 data collected as part of routine care in a chronic conflict zone, reported here. The overall objective
18
19 150 of this paper is to evaluate an Integrated Diabetic Clinic within a Hospital Outpatient Department
20
21 151 (IDC-OPD) in a complex humanitarian setting in North Kivu in Democratic Republic of Congo. The
22
23 152 specific objectives are to: (i) analyse diabetes intermediate clinical and programmatic outcomes
24
25 153 (blood pressure/glycaemic control, visit frequency and volume); (ii) explore the association of key
26
27 154 insecurity and related programmatic events with these outcomes; and (iii) describe incremental IDC
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29 155 OPD programme costs.
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34 156 **Methods**

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36 157 It has been acknowledged that traditional experimental and evaluation methods may be unfeasible,
37
38 158 inappropriate or even unethical to apply in humanitarian settings [26]. Therefore, we have used a
39
40 159 pragmatic approach to utilising programmatic data, with an open cohort design. For the outcome
41
42 160 analysis, we conducted a retrospective analysis of routine data of enrolled adults aged ≥ 18 years
43
44 161 from January 2014 to February 2017, examining trends in diabetes outcomes and their association
45
46 162 with key programmatic events. The study period was divided into five phases, defined by
47
48 163 programmatic changes or periods of heightened insecurity (which impacted service delivery due to
49
50 164 staff evacuation, supply chain interruption and reduced patient access). Period T1 refers to ad-hoc
51
52 165 care delivered before introduction of the IDC-OPD programme (T2). Security incidents in December
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54 166 2015 prompted a period of service suspension (nurse-only care, with drug pick-ups, glucose testing
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3 167 and minimal treatment adjustments) (S1). Complete suspension followed once drug stocks were
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5 168 exhausted (S2). Limited service resumed in April (R1) until full service recommenced from
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7 169 September 2016 (R2) (Table 1).
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11 170 Table 1. Study Periods for Evaluation of IDC-OPD Programme, Mweso, DRC
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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

171

172 **Data**

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

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3 177 Microsoft Excel software application specifically developed by MSF for this programme. Anonymised
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5 178 exports were transferred to the study team on a monthly basis.
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8 179 Demographic data on patients' age, gender, occupation, and village of residence were recorded on
9
10 180 enrolment. Cardiovascular risk factors (smoking status, current alcohol use), family history of
11
12 181 diabetes, year of diabetes diagnosis and self-reported history of childhood malnutrition and/or
13
14 182 tuberculosis were recorded. Clinical parameters: body mass index (BMI), blood pressure (BP)
15
16 183 measured by manual sphygmomanometer according to local MSF protocols [21], fasting capillary
17
18 184 blood glucose (FBG); prescribed diabetes drugs [insulin and/or oral hypoglycaemic drugs (OHGs)];
19
20 185 and diabetes classification (Type I, Type II or other) were recorded at each clinical encounter.
21
22 186 Medical review at enrolment and six monthly thereafter was recorded, including biochemical
23
24 187 markers (serum creatinine) and examination for complications (visual acuity, cataract, proteinuria,
25
26 188 foot check). Numbers of deaths, transfers out of the area and delays in attendance were also
27
28 189 documented. The key intermediate clinical outcome and programme measures used in the analysis
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30 190 are shown in Table 2.
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39 192 Table 2: Outcome measures used to determine effect of different programme periods on
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41 193 programme delivery and intermediate clinical outcomes
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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

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195

196 Analysis

197 Basic demographics were analysed using mean and median and were presented with inter-quartile
 198 ranges. We assessed the relationship of different study periods with the frequency of visits and the
 199 impact of study periods on intermediate clinical outcomes i.e. per visit attainment of blood pressure
 200 (< 140/90 mmHg) and glycaemic (> 4.2 and ≤ 8.3 mmol/L) targets.

201 To estimate the effect of a period change we calculated the odds ratio (OR) of the odds of having the
 202 biomarker under control in a visit in the new period (t) over the odds of having the biomarker
 203 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
 204 chances of the biomarker being under control in a visit in period t was greater than the chances of
 205 the biomarker being under control in a visit in the previous period ($t-1$) (but not necessarily than
 206 other periods, $t-2$, $t-3$, etc.). Likewise, $OR_t < 1$ implied a reduction in the chances of having the
 207 biomarker under control in a visit during period t compared to a visit during the previous period ($t-$
 208 1). To estimate these OR we ran a logistic model with period as a categorical variable, suitably
 209 coded, and adjusted for sex, age (and square and cube terms) and number of visits of the patient
 210 (and square term). The models were stratified by whether the patient was prescribed insulin (+/-
 211 oral hypoglycaemic agents) at the previous visit.

212 Missing data: Our main analysis used only complete data; records with missing data were excluded.

213 Few outcome variable data were missing: less than 3% in BP control (most of it in the pre-training

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3 214 period) and less than 0.3% for glycaemic control (Supplement SM1). There were no missing data for
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5 215 date of visit, sex or age.
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10 217 **Costing data and analysis**

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13 218 For the descriptive, incremental cost analysis we took a health services perspective. Information
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15 219 related to the nature, location and mode of delivery of the NCD services was collected during a field
16
17 220 visit in December 2015 by the study team and was supplemented by informal interviews with clinical
18
19 221 and administrative staff. A data analysis tool was designed to collate the relevant financial costs for
20
21 222 the study period 2014 -2015 from routine programme documents and standard MSF tools including
22
23 223 budget, human resources, drug consumption monitoring, logistics/supply tools, clinic records and
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25 224 programme reports. For salary costs, we included the incremental costs of an MSF-employed
26
27 225 medical doctor and nurse and an MOH-employed nurse (with salary supplement paid by MSF)
28
29 226 dedicating one day, two psychosocial workers dedicating one hour and a nutritionist dedicating 30
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31 227 minutes per month to the IDC-OPD service (based on 22 working days per month). Hence, most
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33 228 costs were related to drugs, equipment, disposables and stationary costs. Key cost items were
34
35 229 grouped into: (a) medicine, (b) supplies, and (c) staff time. Monthly resource use and unit cost data
36
37 230 were recorded and annualised (Supplement SM2); annual total cost, cost per visit and cost per
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39 231 patient were reported in Euro (€) for 2014 before formal implementation of the IDC-OPD
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41 232 programme and 2015 during full implementation.
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47 233 The study was approved by the Ministry of Health of North Kivu Province, DRC, and the Médecins
48
49 234 sans Frontières Ethics Review Board (ID 1542).
50
51

52 235 **Patient and Public Involvement**

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55 236 Patients were not involved in the design or conduct of this study.
56
57

58 237 **Results**

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3 238 Between January 1st 2014 and February 9th 2017, 243 patients were enrolled in the IDC-OPD
4
5 239 programme (Supplement SM3). Median age was 45 years (IQR 32 – 56); 44.6% of the cohort was
6
7 240 female. For adults ≥ 18 years (n=219), mean BMI was 21.3 kg/m² and 31.1% were underweight (BMI
8
9 241 < 18.5 kg/m²). On enrolment, 8.2% were current smokers; 24.4% reported recent alcohol intake;
10
11 242 self-reported medical history included: 9.1% hypertension, 2.2 % CVD, 2.7% tuberculosis (TB) and
12
13 243 8.7% malnutrition. Half were classified clinically as Type 2 diabetic (51%; n=125); 26% (n=62) as Type
14
15 244 1; and 23% (n=56) were either unclassified or classed as “other” (Supplement SM3).

19 245 **Trends in outcomes and impact of programmatic events**

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21
22 246 Numbers of visits and appointment intervals increased after the introduction of the systematic
23
24 247 approach to diabetes care, which included monthly review appointments for stable patients (T2)
25
26 248 (Figure 1; Supplement SM4). During the period of scaled back service (S1), visit numbers initially
27
28 249 climbed while the visit interval decreased, which may reflect increased visit frequency due to short-
29
30 250 term drug supplies. Once drug buffer stock was exhausted, visit numbers dropped off sharply.
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32 251 Patients may have avoided or were prevented from attending due to security conditions.
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46 253 Figure 1: Average number of days from previous visit per month for Mwesio IDC-OPD service
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254
255 BP control was consistently better than glycaemic control (of note, patients without diagnosed
256 hypertension were included in the analysis) (Figure 2). By period T2, approximately 80% of visits
257 achieved BP and 60% achieved glycaemic control. There was a notable drop in control of both
258 parameters during programme suspension with a gradual improvement on resumption. Blood
259 pressure control was consistently better, while glycaemic control was consistently worse, in patients
260 prescribed insulin (+/- OHGs) compared with those prescribed OHGs alone (Supplement SM5), which

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3 261 may be because the former group contained relatively young Type 1 and malnutrition-related
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5 262 diabetics.
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10 264 Figure 2: Proportion of visits with BP or glycaemia at target by month, Mwesio IDC-OPD service
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16 266 The results of the odds ratio (OR) calculations were unexpected. Odds of attaining BP control
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18 267 appeared to worsen following implementation of the formal IDC-OPD programme (T2 vs. T1), while
19
20 268 odds of attaining glucose control improved, perhaps because care was initially focussed on glucose
21
22 269 control (Supplement SM6). On scaling back the service (S1), control of both parameters seemed to
23
24 270 improve, possibly because the service itself or the subset of patients reaching it during the insecure
25
26 271 period were somehow different. Once medications supplies were exhausted (S2), control of both
27
28 272 parameters seemed to worsen, but control was regained on service resumption. Stratifying by
29
30 273 insulin prescription showed similar results (Supplement SM5).
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32

33 274 **Costs of providing diabetes care**

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37 275 The total costs of diabetes care in 2014 and 2015 were approximately €32,000 and €26,000
38
39 276 respectively (Table 3). Supplies were the major driver of costs each year. The greatest costs in 2014
40
41 277 were for latex gloves, glucometers and glucometer strips; in 2015 they were for glucometers, strips
42
43 278 and lancets (Supplement SM3). While medication costs increased in 2015 relative to 2014, staff costs
44
45 279 remained unchanged, and total costs decreased, largely driven by reduced excess consumption of
46
47 280 latex gloves after it was identified during the IDP-OPD training sessions. The total number of patients
48
49 281 and number of visits increased significantly from 2014 to 2015, rising from 77 and 626 to 144 and
50
51 282 1033, respectively. Thus, cost per-patient per-year (PPPY) dropped from €417 to €183 and cost per-
52
53 283 visit was halved from €51 to €24. This was due to the combined effect of higher patient numbers,
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55 284 greater total number of visits and lower supply costs in 2015 compared to 2014 (Supplement SM3).
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285

286 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	

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288

289 **Discussion**

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

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

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3 299 regular supervision, a simplified nurse-provided, algorithm-driven service with consistent medication
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5 300 supply may be as effective as close medical supervision in maintaining disease control, particularly
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7 301 during periods of service interruption. Medical input could thus be focused on achieving glycaemic
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9 302 control in patients prescribed insulin, who appeared most affected by service interruption. We also
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11
12 303 note lack of evidence supporting the management of what we believed to be malnutrition-related
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14 304 diabetes.

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16
17 305 Intermittent outbreaks of armed conflict limited patient access and disrupted supply chains,
18
19 306 impeding continuity of care. We suggest, therefore, that in high-insecurity settings, chronic disease
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21 307 programmes should focus on preparing patients, staff and supply chains to pre-empt treatment
22
23 308 interruption during insecure periods, learning from HIV programme experiences in similar
24
25 309 settings.[28] Preparation could include: patient triage by vulnerability (e.g. prioritising insulin-
26
27 310 dependent diabetic patients, those with established complications and/or living far from the facility);
28
29 311 provision of patient-held personal treatment plans and emergency kits (including several months'
30
31 312 supply of medications, such as insulin, delivery devices and guidance as appropriate); building staff
32
33 313 capacity to allow for flexibility of roles in crises; establishing networks with other chronic disease
34
35 314 programmes; and medication stockpiling and secure storage.[5,28,29] Technology could facilitate
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37 315 continued patient treatment support when access to facilities is impossible e.g. via mobile phone
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39 316 SMS messaging or decentralisation of care to community-based health workers furnished with
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41 317 clinical decision support tools or support via telemedicine.

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47 318 The relatively poorer glycaemic control in insulin-prescribed patients may reflect either disease
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49 319 severity or the challenges associated with insulin therapy. Adherence to daily insulin injections is
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51 320 difficult anywhere; in Mweso, the security, financial and geographical barriers to accessing insulin
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53 321 and the unavailability, unaffordability and burden for families brought by the recommended
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55 322 diabetes diet, may additionally contribute to poor adherence.[22] In this programme, clinicians
56
57 323 adjusted insulin doses, based on a single fasting glucose reading taken in clinic and on patients'
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3 324 reported symptoms in the absence of home glucose monitoring and, therefore, dose adjustment
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5 325 was cautious and treatment targets were conservative.
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7

8 326 There is limited, although growing, evidence on the incidence, prevalence and characterisation of
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10 327 diabetes in Sub-Saharan Africa, which our findings broadly reflect.[30] Several reviews and recent
11
12 328 ethnographic evidence describe “atypical” forms of diabetes, which may complicate diagnosis,
13
14 329 classification and management. These include “*ketosis-prone atypical diabetes mellitus*” and
15
16 330 “*malnutrition-related diabetes*”. [13,16,31] Local prevalence studies support the existence of the
17
18 331 latter in the DRC, which is in keeping with the high proportion of underweight adults and
19
20 332 “unclassified” diabetics in our cohort.[14,32] It is unclear whether malnutrition is causative,
21
22 333 associated with hyperglycaemia or with pancreatic insufficiency and further study of diabetes
23
24 334 epidemiology in DRC is needed, exploring factors such as childhood malnutrition, food insecurity and
25
26 335 underweight and use of calorie-dense therapeutic foods. [31] Moreover, little evidence exists to
27
28 336 guide either malnutrition-related diabetes care or the effective management of insulin in
29
30 337 humanitarian settings, particularly in the absence of home or community-based glucose testing.[3,7]
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32
33 338 The total cost of care delivery decreased by approximately 20% from 2014 to 2015 despite increased
34
35 339 visit and patient numbers. This was largely due to decreased supply costs, driven by the 100-fold
36
37 340 reduction in consumption of latex gloves following IDC-OPD training. Efficiencies of supply
38
39 341 consumption and patient throughput (more visits and more patients seen by the same number of
40
41 342 staff) contributed to reducing PPPY costs by 44% from €417 in 2014 to €183 in 2015.
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47 343 To our knowledge, there is no available literature to compare cost per patient or per visit for
48
49 344 diabetes care (or NCD care generally) delivered in an unstable humanitarian setting. A study from
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51 345 Ghana reported a per patient annual direct cost of US\$372.65 for hospital-delivered diabetes care in
52
53 346 2005. For a potential comparator, we looked at the cost of delivering chronic care for HIV, the main
54
55 347 life-long condition with which humanitarian actors have traditionally engaged. The 2015 PPPY cost
56
57 348 reported in this study is far lower than that reported by PEPFAR and others to deliver chronic HIV
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3 349 care programmes in low and middle income countries in SSA [33,34]. In terms of cost structure,
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5 350 supplies were the major cost driver in the Ghanaian study (syringes, lancets and strips), whereas
6
7 351 other analyses of diabetes care in SSA identified medications, and specifically insulin, as the main
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9
10 352 cost contributor [35,36].
11

12 353 **Strengths and Limitations**

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14
15 354 Using routine clinical and programmatic data, with minimal service disruption, we have explored
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17 355 clinical outcomes of a chronic disease programme in a protracted conflict setting and the influence
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19
20 356 of periods of heightened insecurity on intermediate clinical outcomes and on service delivery. Each
21
22 357 patient who attended in a given month contributed data, irrespective of whether they ever
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24 358 experienced a treatment interruption. Our study provides new costing information for humanitarian
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26 359 actors to support the initiation or adaptation of specific NCD programmes and may potentially
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28 360 support scale up of similar services in DRC (and other conflict-affected settings). We concluded that
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30 361 the incremental cost of adding an outpatient diabetes service to a humanitarian health programme
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32 362 in a rural hospital setting may be achieved at a cost similar to that of delivering chronic HIV
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34 363 programmes. While we cannot confirm whether an external audit of cost data had taken place, we
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36 364 are confident in the quality of these data due to MSF's robust systems and oversight by strong in-
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38 365 country and international teams.
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43 366 Given the logistical and ethical challenges of undertaking research in conflict settings, we
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45 367 acknowledge that there are a number of limitations to our study. We had a relatively small sample
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47 368 size and no control group for comparison. We did not explore per patient control of clinical
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49 369 parameters over time, control by diabetes type (or age), appropriateness of prescribing, patient-
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51 370 reported outcomes or the influence of psychosocial factors, diet, or adherence in each study phase
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53 371 since these data were unavailable. Gestational diabetes was not addressed since this took place
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55 372 within antenatal services. Our costing analysis was descriptive so we could not comment on
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57 373 programme cost-effectiveness. Costing data were presented as average annual costs and did not
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3 374 explore the impact of various programme periods on costs. Since our cost data were aggregate, we
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5 375 could not explore patient-level costs or account for patient heterogeneity. While our findings may
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7 376 not be generalizable to other complex humanitarian settings or to other providers' diabetes
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10 377 programmes in the DRC, our study contributes knowledge on key challenges and suggests solutions,
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12 378 which may be more broadly applicable.

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15 379 Future research is needed in complex humanitarian settings to evaluate simplified, task-shared
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17 380 models of diabetes care, including culturally- and contextually-relevant psychosocial support and
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19 381 dietary advice; to optimise insulin management; and to evaluate emergency preparedness plans and
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21 382 technology-facilitated remote patient support.[3,5,8,13,29] We recommend that future prospective
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23 383 studies should explore per-patient outcomes (as well as exploring programme-level outcomes as
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25 384 done in this study). We suggest including a control group, collection of additional outcome variables,
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27 385 such as complication rates and patient-reported outcomes e.g. related to quality-of-life, including
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29 386 functionality and mental health, and exploration of the impact of psychosocial stressors and
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31 387 treatment interruption on clinical outcomes. We also suggest that the cost-effectiveness of different
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33 388 models of diabetes care, including use of technology-facilitated remote support, and patient level
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35 389 costing studies from both provider and patient perspectives should be undertaken, exploring patient
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37 390 heterogeneity and direct and indirect patient costs.

391 **Conclusion**

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

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3 398 programmes in similar settings. Future research is needed to evaluate simplified, task-shared models
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5 399 of diabetes care and management; and to evaluate emergency preparedness plans and technology-
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7 400 facilitated remote patient support.
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14 402 **List of Abbreviations**

15
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17 403 BMI Body Mass Index
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19 404 BP Blood Pressure
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21 405 DM Diabetes Mellitus
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24 406 DRC Democratic Republic of Congo
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26 407 HIV Human Immunodeficiency Virus
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28 408 IDC-OPD Integrated Diabetic Clinic within Hospital Outpatient Department
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31 409 LMICs Low- and Middle-Income Countries
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33 410 MSF Médecins sans Frontières
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35 411 NCD Noncommunicable Disease
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37 412 OHG Oral Hypoglycaemic Drugs
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39 413 OR Odds Ratio
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42 414 PPPY Per Patient Per Year
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3 418 **Declarations**
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7 419 ***Ethics approval and consent to participate***
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10 420 This study was approved by the Ministry of Health of North Kivu Province, DRC, by the MSF Ethics
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12 421 Review Board, and the Ethics Committee of the London School of Hygiene and Tropical Medicine.
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14 422 Information sheets on the clinic walls provided details of the evaluation; no specific consent was
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16 423 sought from patients for use of their routine clinical data.
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20 424 ***Authors' contributions***
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24 425 KJ and BR were involved in study conception; EA, GC, KJ, DPM, PP and BR contributed to study
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26 426 design and interpretation of data. DPM and ZS analysed the data. MB contributed to data collection.
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28 427 EA drafted the manuscript and all authors reviewed drafts and approved the final version.
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31 428 **Acknowledgements**
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35
36 430 contribution to this study. We thank Sarah Venis for her helpful review of the article. This work was
37
38 431 presented at MSF Scientific Days Conference in London, May 2018.
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41 432 **Competing Interests**
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44 433 The authors declare that they have no competing interests.
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47 434 **Data Sharing**
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50 435 The datasets are available from MSF on request by researchers who fulfil certain criteria and under
51
52 436 the auspices of a data sharing agreement.
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54

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58 438 This study was funded by Médecins sans Frontières.
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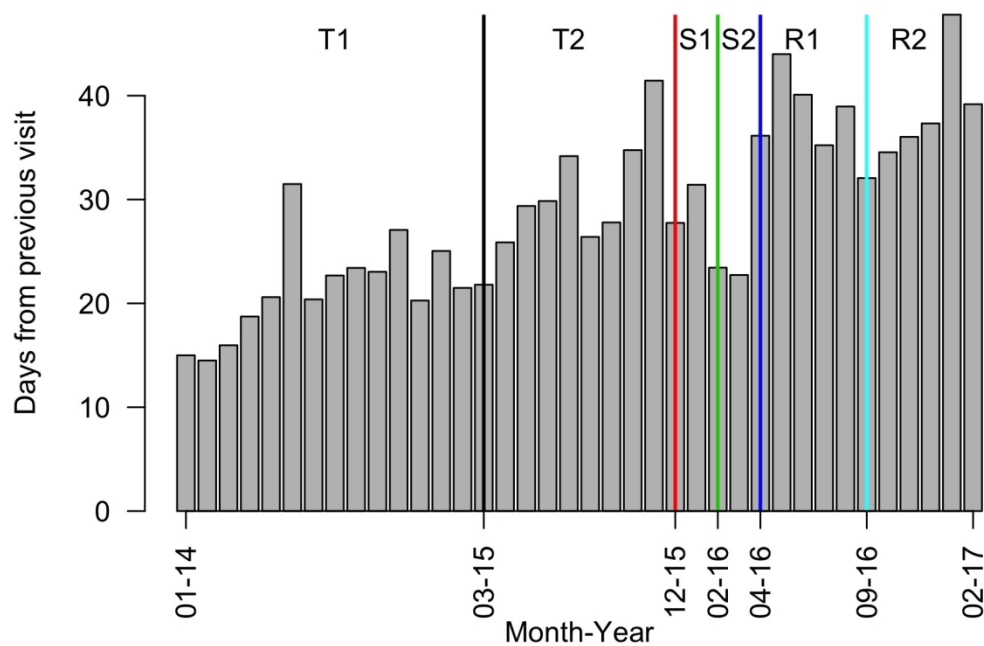


Figure 1: Average number of days from previous visit per month for Mweso IDC-OPD service

615x436mm (72 x 72 DPI)

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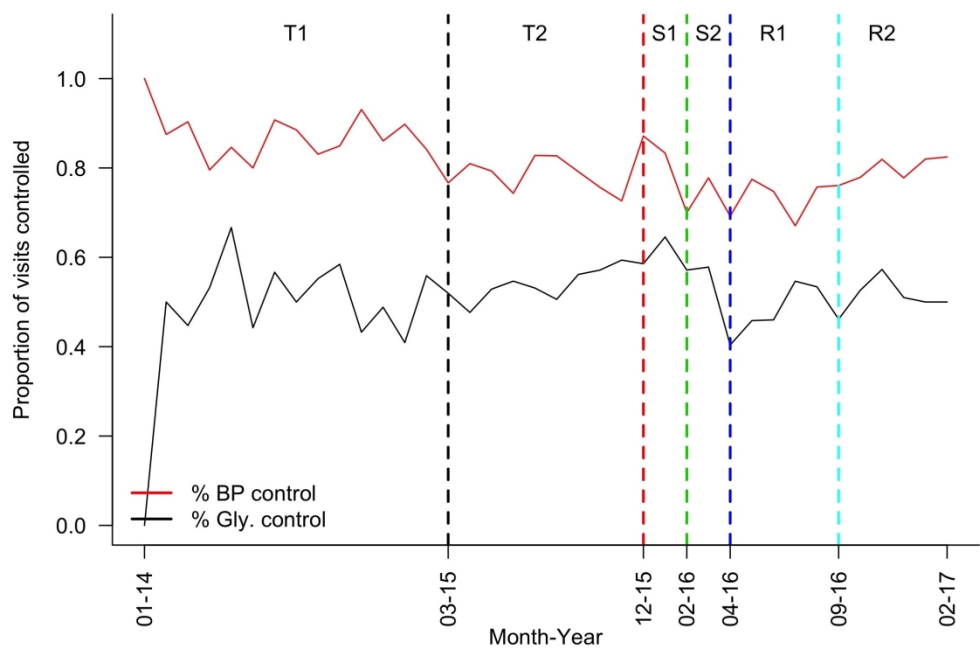
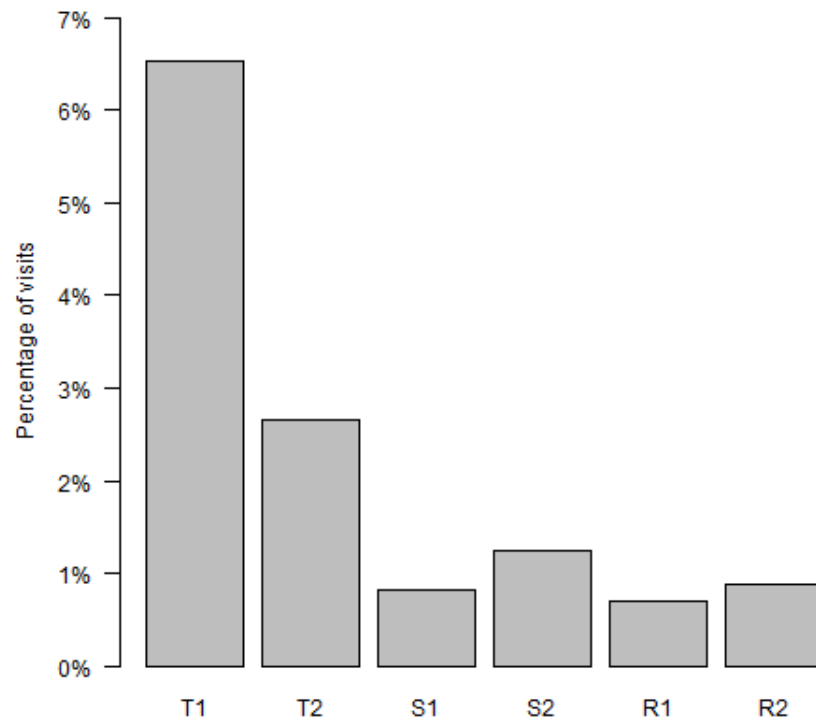


Figure 2: Proportion of visits with BP or glycaemia at target by month, Mweso IDC-OPD service
809x558mm (72 x 72 DPI)

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 Mwes0 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.

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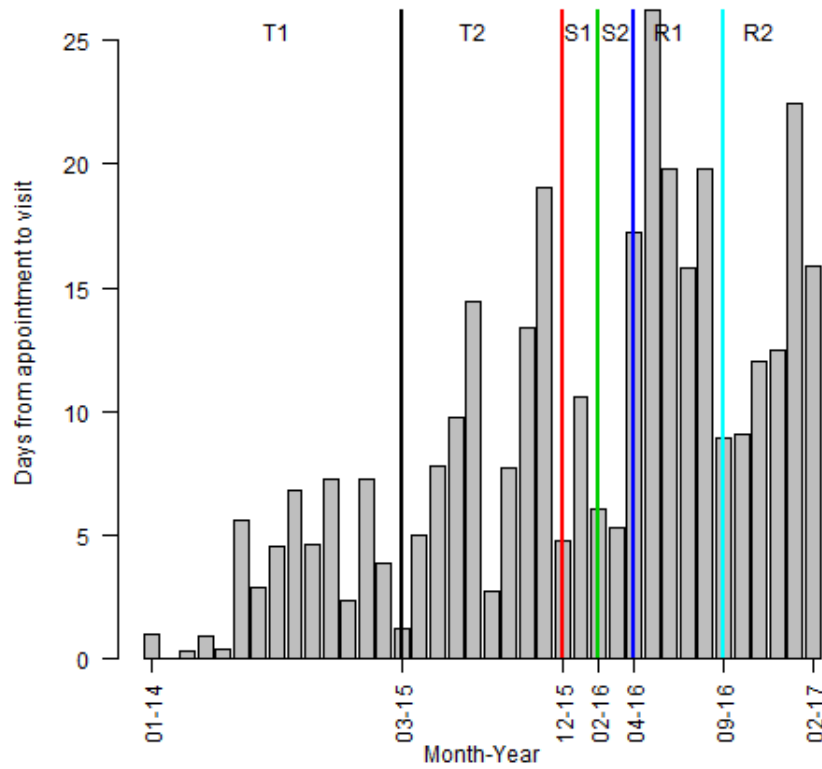
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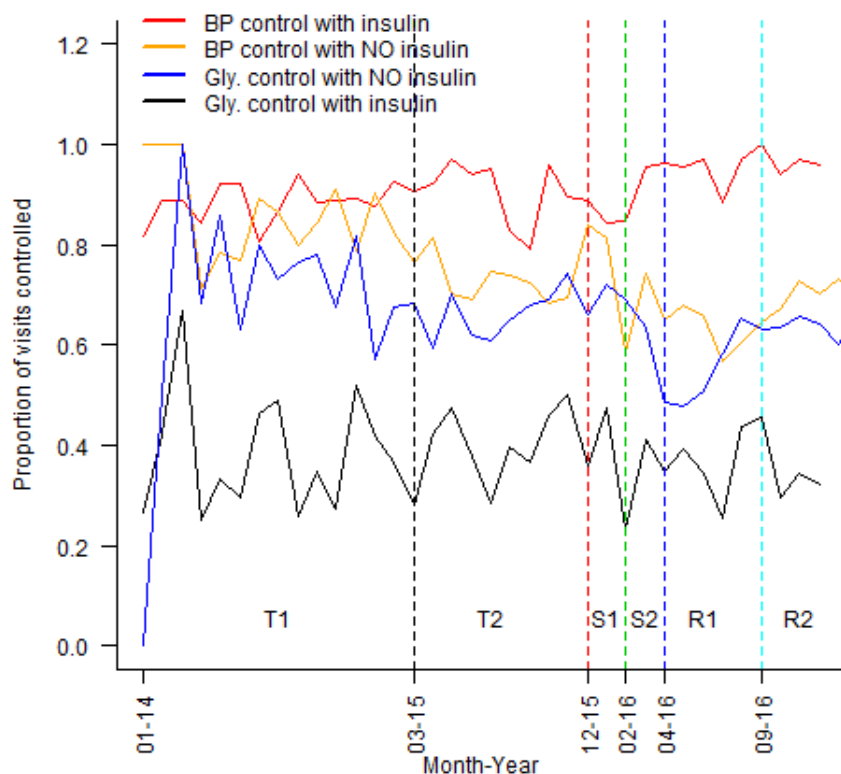
SM4. Average days' delay in attendance since planned appointment per month of

IDC-OPD service, Mweso, DRC



Review only

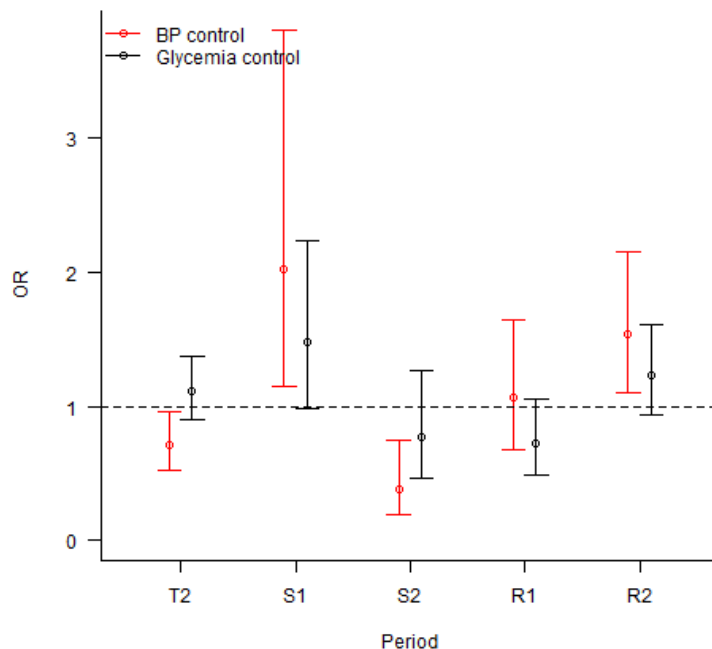
SM5. Proportion of visits at target for BP and glycaemic control, stratified by insulin prescription per month of IDC-OPD service, Mweso, DRC



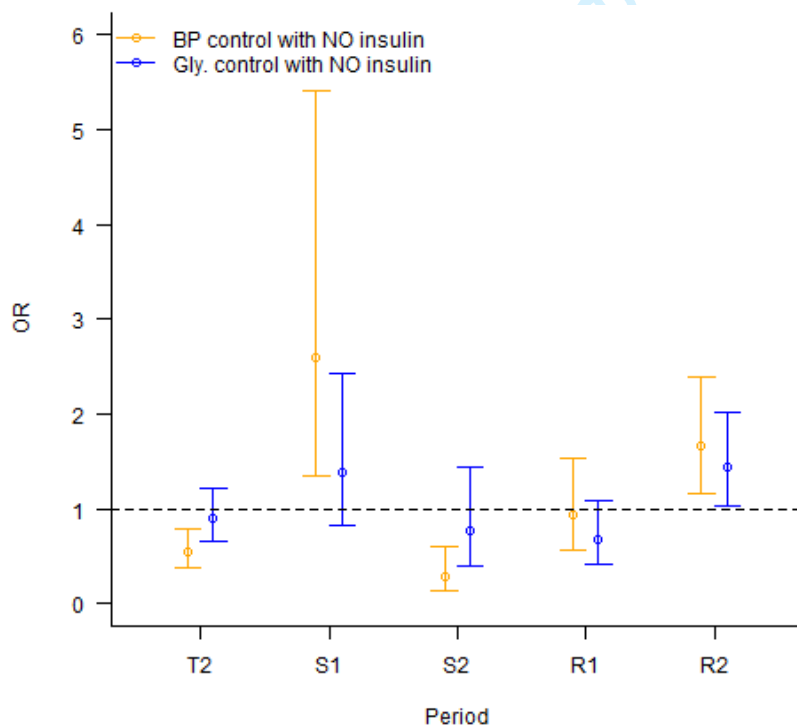
Note: Patients were categorised by whether they were prescribed insulin [+/- oral hypoglycaemic (OHG) drugs] or OHG drugs alone at their last recorded visit. The former group would have included Type 1 diabetics, Type 2 diabetics with more advance illness requiring a combination of OHG and insulin, and 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

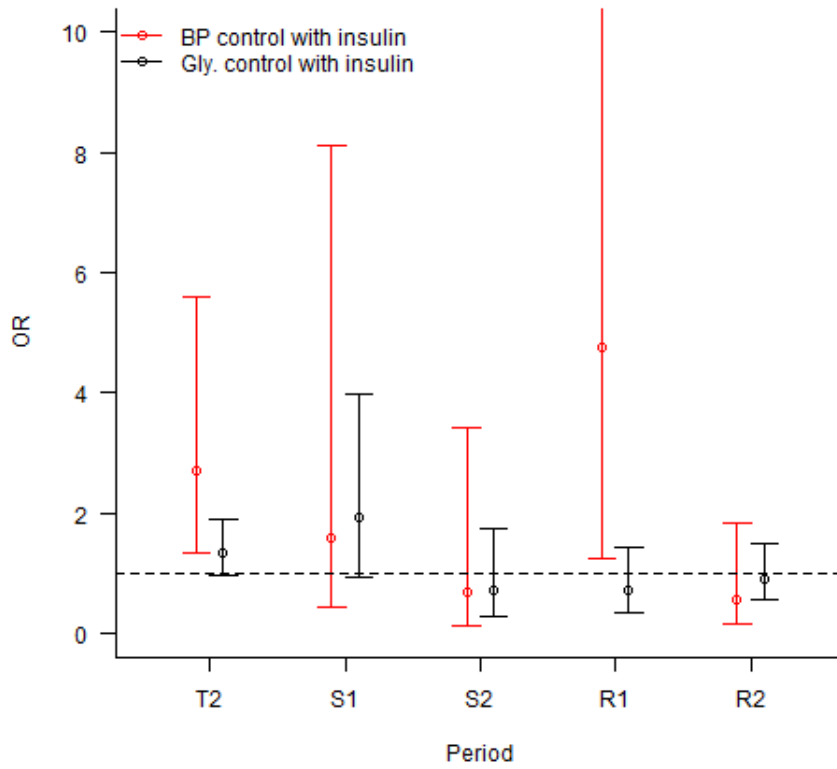
A. Impact (OR) on BP and glycaemia in all patients (not stratified by insulin prescription)



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)



Review only

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

1			
2	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
3			n/a
4			
5			
6			(b) Report category boundaries when continuous variables were categorized
7			Supp
8			Mat 3
9			
10			(c) If relevant, consider translating estimates of relative risk into absolute risk for a meaningful time period
11	Other analyses	17	Report other analyses done—eg analyses of subgroups and interactions, and sensitivity analyses
12			n/a
13			
14	Discussion		
15	Key results	18	Summarise key results with reference to study objectives
16	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			12-14
18			17,18
19			
20	Interpretation	20	Give a cautious overall interpretation of results considering objectives, limitations, multiplicity of analyses, results from similar studies, and other relevant evidence
21			14-16
22			
23			
24	Generalisability	21	Discuss the generalisability (external validity) of the study results
25			18
26	Other information		
27	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
28			20
29			
30			

*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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Manuscripts

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2
3 1 **Title: Management of diabetes and associated costs in a complex humanitarian setting in the**
4
5 2 **Democratic Republic of Congo: a retrospective cohort study.**
6
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49 24 **Word Count: 3999**
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51 25

52 26 **Keywords:** Democratic Republic of Congo, Sub-Saharan Africa, diabetes, hypertension,
53 27 noncommunicable disease, humanitarian, conflict, care model, management, programme, chronic
54 28 care, outpatient, hospital care, task shifting, cost, economic.
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30 **Abstract**

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

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

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

41 **Participants:** Diabetes patients attending IDC-OPD.

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

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

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

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3 53 model maintained control rates until drug stock-outs occurred. Incremental per patient annual costs
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5 54 were lower than chronic HIV care costs in low-income settings. Future operational research should
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7
8 55 define a simplified diabetes care package including emergency preparedness.
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13 57 **Strengths and Limitations**

- 16 58 • This is the first study of its kind to examine diabetes intermediate clinical outcomes and
17 59 programme costs in a complex humanitarian setting in sub-Saharan Africa.
- 19 60 • Using routine clinical and programmatic data collected in a protracted conflict setting, we
20 61 estimated the effect of insecurity and related programmatic changes on diabetes
21 62 intermediate clinical outcomes, which to our knowledge, has not been addressed in the
22 63 literature to date.
- 24 64 • The study was limited by the relatively small sample size and lack of control group for
25 65 comparison.
- 27 66 • The costing analysis was descriptive and based on aggregate data and so neither the cost-
28 67 effectiveness of the programme nor patient-level costs could be determined.

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4 69 **Title: Management of diabetes and associated costs in a complex**
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6 70 **humanitarian setting in the Democratic Republic of Congo: a retrospective**
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9 71 **cohort study.**
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16 73 **Background**

17
18 74 Over the past 40 years, diabetes prevalence has increased sharply worldwide, particularly in low and
19
20 75 middle income countries (LMICs).[1] However, data on the burden and needs related to diabetes
21
22 76 and other non-communicable diseases (NCDs) are scarce from conflict-affected countries,
23
24 77 particularly those in Sub-Saharan Africa.[1,2] Humanitarian actors have been slow to prioritise
25
26 78 diabetes treatment in disaster and post-conflict settings despite reporting increasing presentations
27
28 79 of diabetic patients within their programmes.[3–6] This is due to lack of knowledge on local diabetes
29
30 80 epidemiology, limited research on diabetes management or outcomes in crisis settings; a lack of
31
32 81 programmatic and policy guidance or tools to support diabetes care in such settings; prioritisation of
33
34 82 other health needs; and also a perception that diabetes care is complex and expensive. [2,3,6–8]
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39 83 The humanitarian situation in Democratic Republic of Congo (DRC) is considered one of the most
40
41 84 complex and challenging worldwide. Prolonged conflict over two decades has resulted in over 5
42
43 85 million deaths, over 4.5 million internally displaced people, the exodus of over 800,000 refugees,
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45 86 and ongoing political and social instability. [9,10] The health system, weakened by prolonged
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47 87 conflict, is challenged by competing health needs in a country ranked 176 of 189 on the human
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49 88 development index despite holding rich natural resources. [11]
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53 89 On this backdrop, diabetes prevalence is increasing, currently estimated at 4.0 - 5.4%. [12–14] While
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55 90 some factors implicated in the global rise in diabetes prevalence hold true in DRC (demographic
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57 91 change, urbanisation, changing diets etc.) chronic conflict and political instability add additional
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3 92 complexity. Recent reviews and ethnographic evidence point to a link between chronic food
4
5 93 insecurity, childhood malnutrition and diabetes. [13,15,16] In DRC, 43% of children under 5 years are
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7 94 chronically malnourished and levels of food insecurity have risen sharply, with millions subsisting on
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10 95 World Food Programme rations. [17] Recent evidence also supports an association between chronic
11
12 96 perceived stress and diabetes onset, while patients with diabetes in humanitarian settings focus on
13
14 97 suffering and loss as a cause of their illness. [16,18] Furthermore, in humanitarian crises, people with
15
16 98 diabetes are at increased risk of complications and death due to treatment interruption and
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18 99 precarious access to food and water. [2,6]
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21
22 100 Médecins sans Frontières (MSF), a medical humanitarian organisation, has supported healthcare
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24 101 delivery in Mweso, North Kivu, in collaboration with the Ministry of Health since 2008. North Kivu is
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26 102 a rural, impoverished area bordering Rwanda with an estimated population of 365,000. It remains a
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28 103 flash point in the on-going conflict between shifting rebel groups and government forces, which has
29
30 104 been characterised by brutal violence against civilians and destruction of lives and livelihoods.
31
32
33 105 Outbreaks of violence since 2016 have resulted in recurrent waves of population displacement;
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35 106 North Kivu alone hosts 17 internally displaced person camps. MSF supports health services in 4 out
36
37 107 of 23 Primary Health Care clinics and in Mweso hospital within Masisi District. Mweso hospital
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39 108 serves a catchment area of approximately 145,000 people, with about 65,000 recipients of care
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41 109 living in the immediate vicinity of the hospital.
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45 110 While a national diabetes programme exists in DRC, available diabetes care is concentrated at
46
47 111 hospital level in major cities. [19] In response to growing patient and provider needs in Mweso, MSF
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49 112 implemented a hospital-outpatient based diabetes programme in March 2015, the Integrated
50
51 113 Diabetic Clinic within Hospital Outpatient Department (IDC-OPD) in place of the ad hoc care
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53 114 previously undertaken. The IDC-OPD was integrated at the clinical level into usual outpatient
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55 115 activities, with pre-existing staff trained to provide this additional service. [20] The programme
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58 116 comprised a nurse-led, multi-disciplinary model, using locally adapted clinical guidelines, patient
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3 117 counselling materials and data collection tools, accompanied by three days of specialist training.[21]
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5 118 The clinic team included: a nurse supervisor, nursing assistant, two doctors, a nutritionist, and
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7 119 education and psychosocial support officers. Diabetes was diagnosed according to World Health
8
9 120 Organization (WHO) guidelines using repeated fasting capillary glucose. Most patients were
10
11 121 identified as diabetic and enrolled after acute hospital presentation, while some were identified via
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13 122 the Mweso outpatient department or referring primary care clinics.
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16
17 123 Patients received a detailed enrolment assessment, monthly nurse-led follow-up and 6-monthly
18
19 124 medical review. The program included context-adapted dietary advice (accounting for locally
20
21 125 available and affordable foods and customs) and psychosocial support, including clinician-moderated
22
23 126 peer support groups and involvement of family or friends as treatment supporters. The psychosocial
24
25 127 aspects of patients and providers managing diabetes are discussed in a related paper, with major
26
27 128 themes from the patient perspective including the difficulty adhering to the recommended diet and
28
29 129 barriers to clinic access during outbreaks of violence. [22] Each patient was given a clinic-held
30
31 130 patient file and patient-held passport to facilitate safe passage when armed groups impeded their
32
33 131 travel. Clinical guidelines were adapted from MSF, WHO and other international guidance. [23]
34
35 132 Patient educational tools (disease and diet education leaflets) were adapted from Santé Diabète
36
37 133 [24], a Malian Non-Governmental Organisation, and generic medications, included on MSF's
38
39 134 Essential Drugs List, were prescribed. Insulin doses were adjusted using single fasting capillary blood
40
41 135 glucose readings and patients' reported symptoms of hypo- or hyperglycaemia in the absence of
42
43 136 home glucose monitoring. Insulin-dependent patients were prescribed human insulin, delivered via
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45 137 needle and syringe, and advised to store this at home in a clay pot, recommended as a safe
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47 138 alternative to refrigeration in similar contexts. [25]
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54 139 In early 2016, outbreaks of armed violence restricted movement of patients and supplies. Direct
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56 140 attacks on MSF staff and facilities, including an armed robbery and abductions, led to withdrawal of
57
58 141 the international staff from Mweso and temporary scaling back of the programme, with local nursing
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3 142 staff dispensing medications to any patients reaching the clinic. Later, the programme was
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5 143 suspended for a period of six weeks when supply routes were entirely blocked and drug stocks were
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7 144 exhausted.

9
10 145 A mixed methods evaluation of the Mweso IDC-OPD programme was undertaken by MSF and
11
12 146 included a qualitative evaluation exploring patient and provider clinical and psychosocial challenges,
13
14 147 presented elsewhere [22]; and a retrospective review of quantitative programmatic data and cost
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16 148 data collected as part of routine care in a chronic conflict zone, reported here. The overall aim of
17
18 149 this paper was to evaluate an Integrated Diabetic Clinic within a Hospital Outpatient Department
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20 150 (IDC-OPD) in a complex humanitarian setting in North Kivu in Democratic Republic of Congo. The
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22 151 specific objectives were to: (i) analyse diabetes intermediate clinical and programmatic outcomes
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24 152 (blood pressure/glycaemic control, visit frequency and volume); (ii) explore the association of key
25
26 153 insecurity and related programmatic events with these outcomes; and (iii) describe incremental IDC
27
28 154 OPD programme costs.

33 34 155 **Methods**

35
36 156 It has been acknowledged that traditional experimental and evaluation methods may be unfeasible,
37
38 157 inappropriate or even unethical to apply in humanitarian settings [26]. Therefore, we have used a
39
40 158 pragmatic approach to utilising programmatic data, with an open cohort design. For the outcome
41
42 159 analysis, we conducted a retrospective analysis of routine data of enrolled adults aged ≥ 18 years
43
44 160 from January 2014 to February 2017, examining trends in diabetes outcomes and their association
45
46 161 with key programmatic events. The study period was divided into five phases, defined by
47
48 162 programmatic changes or periods of heightened insecurity (which impacted service delivery due to
49
50 163 staff evacuation, supply chain interruption and reduced patient access). Period T1 refers to ad-hoc
51
52 164 care delivered before introduction of the IDC-OPD programme (T2). Security incidents in December
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54 165 2015 prompted a period of service suspension (nurse-only care, with drug pick-ups, glucose testing
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3 166 and minimal treatment adjustments) (S1). Complete suspension followed once drug stocks were
4
5 167 exhausted (S2). Limited service resumed in April (R1) until full service recommenced from
6
7 168 September 2016 (R2) (Table 1).
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10
11 169 Table 1. Study Periods for Evaluation of IDC-OPD Programme, Mweso, DRC
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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

170

171 **Data**

172 Patients were given a unique identification number on enrolment. Data were recorded in paper-
173 based clinic-held files by clinical staff and transferred to an electronic database by a trained data
174 entry operator on a weekly basis. Missing data were discussed with the nurse manager and gaps
175 were filled during follow-up clinical visits. Single data entry was performed on a password-protected
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3 176 Microsoft Excel software application specifically developed by MSF for this programme. Anonymised
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5 177 exports were transferred to the study team on a monthly basis.
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8 178 Demographic data on patients' age, gender, occupation, and village of residence were recorded on
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10 179 enrolment. Cardiovascular risk factors (smoking status, current alcohol use), family history of
11
12 180 diabetes, year of diabetes diagnosis and self-reported history of childhood malnutrition and/or
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14 181 tuberculosis were recorded. Clinical parameters: body mass index (BMI), blood pressure (BP)
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16 182 measured by manual sphygmomanometer according to local MSF protocols [21], fasting capillary
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18 183 blood glucose (FBG); prescribed diabetes drugs [insulin and/or oral hypoglycaemic drugs (OHGs)];
19
20 184 and diabetes classification (Type I, Type II or other) were recorded at each clinical encounter.
21
22 185 Medical review at enrolment and six monthly thereafter was recorded, including biochemical
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24 186 markers (serum creatinine) and examination for complications (visual acuity, cataract, proteinuria,
25
26 187 foot check). Numbers of deaths, transfers out of the area and delays in attendance were also
27
28 188 documented. The key intermediate clinical outcome and programme measures used in the analysis
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30 189 are shown in Table 2.
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39 191 Table 2: Outcome measures used to determine effect of different programme periods on
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41 192 programme delivery and intermediate clinical outcomes
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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

193

194

195 Analysis

196 Basic demographics were analysed using mean and median and were presented with inter-quartile
 197 ranges. We assessed the relationship of different study periods with the frequency of visits and the
 198 impact of study periods on intermediate clinical outcomes i.e. per visit attainment of blood pressure
 199 (< 140/90 mmHg) and glycaemic (> 4.2 and ≤ 8.3 mmol/L) targets.

200 To estimate the effect of a period change we calculated the odds ratio (OR) of the odds of having the
 201 biomarker under control in a visit in the new period (t) over the odds of having the biomarker
 202 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
 203 chances of the biomarker being under control in a visit in period t was greater than the chances of
 204 the biomarker being under control in a visit in the previous period ($t-1$) (but not necessarily than
 205 other periods, $t-2$, $t-3$, etc.). Likewise, $OR_t < 1$ implied a reduction in the chances of having the
 206 biomarker under control in a visit during period t compared to a visit during the previous period ($t-1$).
 207 To estimate these OR we ran a logistic model with period as a categorical variable, suitably
 208 coded, and adjusted for sex, age (and square and cube terms) and number of visits of the patient
 209 (and square term). The models were stratified by whether the patient was prescribed insulin (+/-
 210 oral hypoglycaemic agents) at the previous visit.

211 Missing data: Our main analysis used only complete data; records with missing data were excluded.

212 Few outcome variable data were missing: less than 3% in BP control (most of it in the pre-training

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3 213 period) and less than 0.3% for glycaemic control (Supplement SM1). There were no missing data for
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5 214 date of visit, sex or age.
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10 216 **Costing data and analysis**

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13 217 For the descriptive, incremental cost analysis we took a health services perspective. Information
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15 218 related to the nature, location and mode of delivery of the NCD services was collected during a field
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17 219 visit in December 2015 by the study team and was supplemented by informal interviews with clinical
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19 220 and administrative staff. A data analysis tool was designed to collate the relevant financial costs for
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21 221 the study period 2014 -2015 from routine programme documents and standard MSF tools including
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23 222 budget, human resources, drug consumption monitoring, logistics/supply tools, clinic records and
24
25 223 programme reports. For salary costs, we included the incremental costs of an MSF-employed
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27 224 medical doctor and nurse and an MOH-employed nurse (with salary supplement paid by MSF)
28
29 225 dedicating one day, two psychosocial workers dedicating one hour and a nutritionist dedicating 30
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31 226 minutes per week to the IDC-OPD service (based on 22 working days per month). Hence, most costs
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33 227 were related to drugs, equipment, disposables and stationary. Key cost items were grouped into: (a)
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35 228 medicine, (b) supplies, and (c) staff time. Monthly resource use and unit cost data were recorded
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37 229 and annualised (Supplement SM2); annual total cost, cost per visit and cost per patient were
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39 230 reported in Euro (€) for 2014 before formal implementation of the IDC-OPD programme and for
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41 231 2015 during full implementation.
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47 232 The study was approved by the Ministry of Health of North Kivu Province, DRC, and the Médecins
48
49 233 sans Frontières Ethics Review Board (ID 1542).
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52 234 **Patient and Public Involvement**

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55 235 Patients were not involved in the design or conduct of this study.
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58 236 **Results**

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3 237 Between January 1st 2014 and February 9th 2017, 243 patients were enrolled in the IDC-OPD
4
5 238 programme (Supplement SM3). Median age was 45 years (IQR 32 – 56); 44.6% of the cohort was
6
7 239 female. For adults ≥ 18 years ($n=219$), mean BMI was 21.3 kg/m² and 31.1% were underweight (BMI
8
9 240 < 18.5 kg/m²). On enrolment, 8.2% were current smokers; 24.4% reported recent alcohol intake;
10
11 241 self-reported medical history included: 9.1% hypertension, 2.2 % CVD, 2.7% tuberculosis and 8.7%
12
13 242 malnutrition. Half were classified clinically as Type 2 diabetic (51%; $n=125$); 26% ($n=62$) as Type 1;
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15 243 and 23% ($n=56$) were either unclassified or classed as “other” (Supplement SM3).

19 244 **Trends in outcomes and impact of programmatic events**

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22 245 Numbers of visits and appointment intervals increased after the introduction of the systematic
23
24 246 approach to diabetes care, which included monthly review appointments for stable patients (T2)
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26 247 (Figure 1; Supplement SM4). During the period of scaled back service (S1), visit numbers initially
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28 248 climbed while the visit interval decreased, which may reflect increased visit frequency due to short-
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30 249 term drug supplies. Once drug buffer stock was exhausted, visit numbers dropped off sharply.
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32 250 Patients may have avoided or were prevented from attending due to security conditions.
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252 Figure 1: Average number of days from previous visit per month for Mwesio IDC-OPD service

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

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3 260 may be because the former group contained relatively young Type 1 and malnutrition-related
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5 261 diabetics.
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10 263 Figure 2: Proportion of visits with BP or glycaemia at target by month, Mwesio IDC-OPD service
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16 265 The results of the odds ratio (OR) calculations were unexpected. Odds of attaining BP control
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18 266 appeared to worsen following implementation of the formal IDC-OPD programme (T2 vs. T1), while
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20 267 odds of attaining glucose control improved, perhaps because care was initially focussed on glucose
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22 268 control (Supplement SM6). On scaling back the service (S1), control of both parameters seemed to
23
24 269 improve, possibly because the service itself or the subset of patients reaching it during the insecure
25
26 270 period were somehow different. Once medications supplies were exhausted (S2), control of both
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28 271 parameters seemed to worsen, but control was regained on service resumption. Stratifying by
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30 272 insulin prescription showed similar results (Supplement SM5).
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33 273 **Costs of providing diabetes care**

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37 274 The total costs of diabetes care in 2014 and 2015 were approximately €37,000 and €31,000
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39 275 respectively (Table 3). Supplies were the major driver of costs each year. The greatest costs in 2014
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41 276 were for latex gloves, glucometers and glucometer strips; in 2015 they were for glucometers, strips
42
43 277 and lancets (Supplement SM2). While medication costs increased in 2015 relative to 2014, staff costs
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45 278 remained unchanged, and total costs decreased, largely driven by reduced excess consumption of
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47 279 latex gloves after it was identified during the IDP-OPD training sessions. The total number of patients
48
49 280 and number of visits increased significantly from 2014 to 2015, rising from 77 and 626 to 144 and
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51 281 1103, respectively. Thus, cost per-patient per-year (PPPY) dropped from €475 to €214 and cost per-
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53 282 visit was halved from €58 to €28. This was due to the combined effect of higher patient numbers,
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55 283 greater total number of visits and lower supply costs in 2015 compared to 2014 (Supplement SM2).
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285 Table 3. Costs (€) of diabetes care in 2014 and 2015, Mwesio 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	

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288 **Discussion**

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

294 Our results show that glycaemic control was similar or better to that documented in other
 295 humanitarian or low-income settings (using different targets) and, while it was positively impacted
 296 by programmatic changes, control clearly deteriorated during periods of heightened insecurity.[27]

297 Our findings also indicate that, in a population previously undergoing regular supervision, a
 298 simplified nurse-provided, algorithm-driven service with consistent medication supply may be as

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3 299 effective as close medical supervision in maintaining disease control, particularly during periods of
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5 300 service interruption. Medical input could thus be focused on achieving glycaemic control in patients
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7 301 prescribed insulin, who appeared most affected by service interruption. We also note the lack of
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9 302 evidence supporting management of what we believed to be malnutrition-related diabetes.
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12 303 Intermittent outbreaks of armed conflict limited patient access and disrupted supply chains,
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14 304 impeding continuity of care. We suggest that in high-insecurity settings, chronic disease
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16 305 programmes should focus on preparing patients, staff and supply chains to pre-empt treatment
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18 306 interruption during insecure periods, learning from HIV programme experiences in similar
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20 307 settings.[28] Preparation could include: triaging patients by vulnerability (e.g. prioritising insulin-
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22 308 dependent diabetic patients, those with established complications and/or living far from the facility);
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24 309 enhancing patients' health literacy and self-management education and provision of patient-held
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26 310 personal treatment plans and emergency kits (including several months' supply of medications, such
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28 311 as insulin, delivery devices and guidance as appropriate) to facilitate self-care during insecure
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30 312 periods; building staff capacity to allow for flexibility of roles in crises; establishing networks with
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32 313 other chronic disease programmes; and stockpiling and secure storage of medications.[5,28,29]
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34 314 Technology could facilitate continued patient treatment support when access to facilities is
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36 315 impossible e.g. via mobile phone SMS messaging or decentralisation of care to community-based
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38 316 health workers furnished with clinical decision support tools or supported via telemedicine.
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42 317 The relatively poorer glycaemic control in insulin-prescribed patients may reflect either disease
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44 318 severity or the challenges associated with insulin therapy. Adherence to daily insulin injections is
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46 319 difficult anywhere; in Mweso, the security, financial and geographical barriers to accessing insulin
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48 320 and the unavailability, unaffordability and burden for families of the recommended diabetes diet,
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50 321 may additionally contribute to poor adherence.[22] In this programme, clinicians adjusted insulin
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52 322 doses based on a single fasting glucose reading taken in clinic and on patients' reported symptoms in
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3 323 the absence of home glucose monitoring and, therefore, dose adjustment was cautious and
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5 324 treatment targets were conservative.
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8 325 There is limited, although growing, evidence on the incidence, prevalence and characterisation of
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10 326 diabetes in Sub-Saharan Africa, which our findings broadly reflect.[30] Several reviews and recent
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12 327 ethnographic evidence describe “atypical” forms of diabetes, which may complicate diagnosis,
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14 328 classification and management. These include “*ketosis-prone atypical diabetes mellitus*” and
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16 329 “*malnutrition-related diabetes*”. [13,16,31] Local prevalence studies support the existence of the
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18 330 latter in the DRC, which is in keeping with the high proportion of underweight adults and
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20 331 “unclassified” diabetics in our cohort.[14,32] It is unclear whether malnutrition is causative,
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22 332 associated with hyperglycaemia or with pancreatic insufficiency and further study of diabetes
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24 333 epidemiology in DRC is needed, exploring factors such as childhood malnutrition, food insecurity and
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26 334 underweight and use of calorie-dense therapeutic foods. [31] Moreover, little evidence exists to
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28 335 guide either malnutrition-related diabetes care or the effective management of insulin in
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30 336 humanitarian settings, particularly in the absence of home or community-based glucose testing.[3,7]
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33 337 The total cost of care delivery decreased by 16% from 2014 to 2015 despite increased visit and
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35 338 patient numbers. This was largely due to decreased supply costs, driven by the 100-fold reduction in
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37 339 consumption of latex gloves following IDC-OPD training. Efficiencies of supply consumption and
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39 340 patient throughput (more visits and more patients seen by the same number of staff) contributed to
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41 341 reducing PPPY costs by 55% from €475 in 2014 to €214 in 2015.
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44 342 To our knowledge, there is no available literature to compare cost per patient or per visit for
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46 343 diabetes care (or NCD care generally) delivered in unstable humanitarian settings. A study from
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48 344 Ghana reported a per patient annual direct cost of US\$372.65 for hospital-delivered diabetes care in
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50 345 2005. For a potential comparator, we looked at the cost of delivering chronic care for HIV, the main
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52 346 life-long condition with which humanitarian actors have traditionally engaged. The 2015 PPPY cost
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54 347 reported in this study is far lower than that reported by PEPFAR and others to deliver chronic HIV
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3 348 care programmes in low and middle income countries in SSA [33,34]. In terms of cost structure,
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5 349 supplies were the major cost driver in the Ghanaian study (syringes, lancets and strips), whereas
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8 350 other analyses of diabetes care in SSA identified medications, and specifically insulin, as the main
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10 351 cost contributor [35,36].
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12 352 **Strengths and Limitations**

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15 353 Using routine clinical and programmatic data, with minimal service disruption, we have explored
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17 354 clinical outcomes of a chronic disease programme in a protracted conflict setting and the influence
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20 355 of periods of heightened insecurity on intermediate clinical outcomes and on service delivery. Each
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22 356 patient who attended in a given month contributed data, irrespective of whether they ever
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24 357 experienced a treatment interruption. Our study provides new costing information for humanitarian
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26 358 actors to support the initiation or adaptation of specific NCD programmes and may potentially
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28 359 support scale up of similar services in DRC (and other conflict-affected settings). We concluded that
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30 360 the incremental cost of adding an outpatient diabetes service to a humanitarian health programme
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32 361 in a rural hospital setting may be achieved at a cost similar to that of delivering chronic HIV
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34 362 programmes. While we cannot confirm whether an external audit of cost data had taken place, we
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36 363 are confident in the quality of these data due to MSF's robust systems and oversight by strong in-
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38 364 country and international teams.
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43 365 Given the logistical and ethical challenges of undertaking research in conflict settings, we
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45 366 acknowledge that there are a number of study limitations. We had a relatively small sample size and
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47 367 no control group for comparison. We did not explore per patient control of clinical parameters over
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49 368 time, control by diabetes type (or age), appropriateness of prescribing, patient-reported outcomes
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51 369 or the influence of psychosocial factors, diet, or adherence in each study phase since these data
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53 370 were unavailable. Gestational diabetes was not addressed since this was managed within antenatal
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55 371 services. Our costing analysis was descriptive so we could not comment on programme cost-
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57 372 effectiveness. Costing data were presented as average annual costs and did not explore the impact
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3 373 of various programme periods on costs. Since our cost data were aggregate, we could not explore
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5 374 patient-level costs or account for patient heterogeneity. While our findings may not be generalizable
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7 375 to other complex humanitarian settings or to other providers' diabetes programmes in the DRC, our
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9 376 study contributes knowledge on key challenges and suggests solutions, which may be more broadly
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12 377 applicable.

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15 378 Future research is needed in complex humanitarian settings to evaluate simplified, task-shared
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17 379 models of diabetes care, including culturally- and contextually-relevant psychosocial support and
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19 380 dietary advice; to optimise insulin management; and to evaluate emergency preparedness plans and
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21 381 technology-facilitated remote patient support.[3,5,8,13,29] We recommend that future prospective
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23 382 studies should explore per-patient outcomes (while also exploring programme-level outcomes as
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25 383 done in this study). We suggest including a control group; collecting additional outcome variables,
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27 384 such as complication rates and patient-reported outcomes e.g. related to quality-of-life, including
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29 385 functionality and mental health; and exploring the impact of psychosocial stressors and treatment
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31 386 interruption on clinical outcomes. We also suggest that cost-effectiveness studies of different
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33 387 models of diabetes care, including use of technology-facilitated remote support, and patient level
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35 388 costing studies from both provider and patient perspectives should be undertaken, exploring patient
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37 389 heterogeneity and direct and indirect patient costs.

390 **Conclusion**

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

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3 397 programmes in similar settings. Future research is needed to evaluate simplified, task-shared models
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5 398 of diabetes care and management; and to evaluate emergency preparedness plans and technology-
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7 399 facilitated remote patient support.
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14 401 **List of Abbreviations**

17 402	BMI	Body Mass Index
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19 403	BP	Blood Pressure
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21 404	DM	Diabetes Mellitus
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24 405	DRC	Democratic Republic of Congo
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26 406	HIV	Human Immunodeficiency Virus
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28 407	IDC-OPD	Integrated Diabetic Clinic within Hospital Outpatient Department
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31 408	LMICs	Low- and Middle-Income Countries
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33 409	MSF	Médecins sans Frontières
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35 410	NCD	Noncommunicable Disease
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37 411	OHG	Oral Hypoglycaemic Drugs
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39 412	OR	Odds Ratio
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42 413	PPPY	Per Patient Per Year
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3 417 **Declarations**
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7 418 ***Ethics approval and consent to participate***
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10 419 This study was approved by the Ministry of Health of North Kivu Province, DRC, by the MSF Ethics
11
12 420 Review Board, and the Ethics Committee of the London School of Hygiene and Tropical Medicine.
13
14 421 Information sheets on the clinic walls provided details of the evaluation; no specific consent was
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16 422 sought from patients for use of their routine clinical data.
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20 423 ***Authors' contributions***
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24 424 KJ and BR were involved in study conception; EA, GC, KJ, DPM, PP and BR contributed to study
25
26 425 design and interpretation of data. DPM and ZS analysed the data. MB contributed to data collection.
27
28 426 EA drafted the manuscript and all authors reviewed drafts and approved the final version.
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30

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35
36 429 contribution to this study. We thank Sarah Venis for her helpful review of the article. This work was
37
38 430 presented at MSF Scientific Days Conference in London, May 2018.
39
40

41 431 **Competing Interests**
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43

44 432 The authors declare that they have no competing interests.
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47 433 **Data Sharing**
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50 434 The datasets are available from MSF on request by researchers who fulfil certain criteria and under
51
52 435 the auspices of a data sharing agreement.
53
54

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56
57

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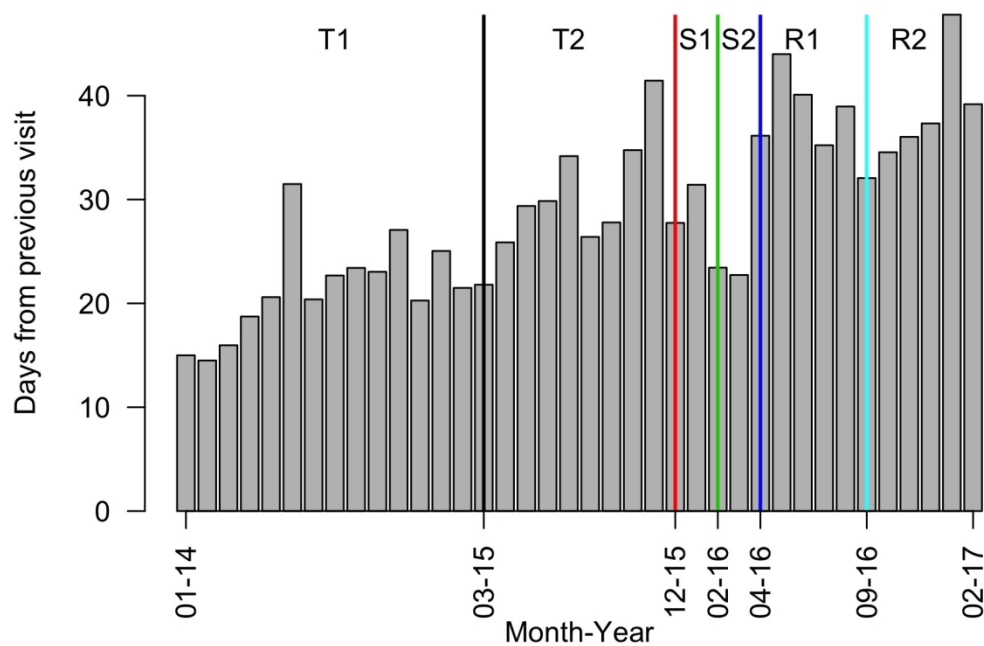


Figure 1: Average number of days from previous visit per month for Mweso IDC-OPD service

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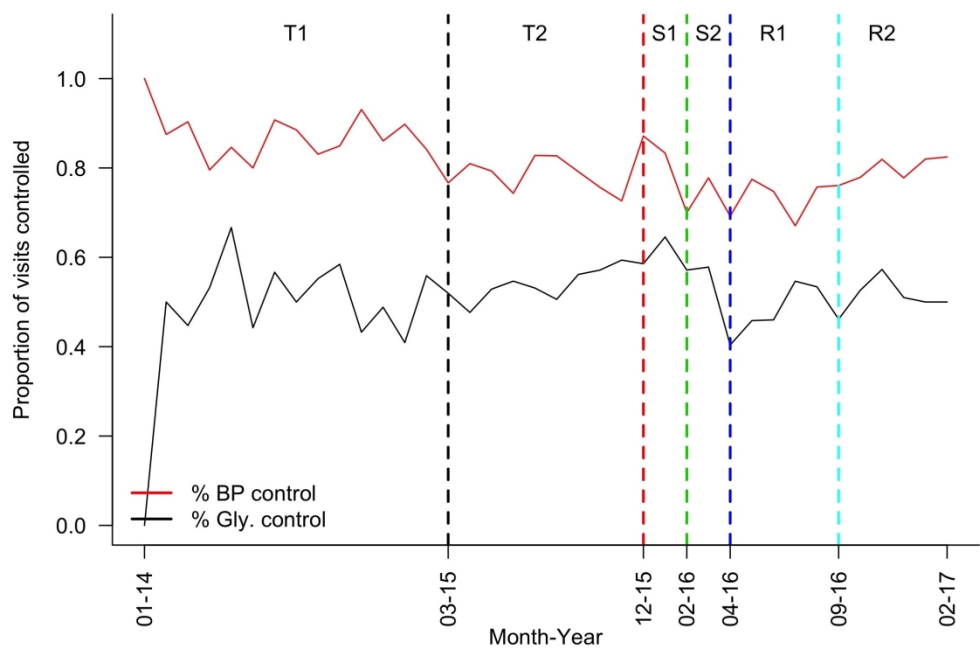
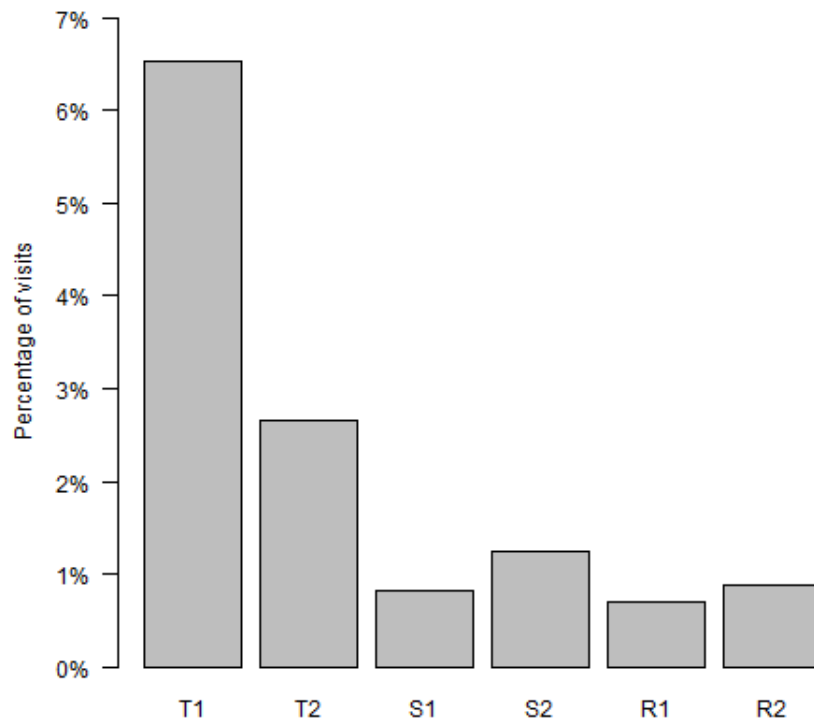


Figure 2: Proportion of visits with BP or glycaemia at target by month, Mweso IDC-OPD service
809x558mm (72 x 72 DPI)

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 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.

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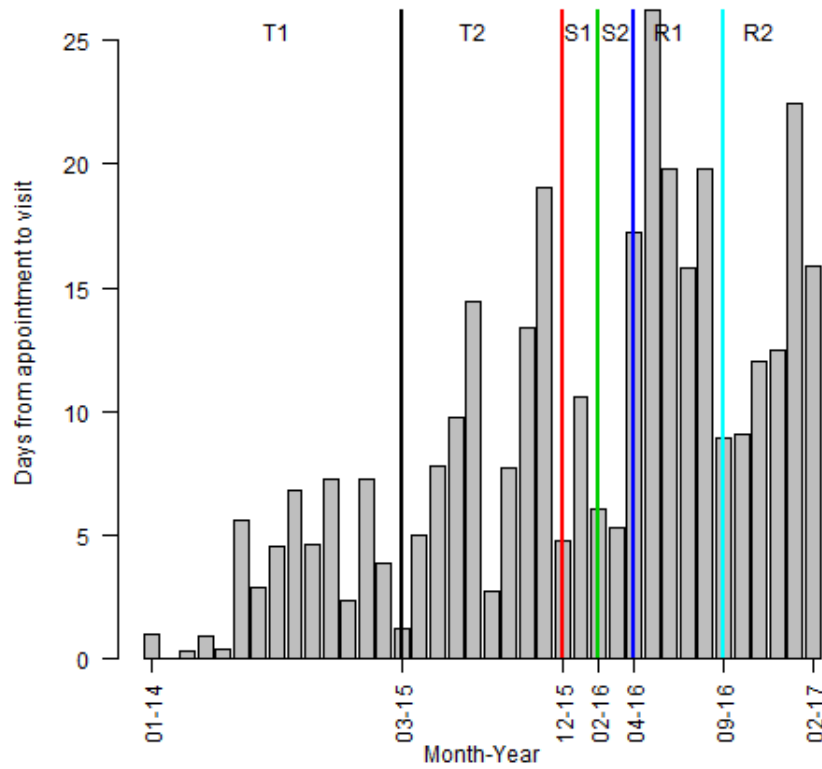
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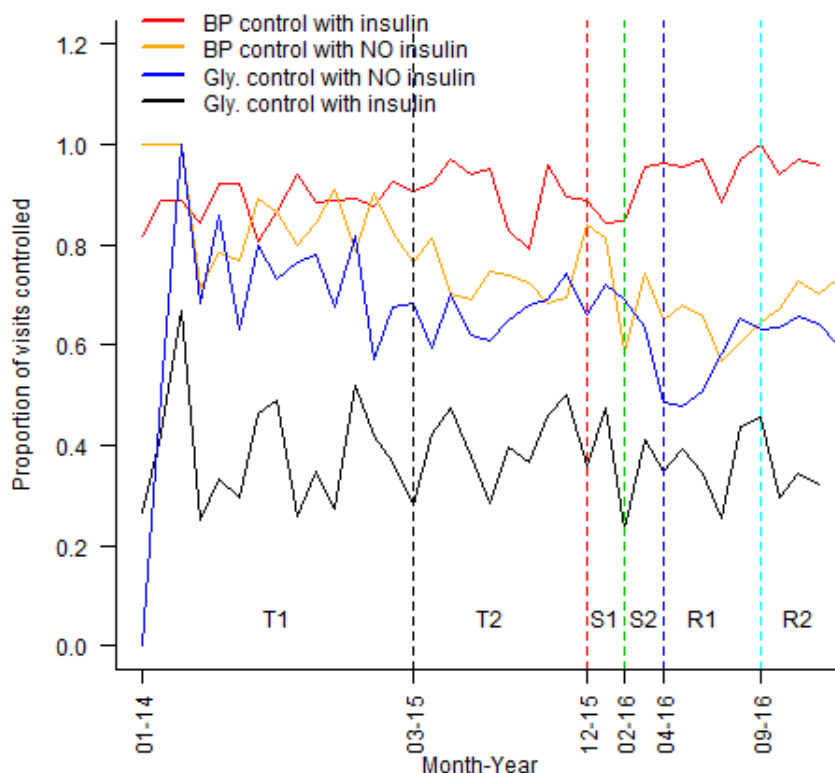
SM4. Average days' delay in attendance since planned appointment per month of

IDC-OPD service, Mweso, DRC



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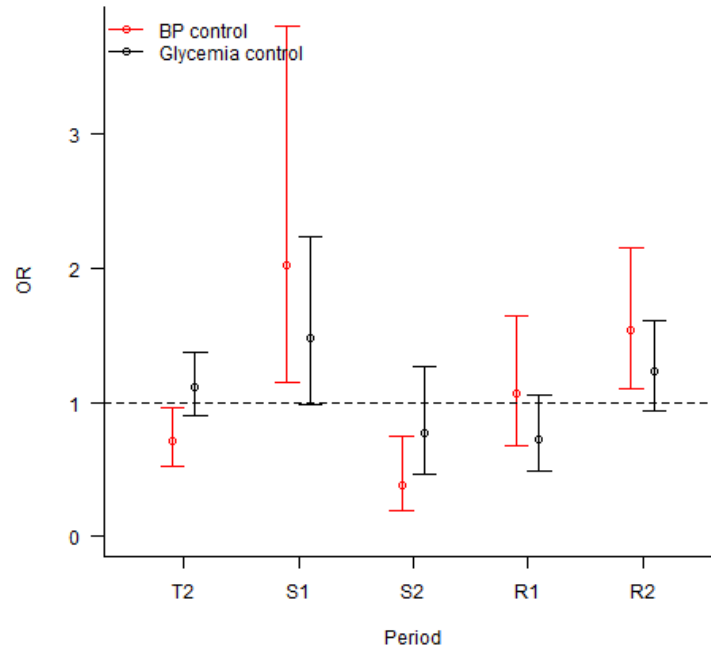
SM5. Proportion of visits at target for BP and glycaemic control, stratified by insulin prescription per month of IDC-OPD service, Mweso, DRC



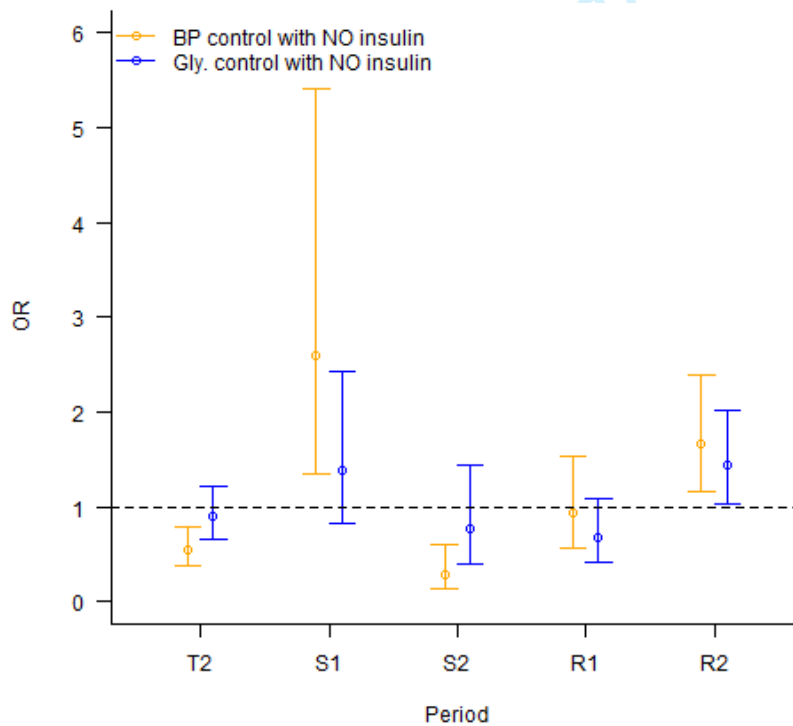
Note: Patients were categorised by whether they were prescribed insulin [+/- oral hypoglycaemic (OHG) drugs] or OHG drugs alone at their last recorded visit. The former group would have included Type 1 diabetics, Type 2 diabetics with more advanced illness requiring a combination of OHG and insulin, 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

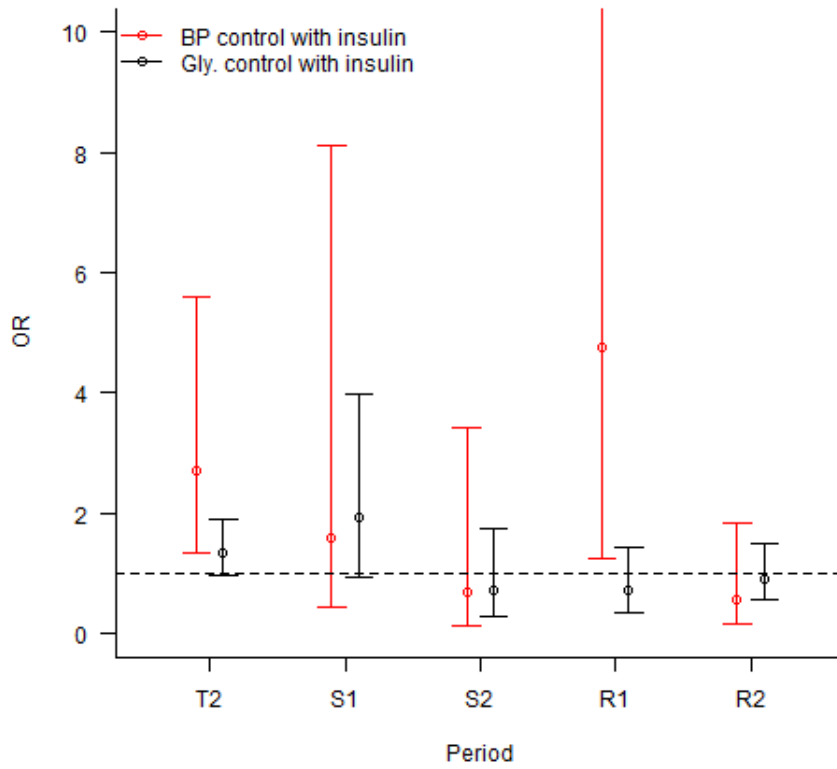
A. Impact (OR) on BP and glycaemia in all patients (not stratified by insulin prescription)



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)



Review only

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

1			
2	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
3			n/a
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6			(b) Report category boundaries when continuous variables were categorized
7			Supp
8			Mat 3
9			
10			(c) If relevant, consider translating estimates of relative risk into absolute risk for a meaningful time period
11	Other analyses	17	Report other analyses done—eg analyses of subgroups and interactions, and sensitivity analyses
12			n/a
13			
14	Discussion		
15	Key results	18	Summarise key results with reference to study objectives
16	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			12-14
18			17,18
19			
20	Interpretation	20	Give a cautious overall interpretation of results considering objectives, limitations, multiplicity of analyses, results from similar studies, and other relevant evidence
21			14-16
22			
23			
24	Generalisability	21	Discuss the generalisability (external validity) of the study results
25			18
26	Other information		
27	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
28			20
29			
30			

*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.