


# BMJ Open Expanding access to non-communicable disease care in rural Malawi: outcomes from a retrospective cohort in an integrated NCD-HIV model

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## ABSTRACT

**Objectives** Non-communicable diseases (NCDs) account for one-third of disability-adjusted life years in Malawi, and access to care is exceptionally limited. Integrated services with HIV are widely recommended, but few examples exist globally. We report descriptive outcomes from an Integrated Chronic Care Clinic (IC3).

**Design** This is a retrospective cohort study.

**Setting** The study includes an HIV-NCD clinic across 14 primary care facilities in the rural district of Neno, Malawi.

**Participants** All new patients, including 6233 HIV-NCD diagnoses, enrolled between January 2015 and December 2017 were included. This included 3334 patients with HIV (59.7% women) and 2990 patients with NCD (67.3% women), 10% overall under age 15 years.

**Interventions** Patients were seen at their nearest health centre, with a hospital team visiting routinely to reinforce staffing. Data were collected on paper forms and entered into an electronic medical record.

**Primary and secondary outcome measures** Routine clinical measurements are reported at 1-year post-enrolment for patients with more than one visit. One-year retention is reported by diagnosis.

**Results** NCD diagnoses were 1693 hypertension, 668 asthma, 486 epilepsy, 149 diabetes and 109 severe mental illness. By December 2018, 8.3% of patients with NCD over 15 years were also on HIV treatment. One-year retention was 85% for HIV and 72% for NCDs, with default in 8.4% and 25.5% and deaths in 4.0% and 1.4%, respectively. Clinical outcomes showed statistically significant improvement for hypertension, diabetes, asthma and epilepsy. Of the 1807 (80%) of patients with HIV with viral load results, 85% had undetectable viral load.

**Conclusions** The IC3 model, built on an HIV platform, facilitated rapid decentralisation and access to NCD services in rural Malawi. Clinical outcomes and retention in care are favourable, suggesting that integration of chronic disease care at the primary care level poses a way forward for the large dual burden of HIV and chronic NCDs.

## Strengths and limitations of this study

- There is a large body of literature recommending integrated HIV-non-communicable disease (NCD) care, but extremely few real world examples exist. Those that do exist are largely examples of NCD care limited to people living with HIV. This work provides enrolment and clinical outcomes data for a fully integrated HIV-NCD primary care clinic, providing care for all-comers with chronic disease in rural Malawi.
- This study provides one of the first examples of comprehensive primary care for NCDs in rural Malawi.
- This work's major limitation is that is an observational cohort using routinely collected clinical data, limiting the ability to evaluate all relevant clinical measures we would ideally include as well as isolate certain components of the intervention.

## INTRODUCTION

Globally, the burden of non-communicable diseases (NCDs) is growing every year, and is the leading cause of death and disability, accounting for 70% of mortality.<sup>1</sup> In Africa, infectious diseases such as HIV, malaria and tuberculosis (TB) have long been significant causes of morbidity, however NCDs are quickly overtaking these infectious diseases, and are predicted to become the most common cause of death by 2030.<sup>2,3</sup> While the 2011 United Nations High Level meeting set out plans to combat this growing burden, the response has yet to fully meet this need.<sup>4</sup> For instance, the disability-adjusted life year (DALY) burden from NCDs is estimated to be 37% in low-income countries, but development assistance allocated to NCDs was estimated to be just 1.3% in 2015.<sup>5</sup> In Malawi, a similar pattern emerges: the non-communicable disease and injury DALY burden is estimated to be 31% of total DALYs, yet for the 2015–2016 fiscal year,

only 0.1% of targeted programmatic funding was designated to these conditions.<sup>6 7</sup>

In Malawi, a high proportion of this burden falls on patients under 40 years, and the Ministry of Health (MOH) is increasingly recognising the importance of care delivery systems for NCDs.<sup>6 8</sup> Estimates of condition-specific prevalence estimate hypertension rates between 14%–16% for urban adults and 13%–14% for rural adults.<sup>9</sup> Diabetes occurs in up to 5.6% of adults, with a cohort study of urban and rural finding 3% of urban adults and 2% of rural adults presenting with diabetes.<sup>9 10</sup> Asthma affects approximately 5.1% of adults, and mental illness is common in Malawi, with the prevalence of common mental disorders in primary care settings suspected to be around 20%.<sup>10 11</sup> Access to care, particularly in the rural districts, is limited: for example, less than half of the health centres were equipped with the country's first-line anti-hypertensive in 2014.<sup>12</sup> While care is available at central hospitals in large cities, 83% of the country lives in rural areas.<sup>13</sup> In rural health facilities, studies have found that there is a basic lack of health commodities available to screen for and treat type 1 and 2 diabetes.<sup>8 14 15</sup> Studies have also suggested that low care and utilisation rates may be due to limited diagnosis as well as limited continuity of care.<sup>15 16</sup>

Successful implementation of programmes to address chronic diseases is not a new concept in Malawi. Having suffered from a high HIV burden for many years, Malawi has implemented a strong HIV programme with care decentralised throughout the country, overseen by a strong central monitoring system.<sup>17</sup> From 2010 to 2016, the HIV prevalence among persons 15–49 years old dropped from 10.6% to 8.8%.<sup>18</sup> An estimated 72.7% of people living with HIV and AIDS knew their status in 2016, with 90.8% of those on treatment virally suppressed.<sup>19</sup> The MOH has also become a leader in progressive antiretroviral therapy programmes, such as Option B+ and universal treatment.<sup>20–22</sup>

Given this ongoing success in treating chronic infectious disease as well as the resources invested in these programmes, and Malawi's growing burden of chronic NCDs, integrated care for chronic diseases is an attractive solution. Applying lessons from HIV care delivery to NCDs is well described, and an integrated approach is increasingly recognised as a possible delivery model, particularly for primary care, with much of the literature focused on calling for various integrated approaches.<sup>23–25 25–29 29</sup>

There exist many examples of combining HIV with other clinical programmes and into primary care; however, much of the early work in HIV–NCD integrated chronic care focuses primarily on screening and treating NCDs within HIV cohorts exclusively.<sup>30–35</sup> Fully integrated HIV and NCD care is put forward as a model by several authors, but examples of fully integrated HIV–NCD clinics, serving patients with and without HIV, are limited.<sup>29 30 39</sup> Practical experience and implementation research is needed to assess the feasibility and outcomes of fully integrated HIV–NCD care.<sup>25</sup>

Situated in southwest Malawi, the rural district of Neno was formed in 2003 and did not have a hospital until 2007. HIV care was fully decentralised from 2 hospitals in Neno to 11 primary health centres by 2011 through a long-term partnership between the international non-profit Partners In Health (PIH) and the MOH, with a comprehensive approach featuring community health workers (CHWs), nutrition and cash transfer support for most vulnerable patients.<sup>40 41</sup> Neno District is consistently achieving significantly higher HIV retention and survival rates than any other district in the country.<sup>41</sup> Leveraging this experience, in 2015, PIH and the MOH launched the Integrated Chronic Care Clinic (IC3) in Neno. At the two hospitals, IC3 replaced an earlier clinic for NCDs, modelled off PIH's partnership with the government of Rwanda.<sup>42–44</sup> At the time, the NCD clinic at the two hospitals was experiencing high rates of patient default, rotating staff, and a lack of streamlined monitoring and evaluation and supply chain systems. The clinics used the HIV platform of care to include treatment for any chronic illness including hypertension, diabetes, asthma, epilepsy and mental illness regardless of a patient's HIV status. Through utilisation of the existing HIV platform, we were able to maximise staff, clinic space and overall efficiency and resources.<sup>45</sup> In 2015, IC3 rapidly decentralised integrated HIV–NCD primary care to the existing 2 hospitals and 11 health centres in the district, and later to a newly opened 12th health centre in mid-2016.

While integrating care makes sense in resource-poor settings with high infectious and NCD burdens, the evidence base surrounding how best to prevent and manage NCDs, or integrate NCD care, in sub-Saharan Africa is severely lacking.<sup>26 27 46</sup> This paper therefore seeks to describe our clinical outcomes after integrating NCD and HIV care into one system for all-comers with a chronic disease in Neno District, Malawi.<sup>45</sup>

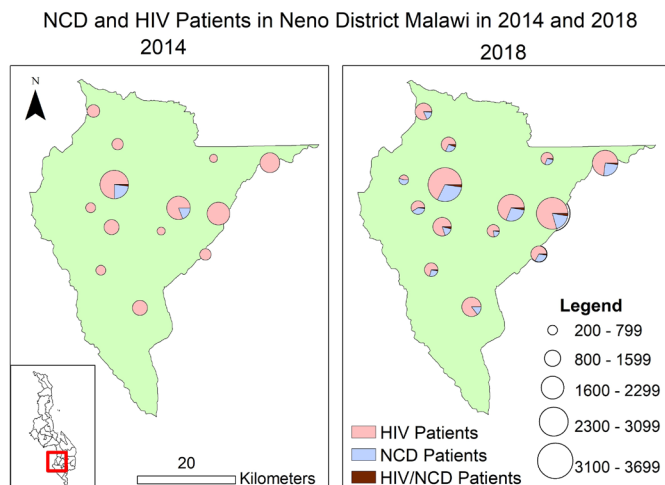
## METHODS

### Setting and population

Neno District is a district with population of 165 000 in 2017, situated in the southwest zone in Malawi.<sup>47</sup> An extremely rural setting, the majority of the population relies on subsistence agriculture, with only 4.5% of the population with electricity.<sup>48</sup> Since 2007 PIH has partnered with the MOH in Neno to strengthen health services. In 2011, the Chronic Care Clinic (CCC) began enrolling patients with NCDs at Neno District Hospital, and in 2013 NCD services opened at Lisungwi Community Hospital. In early 2015, CCC was combined with the HIV programme to form IC3, and decentralised to the 11 primary health centres across the district<sup>45</sup> (figure 1).

### IC3 program design

The clinic-treated patients with one or more of any of the following conditions: HIV, hypertension, epilepsy, asthma, diabetes and mental illness. Patients were referred to IC3 from several settings including inpatient



**Figure 1** NCD and HIV diagnoses in Neno District over time. NCD, non-communicable disease.

wards, outpatient clinics and community-screening events. The latter were held in remote parts of the district, with participants receiving age-appropriate and gender-appropriate screening for hypertension, diabetes, HIV, TB and malnutrition. Those with high blood pressure or high blood sugar were referred to their nearest facility for IC3 staff to confirm diagnosis and enrol them into care. In order to ensure the sickest patients were found early and treated, and to avoid clinic overcrowding, the referral threshold for blood pressure was systolic blood pressure (SBP)  $\geq 160$  and/or diastolic blood pressure (DBP)  $> 110$ . Cut-off for blood sugar for referral was fasting  $\geq 126$  mg/dL and random  $\geq 200$  mg/dL.<sup>49</sup> For mental health conditions, patients were referred from inpatient and outpatient clinics and assessed and diagnosed on admission to IC3. Once the diagnosis of mental health was confirmed, patients received both psychotherapy and pharmacotherapy at clinic visits. Mental illnesses included in the cohort are: schizophrenia, mood and anxiety disorders, schizoaffective disorder, psychosis, organic mental disorder, and alcohol and drug use-related mental disorders. Patients with a pre-existing NCD diagnosis and on medications were automatically enrolled. Patients were diagnosed using predefined NCD protocols, set by the IC3 team and HIV protocols from central MOH.<sup>50</sup>

Patients enrolled in IC3 were seen at the health facility nearest to their home at regular intervals. Patients with a complex diagnosis or those starting care had a scheduled visit every month, while most other patients visited every 3 months. The clinic was staffed by clinical officers, nurses, and support staff employed both by PIH and MOH. Supervision and mentorship were performed by several physicians within the district, also employed both by MOH and PIH. Hospital-based staff would travel out to the health centres 3 or 4 days a week to conduct IC3 with health center-based counterparts. This was a solution for staffing shortages—given high volumes of maternal child health and other acute needs at primary health centres, these facilities were not equipped to handle the

large influx of patients with HIV and NCDs. This system, of hospital staff travelling to support health center-based staff, had been in place for Neno's HIV care for several years.<sup>40</sup> The HIV programme, well described elsewhere, was characterised by a strong community footprint with a network of over 900 CHWs who received a monthly stipend to assist patients with adherence, perform missed visit tracking and provide social support to especially vulnerable patients in the form of cash transfers.<sup>41</sup> These principles were applied to IC3, with the CHW network undergoing a gradual transformation in 2017 and 2018 so that all patients with NCD were eventually assigned a CHW.<sup>51</sup>

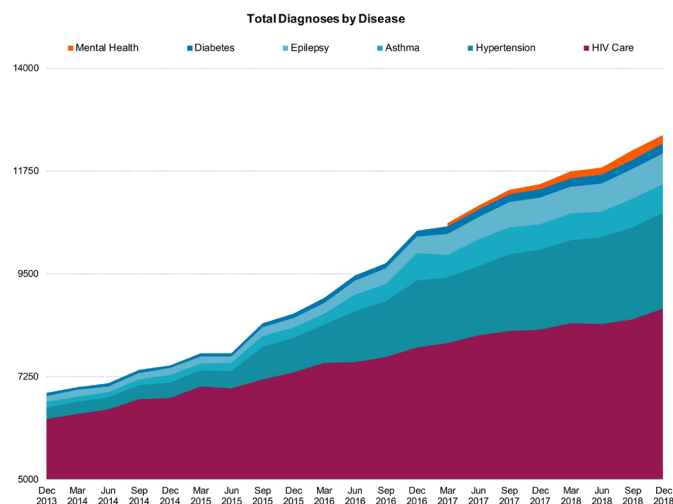
### Data collection and analysis

This is a retrospective cohort comprised of all patients newly enrolled in IC3 at any facility in Neno District in the 36-month period between January 2015 and December 2017. Data were collected at enrolment and at routine clinical visits by clinical staff on paper forms also called master cards, which were approved and standardised by the national MOH. Data from the master cards were then regularly entered into an OpenMRS electronic medical record (EMR) system by data clerks. EMR data were extracted and used in this analysis.

Baseline demographics and clinical characteristics specific to each disease are reported using descriptive statistics. Key indicators for each condition were chosen based on available routine clinical measurements that were taken each visit based on MOH protocols, which include: blood pressure for patients with hypertension, random or fasting fingerstick for patients with diabetes, asthma severity for patients with asthma and number of monthly seizures for patients with epilepsy. Routine clinical measurements for patients with mental health illness were not available as part of this analysis. Clinical outcomes are reported at 1-year post-enrolment to the clinic for the 36-month period for all patients with more than one visit. The 1-year values were included in this analysis if it was within 3 months of the patients' 1-year anniversary. Patients were defined as default if they were still missing from clinic more than 8 weeks past their missed appointment, which is consistent with the national definition for default to care for patients with HIV. One-year survival is also reported as patients known to be alive and retained in care 12 months after their enrolment date. SDs are reported for averages for clinical outcomes such as blood pressure or blood sugar, and statistical significance for comparisons between baseline and 1 year were computed using one-sided paired t-tests for continuous values and McNemar's  $X^2$  test for proportions. Data were analysed using Stata V.14.2 statistical software.<sup>52</sup>

### Patient and public involvement

The MOH and Neno District Executive Council (DEC) were involved at the conception of the clinic programme design and responsible for approval for the clinic to enrol patients. The clinical services were implemented



**Figure 2** Cumulative enrolments in IC3 over time, by diagnosis. IC3, Integrated Chronic Care Clinic.

in tandem by the MOH and PIH, and routine updates were given to the DEC. Patients were involved informally through discussions on clinic design, and formally through patient satisfaction surveys (unpublished). The design of the intervention was meant to address the burden of disease in Neno District, and patients with any chronic condition were eligible for enrolment into the clinic.

## RESULTS

Between 2015 and 2017, 6233 patients were enrolled in IC3. These new enrolments included 2990 diagnoses of a chronic NCD and 3334 diagnoses of HIV. As of the end of 2018, these new enrolments made up 56% of all active patients in the programme, with the remaining 44% being enrolled before or after the study period. Overall in IC3, 7.6% of patients with an NCD in care had HIV, and 11.0% of patients with an NCD in care between the ages of 15 and 49 years had HIV. Among all of the newly enrolled patients with an NCD in this cohort, 2.3% had HIV and 8% of clients with an NCD had two or more NCDs. Of these patients, 10% (N=624) were under 15 years, including 13% of patients with an NCD (N=379) and 7% of patients with HIV (N=232). [Figure 1](#) shows a map of Neno with NCD enrolment limited to the 2 hospitals in 2014 and expanded to all 14 facilities in 2018.

[Figure 2](#) shows overall enrolment for HIV and NCDs between December 2013 and December 2018 with an uptick in NCD enrolments starting in mid-2015 with the decentralisation of NCD care through IC3 as well as community-screening events across the district. After IC3 opened, HIV enrolments remained steady, while there was an increase in NCD enrolment.

Overall enrolment and outcomes are shown in [table 1](#) by diagnosis. Of the 2990 NCD total diagnoses, the most common diagnoses were hypertension (N=1693), asthma (N=668) and epilepsy (N=486). Overall, 25.5% of patients with NCD defaulted (N=763) and 1.4% died (N=41). This is compared with defaulting in 8.4% and deaths in 4.0% of patients with HIV. ([table 1](#)). The default rate among specific NCDs is highest in asthma at 38.1%, followed by mental illness and epilepsy in 24.8% and 23.0% of patients, respectively. One-year retention and survival was 72% in patients with NCD and 85% in patients with HIV, with a range among specific NCDs from 60% in patients with asthma to 78% in patients with hypertension or diabetes ([table 1](#)).

[Table 2](#) shows clinical characteristics of patients at their enrolment for all patients enrolled during the study period who had at least two visits to clinic. On average, patients with NCD were 46 years old and patients with HIV were 32 years old. Patients with epilepsy, mental illness and asthma tended to be younger with average ages of 24, 30 and 32 years, respectively. Gender also varied across NCD diagnoses, with 67.3% of the cohort with NCD being women, ranging from 45.9% of patients with mental illness and 75.2% of patients with hypertension. Dual-diagnosis patients included patients with NCD over the age of 15 years with HIV, making up 2.6% of the cohort, while 2.2% of patients with HIV over the age of 15 years were diagnosed with an NCD.

Clinical outcomes were measured at 1-year post-enrolment for all patients enrolled in IC3 over the 3-year period who had more than one visit to clinic ([table 3](#)). Most clinical measurements showed statistically significant improvement for the cohort on average, including blood pressure, asthma severity, blood sugar and the number of seizures occurring in a month.

In patients with hypertension, at 1-year post-enrolment, less than 5% remained with blood pressures in the stage III range of SBP >180 and/or DBP >110 mm Hg, and

**Table 1** IC3 enrolment, retention and survival by diagnosis

	All patients with NCD	Hypertension	Asthma	Epilepsy	Diabetes	Mental illness	HIV
Total patients Enrolled	2990	1693	668	486	149	109	3334
Patients defaulted	25.5% (763)	19.8% (336)	38.1% (255)	23.0% (112)	18.8% (28)	24.8% (27)	8.4% (280)
Patients died	1.4% (41)	1.3% (22)	1.0% (7)	1.2% (6)	2.7% (4)	1.8% (2)	4.0% (133)
1-year retention and survival rate	72%	78%	60%	75%	78%	72%	85%

IC3, Integrated Chronic Care Clinic; NCD, non-communicable disease.

**Table 2** Characteristics at enrolment

	All patients with NCD	Hypertension	Asthma	Epilepsy	Diabetes	Mental illness	HIV
N	2990	1693	668	486	149	109	3334
Average age	46 ( $\pm 23$ )*	59 ( $\pm 15$ )	32 ( $\pm 23$ )	24 ( $\pm 17$ )	53 ( $\pm 17$ )	30 ( $\pm 16$ )	32 ( $\pm 14$ )
Female	67.3%	75.2%	64.4%	50.0%	64.4%	45.9%	59.7%
Patients with NCD >15 years with HIV	2.6% (68)	2.5% (42)	3.0% (14)	2.2% (7)	3.4% (5)	3.4% (3)	
Patients with HIV >15 years with at least one NCD							2.2% (68)

\*SDs are shown in parentheses for averages.  
NCD, non-communicable disease.

53.6% had controlled blood pressure defined as <140/90 mm Hg. Of patients with hypertension, 84% had their blood pressure checked at their last visit. Supporting the strategy to enrol sicker patients with higher blood pressures first, 70% of the cohort with hypertension was on two or more medications.

Among patients with asthma, 87% had a recorded severity at their last visit, and those reporting their severity as moderate or severe persistent made up 21.8% of the patients at enrolment and 13.7% of the patients at their 1-year visit. A steroid inhaler was prescribed in 86% of patients with asthma.

Similarly, patients with epilepsy reported fewer seizures overall after 1 year of treatment, from an average of 2.4 seizures per quarter at enrolment to 1.5 per quarter at 1-year follow-up. In addition, almost 40% of patients had not had any seizures since their last visit. Most patients were only on one medication; 14% of patients with epilepsy were on two or more medications.

Fingerstick glucose results for diabetes were combined among the fasting and random results due to the fact that data indicating type of test were often missing. This average improved from 230 to 179 mg/dL at 1 year, with 73% of patients having a fingerstick at their 1-year visit under 200 mg/dL. Almost 70% of patients with diabetes had their blood pressure controlled at follow-up (81% of patients with diabetes had their blood pressure checked at their last visit). Patients on insulin made up 18% of the cohort with diabetes.

The cohort with HIV in this study maintained excellent outcomes as had been previously demonstrated.<sup>53</sup> For patients with HIV enrolled during the 3-year study period, 80% had viral load results recorded after 12 months of antiretroviral therapy, and 85% of them had an undetectable viral load, with 94% below Malawi's threshold of 1000 copies/mL.

## DISCUSSION

The IC3 model is a bold attempt at rapid NCD care decentralisation in a rural district. Here we present a descriptive cohort of an integrated service delivery model treating patients with HIV and/or one or more

NCDs concurrently, decentralised from 2 hospitals to 12 primary care facilities. Our study shows an increase in the number of patients with NCD accessing services since the inception of the IC3 and demonstrates favourable 1-year clinical outcomes and retention in care for patients with NCDs while maintaining the excellent clinical outcomes and the rate of enrolment for patients with HIV.

To our knowledge this is the first description of clinical outcomes for comprehensive NCD care in Malawi that is fully decentralised to the primary care level. It is also the sole example in Malawi of fully integrated HIV–NCD care for all patients with chronic illness, regardless of their HIV status. Furthermore, very few examples of such a model exist in the global literature to date. In Kruk *et al's* description of redesigning primary care to address chronic NCDs, four elements are suggested as essential for addressing NCDs through primary care models: 'integration of services, innovative service delivery, a focus on patients and communities, and adoption of new technologies for communication'. The IC3 model encompasses the first three of these, and a future implementation of point-of-care medical record data entry is planned.<sup>27 45</sup>

Increasing enrolment following care integration and decentralisation indicates success in implementation: 6233 new patients were enrolled during the 3-year period of the study, 48% of them with chronic NCDs. Given the long history of the HIV programme in Neno, the HIV program was much closer to total case finding—that is, finding all of the anticipated patients with HIV living in the district—than for NCDs.<sup>41</sup> At the end of the study period, 8.1% of all patients with NCD, and 11.0% of patients with NCD aged 15–49 years ever enrolled in IC3 were also being treated for HIV. These percentages are higher than the entirety of the study cohort because as screening improved, more NCDs were found and diagnosed in existing patients with HIV who were enrolled before the start of the study period.

The distribution of diagnoses in Neno District is partly reflective of the prevalence of conditions and partly reflective of what conditions are actively screened for in community programmes and in clinics. Of the NCDs, hypertension is, unsurprisingly, the most common, despite

**Table 3** One-year clinical outcomes

<b>Hypertension</b>			P value‡
	<b>Enrolment</b>	<b>After 1 year</b>	<b>N=1075</b>
Average blood pressure	157/94 (SD†: systolic 28, diastolic 18)	136*/83* (SD: systolic 21, diastolic 13)	Systolic: <0.0001 Diastolic: <0.0001
Stage III hypertension BP >180/110	26.2% (n=322)	4.7%* (n=50)	<0.0001
Controlled hypertension BP <140/90		53.6% (n=575)	
<b>Asthma</b>			P value‡
	<b>Enrolment</b>	<b>After 1 year</b>	<b>N=331</b>
Asthma severity: moderate or severe persistent	21.8% (n=72)	12.6%* (n=42)	0.0007
<b>Epilepsy</b>			P value‡
	<b>Enrolment</b>	<b>After 1 year</b>	<b>N=207</b>
Average number of seizures in the past 3 months	2.4	1.5*	0.0003
Zero seizures since last visit		38.2% (n=79)	
<b>Diabetes</b>			P value‡
	<b>Enrolment</b>	<b>After 1 year</b>	<b>N=52</b>
Average fingerstick glucose§	230 (SD 155)	179* (SD 90)	0.0124
Fingerstick glucose <200		73% (n=38)	
Average blood pressure	143/89 (SD: systolic 25, diastolic 14)	130*/84* (SD: systolic 22, diastolic 11)	Systolic: <0.0001 Diastolic: <0.0001
BP <140/90		69% (n=36)	
<b>HIV</b>			P value‡
		<b>After 1 year (N=2250)</b>	
Patients with a recorded viral load		80% (n=1807)	
Patients with a viral load <1000		94% (n=1692)	
Patients with an undetectable viral load		85% (n=1527)	

Greyed boxes indicate analysis that was not included as part of the study because these measurements were not relevant at the baseline clinic visit.

\*Statistically significant at  $p < 0.05$  level.

†SD showed for all averages.

‡Paired one-sided t-test for normal continuous values, Wilcoxon signed rank test for non-normal continuous variables (number of seizures for patients with epilepsy) and McNemar's  $X^2$  for proportions.

§Combines random, fasting and unlabelled.

BP, blood pressure.

using a high threshold for enrolment. Neno District has several, unique screening programmes for hypertension and diabetes, including integrated community-screening events.<sup>9 49</sup> Notably, as Malawi works toward Universal Health Coverage, there is still a large number of patients who need diagnosis and treatment for common NCDs in Neno. For example, the estimated adult hypertension prevalence of 15% suggests there are approximately 12 000 adults with hypertension in Neno. This means that at the time of this study the clinic was only reaching 18% of expected patients, with a focus on those with the most severe hypertension. Similar rationale indicates that diabetes coverage thus far is 13%.<sup>9</sup>

The next most common NCDs were the symptomatic conditions of asthma and epilepsy. Indoor cooking with solid biomass fuel is the mainstay in this rural impoverished district, likely contributing to asthma cases, and epilepsy risk factors of childhood cerebral malaria or meningitis, birth asphyxia and head trauma are abundant in this setting.<sup>54 55</sup>

The conditions treated at IC3 are only a component of the chronic NCD picture in Malawi: NCDs comprise a family of over 200 conditions, that range from less prevalent but often more severe to those affecting large populations of people.<sup>8</sup> This broad burden of NCDs in Malawi is a critical factor in scale up: while traditionally

NCD programmes focus on ‘the big four’, that is, cardiovascular disease, diabetes, chronic respiratory disease and cancer, these conditions account for just 39% of the NCD DALYs in Malawi.<sup>8 56</sup> Thus, we expect the range of diagnoses in this clinic to diversify over time to reach even more patients with chronic conditions. Additionally, the Neno cohort is primarily adults, although the NCD cohort has 13% under age 15 years. As the chronic care system expands to include this wider range of diagnoses, we anticipate this proportion may increase to include conditions that tend to affect younger people such as type 1 diabetes, sickle cell disease and nephrotic syndrome. There is discussion whether such a chronic care platform could include support for congenital conditions and disability as well, which would nudge the cohort toward younger ages.

Enrolment of some NCD diagnoses favoured women, such as hypertension and diabetes, which has been seen in previous studies.<sup>9</sup> This may be related to increased interaction with the health system and thus increased opportunities for screening, through pregnancy care for example.<sup>57</sup> For some NCD diagnoses that tend to be more overtly symptomatic, such as mental illness and epilepsy, the gender distribution was fairly equal.

Previous research has shown that distance to clinic is a factor for missed visits and default for patients with chronic illness, a barrier that decentralisation to all primary care clinics was designed to address.<sup>15 58</sup> This cohort did have a high proportion of patients with a visit in the preceding 3 months, a common way to longitudinally follow retention in HIV care in Malawi. Prior to IC3 roll out in 2014, patient default often exceeded 50% in Neno.<sup>59</sup> One hypothesis is that simply decentralising care to be available closer to the patient was a large factor in this observed trend.

One-year retention in the cohort was also favourable, remaining high and stable over time for patients with HIV at 85%. This is encouraging as it is similar to rates of HIV retention prior to integration, suggesting that the addition of NCD care to HIV clinics does not compromise HIV outcomes. NCD default was higher than HIV in this cohort, likely due to active default tracking for all clients with HIV in Neno since 2007 by CHWs and the clinical team, whereas this started for patients with chronic NCDs much later, in mid-2017. This also likely means that certainty of outcomes such as death are higher for patients with HIV: we see a slightly higher rate of deaths among the patients with HIV, but it may be that some of the patients with NCD labelled as default had in fact died and follow-up systems were not able to ascertain this information. Despite this, retention rates for NCDs were quite favourable. One-year retention for hypertension, diabetes and epilepsy was in the range of 75%–80%, which are excellent results compared with the retention in care literature for chronic NCDs which can be as low as 25% and some interventions increasing retention to 60%–70%.<sup>15 60–62</sup>

Interestingly, retention in care for asthma was the lowest at 60%. There are a few possibilities that may account for this result. One is that many of these patients did not actually

have true asthma, and that the diagnosis was triggered by an acute illness and thereafter improved, or that asthma is occurring more seasonally, so when patients stabilise they drop out of care. A second possibility is that these patients did not experience improved symptoms and thus dropped out of care. Or the opposite could be true: that patients did in fact improve and thus stopped seeing the need for attending clinic when they were feeling better. This could relate to a need for better counselling and teaching for inhaler technique, better control of triggers and additional education around disease chronicity.

Clinical outcomes overall were also favourable, with clinical measures generally improving in the cohort, and though there are some limitations in the observational data, it is encouraging for the provision of primary NCD care in Malawi. However, the limitations to access to primary care for NCDs are real, with significant human resource and drug shortages.<sup>8 31</sup> While this programme leveraged many existing resources already in the system through the HIV programme, there was a need for additional staff. The IC3 model is heavily supported by the non-governmental organisation partner, PIH, including for resources for some staff as well as purchasing of a significant quantity of the NCD medications and other commodities. Both of these considerations are critical to address in thinking about the potential for scale for the IC3 model.<sup>45</sup>

There are many lessons learnt in the scale up of the IC3 model to all facilities in Neno. Key considerations for implementers to consider are highlighted in our earlier work and include: (1) a high degree of attention to how patients flow through the clinic; (2) what tasks are shared between different cadres of workers; (3) early and often attention to data management; (4) active strengthening of supply chain needs; (5) how to maintain confidentiality for patients’ diagnoses and (6) using higher NCD screening thresholds to avoid overwhelming clinic at the start and ensuring care for the sickest patients. Additionally, critical lessons are in clear leadership in the clinic, identification of where efficiency can be maximised, and an approach using continuous quality improvement.<sup>45</sup> During the early years of implementation, a critical focus has been training and longitudinal mentorship of clinical and other technical staff. An important staffing intervention was to consistently have the same clinical staff assigned to the clinic, so that long-term investment in clinical teaching and mentorship could be focused on a smaller group of clinicians and nurses. In addition, this approach has revealed that, given the high volume of patients seen in this clinic, it is most suited to patients where diagnosis and management is straightforward, consistent with the WHO Package of Essential Noncommunicable Disease Interventions (PEN) guidelines.<sup>63</sup> Our experience suggests that patients who need more complex care for more severe disease for diagnoses such as insulin-dependent diabetes, advanced heart disease, kidney or liver failure, or severe rheumatic heart disease, may be better served in an additional level of clinic. Currently, the MOH in Malawi is exploring the role of district hospitals to treat these conditions, through a model called PEN Plus.<sup>64</sup>

## Limitations

There are several limitations to this work. It is an observational cohort using routinely collected clinical data, which limits our ability to evaluate impact based on certain components of the intervention and to know outcomes for patients who default. There are also some limitations in our data. For example, in patients with diabetes, we combined fasting and random fingerstick in the results as it often was not clear in the paper records which state applied. Though the clinic started measuring haemoglobin A1C for patients with diabetes, there were not enough results available during this time period for inclusion. In addition, we were not able to include a reliable clinical outcome indicator for our patients with severe mental illness due to limited data and a small cohort at the time of this study. One of the additional weaknesses of this analysis is that there are some missing data for our disease-control variables (blood pressure, number of seizures, asthma severity and blood glucose) at the 1-year mark. This reflects many operational issues including suboptimal documentation by clinical providers, lack of measurement overall and data entry errors, but we do not have reason to believe that missing data are associated with individual characteristics in our cohort. We are currently working on decreasing missing data in our documentation and aim to follow up with more complete data in future analyses.

## CONCLUSION

This descriptive cohort displays good clinical outcomes and retention in care for patients enrolled in longitudinal primary care for chronic conditions including both HIV and NCDs in rural Malawi. This suggests that integration of HIV and NCD care at primary care clinics may be feasible and effective. Additional work is needed on cost, patient satisfaction, quality of care and possibly integration of other chronic services such as palliative care.

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