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Expanding access to Non-Communicable Disease care in rural Malawi: descriptive outcomes from an integrated NCD-HIV model

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Expanding access to Non-Communicable Disease care in rural Malawi: descriptive outcomes from an integrated NCD-HIV model

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ABSTRACT

Objectives

Non-Communicable Diseases (NCDs) account for a 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).

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 6,233 HIV-NCD diagnoses, enrolled between January 2015 and December 2017 were included in a retrospective analysis. This included 3,334 HIV patients (59.7% female) and 2,990 NCD patients (67.3% female), 10% overall under age 15.

Interventions

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

Primary and secondary outcome measures

Routine clinical measurements are reported at one-year post enrollment for patients with more than one visit. One-year retention is reported by diagnosis.

Results

NCD diagnoses were 1,693 hypertension, 668 asthma, 486 epilepsy, 149 diabetes, and 109 severe mental illness. By December 2018, 8.3% of NCD patients 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 HIV patients with viral load results, 85% had undetectable viral load.

Conclusions

The IC3 model, built on an HIV platform, facilitated rapid decentralization and access to NCD services in rural Malawi. Clinical outcomes and retention in care are favorable, 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.

Article Summary

Strengths and limitations of this study

- There is a large body of literature recommending integrated HIV-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 enrollment 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 an example of achieving a rapid increase in access to primary care for chronic NCDs in rural Malawi through integration with an existing HIV program, and it is one of the first examples of comprehensive primary care availability 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.
- Integrated care is possible for HIV and chronic NCDs, regardless of HIV status, and as governments and the global community strive toward Universal Health Care, efficient and effective primary care models that integrate systems and care for chronic conditions will be very valuable.

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.[1] In Africa, where infectious diseases such as HIV, malaria, and tuberculosis (TB) have long been the significant causes of morbidity, NCDs are fast becoming the predominant causes of disease burden, with the expectation that NCDs will become the most common cause of death by 2030. [2][3] While the 2011 UN High Level meeting set out plans to combat this growing burden, the response has yet to fully meet this need.[4] For instance, while the disability-adjusted life year (DALY) burden from NCDs is estimated to be 37% in low-income countries, development assistance for health allocated to NCDs was estimated to be just 1.3% in 2015.[5] In Malawi, a similar pattern emerges: the non-communicable disease and injury (NCDI) 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.[6][7]

In Malawi, a high proportion of this burden falls on patients under the age of 40, and the Ministry of Health (MOH) is increasingly recognizing the importance of care delivery systems for NCDs.[6][8] Estimates of condition-specific prevalence estimate hypertension rates between 14-16% for urban adults and 13-14% for rural adults.[9] 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.[9], [10] 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%.[10][11] Access to care, particularly in the rural districts, is limited: for example, less than half of the health centers were equipped with the country's first line anti-hypertensive in 2014.[12] While care is available at central hospitals in large cities, 83% of the country lives in rural areas.[13] 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.[14][15][8] Studies have also suggested that low care and utilization rates may be due to limited recognition and diagnosis as well as limited linkage and retention in care. [15], [16]

Successful implementation of programs 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 program with care decentralized throughout the country, overseen by a strong central monitoring system.[17] From 2010 to 2016, the HIV prevalence amongst persons 15-49 years old dropped from 10.6% to 8.8%.[18] 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.[19] The MOH has also become a leader in progressive antiretroviral therapy programs, such as Option B+ and universal treatment.[20][21][22]

Given this ongoing success in treating chronic infectious disease as well as the resources invested in these programs, 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 recognized as a possible delivery model,

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3 particularly for primary care, with much of the literature focused on calling for various integrated
4 approaches.[23]–[29] [25] [29]
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7 There exist many examples of combining HIV with other clinical programs and into
8 primary care; however, much of the early work in HIV-NCD integrated chronic care focuses
9 primarily on screening and treating NCDs within HIV cohorts exclusively.[30]–[38] Fully integrated
10 HIV and NCD care is put forward as a model by several authors, but examples of fully integrated
11 HIV-NCD clinics, serving patients with and without HIV, are limited. [29], [30], [39]. Practical
12 experience and implementation research is needed to assess the feasibility and outcomes of fully
13 integrated HIV-NCD care.[25]
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17 Situated in southwest Malawi, the rural district of Neno was formed in 2003 and did not
18 have a hospital until 2007. HIV care was fully decentralized from two hospitals in Neno to 11
19 primary health centres by 2011 through a long-term partnership between the international non-
20 profit Partners In Health (PIH) and the Ministry of Health (MOH), with a comprehensive approach
21 featuring Community Health Workers, nutrition, and cash transfer support for most vulnerable
22 patients.[40][41] Neno District is consistently achieving significantly higher HIV retention and
23 survival rates than any other district in the country.[41] Leveraging this experience, in 2015, PIH
24 and the MOH launched the Integrated Chronic Care Clinic (IC3) in Neno. The clinics converted the
25 HIV platform to expand care to include treatment for any chronic illness including hypertension,
26 diabetes, asthma, epilepsy and mental illness regardless of a patient's HIV status.[42] At the two
27 hospitals, IC3 replaced an earlier chronic care clinic for NCDs, which was modeled off PIH's
28 partnership with the government of Rwanda.[43]–[45] The work in Rwanda specifically focuses
29 on increasing levels of chronic care integration at the primary care and community levels, with
30 specialist clinics at the hospital level.[46] At the time, the NCD clinic at the two hospitals was
31 experiencing high rates of patient default, rotating staff making training and mentorship a
32 challenge, and a lack of streamlined M&E and supply chain systems. In 2015, IC3 rapidly
33 decentralized integrated HIV-NCD primary care to the existing 2 hospitals and 11 health centers
34 in the district, and later to a newly opened 12th health center in mid 2016. This effort utilized the
35 existing HIV program infrastructure, staff, and systems.[42]
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41 While integrating care makes sense in resource-poor settings with high infectious and
42 NCD burdens, the evidence base surrounding how best to prevent and manage NCDs, or integrate
43 NCD care, in sub-Saharan Africa is severely lacking.[26], [27], [47] Despite a general support for
44 integration of chronic disease systems, few examples of fully integrated HIV-NCD models exist in
45 the literature. This paper therefore seeks to describe our clinical outcomes after integrating NCD
46 and HIV care into one system for all comers with a chronic disease in Neno District, Malawi.[42]
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49 **METHODS**

50 **Setting and Population**

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52 Neno District is a district with population of 165,000 in 2017, situated in the southwest
53 zone in Malawi.[48] An extremely rural setting, the majority of the population relies on
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3 subsistence agriculture, with only 4.5% of the population with electricity.[49] Since 2007 PIH has
4 partnered with the MOH in Neno to strengthen health services. In 2011, the Chronic Care Clinic
5 (CCC) began enrolling NCD patients at the district hospital, and in 2013 NCD services opened at
6 the community hospital. In early 2015, CCC was combined with the HIV program to form IC3, and
7 decentralized to the 11 primary health centers across the district.[42] (Figure 1)
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10 **Integrated Chronic Care Clinic program design**

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13 This is a retrospective cohort comprised of all patients newly enrolled in IC3 at any facility
14 in Neno District in the 36-month period between January 2015 and December 2017. This includes
15 patients with one or more of any of the following conditions: HIV, hypertension, epilepsy,
16 asthma, diabetes, and mental illness.
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19 Patients were referred to IC3 based from several settings including inpatient wards,
20 outpatient clinics, and community screening events. The latter were held in remote parts of the
21 district, with participants receiving age and gender appropriate screening for hypertension,
22 diabetes, HIV, tuberculosis, and malnutrition. Those with high blood pressure or high blood sugar
23 were referred to their nearest facility for IC3 staff to confirm diagnosis and enroll them into care.
24 In order to ensure the sickest patients were found early and treated, and to avoid clinic
25 overcrowding, the referral threshold for blood pressure was $SBP \geq 160$ and/or $DBP \geq 110$. Cutoff
26 for blood sugar for referral was fasting ≥ 126 mg/dl and random ≥ 200 mg/dl.[50] Patients with a
27 pre-existing NCD diagnosis and on medications were automatically enrolled. Patients were
28 diagnosed using predefined NCD protocols, set by the IC3 team, and HIV protocols from central
29 MOH, with screening programs described elsewhere.[51]
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34 Patients enrolled in IC3 were seen at the health facility nearest to their home at regular
35 intervals. Most commonly patients were scheduled every 3 months unless they was starting care
36 or had more complexity, when monthly appointments were scheduled. The clinic was staffed by
37 clinical officers, nurses, and support staff employed both by PIH and MOH. Supervision and
38 mentorship were performed by several physicians within the district, also employed both by
39 MOH and PIH. Staff were based at one of two hospitals as their primary workstation and would
40 travel out to health centers three or four days a week to join facility-based staff and conduct IC3
41 regularly at every facility in the district. This was a solution for staffing shortages -given high
42 volumes of maternal child health and other acute needs at primary health centers, these facilities
43 were not equipped to handle the large influx of patients with HIV and NCDs. This system,
44 combining a roving team of clinical staff and existing staff at primary health centers, had been in
45 place for Neno's HIV care for several years.[40] The HIV program, well described elsewhere, was
46 characterized by a strong community footprint with a network of over 900 Community Health
47 Workers (CHWs) who received a monthly stipend to assist patients with adherence and perform
48 missed visit tracking, a focus on social determinants of health in which the most vulnerable
49 patients would be eligible for cash transfers, and significant investment into the public sector.[41]
50 These principles were applied to IC3, with the CHW network undergoing a gradual transformation
51 in 2017 and 2018 so that all NCD patients were eventually assigned a CHW.[52]
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Data Collection and Analysis

Data was collected at enrollment and routine clinical visits by clinical staff on paper forms, which were the national MOH approved and standardized HIV and NCD Master Cards. This data was and then entered into an OpenMRS electronic medical record (EMR) system by data clerks. EMR data was extracted and utilized in this analysis.

Baseline demographics and clinical characteristics specific to each disease are reported utilizing 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 hypertension patients, random or fasting fingerstick for diabetic patients, asthma severity for asthma patients, and number of monthly seizures for epilepsy patients. Clinical outcomes are reported at one-year post enrollment to the clinic for the 36-month period for all patients with more than one visit. Retention in care is measured according to the standard indicator in Malawi, as the proportion of patients with a given condition with a visit in the preceding three months. Patients were defined as default if they were still missing from clinic more than 8 weeks past their missed appointment. One-year survival is also reported as patients known to be alive and retained in care 12 months after their enrollment date. Standard deviations are reported for averages for clinical outcomes such as blood pressure or blood sugar, and statistical significance for comparisons between baseline and one year were computed using one-sided paired t-tests for continuous values and McNemar's Chi-square test for proportions. Data were analyzed using Stata 14.2 Statistical Software.[53]

Patient and Public Involvement

The Ministry of Health (MOH) and Neno District Executive Council (DEC) were involved at the conception of the clinic program design and responsible for approval for the clinic to enroll patients. The clinical services were implemented in tandem by the MOH and PIH, and routine updates were given to the DEC. Patients were involved in clinic design initially through informal discussions as integration was pursued and later, 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 enrollment into the clinic. The study is one of routine clinical data using de-identified outcomes, so no patient was enrolled in a study outside of routine clinical care.

Ethics

All data for this study was routinely collected and de-identified clinical data. Ethical approval was received by the Malawi National Health Sciences Research Committee (NHSRC) and Partners Healthcare Institutional Review Board at Brigham & Women's Hospital in Boston, MA.

RESULTS

Between 2015 and 2017, 6,233 patients were enrolled in IC3, 10% (N=624) of whom were 15 years or younger. Of these newly enrolled patients, those aged 15 years or younger made up 13% of NCD patients (N=379) and 7% of HIV patients (N=232). New enrollments included 2,990 diagnoses of a chronic NCD and 3,334 diagnoses of HIV. As of the end of 2018, these new enrolments made up 56% of the active patient cohort. Overall in IC3, 7.6% of NCD patients in care had HIV, and 11.0% of NCD patients in care between the ages of 15 and 49 years had HIV. Among all of the newly enrolled NCD patients in this cohort, 2.3% had HIV and 8% of NCD clients had two or more NCDs. Figure 1 shows a map of Neno with NCD enrollment limited to the two hospitals in 2014 and expanded to all 14 facilities in 2018.

Figure 2 shows overall enrollment for HIV and NCDs between December 2013 and December 2017 with an uptick in NCD enrollments starting in mid-2015 with the decentralization of NCD care through IC3 as well as community screening events across the district. After IC3 opened, HIV enrollments remained steady, while there was an increase in NCD enrollment.

Overall enrollment and outcomes are shown in Table 1 by diagnosis. Of the 2,990 NCD total diagnoses, the most common diagnoses were hypertension (N=1,693), asthma (N=668), and epilepsy (N=486). Overall, 25.5% of NCD patients defaulted (N=763) and 1.4% died (N=41). This is compared to defaulting in 8.4% and deaths in 4.0% of HIV patients. (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 NCD patients and 85% in HIV patients, with a range among specific NCDs from 60% in patients with asthma to 78% in patients with hypertension or diabetes. (Table 1)

Table 1: IC3 enrollment, retention, and survival by diagnosis

	All NCD Patients (N)	Hypertension (N)	Asthma (N)	Epilepsy (N)	Diabetes (N)	Mental Illness (N)	HIV (N)
Total Patients Enrolled	2,990	1,693	668	486	149	109	3,334
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 & Survival Rate	72%	78%	60%	75%	78%	72%	85%

Table 2 shows clinical characteristics of patients at their enrollment for all patients enrolled during the study period who had at least two visits to clinic. On average, NCD patients were 46 years old and HIV patients 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 NCD cohort being female, ranging from 45.9% of patients with mental illness and 75.2% of patients with hypertension.

Table 2: Characteristics at enrollment

	All NCD Patients	Hypertension	Asthma	Epilepsy	Diabetes	Mental illness	HIV
N	2,990	1,693	668	486	149	109	3,334
Average Age	46 (± 23)*	59 (± 15)	32 (± 23)	24 (± 17)	53 (± 17)	30 (± 16)	32 (± 14)
Female	67.3%	75.2%	64.4%	50.0%	64.4%	45.9%	59.7%
HIV positive (NCD patients >15 years)	2.6% (68)	2.5% (42)	3.0% (14)	2.2% (7)	3.4% (5)	3.4% (3)	

* Standard deviations (SD) are shown in parentheses for averages

Clinical outcomes were measured at one-year post enrollment 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 one-year post enrollment less than 5% remained with blood pressures in the Stage III range of SBP > 180 and/or DBP > 110mmHg, and 53.6% had controlled blood pressure defined as <140/90mmHg. Of hypertension patients, 84% had their blood pressure checked at their last visit. Supporting the strategy to enroll sicker patients with higher blood pressures first, 70% of the hypertension cohort was on 2 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 enrollment and 13.7% of the patients at their one year visit. A steroid inhaler was prescribed in 86% of patients with asthma.

Similarly, epilepsy patients reported less seizures overall after one year of treatment, from an average of 2.4 seizures per quarter at enrollment to 1.5 per quarter at one 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 2 or more medications.

Fingerstick glucose results for diabetes were combined among the fasting and random results due to low numbers and that sometimes the data to indicate the type of fingerstick was missing. This average improved from 230 to 179mg/dl at one year, with 73% of patients having a fingerstick at their one year visit under 200 mg/dl. Almost 70% of patients with diabetes had their

blood pressure controlled at follow up (81% of diabetes patients had their blood pressure checked at their last visit). Patients on insulin made up 18% of the diabetes cohort.

The HIV cohort in this study maintained excellent outcomes as had been previously demonstrated.[54] For HIV patients 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.

Table 3: One Year Clinical Outcomes

Hypertension			p-value²
	Enrollment	After One Year	N= 1,075
Average Blood Pressure	157/94 (SD ¹ systolic 28, diastolic 18)	136*/83* (SD: systolic 21, diastolic 13)	Systolic: <0.0001 Diastolic: <0.0001
BP ≥ 180/110	26.2% (n=322)	4.7%* (n=50)	<0.0001
BP ≤ 140 / 90		53.6% (n=575)	
Asthma			p-value²
	Enrollment	After One Year	N= 331
Asthma Severity: Moderate or Severe Persistent	21.8% (n=72)	12.6%* (n=42)	0.0007
Epilepsy			p-value²
	Enrollment	After One Year	N= 207
Average Number of Seizures in the past 3 months	2.4	1.5*	0.0003
Zero seizures since last visit		38.2% (n=79)	
Diabetes			p-value²
	Enrollment	After One Year	N= 52
Average fingerstick glucose ³	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)	
HIV			p-value²
		After One Year (N=2,250)	
Patients with a recorded viral load		80% (n=1,807)	

Patients with a viral load <1000		94% (n=1,692)	
Patients with an undetectable viral load		85% (n=1,527)	

¹ Standard Deviation (SD) showed for all averages

² Paired one-sided t-test for normal continuous values, Wilcoxon signed rank test for non-normal continuous variables (Number of Seizures for Epilepsy patients) and McNemar's Chi-square for proportions

³ Combines random, fasting, and unlabeled

* Statistically significant at p<0.05 level

DISCUSSION

The IC3 model is a bold attempt at rapid NCD care decentralization in a rural district, and here we present a descriptive cohort of an integrated service delivery model treating patients with HIV and/or an NCD(s) concurrently, decentralized to all 12 primary care facilities. Our study shows an increase in the number of NCD patients accessing services since the inception of the IC3 and demonstrates favorable one-year clinical outcomes and retention in care for patients with NCDs whilst maintaining the excellent clinical outcomes and the rate of enrollment for patients with HIV.

To our knowledge this is the first description of clinical outcomes for comprehensive NCD care in Malawi that is fully decentralized 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 future work is planned on the utilization of point-of-care technology for data utilization and entry.[27], [42]

The growth in the cohort of patients with NCDs over time indicates success with a decentralized primary care approach, with increasing enrollment following integration and decentralization: 6,233 new patients were enrolled during the 3-year period of the study, 48% of them with a chronic NCDs. Given the long history of the HIV program in Neno, the HIV program was much closer to total case finding – i.e. finding all of the anticipated HIV patients living in the district - than for NCDs.[41] At the end of the study period, 8.1% of NCD clients were also on treatment for an HIV diagnosis, and 11.0% of NCD clients between ages 15 and 49 years were dual-diagnosed with HIV.

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 programs and in clinics. Of the NCDs, hypertension is, unsurprisingly, the most common, despite using a high threshold for enrollment. Neno District has several, unique screening programs for

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3 hypertension and diabetes, including integrated community screening events.[9], [50] Notably,
4 as Malawi works toward Universal Health Coverage, there is still a large number of patients who
5 need diagnosis and treatment for common NCDs in Neno. For example, the estimated adult
6 hypertension prevalence of 15% suggests approximately 12,000 adults with hypertension in
7 Neno, meaning at the time of this study the clinic was only reaching 18% of expected patients,
8 with a focus on patients with the most severe hypertension. Similar rationale indicates that
9 diabetes coverage thus far is 13%.[9]
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13 The next most common NCDs were the symptomatic conditions of asthma and epilepsy.
14 Indoor cooking with solid biomass fuel is the mainstay in this rural impoverished district, likely
15 contributing to asthma cases, and epilepsy risk factors of childhood cerebral malaria or
16 meningitis, birth asphyxia, and head trauma are abundant in this setting.[55], [56]
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19 This range of diagnoses that this cohort was able to screen for, enroll, treat, and enable
20 data systems for reporting is only a component of the chronic NCD picture in Malawi: NCDs are
21 comprised of a family of over 200 conditions, and there is a spread of relatively less prevalent,
22 often more severe, and in aggregate a large number of patients that needs addressing.[8] This
23 broad burden of NCDs in Malawi is a critical factor in scale up and supports a platform of
24 integrated primary care for chronic conditions: while traditionally NCD programs focus on 'the
25 big four', i.e. cardiovascular disease, diabetes, chronic respiratory disease, and cancer these
26 conditions account for just 39% of the NCD DALYs in Malawi.[8], [57] Thus, we expect the range
27 of diagnoses in this clinic to diversify over time. Additionally, the Neno cohort is primarily adults,
28 although the NCD cohort has 13% under age 15. As the chronic care system expands to include
29 this wider range of diagnoses, we anticipate this proportion may increase to include the relatively
30 less prevalent conditions that tend to affect younger people such as Type 1 diabetes, sickle cell
31 disease, and nephrotic syndrome, and there is discussion whether such a chronic care platform
32 could include support for congenital conditions and disability as well which would nudge the
33 cohort toward younger ages.
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39 Enrollment of some NCD diagnoses favored females, such as hypertension and diabetes,
40 which has been seen in previous studies.[9] This may be related to increased interaction with the
41 health system and thus increased opportunities for screening, through pregnancy care for
42 example.[58] For some NCD diagnoses that tend to be more overtly symptomatic, such as mental
43 illness and epilepsy, the gender distribution was fairly equal.
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46 Previous research has shown that distance to clinic is a factor for missed visits and default
47 for patients with chronic illness, a barrier that decentralization to all primary care clinics was
48 designed to address.[15], [59] This cohort did have a high proportion of patients with a visit in
49 the preceding three months, a common way to longitudinally follow retention in HIV care in
50 Malawi. Prior to IC3 roll out in 2014, patient default often exceeded 50% in Neno.[60] One
51 hypothesis is that simply decentralizing care to be available closer to the patient was a large
52 factor in this observed trend.
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One year retention in the cohort was also favorable, remaining high and stable over time for HIV patients 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 primarily due to active default tracking for all HIV clients 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 HIV patients, but it may be that some of the NCD patients labeled as default had in fact died, but the follow up systems for NCD patients were not as robust as for HIV for the duration of the period studied. Despite this, retention rates for NCDs were quite favorable. 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%.[15], [61]–[63]

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 stabilize 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 counseling and teaching for inhaler technique, better control of triggers, and additional education around disease chronicity.

Clinical outcomes overall were also favorable, 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.[8], [31] While this program leveraged many existing resources already in the system through the HIV program, there was a need for additional staff. The IC3 model is heavily supported by the NGO 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.[42]

There are many lessons learned 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 work; 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 maximized, and an approach utilizing continuous quality improvement.[42] During the early years of implementation, a critical focus has been training and longitudinal mentorship of clinical and other technical staff. An important staffing

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3 intervention was to consistently have the same clinical staff assigned to the clinic, so that long
4 term investment in clinical teaching and mentorship could be focused on a smaller group of
5 clinicians and nurses. In addition, this approach has revealed that, given the high volume of
6 patients seen in this clinic, it is most suited to patients where diagnosis and management is
7 straightforward, consistent with the WHO PEN guidelines.[64] Our experience suggests that
8 patients who need more complex care for more severe disease for diagnoses such as insulin
9 dependent diabetes, advanced heart disease, kidney, or liver failure, or severe rheumatic heart
10 disease, may be better served in an additional level of clinic. Currently, the MOH in Malawi is
11 exploring the role of district hospitals to treat these conditions, through a model called PEN
12 Plus.[65]
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16 17 **Limitations**

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19 There are several limitations to this work. It is an observational cohort using routinely
20 collected clinical data, which limits our ability to evaluate impact based on certain components
21 of the intervention and to know outcomes for patients who default. There are also some
22 limitations in our data. For example, in patients with diabetes, we combined fasting and random
23 fingerstick in the results as it often was not clear in the paper records which state applied. Though
24 the clinic started measuring Hemoglobin A1C for patients with diabetes, there were not enough
25 results available during this time period for inclusion. In addition, we were not able to include a
26 reliable clinical outcome indicator for our patients with severe mental illness due to limited data
27 and a small cohort at the time of this study. One of the additional weaknesses of this analysis is
28 that there is some missing data for our disease control variables (blood pressure, number of
29 seizures, asthma severity, and blood glucose) at the one-year mark. This reflects many
30 operational issues including suboptimal documentation by clinical providers, lack of
31 measurement overall, and data entry errors, but we do not have reason to believe that missing
32 data is associated with individual characteristics in our cohort. We are currently working on
33 decreasing missing data in our documentation and aim to follow up with more complete data in
34 future analyses.
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40 41 **CONCLUSION**

42 This descriptive cohort displays good clinical outcomes and retention in care for patients
43 enrolled in longitudinal primary care for chronic conditions including both HIV and NCDs in rural
44 Malawi. This suggests that integration of HIV and NCD care at primary care clinics may be feasible
45 and effective. Additional work is needed on cost, patient satisfaction, quality of care, and possibly
46 integration of other chronic services such as palliative care.
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5 as the team was striving to integrate services and improve quality and systems.
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8 Contributorship

9
10 EBW, CK, and NK conceptualized the study. EBW oversaw the analysis and drafted the
11 manuscript. AS and NP led the analysis, and ELD supported the analysis. All authors were involved
12 in design and execution of the clinic and oversaw the clinical work, and all authors provided
13 revisions and comments to the manuscript.
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16 Data sharing

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18 No additional data available, but data questions may be directed to the lead author at
19 ewroe@pih.org.
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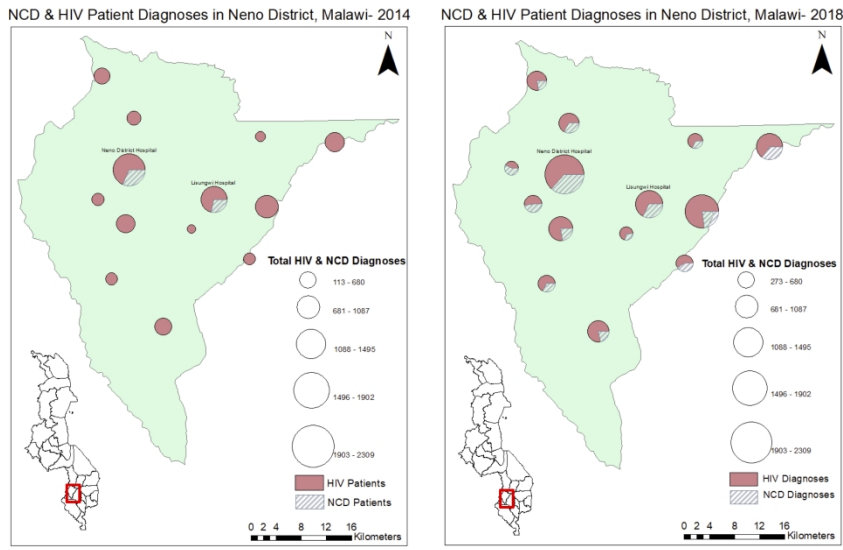


Figure 1. NCD & HIV Diagnoses in Neno District over time
338x190mm (300 x 300 DPI)

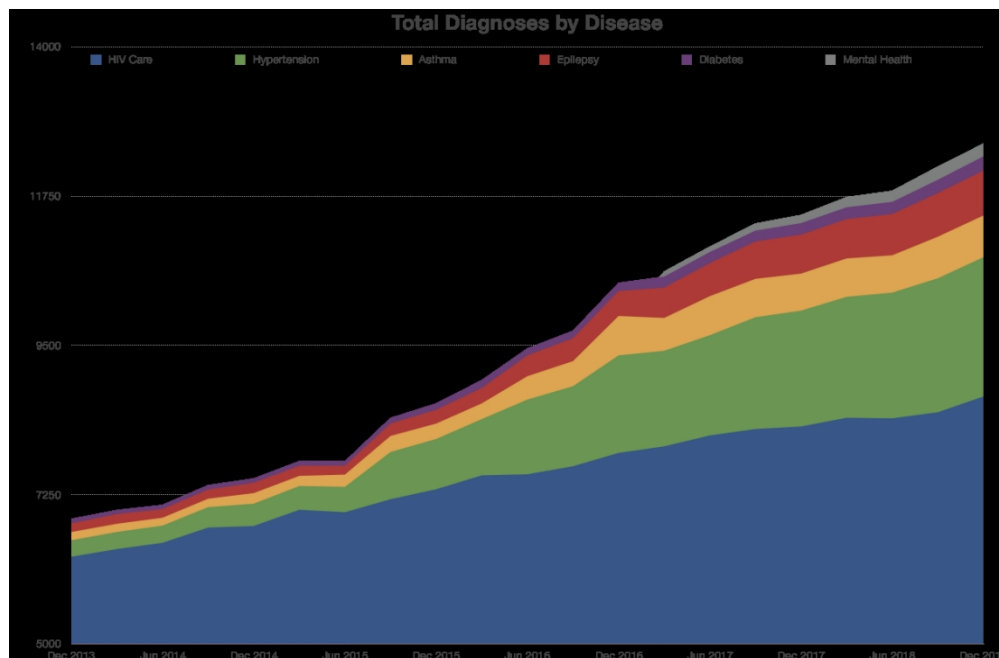


Figure 2. Cumulative enrollments in IC3 over time, by diagnosis

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BMJ Open

Expanding access to Non-Communicable Disease care in rural Malawi: descriptive outcomes from an integrated NCD-HIV model

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Expanding access to Non-Communicable Disease care in rural Malawi: descriptive outcomes from an integrated NCD-HIV model

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ABSTRACT

Objectives

Non-Communicable Diseases (NCDs) account for a 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).

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 6,233 HIV-NCD diagnoses, enrolled between January 2015 and December 2017 were included in a retrospective analysis. This included 3,334 HIV patients (59.7% female) and 2,990 NCD patients (67.3% female), 10% overall under age 15.

Interventions

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

Primary and secondary outcome measures

Routine clinical measurements are reported at one-year post enrollment for patients with more than one visit. One-year retention is reported by diagnosis.

Results

NCD diagnoses were 1,693 hypertension, 668 asthma, 486 epilepsy, 149 diabetes, and 109 severe mental illness. By December 2018, 8.3% of NCD patients 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 HIV patients with viral load results, 85% had undetectable viral load.

Conclusions

The IC3 model, built on an HIV platform, facilitated rapid decentralization and access to NCD services in rural Malawi. Clinical outcomes and retention in care are favorable, 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.

Article Summary

Strengths and limitations of this study

- There is a large body of literature recommending integrated HIV-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 enrollment 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 an example of achieving a rapid increase in access to primary care for chronic NCDs in rural Malawi through integration with an existing HIV program, and it is one of the first examples of comprehensive primary care availability for NCDs in rural Malawi.
- This work's major limitation is that it 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.
- Integrated care is possible for HIV and chronic NCDs, regardless of HIV status, and as governments and the global community strive toward Universal Health Care, efficient and effective primary care models that integrate systems and care for chronic conditions will be very valuable.

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.[1] 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. [2][3] While the 2011 UN High Level meeting set out plans to combat this growing burden, the response has yet to fully meet this need.[4] 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.[5] In Malawi, a similar pattern emerges: the non-communicable disease and injury (NCDI) 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.[6][7]

In Malawi, a high proportion of this burden falls on patients under 40, and the Ministry of Health (MOH) is increasingly recognizing the importance of care delivery systems for NCDs.[6][8] Estimates of condition-specific prevalence estimate hypertension rates between 14-16% for urban adults and 13-14% for rural adults.[9] 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.[9], [10] 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%.[10][11] Access to care, particularly in the rural districts, is limited: for example, less than half of the health centers were equipped with the country's first line anti-hypertensive in 2014.[12] While care is available at central hospitals in large cities, 83% of the country lives in rural areas.[13] 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.[14][15][8] Studies have also suggested that low care and utilization rates may be due to limited diagnosis as well as limited continuity of care. [15], [16]

Successful implementation of programs 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 program with care decentralized throughout the country, overseen by a strong central monitoring system.[17] From 2010 to 2016, the HIV prevalence amongst persons 15-49 years old dropped from 10.6% to 8.8%.[18] 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.[19] The MOH has also become a leader in progressive antiretroviral therapy programs, such as Option B+ and universal treatment.[20][21][22]

Given this ongoing success in treating chronic infectious disease as well as the resources invested in these programs, 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 recognized as a possible delivery model, particularly for primary care, with much of the literature focused on calling for various integrated approaches.[23]-[29] [25] [29]

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There exist many examples of combining HIV with other clinical programs 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.[30]–[38] 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. [29], [30], [39]. Practical experience and implementation research is needed to assess the feasibility and outcomes of fully integrated HIV-NCD care.[25]

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 decentralized from two 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 Ministry of Health (MOH), with a comprehensive approach featuring Community Health Workers, nutrition, and cash transfer support for most vulnerable patients.[40][41] Neno District is consistently achieving significantly higher HIV retention and survival rates than any other district in the country.[41] 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, modeled off PIH's partnership with the government of Rwanda.[43]–[46] 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 utilized 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 utilization of the existing HIV platform, we were able to maximize staff, clinic space and overall efficiency and resources.[42] In 2015, IC3 rapidly decentralized integrated HIV-NCD primary care to the existing 2 hospitals and 11 health centers in the district, and later to a newly opened 12th health center 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.[26], [27], [47] 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.[42]

METHODS

Setting and Population

Neno District is a district with population of 165,000 in 2017, situated in the southwest zone in Malawi.[48] An extremely rural setting, the majority of the population relies on subsistence agriculture, with only 4.5% of the population with electricity.[49] Since 2007 PIH has partnered with the MOH in Neno to strengthen health services. In 2011, the Chronic Care Clinic (CCC) began enrolling NCD patients at Neno District Hospital, and in 2013 NCD services opened at Lisungwi Community Hospital. In early 2015, CCC was combined with the HIV program to form IC3, and decentralized to the 11 primary health centers across the district.[42] (Figure 1)

Integrated Chronic Care Clinic program design

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3 The clinic treated patients with one or more of any of the following conditions: HIV,
4 hypertension, epilepsy, asthma, diabetes, and mental illness. Patients were referred to IC3 from
5 several settings including inpatient wards, outpatient clinics, and community screening events. The
6 latter were held in remote parts of the district, with participants receiving age and gender
7 appropriate screening for hypertension, diabetes, HIV, tuberculosis, and malnutrition. Those with
8 high blood pressure or high blood sugar were referred to their nearest facility for IC3 staff to
9 confirm diagnosis and enroll them into care. In order to ensure the sickest patients were found
10 early and treated, and to avoid clinic overcrowding, the referral threshold for blood pressure was
11 SBP \geq 160 and/or DBP \geq 110. Cutoff for blood sugar for referral was fasting \geq 126 mg/dl and random
12 \geq 200 mg/dl.[50] For mental health conditions, patients were referred from inpatient and outpatient
13 clinics and assessed and diagnosed on admission to IC3. Once the diagnosis of mental health was
14 confirmed, patients received both psychotherapy and pharmacotherapy at clinic visits. Mental
15 illnesses included in the cohort are: schizophrenia, mood and anxiety disorders, schizoaffective
16 disorder, psychosis, organic mental disorder and alcohol and drug use-related mental disorders.
17 Patients with a pre-existing NCD diagnosis and on medications were automatically enrolled.
18 Patients were diagnosed using predefined NCD protocols, set by the IC3 team, and HIV protocols
19 from central MOH.[51]

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25 Patients enrolled in IC3 were seen at the health facility nearest to their home at regular
26 intervals. Patients with a complex diagnosis or those starting care had a scheduled visit every
27 month, while most other patients visited every 3 months. The clinic was staffed by clinical officers,
28 nurses, and support staff employed both by PIH and MOH. Supervision and mentorship were
29 performed by several physicians within the district, also employed both by MOH and PIH.
30 Hospital-based staff would travel out to the health centers three or four days a week to conduct
31 IC3 with health center-based counterparts. This was a solution for staffing shortages -given high
32 volumes of maternal child health and other acute needs at primary health centers, these facilities
33 were not equipped to handle the large influx of patients with HIV and NCDs. This system, of
34 hospital staff traveling to support health center-based staff, had been in place for Neno's HIV care
35 for several years.[40] The HIV program, well described elsewhere, was characterized by a strong
36 community footprint with a network of over 900 Community Health Workers (CHWs) who
37 received a monthly stipend to assist patients with adherence, perform missed visit tracking, and
38 provide social support to especially vulnerable patients in the form of cash transfers.[41] These
39 principles were applied to IC3, with the CHW network undergoing a gradual transformation in
40 2017 and 2018 so that all NCD patients were eventually assigned a CHW.[52]

41 42 43 44 **Data Collection and Analysis**

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

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55 Baseline demographics and clinical characteristics specific to each disease are reported
56 using descriptive statistics. Key indicators for each condition were chosen based on available

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3 routine clinical measurements that were taken each visit based on MOH protocols, which include:
4 blood pressure for hypertension patients, random or fasting fingerstick for diabetic patients, asthma
5 severity for asthma patients, and number of monthly seizures for epilepsy patients. Routine clinical
6 measurements for mental health patients were not available as part of this analysis. Clinical
7 outcomes are reported at one-year post enrollment to the clinic for the 36-month period for all
8 patients with more than one visit. The one-year values were included in this analysis if it was
9 within 3 months of the patients' one-year anniversary. Patients were defined as default if they were
10 still missing from clinic more than 8 weeks past their missed appointment, which is consistent with
11 the national definition for default to care for HIV patients. One-year survival is also reported as
12 patients known to be alive and retained in care 12 months after their enrollment date. Standard
13 deviations are reported for averages for clinical outcomes such as blood pressure or blood sugar,
14 and statistical significance for comparisons between baseline and one year were computed using
15 one-sided paired t-tests for continuous values and McNemar's Chi-square test for proportions.
16 Data were analyzed using Stata 14.2 Statistical Software.[53]
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20 **Patient and Public Involvement**

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22 The Ministry of Health (MOH) and Neno District Executive Council (DEC) were involved at the
23 conception of the clinic program design and responsible for approval for the clinic to enroll
24 patients. The clinical services were implemented in tandem by the MOH and PIH, and routine
25 updates were given to the DEC. Patients were involved informally through discussions on clinic
26 design, and formally through patient satisfaction surveys (unpublished). The design of the
27 intervention was meant to address the burden of disease in Neno District, and patients with any
28 chronic condition were eligible for enrollment into the clinic.
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31 **Ethics**

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33 All data for this study was routinely collected and de-identified clinical data, and no patient was
34 enrolled in a study outside of routine care. Ethical approval was received by the Malawi National
35 Health Sciences Research Committee (NHSRC) and Partners Healthcare Institutional Review
36 Board at Brigham & Women's Hospital in Boston, MA.
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40 **RESULTS**

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42 Between 2015 and 2017, 6,233 patients were enrolled in IC3. These new enrollments
43 included 2,990 diagnoses of a chronic NCD and 3,334 diagnoses of HIV. As of the end of 2018,
44 these new enrolments made up 56% of all active patients in the program, with the remaining 44%
45 being enrolled before or after the study period. Overall in IC3, 7.6% of NCD patients in care had
46 HIV, and 11.0% of NCD patients in care between the ages of 15 and 49 years had HIV. Among
47 all of the newly enrolled NCD patients in this cohort, 2.3% had HIV and 8% of NCD clients had
48 two or more NCDs. Of these patients, 10% (N=624) were under 15, including 13% of NCD
49 patients (N=379) and 7% of HIV patients (N=232). Figure 1 shows a map of Neno with NCD
50 enrollment limited to the two hospitals in 2014 and expanded to all 14 facilities in 2018.
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54 Figure 2 shows overall enrollment for HIV and NCDs between December 2013 and
55 December 2017 with an uptick in NCD enrollments starting in mid-2015 with the decentralization
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of NCD care through IC3 as well as community screening events across the district. After IC3 opened, HIV enrollments remained steady, while there was an increase in NCD enrollment.

Overall enrollment and outcomes are shown in Table 1 by diagnosis. Of the 2,990 NCD total diagnoses, the most common diagnoses were hypertension (N=1,693), asthma (N=668), and epilepsy (N=486). Overall, 25.5% of NCD patients defaulted (N=763) and 1.4% died (N=41). This is compared to defaulting in 8.4% and deaths in 4.0% of HIV patients. (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 NCD patients and 85% in HIV patients, with a range among specific NCDs from 60% in patients with asthma to 78% in patients with hypertension or diabetes. (Table 1)

Table 1: IC3 enrollment, retention, and survival by diagnosis

	All NCD Patients	Hypertension	Asthma	Epilepsy	Diabetes	Mental Illness	HIV
Total Patients Enrolled	2,990	1,693	668	486	149	109	3,334
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 & Survival Rate	72%	78%	60%	75%	78%	72%	85%

Table 2 shows clinical characteristics of patients at their enrollment for all patients enrolled during the study period who had at least two visits to clinic. On average, NCD patients were 46 years old and HIV patients 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 NCD cohort being female, ranging from 45.9% of patients with mental illness and 75.2% of patients with hypertension. Dual diagnosis patients included NCD patients over the age of 15 with HIV, making up 2.6% of the cohort, while 2.2% of HIV patients over the age of 15 were diagnosed with an NCD.

Table 2: Characteristics at enrollment

	All NCD Patients	Hypertension	Asthma	Epilepsy	Diabetes	Mental Illness	HIV
N	2,990	1,693	668	486	149	109	3,334
Average Age	46 (± 23)*	59 (± 15)	32 (± 23)	24 (± 17)	53 (± 17)	30 (± 16)	32 (± 14)
Female	67.3%	75.2%	64.4%	50.0%	64.4%	45.9%	59.7%

NCD Patients >15 yrs with HIV	2.6% (68)	2.5% (42)	3.0% (14)	2.2% (7)	3.4% (5)	3.4% (3)	
HIV Patients >15 yrs with at least one NCD							2.2% (68)

* Standard deviations (SD) are shown in parentheses for averages

Clinical outcomes were measured at one-year post enrollment 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 one-year post enrollment less than 5% remained with blood pressures in the Stage III range of SBP > 180 and/or DBP > 110mmHg, and 53.6% had controlled blood pressure defined as <140/90mmHg. Of hypertension patients, 84% had their blood pressure checked at their last visit. Supporting the strategy to enroll sicker patients with higher blood pressures first, 70% of the hypertension cohort was on 2 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 enrollment and 13.7% of the patients at their one year visit. A steroid inhaler was prescribed in 86% of patients with asthma.

Similarly, epilepsy patients reported fewer seizures overall after one year of treatment, from an average of 2.4 seizures per quarter at enrollment to 1.5 per quarter at one 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 2 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 was often missing. This average improved from 230 to 179mg/dl at one year, with 73% of patients having a fingerstick at their one year visit under 200 mg/dl. Almost 70% of patients with diabetes had their blood pressure controlled at follow up (81% of diabetes patients had their blood pressure checked at their last visit). Patients on insulin made up 18% of the diabetes cohort.

The HIV cohort in this study maintained excellent outcomes as had been previously demonstrated.[54] For HIV patients 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.

Table 3: One Year Clinical Outcomes

Hypertension	Enrollment	After One Year	p-value²
	N= 1,075		
Average Blood Pressure	157/94 (SD ¹ : systolic 28, diastolic 18)	136*/83* (SD: systolic 21, diastolic 13)	Systolic: <0.0001 Diastolic: <0.0001

Stage III Hypertension BP \geq 180/110	26.2% (n=322)	4.7%* (n=50)	<0.0001
Controlled Hypertension BP \leq 140 / 90		53.6% (n=575)	
Asthma			p-value²
	Enrollment	After One Year	N= 331
Asthma Severity: Moderate or Severe Persistent	21.8% (n=72)	12.6%* (n=42)	0.0007
Epilepsy			p-value²
	Enrollment	After One Year	N= 207
Average Number of Seizures in the past 3 months	2.4	1.5*	0.0003
Zero seizures since last visit		38.2% (n=79)	
Diabetes			p-value²
	Enrollment	After One Year	N= 52
Average fingerstick glucose ³	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)	
HIV			p-value²
		After One Year (N=2,250)	
Patients with a recorded viral load		80% (n=1,807)	
Patients with a viral load <1000		94% (n=1,692)	
Patients with an undetectable viral load		85% (n=1,527)	

¹ Standard Deviation (SD) showed for all averages

² Paired one-sided t-test for normal continuous values, Wilcoxon signed rank test for non-normal continuous variables (Number of Seizures for Epilepsy patients) and McNemar's Chi-square for proportions

³ Combines random, fasting, and unlabeled

* Statistically significant at p<0.05 level

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

DISCUSSION

The IC3 model is a bold attempt at rapid NCD care decentralization 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, decentralized from two hospitals to 12 primary care

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3 facilities. Our study shows an increase in the number of NCD patients accessing services since the
4 inception of the IC3 and demonstrates favorable one-year clinical outcomes and retention in care
5 for patients with NCDs whilst maintaining the excellent clinical outcomes and the rate of
6 enrollment for patients with HIV.
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9 To our knowledge this is the first description of clinical outcomes for comprehensive NCD
10 care in Malawi that is fully decentralized to the primary care level. It is also the sole example in
11 Malawi of fully integrated HIV-NCD care for all patients with chronic illness, regardless of their
12 HIV status. Furthermore, very few examples of such a model exist in the global literature to date.
13 In Kruk et al's description of redesigning primary care to address chronic NCDs, four elements
14 are suggested as essential for addressing NCDs through primary care models: "integration of
15 services, innovative service delivery, a focus on patients and communities, and adoption of new
16 technologies for communication." The IC3 model encompasses the first three of these, and a future
17 implementation of point-of-care medical record data entry is planned.[27], [42]
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21 Increasing enrollment following care integration and decentralization indicates success in
22 implementation: 6,233 new patients were enrolled during the 3-year period of the study, 48% of
23 them with a chronic NCDs. Given the long history of the HIV program in Neno, reported incidence
24 of HIV case finding – i.e. finding all of the anticipated HIV patients living in the district - than for
25 NCDs.[41] At the end of the study period, 8.1% of all NCD patients, and 11.0% of NCD patients
26 ages 15-49 ever enrolled in IC3 were also being treated for HIV. These percentages are higher
27 than for the entirety of the study cohort because as screening improved, more NCDs were found
28 and diagnosed in existing HIV patients who were enrolled before the start of the study period.
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31 The distribution of diagnoses in Neno District is partly reflective of the prevalence of
32 conditions and partly reflective of what conditions are actively screened for in community
33 programs and in clinics. Of the NCDs, hypertension is, unsurprisingly, the most common, despite
34 using a high threshold for enrollment. Neno District has several, unique screening programs for
35 hypertension and diabetes, including integrated community screening events.[9], [50] Notably, as
36 Malawi works toward Universal Health Coverage, there is still a large number of patients who
37 need diagnosis and treatment for common NCDs in Neno. For example, the estimated adult
38 hypertension prevalence of 15% suggests there are approximately 12,000 adults with hypertension
39 in Neno. This means that at the time of this study the clinic was only reaching 18% of expected
40 patients, with a focus on those with the most severe hypertension. Similar rationale indicates that
41 diabetes coverage thus far is 13%.[9]
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45 The next most common NCDs were the symptomatic conditions of asthma and epilepsy.
46 Indoor cooking with solid biomass fuel is the mainstay in this rural impoverished district, likely
47 contributing to asthma cases, and epilepsy risk factors of childhood cerebral malaria or meningitis,
48 birth asphyxia, and head trauma are abundant in this setting.[55], [56]
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51 The conditions treated at IC3 are only a component of the chronic NCD picture in Malawi:
52 NCDs comprise a family of over 200 conditions, that range from less prevalent but often more
53 severe to those affecting large populations of people.[8] This broad burden of NCDs in Malawi is
54 a critical factor in scale up: while traditionally NCD programs focus on 'the big four', i.e.
55 cardiovascular disease, diabetes, chronic respiratory disease, and cancer these conditions account
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3 for just 39% of the NCD DALYs in Malawi.[8], [57] Thus, we expect the range of diagnoses in
4 this clinic to diversify over time to reach even more patients with chronic conditions. Additionally,
5 the Neno cohort is primarily adults, although the NCD cohort has 13% under age 15. As the chronic
6 care system expands to include this wider range of diagnoses, we anticipate this proportion may
7 increase to include conditions that tend to affect younger people such as Type 1 diabetes, sickle
8 cell disease, and nephrotic syndrome. There is discussion whether such a chronic care platform
9 could include support for congenital conditions and disability as well which would nudge the
10 cohort toward younger ages.
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14 Enrollment of some NCD diagnoses favored females, such as hypertension and diabetes,
15 which has been seen in previous studies.[9] This may be related to increased interaction with the
16 health system and thus increased opportunities for screening, through pregnancy care for
17 example.[58] For some NCD diagnoses that tend to be more overtly symptomatic, such as mental
18 illness and epilepsy, the gender distribution was fairly equal.
19

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21 Previous research has shown that distance to clinic is a factor for missed visits and default
22 for patients with chronic illness, a barrier that decentralization to all primary care clinics was
23 designed to address.[15], [59] This cohort did have a high proportion of patients with a visit in the
24 preceding three months, a common way to longitudinally follow retention in HIV care in Malawi.
25 Prior to IC3 roll out in 2014, patient default often exceeded 50% in Neno.[60] One hypothesis is
26 that simply decentralizing care to be available closer to the patient was a large factor in this
27 observed trend.
28

29
30 One year retention in the cohort was also favorable, remaining high and stable over time
31 for HIV patients at 85%. This is encouraging as it is similar to rates of HIV retention prior to
32 integration, suggesting that the addition of NCD care to HIV clinics does not compromise HIV
33 outcomes. NCD default was higher than HIV in this cohort, likely due to active default tracking
34 for all HIV clients in Neno since 2007 by CHWs and the clinical team, whereas this started for
35 patients with chronic NCDs much later, in mid 2017. This also likely means that certainty of
36 outcomes such as death are higher for patients with HIV: we see a slightly higher rate of deaths
37 among the HIV patients, but it may be that some of the NCD patients labeled as default had in fact
38 died and follow up systems were not able to ascertain this information. Despite this, retention rates
39 for NCDs were quite favorable. One-year retention for hypertension, diabetes, and epilepsy was
40 in the range of 75-80%, which are excellent results compared with the retention in care literature
41 for chronic NCDs which can be as low as 25% and some interventions increasing retention to 60-
42 70%.[15], [61]–[63]
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46 Interestingly, retention in care for asthma was the lowest at 60%. There are a few
47 possibilities that may account for this result. One is that many of these patients did not actually
48 have true asthma, and that the diagnosis was triggered by an acute illness and thereafter improved,
49 or that asthma is occurring more seasonally, so when patients stabilize they drop out of care. A
50 second possibility is that these patients did not experience improved symptoms and thus dropped
51 out of care. Or the opposite could be true: that patients did in fact improve and thus stopped seeing
52 the need for attending clinic when they were feeling better. This could relate to a need for better
53 counseling and teaching for inhaler technique, better control of triggers, and additional education
54 around disease chronicity.
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Clinical outcomes overall were also favorable, 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.[8], [31] While this program leveraged many existing resources already in the system through the HIV program, there was a need for additional staff. The IC3 model is heavily supported by the NGO 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.[42]

There are many lessons learned 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 maximized, and an approach utilizing continuous quality improvement.[42] 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 PEN guidelines.[64] 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.[65]

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 Hemoglobin 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 is some missing data for our disease control variables (blood pressure, number of seizures, asthma severity, and blood glucose) at the one-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 is 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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Contributorship

EBW, CK, and NK conceptualized the study. EBW, CK, NK, ELD, LN, LD, BM, GG, EN, GT, LK, and EC designed and implemented the program and data systems and oversaw data collection and interpretation. ELD, LK, CK, NK, and EBW designed the data collection system. EBW, AS, NP, CK, and NK contributed to the analysis plan. EBW drafted the manuscript. AS and NP led the analysis, and ELD supported the analysis. GB, CK, EBW, NK, BM, EN, and LN provided contextual information for framing of the manuscript background and importance. All authors were involved in design and execution of the clinic and oversaw the clinical work. Each authors provided revisions and comments to the manuscript.

Data sharing

No additional data available, but data questions may be directed to the lead author at ewroe@pih.org.

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9 **Figure 1. NCD & HIV Diagnoses in Neno District over time.**

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11 **Figure 2. Cumulative enrollments in IC3 over time, by diagnosis.**
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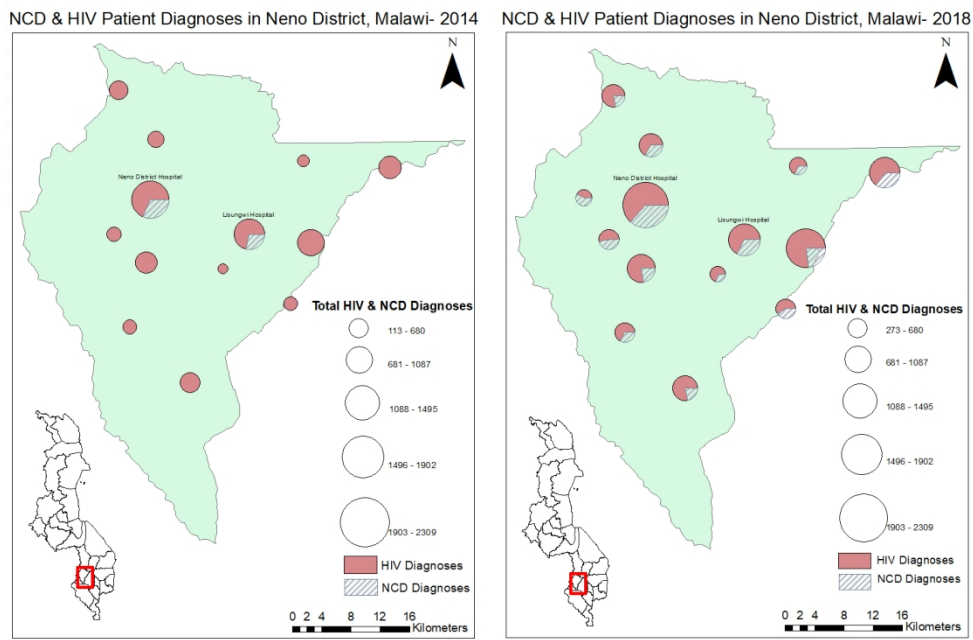


Figure 1. NCD & HIV Diagnoses in Neno District over time.

567x372mm (72 x 72 DPI)

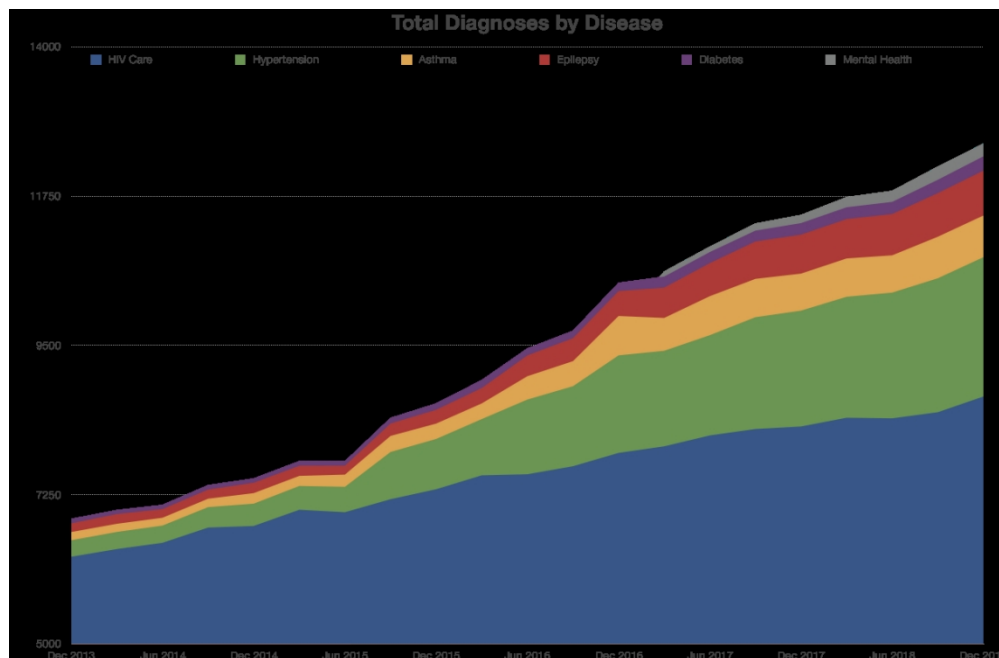


Figure 2. Cumulative enrollments in IC3 over time, by diagnosis

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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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Expanding access to Non-Communicable Disease care in rural Malawi: outcomes from a retrospective cohort in an integrated NCD-HIV model

Authors

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31 ABSTRACT

33 Objectives

34 Non-Communicable Diseases (NCDs) account for a third of disability-adjusted life years in
35 Malawi, and access to care is exceptionally limited. Integrated services with HIV are widely
36 recommended, but few examples exist globally. We report descriptive outcomes from an
37 Integrated Chronic Care Clinic (IC3).

39 Design

40 This is a retrospective cohort study.

42 Setting

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

46 Participants

47 All new patients, including 6,233 HIV-NCD diagnoses, enrolled between January 2015 and
48 December 2017 were included. This included 3,334 HIV patients (59.7% female) and 2,990 NCD
49 patients (67.3% female), 10% overall under age 15.

51 Interventions

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

55 Primary and secondary outcome measures

56 Routine clinical measurements are reported at one-year post enrollment for patients with more than
57 one visit. One-year retention is reported by diagnosis.

59 Results

60 NCD diagnoses were 1,693 hypertension, 668 asthma, 486 epilepsy, 149 diabetes, and 109 severe
61 mental illness. By December 2018, 8.3% of NCD patients over 15 years were also on HIV
62 treatment. One-year retention was 85% for HIV and 72% for NCDs, with default in 8.4% and
63 25.5% and deaths in 4.0% and 1.4%, respectively. Clinical outcomes showed statistically
64 significant improvement for hypertension, diabetes, asthma, and epilepsy. Of the 1807 (80%) of
65 HIV patients with viral load results, 85% had undetectable viral load.

67 Conclusions

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

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3 75 **Article Summary**

4 76
5 77 *Strengths and limitations of this study*

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- There is a large body of literature recommending integrated HIV-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 enrollment 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.[1] 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. [2][3] While the 2011 UN High Level meeting set out plans to combat this growing burden, the response has yet to fully meet this need.[4] 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.[5] In Malawi, a similar pattern emerges: the non-communicable disease and injury (NCDI) 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.[6][7]

In Malawi, a high proportion of this burden falls on patients under 40, and the Ministry of Health (MOH) is increasingly recognizing the importance of care delivery systems for NCDs.[6][8] Estimates of condition-specific prevalence estimate hypertension rates between 14-16% for urban adults and 13-14% for rural adults.[9] 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.[9], [10] 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%.[10][11] Access to care, particularly in the rural districts, is limited: for example, less than half of the health centers were equipped with the country's first line anti-hypertensive in 2014.[12] While care is available at central hospitals in large cities, 83% of the country lives in rural areas.[13] 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.[14][15][8] Studies have also suggested that low care and utilization rates may be due to limited diagnosis as well as limited continuity of care. [15], [16]

Successful implementation of programs 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 program with care decentralized throughout the country, overseen by a strong central monitoring system.[17] From 2010 to 2016, the HIV prevalence amongst persons 15-49 years old dropped from 10.6% to 8.8%.[18] 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.[19] The MOH has also become a leader in progressive antiretroviral therapy programs, such as Option B+ and universal treatment.[20][21][22]

Given this ongoing success in treating chronic infectious disease as well as the resources invested in these programs, 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 recognized as a possible delivery model, particularly for primary care, with much of the literature focused on calling for various integrated approaches.[23]–[29] [25] [29]

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3 135 There exist many examples of combining HIV with other clinical programs and into
4 136 primary care; however, much of the early work in HIV-NCD integrated chronic care focuses
5 137 primarily on screening and treating NCDs within HIV cohorts exclusively.[30]–[38] Fully
6 138 integrated HIV and NCD care is put forward as a model by several authors, but examples of fully
7 139 integrated HIV-NCD clinics, serving patients with and without HIV, are limited. [29], [30], [39].
8 140 Practical experience and implementation research is needed to assess the feasibility and outcomes
9 141 of fully integrated HIV-NCD care.[25]
10 142

11 143 Situated in southwest Malawi, the rural district of Neno was formed in 2003 and did not
12 144 have a hospital until 2007. HIV care was fully decentralized from two hospitals in Neno to 11
13 145 primary health centres by 2011 through a long-term partnership between the international non-
14 146 profit Partners In Health (PIH) and the Ministry of Health (MOH), with a comprehensive
15 147 approach featuring Community Health Workers, nutrition, and cash transfer support for most
16 148 vulnerable patients.[40][41] Neno District is consistently achieving significantly higher HIV
17 149 retention and survival rates than any other district in the country.[41] Leveraging this experience,
18 150 in 2015, PIH and the MOH launched the Integrated Chronic Care Clinic (IC3) in Neno. At the
19 151 two hospitals, IC3 replaced an earlier clinic for NCDs, modeled off PIH's partnership with the
20 152 government of Rwanda.[42]–[44] At the time, the NCD clinic at the two hospitals was
21 153 experiencing high rates of patient default, rotating staff, and a lack of streamlined monitoring and
22 154 evaluation and supply chain systems. The clinics utilized the HIV platform of care to include
23 155 treatment for any chronic illness including hypertension, diabetes, asthma, epilepsy and mental
24 156 illness regardless of a patient's HIV status. Through utilization of the existing HIV platform, we
25 157 were able to maximize staff, clinic space and overall efficiency and resources.[45] In 2015, IC3
26 158 rapidly decentralized integrated HIV-NCD primary care to the existing 2 hospitals and 11 health
27 159 centers in the district, and later to a newly opened 12th health center in mid 2016.
28 160

29 161 While integrating care makes sense in resource-poor settings with high infectious and NCD
30 162 burdens, the evidence base surrounding how best to prevent and manage NCDs, or integrate NCD
31 163 care, in sub-Saharan Africa is severely lacking.[26], [27], [46] This paper therefore seeks to
32 164 describe our clinical outcomes after integrating NCD and HIV care into one system for all comers
33 165 with a chronic disease in Neno District, Malawi.[45]
34 166

35 167 **METHODS**

36 168 **Setting and Population**

37 169 Neno District is a district with population of 165,000 in 2017, situated in the southwest
38 170 zone in Malawi.[47] An extremely rural setting, the majority of the population relies on subsistence
39 171 agriculture, with only 4.5% of the population with electricity.[48] Since 2007 PIH has partnered
40 172 with the MOH in Neno to strengthen health services. In 2011, the Chronic Care Clinic (CCC)
41 173 began enrolling NCD patients at Neno District Hospital, and in 2013 NCD services opened at
42 174 Lisungwi Community Hospital. In early 2015, CCC was combined with the HIV program to form
43 175 IC3, and decentralized to the 11 primary health centers across the district.[45] (Figure 1)
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47 179 **Integrated Chronic Care Clinic program design**

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181 The clinic treated patients with one or more of any of the following conditions: HIV,
182 hypertension, epilepsy, asthma, diabetes, and mental illness. Patients were referred to IC3 from
183 several settings including inpatient wards, outpatient clinics, and community screening events. The
184 latter were held in remote parts of the district, with participants receiving age and gender
185 appropriate screening for hypertension, diabetes, HIV, tuberculosis, and malnutrition. Those with
186 high blood pressure or high blood sugar were referred to their nearest facility for IC3 staff to
187 confirm diagnosis and enroll them into care. In order to ensure the sickest patients were found
188 early and treated, and to avoid clinic overcrowding, the referral threshold for blood pressure was
189 SBP \geq 160 and/or DBP \geq 110. Cutoff for blood sugar for referral was fasting \geq 126 mg/dl and random
190 \geq 200 mg/dl.[49] For mental health conditions, patients were referred from inpatient and outpatient
191 clinics and assessed and diagnosed on admission to IC3. Once the diagnosis of mental health was
192 confirmed, patients received both psychotherapy and pharmacotherapy at clinic visits. Mental
193 illnesses included in the cohort are: schizophrenia, mood and anxiety disorders, schizoaffective
194 disorder, psychosis, organic mental disorder and alcohol and drug use-related mental disorders.
195 Patients with a pre-existing NCD diagnosis and on medications were automatically enrolled.
196 Patients were diagnosed using predefined NCD protocols, set by the IC3 team, and HIV protocols
197 from central MOH.[50]

199 Patients enrolled in IC3 were seen at the health facility nearest to their home at regular
200 intervals. Patients with a complex diagnosis or those starting care had a scheduled visit every
201 month, while most other patients visited every 3 months. The clinic was staffed by clinical officers,
202 nurses, and support staff employed both by PIH and MOH. Supervision and mentorship were
203 performed by several physicians within the district, also employed both by MOH and PIH.
204 Hospital-based staff would travel out to the health centers three or four days a week to conduct
205 IC3 with health center-based counterparts. This was a solution for staffing shortages -given high
206 volumes of maternal child health and other acute needs at primary health centers, these facilities
207 were not equipped to handle the large influx of patients with HIV and NCDs. This system, of
208 hospital staff traveling to support health center-based staff, had been in place for Neno's HIV care
209 for several years.[40] The HIV program, well described elsewhere, was characterized by a strong
210 community footprint with a network of over 900 Community Health Workers (CHWs) who
211 received a monthly stipend to assist patients with adherence, perform missed visit tracking, and
212 provide social support to especially vulnerable patients in the form of cash transfers.[41] These
213 principles were applied to IC3, with the CHW network undergoing a gradual transformation in
214 2017 and 2018 so that all NCD patients were eventually assigned a CHW.[51]

215 216 **Data Collection and Analysis**

217
218 This is a retrospective cohort comprised of all patients newly enrolled in IC3 at any facility
219 in Neno District in the 36-month period between January 2015 and December 2017. Data was
220 collected at enrollment and at routine clinical visits by clinical staff on paper forms also called
221 master cards, which were approved and standardized by the national MOH. Data from the master
222 cards was then regularly entered into an OpenMRS electronic medical record (EMR) system by
223 data clerks. EMR data was extracted and utilized in this analysis.

224
225 Baseline demographics and clinical characteristics specific to each disease are reported
226 using descriptive statistics. Key indicators for each condition were chosen based on available

227 routine clinical measurements that were taken each visit based on MOH protocols, which include:
228 blood pressure for hypertension patients, random or fasting fingerstick for diabetic patients, asthma
229 severity for asthma patients, and number of monthly seizures for epilepsy patients. Routine clinical
230 measurements for mental health patients were not available as part of this analysis. Clinical
231 outcomes are reported at one-year post enrollment to the clinic for the 36-month period for all
232 patients with more than one visit. The one-year values were included in this analysis if it was
233 within 3 months of the patients' one-year anniversary. Patients were defined as default if they were
234 still missing from clinic more than 8 weeks past their missed appointment, which is consistent with
235 the national definition for default to care for HIV patients. One-year survival is also reported as
236 patients known to be alive and retained in care 12 months after their enrollment date. Standard
237 deviations are reported for averages for clinical outcomes such as blood pressure or blood sugar,
238 and statistical significance for comparisons between baseline and one year were computed using
239 one-sided paired t-tests for continuous values and McNemar's Chi-square test for proportions.
240 Data were analyzed using Stata 14.2 Statistical Software.[52]

241 242 **Patient and Public Involvement**

243
244 The Ministry of Health (MOH) and Neno District Executive Council (DEC) were involved at the
245 conception of the clinic program design and responsible for approval for the clinic to enroll
246 patients. The clinical services were implemented in tandem by the MOH and PIH, and routine
247 updates were given to the DEC. Patients were involved informally through discussions on clinic
248 design, and formally through patient satisfaction surveys (unpublished). The design of the
249 intervention was meant to address the burden of disease in Neno District, and patients with any
250 chronic condition were eligible for enrollment into the clinic.

251 252 **Ethics**

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254 All data for this study was routinely collected and de-identified clinical data, and no patient was
255 enrolled in a study outside of routine care. Ethical approval was received by the Malawi National
256 Health Sciences Research Committee (NHSRC) and Partners Healthcare Institutional Review
257 Board at Brigham & Women's Hospital in Boston, MA.

258 259 **RESULTS**

260
261 Between 2015 and 2017, 6,233 patients were enrolled in IC3. These new enrollments
262 included 2,990 diagnoses of a chronic NCD and 3,334 diagnoses of HIV. As of the end of 2018,
263 these new enrolments made up 56% of all active patients in the program, with the remaining 44%
264 being enrolled before or after the study period. Overall in IC3, 7.6% of NCD patients in care had
265 HIV, and 11.0% of NCD patients in care between the ages of 15 and 49 years had HIV. Among
266 all of the newly enrolled NCD patients in this cohort, 2.3% had HIV and 8% of NCD clients had
267 two or more NCDs. Of these patients, 10% (N=624) were under 15, including 13% of NCD
268 patients (N=379) and 7% of HIV patients (N=232). Figure 1 shows a map of Neno with NCD
269 enrollment limited to the two hospitals in 2014 and expanded to all 14 facilities in 2018.

270
271 Figure 2 shows overall enrollment for HIV and NCDs between December 2013 and
272 December 2017 with an uptick in NCD enrollments starting in mid-2015 with the decentralization

of NCD care through IC3 as well as community screening events across the district. After IC3 opened, HIV enrollments remained steady, while there was an increase in NCD enrollment.

Overall enrollment and outcomes are shown in Table 1 by diagnosis. Of the 2,990 NCD total diagnoses, the most common diagnoses were hypertension (N=1,693), asthma (N=668), and epilepsy (N=486). Overall, 25.5% of NCD patients defaulted (N=763) and 1.4% died (N=41). This is compared to defaulting in 8.4% and deaths in 4.0% of HIV patients. (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 NCD patients and 85% in HIV patients, with a range among specific NCDs from 60% in patients with asthma to 78% in patients with hypertension or diabetes. (Table 1)

Table 1: IC3 enrollment, retention, and survival by diagnosis

	All NCD Patients	Hypertension	Asthma	Epilepsy	Diabetes	Mental Illness	HIV
Total Patients Enrolled	2,990	1,693	668	486	149	109	3,334
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 & Survival Rate	72%	78%	60%	75%	78%	72%	85%

Table 2 shows clinical characteristics of patients at their enrollment for all patients enrolled during the study period who had at least two visits to clinic. On average, NCD patients were 46 years old and HIV patients 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 NCD cohort being female, ranging from 45.9% of patients with mental illness and 75.2% of patients with hypertension. Dual diagnosis patients included NCD patients over the age of 15 with HIV, making up 2.6% of the cohort, while 2.2% of HIV patients over the age of 15 were diagnosed with an NCD.

Table 2: Characteristics at enrollment

	All NCD Patients	Hypertension	Asthma	Epilepsy	Diabetes	Mental Illness	HIV
N	2,990	1,693	668	486	149	109	3,334
Average Age	46 (± 23)*	59 (± 15)	32 (± 23)	24 (± 17)	53 (± 17)	30 (± 16)	32 (± 14)
Female	67.3%	75.2%	64.4%	50.0%	64.4%	45.9%	59.7%

NCD Patients >15 yrs with HIV	2.6% (68)	2.5% (42)	3.0% (14)	2.2% (7)	3.4% (5)	3.4% (3)	
HIV Patients >15 yrs with at least one NCD							2.2% (68)

* Standard deviations (SD) are shown in parentheses for averages

Clinical outcomes were measured at one-year post enrollment 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 one-year post enrollment less than 5% remained with blood pressures in the Stage III range of SBP > 180 and/or DBP > 110mmHg, and 53.6% had controlled blood pressure defined as <140/90mmHg. Of hypertension patients, 84% had their blood pressure checked at their last visit. Supporting the strategy to enroll sicker patients with higher blood pressures first, 70% of the hypertension cohort was on 2 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 enrollment and 13.7% of the patients at their one year visit. A steroid inhaler was prescribed in 86% of patients with asthma.

Similarly, epilepsy patients reported fewer seizures overall after one year of treatment, from an average of 2.4 seizures per quarter at enrollment to 1.5 per quarter at one 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 2 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 was often missing. This average improved from 230 to 179mg/dl at one year, with 73% of patients having a fingerstick at their one year visit under 200 mg/dl. Almost 70% of patients with diabetes had their blood pressure controlled at follow up (81% of diabetes patients had their blood pressure checked at their last visit). Patients on insulin made up 18% of the diabetes cohort.

The HIV cohort in this study maintained excellent outcomes as had been previously demonstrated.[53] For HIV patients 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.

Table 3: One Year Clinical Outcomes

Hypertension	Enrollment	After One Year	p-value²
	N= 1,075		
Average Blood Pressure	157/94 (SD ¹ : systolic 28, diastolic 18)	136*/83* (SD: systolic 21, diastolic 13)	Systolic: <0.0001 Diastolic: <0.0001

Stage III Hypertension BP \geq 180/110	26.2% (n=322)	4.7%* (n=50)	<0.0001
Controlled Hypertension BP \leq 140 / 90		53.6% (n=575)	
Asthma			p-value²
	Enrollment	After One Year	N= 331
Asthma Severity: Moderate or Severe Persistent	21.8% (n=72)	12.6%* (n=42)	0.0007
Epilepsy			p-value²
	Enrollment	After One Year	N= 207
Average Number of Seizures in the past 3 months	2.4	1.5*	0.0003
Zero seizures since last visit		38.2% (n=79)	
Diabetes			p-value²
	Enrollment	After One Year	N= 52
Average fingerstick glucose ³	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)	
HIV			p-value²
		After One Year (N=2,250)	
Patients with a recorded viral load		80% (n=1,807)	
Patients with a viral load <1000		94% (n=1,692)	
Patients with an undetectable viral load		85% (n=1,527)	

¹ Standard Deviation (SD) showed for all averages

² Paired one-sided t-test for normal continuous values, Wilcoxon signed rank test for non-normal continuous variables (Number of Seizures for Epilepsy patients) and McNemar's Chi-square for proportions

³ Combines random, fasting, and unlabeled

* Statistically significant at p<0.05 level

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

DISCUSSION

The IC3 model is a bold attempt at rapid NCD care decentralization 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, decentralized from two hospitals to 12 primary care

349 facilities. Our study shows an increase in the number of NCD patients accessing services since the
350 inception of the IC3 and demonstrates favorable one-year clinical outcomes and retention in care
351 for patients with NCDs whilst maintaining the excellent clinical outcomes and the rate of
352 enrollment for patients with HIV.

353
354 To our knowledge this is the first description of clinical outcomes for comprehensive NCD
355 care in Malawi that is fully decentralized to the primary care level. It is also the sole example in
356 Malawi of fully integrated HIV-NCD care for all patients with chronic illness, regardless of their
357 HIV status. Furthermore, very few examples of such a model exist in the global literature to date.
358 In Kruk et al's description of redesigning primary care to address chronic NCDs, four elements
359 are suggested as essential for addressing NCDs through primary care models: "integration of
360 services, innovative service delivery, a focus on patients and communities, and adoption of new
361 technologies for communication." The IC3 model encompasses the first three of these, and a future
362 implementation of point-of-care medical record data entry is planned.[27], [45]

363
364 Increasing enrollment following care integration and decentralization indicates success in
365 implementation: 6,233 new patients were enrolled during the 3-year period of the study, 48% of
366 them with a chronic NCDs. Given the long history of the HIV program in Neno, reported incidence
367 of HIV case finding – i.e. finding all of the anticipated HIV patients living in the district - than for
368 NCDs.[41] At the end of the study period, 8.1% of all NCD patients, and 11.0% of NCD patients
369 ages 15-49 ever enrolled in IC3 were also being treated for HIV. These percentages are higher
370 than for the entirety of the study cohort because as screening improved, more NCDs were found
371 and diagnosed in existing HIV patients who were enrolled before the start of the study period.

372
373 The distribution of diagnoses in Neno District is partly reflective of the prevalence of
374 conditions and partly reflective of what conditions are actively screened for in community
375 programs and in clinics. Of the NCDs, hypertension is, unsurprisingly, the most common, despite
376 using a high threshold for enrollment. Neno District has several, unique screening programs for
377 hypertension and diabetes, including integrated community screening events.[9], [49] Notably, as
378 Malawi works toward Universal Health Coverage, there is still a large number of patients who
379 need diagnosis and treatment for common NCDs in Neno. For example, the estimated adult
380 hypertension prevalence of 15% suggests there are approximately 12,000 adults with hypertension
381 in Neno. This means that at the time of this study the clinic was only reaching 18% of expected
382 patients, with a focus on those with the most severe hypertension. Similar rationale indicates that
383 diabetes coverage thus far is 13%.[9]

384
385 The next most common NCDs were the symptomatic conditions of asthma and epilepsy.
386 Indoor cooking with solid biomass fuel is the mainstay in this rural impoverished district, likely
387 contributing to asthma cases, and epilepsy risk factors of childhood cerebral malaria or meningitis,
388 birth asphyxia, and head trauma are abundant in this setting.[54], [55]

389
390 The conditions treated at IC3 are only a component of the chronic NCD picture in Malawi:
391 NCDs comprise a family of over 200 conditions, that range from less prevalent but often more
392 severe to those affecting large populations of people.[8] This broad burden of NCDs in Malawi is
393 a critical factor in scale up: while traditionally NCD programs focus on 'the big four', i.e.
394 cardiovascular disease, diabetes, chronic respiratory disease, and cancer these conditions account

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3 395 for just 39% of the NCD DALYs in Malawi.[8], [56] Thus, we expect the range of diagnoses in
4 396 this clinic to diversify over time to reach even more patients with chronic conditions. Additionally,
5 397 the Neno cohort is primarily adults, although the NCD cohort has 13% under age 15. As the chronic
6 398 care system expands to include this wider range of diagnoses, we anticipate this proportion may
7 399 increase to include conditions that tend to affect younger people such as Type 1 diabetes, sickle
8 400 cell disease, and nephrotic syndrome. There is discussion whether such a chronic care platform
9 401 could include support for congenital conditions and disability as well which would nudge the
10 402 cohort toward younger ages.

11 403
12 404 Enrollment of some NCD diagnoses favored females, such as hypertension and diabetes,
13 405 which has been seen in previous studies.[9] This may be related to increased interaction with the
14 406 health system and thus increased opportunities for screening, through pregnancy care for
15 407 example.[57] For some NCD diagnoses that tend to be more overtly symptomatic, such as mental
16 408 illness and epilepsy, the gender distribution was fairly equal.

17 409
18 410 Previous research has shown that distance to clinic is a factor for missed visits and default
19 411 for patients with chronic illness, a barrier that decentralization to all primary care clinics was
20 412 designed to address.[15], [58] This cohort did have a high proportion of patients with a visit in the
21 413 preceding three months, a common way to longitudinally follow retention in HIV care in Malawi.
22 414 Prior to IC3 roll out in 2014, patient default often exceeded 50% in Neno.[59] One hypothesis is
23 415 that simply decentralizing care to be available closer to the patient was a large factor in this
24 416 observed trend.

25 417
26 418 One year retention in the cohort was also favorable, remaining high and stable over time
27 419 for HIV patients at 85%. This is encouraging as it is similar to rates of HIV retention prior to
28 420 integration, suggesting that the addition of NCD care to HIV clinics does not compromise HIV
29 421 outcomes. NCD default was higher than HIV in this cohort, likely due to active default tracking
30 422 for all HIV clients in Neno since 2007 by CHWs and the clinical team, whereas this started for
31 423 patients with chronic NCDs much later, in mid 2017. This also likely means that certainty of
32 424 outcomes such as death are higher for patients with HIV: we see a slightly higher rate of deaths
33 425 among the HIV patients, but it may be that some of the NCD patients labeled as default had in fact
34 426 died and follow up systems were not able to ascertain this information. Despite this, retention rates
35 427 for NCDs were quite favorable. One-year retention for hypertension, diabetes, and epilepsy was
36 428 in the range of 75-80%, which are excellent results compared with the retention in care literature
37 429 for chronic NCDs which can be as low as 25% and some interventions increasing retention to 60-
38 430 70%.[15], [60]–[62]

39 431
40 432 Interestingly, retention in care for asthma was the lowest at 60%. There are a few
41 433 possibilities that may account for this result. One is that many of these patients did not actually
42 434 have true asthma, and that the diagnosis was triggered by an acute illness and thereafter improved,
43 435 or that asthma is occurring more seasonally, so when patients stabilize they drop out of care. A
44 436 second possibility is that these patients did not experience improved symptoms and thus dropped
45 437 out of care. Or the opposite could be true: that patients did in fact improve and thus stopped seeing
46 438 the need for attending clinic when they were feeling better. This could relate to a need for better
47 439 counseling and teaching for inhaler technique, better control of triggers, and additional education
48 440 around disease chronicity.

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Clinical outcomes overall were also favorable, 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.[8], [31] While this program leveraged many existing resources already in the system through the HIV program, there was a need for additional staff. The IC3 model is heavily supported by the NGO 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.[45]

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There are many lessons learned 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 maximized, and an approach utilizing continuous quality improvement.[45] 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 PEN guidelines.[63] 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.[64]

472 **Limitations**

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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 Hemoglobin 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 is some missing data for our disease control variables (blood pressure, number of seizures, asthma severity, and blood glucose) at the one-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 is associated with individual

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3 487 characteristics in our cohort. We are currently working on decreasing missing data in our
4 488 documentation and aim to follow up with more complete data in future analyses.
5 489

6 490 **CONCLUSION**

7 491
8 492 This descriptive cohort displays good clinical outcomes and retention in care for patients
9 493 enrolled in longitudinal primary care for chronic conditions including both HIV and NCDs in rural
10 494 Malawi. This suggests that integration of HIV and NCD care at primary care clinics may be
11 495 feasible and effective. Additional work is needed on cost, patient satisfaction, quality of care, and
12 496 possibly integration of other chronic services such as palliative care.
13 497

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19 503 hardworking IC3 team members. We are also grateful to the support in fundraising and data
20 504 systems supported by Partners In Health. Finally, we would like to express our appreciation and
21 505 gratitude to the patients and community in Neno who provided key feedback and support as the
22 506 team was striving to integrate services and improve quality and systems.
23 507

24 508 **Contributorship**

25 509
26 510 EBW, CK, and NK conceptualized the study. EBW, CK, NK, ELD, LN, LD, BM, GG, EN,
27 511 GT, LK, and EC designed and implemented the program and data systems and oversaw data
28 512 collection and interpretation. ELD, LK, CK, NK, and EBW designed the data collection system.
29 513 EBW, AS, NP, CK, and NK contributed to the analysis plan. EBW drafted the manuscript. AS and
30 514 NP led the analysis, and ELD supported the analysis. GB, CK, EBW, NK, BM, EN, and LN
31 515 provided contextual information for framing of the manuscript background and importance. All
32 516 authors were involved in design and execution of the clinic and oversaw the clinical work. Each
33 517 authors provided revisions and comments to the manuscript.
34 518

35 519 **Competing Interests**

36 520
37 521 There are no competing interests for any author.
38 522
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40 524 **Data sharing**

41 525
42 526 No additional data available, but data questions may be directed to the lead author at
43 527 ewroe@pih.org.
44 528

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12 **Figure 1. NCD & HIV Diagnoses in Neno District over time.**
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14 **Figure 2. Cumulative enrollments in IC3 over time, by diagnosis.**
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For peer review only

NCD and HIV Patients in Neno District Malawi in 2014 and 2018

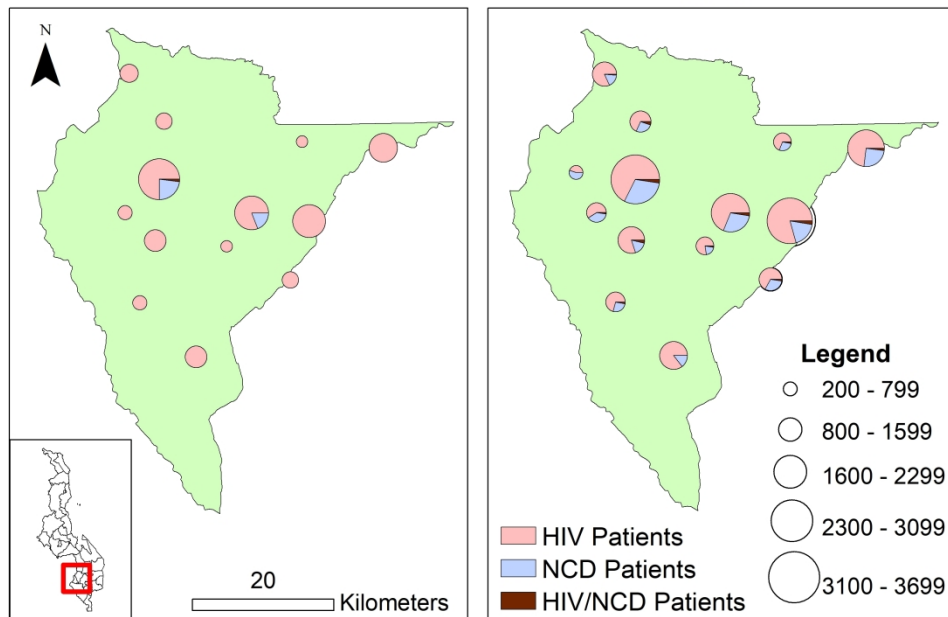


Figure 1. Cumulative enrollments in IC3 in 2014 and 2018, by health facility and diagnosis.

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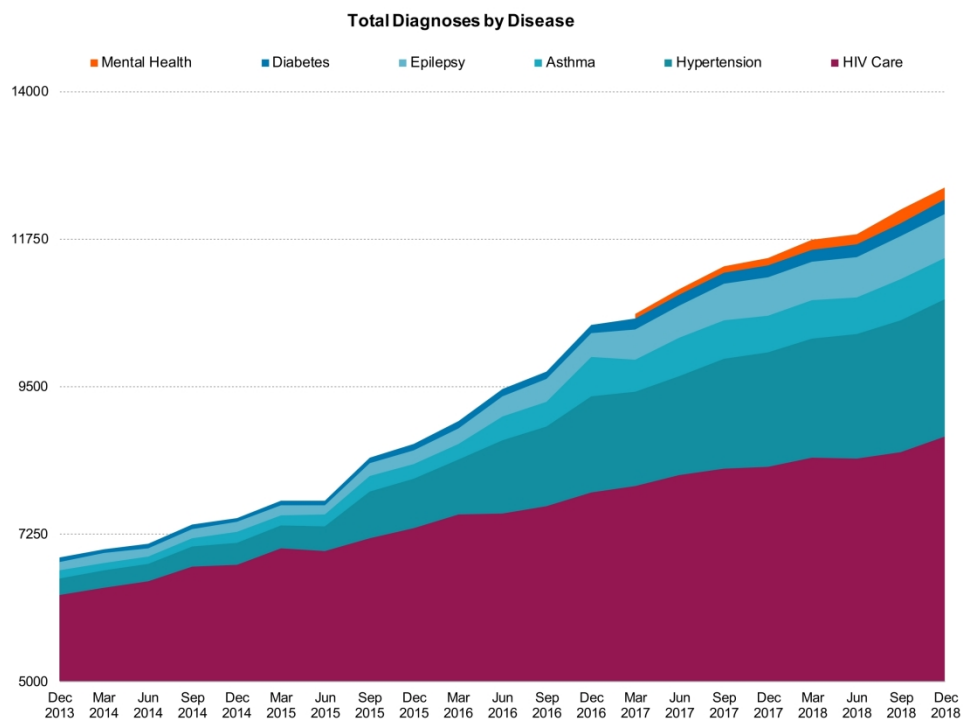


Figure 2. Cumulative enrollments in IC3 over time, by diagnosis.

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