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Strengthening integration of chronic care in Africa: protocol for the qualitative process evaluation of the integrating and decentralising HIV, diabetes and hypertension cluster randomised controlled trial in Uganda and Tanzania

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Title

Strengthening integration of chronic care in Africa: protocol for the qualitative process evaluation of the integrating and decentralising HIV, diabetes and hypertension cluster randomised controlled trial in Uganda and Tanzania

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Abstract

Introduction In sub-Saharan Africa (SSA), the burden of non-communicable diseases (NCDs), particularly diabetes mellitus (DM) and hypertension, has increased rapidly in recent years, although HIV infections remain a leading cause of death among young-middle aged adults. Health service coverage for NCDs remains very low in contrast to HIV, despite increasing prevalence of co-morbidity of NCDs with HIV. There is an urgent need to expand healthcare capacity to provide integrated services to address these chronic conditions.

Methods and Analysis: This protocol describes procedures for a qualitative process evaluation of the INTE-AFRICA, a cluster-randomised trial comparing integrated health service provision for HIV-infection, DM and hypertension, to the current stand-alone vertical care. Interviews, focus group discussions and observations of consultations and other care processes in two clinics (Tanzania, Uganda) will be used to explore the experiences of stakeholders (service users, policy makers, healthcare providers, community leaders and members, researchers, non-governmental (NGO) and international organisations) during implementation alongside an understanding of the impact of broader structural and contextual factors.

Ethics and Dissemination: Ethical approval has been granted by Liverpool School of Tropical Medicine (UK), the National Institute of Medical Research (Tanzania) and Medical Research Council (Uganda). The evaluation will provide the opportunity to document implementation of integration over several time points (six, 12 and 18 months) and refine integrated service provision prior to scale-up. This synergistic approach to evaluate, understand and respond will support service integration and inform monitoring, policy and practice development efforts to involve and educate communities in Uganda and Tanzania. It will create a model of care and a platform of best practices and lessons learnt for other countries implementing integrated and decentralised community health services.

Key Words

Health service delivery, Non communicable disease, HIV, integration, task-shifting, sub-Saharan Africa

Article Summary: Strengths and Limitations of this study

- Whilst HIV continues to be the leading cause of death among young-middle aged adults in sub-Saharan Africa (SSA), the burden of non-communicable diseases (NCDs) has increased rapidly in recent years, particularly diabetes mellitus and hypertension,
- There is an urgent need to expand the capacity of healthcare systems to manage NCDs, either alongside or integrated with HIV.
- Implementation of INTE-AFRICA in Tanzania and Uganda is complex, requiring concurrent process evaluation to understand and document stakeholders experiences, attitudes, and practices during implementation, and to understand the impact of structural and contextual factors on implementation.
- Limitations of the process evaluation may centre on patient drop out, characteristics of the two selected sites and other external mitigating factors.

BACKGROUND

The non-communicable disease (NCD) burden is increasing globally and poses a serious public health threat, with type 2 diabetes mellitus (DM) and hypertension contributing to about 9.4 million deaths annually,¹⁻³ in addition to long-term illness and disability. Over three-quarters of global NCD mortality and the majority of premature deaths occur in low- and middle-income countries (LMICs).^{4,5} The International Diabetes Federation has projected that incidence of DM will increase from 415 million in 2015 to 642 million by 2040, and over 70% of cases will be in LMICs.⁶ People living with HIV may have increased risks of developing hypertension and DM, with prevalence rates exceeding 5% and 20-30%, respectively.⁷ HIV/AIDS remains a major cause of morbidity and mortality among young-middle aged adults in sub-Saharan Africa (SSA), but the region is also experiencing a rapidly rising burden of NCDs (particularly DM and hypertension), rise to a dual HIV-NCD epidemic.⁸⁻¹⁰ While lifestyle changes associated with urbanisation and globalization (such as eating habits and lack of physical exercise) underpin the ongoing demographic and epidemiologic transition toward increasing NCDs, these changes also effect chronic infections (such as HIV), resultant inflammation and antiretroviral therapy ⁸⁻¹⁰ About 65% of people estimated to be living with HIV-infection in Africa are in regular HIV care; and this number is rising.¹¹ Chronic conditions requiring lifelong regular care, however, have an equal or higher burden than acute infections, with hypertension representing the single largest risk factor for death, and DM which has seen a massive increase in prevalence in a short period of time.^{1 9 12 13 1} Patient populations are increasingly demonstrating younger age of onset, and comorbidity conditions of NCDs with HIV, and the impact of NCDs is particularly severe in populations affected by poverty in SSA.^{10 15-18}

The majority of the healthcare systems in LMICs, particularly those in Africa, are already overburdened. Moreover, they are ill-prepared to provide chronic care required for most NCDs, since they were designed for episodic care to manage acute infection (e.g. malaria). However, since 2003, significant global investment and development partner engagement has facilitated the establishment of HIV screening and treatment programmes as the first large-scale chronic disease initiatives in Africa. Within these programmes, health services for HIV are typically stand-alone and vertically delivered. They are also often combined with decentralisation and task-shifting, which has enabled primary health centres to treat large numbers of patients while allowing non-clinically qualified health workers to play a major role in supporting patients on HIV treatment. In contrast, health service coverage for NCDs remains very low.^{9 19} Coordinated national NCD control and care programmes are relatively new with significant gaps in funding and operational evidence for program implementation.^{18 20} For example, fewer than 5% of persons with DM are thought to be in regular diabetes care, and the figure is likely to be similar for persons with hypertension.^{9 15 18} For those in care, health service provision for the diagnosis and management of diabetes and hypertension is insufficient.^{9 19 21-24} The expansion of and improvements in antiretroviral therapy (ART) has decreased HIV-related morbidity and

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3 mortality and contributed to increased survival rate. However, this population is now at risk of
4 developing NCDs, which will diminish the gains from the scale-up of HIV care services.²⁵
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8 It is important to learn from and leverage HIV services to improve care for persons with NCDs. There
9 is an urgent need to expand the capacity of healthcare systems to provide services for NCDs, either
10 alongside, or preferably integrated, with HIV.²⁶ DM, hypertension and HIV-infection require lifelong
11 care. Key challenges in Africa are linkage and retention in care, access and adherence to ART and
12 promotion of healthy behaviours.^{27 28} Addressing these challenges requires a common approach, yet
13 current services are primarily stand alone and vertically delivered in clinics within district hospitals or
14 larger primary care facilities. Additionally, duplication of services and crippling costs of accessing
15 health services for patients (typically 10-30% of monthly income) are major factors in patient drop-
16 out. As such, the infrastructure and lessons learnt from the HIV chronic disease prevention, testing
17 and care model can serve as important resources for the expansion of NCD prevention, care and
18 treatment. HIV chronic care management pathways, resources and infrastructure can be leveraged to
19 integrate with newly developing NCD services, which would strengthen the platform for NCD
20 services delivery.²⁹⁻³¹ Health systems have developed experience managing HIV as a chronic disease,
21 including linking and retaining patients in care and supporting treatment adherence in drugs,
22 diagnostics procurement and other key health systems indicators.^{28 32-34} Integration of services would
23 therefore reduce duplication and fragmentation of services and could mean that these practices can be
24 applied quickly to NCD control. This will enable effective management of DM and hypertension,
25 prevention of complications, cost savings to the health system and greater access to services and
26 clinical management (e.g. drug-drug interactions, adherence and support) for co-morbid or multi-
27 morbid patients. See **Figure One**. HIV, diabetes and hypertension are common and many people in
28 communities will have two or more chronic conditions, known as multi-morbidity. For these
29 individuals, a single integrated clinic that can cater for multiple (common) conditions would be
30 hugely beneficial both in terms of them accessing health care and also in considering clinical
31 management (e.g. drug-drug interactions, adherence and support).
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48 **Insert Figure One ‘Potential benefits of integrating diabetes, hypertension and HIV services for**
49 **a) DM and hypertension control, and b HIV control’ about here**
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52 Despite the increase in academic and clinical interest in HIV/NCD integration in SSA,^{16 33 35-40} there
53 remains little evidence about integration in terms of both scope and generalizability as evidence is
54 limited to small scale feasibility studies in largely different contexts.⁴¹⁻⁴⁷ The lack of large scale or
55 randomized and/or controlled evaluations and context-specific clinical, cost effectiveness and process
56 outcomes data constrains policymaking and development of integrated care models, which strengthen
57 health systems and are tailored to the distinct needs of each specific SSA country. SSA policy
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3 frameworks identify three forms of integration: i) integration of HIV/AIDS and NCD responses into
4 the health system, ii) integration within HIV/AIDS or NCD response (intra-), and iii) integration
5 between HIV/AIDS and NCD responses (inter-), and within the latter, *full* integration of HIV/NCD
6 care services into a chronic disease clinic; *partial* integration of certain aspects of NCD care such as
7 screening for NCD risk factors into HIV interventions; or *adaptation* of HIV strategies, systems and
8 tools for NCD care without actual service integration.^{26 28 44} There is however a lack of large scale or
9 randomized and/or controlled evaluations, as well as a lack of context specific clinical, cost
10 effectiveness and process outcomes data. This evidence is paramount to inform policy, government
11 resource prioritisation, and to develop integrated care models which strengthen health systems best
12 suited to the needs of that specific SSA country. We present here on the qualitative process
13 evaluation protocol designed to evaluate INTE-AFRICA, a European Commission Horizon 2020
14 funded implementation research project (protocol number 19-100) operating in Uganda and Tanzania.
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24 ***The INTE-AFRICA Project***

25 The aim of INTE-AFRICA is to implement and assess the effectiveness of integration of HIV, DM
26 and hypertension services at the point of service delivery covering many health facilities where
27 common approaches to clinical decision-making, drug procurement and human resource management
28 occur. The project will generate the research evidence needed by the health service in Uganda,
29 Tanzania and potentially the rest of Africa, to scale-up and sustain the chronic disease management
30 and services in an integrated manner. We recognise that stigma and discrimination associated with
31 HIV may prevent people from accessing health services.⁴⁸ Likewise, persons with DM and
32 hypertension may be reluctant to attend clinics where HIV-infected persons are seeking care either
33 because of the stigma associated with HIV-infection or for other reasons – e.g. because of fear of
34 contracting infection. Nonetheless, managing HIV-infection, like any other chronic condition, could
35 reduce the stigma, thus facilitating increased access to HIV services as well as improved NCD
36 control.
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46 Tanzania and Uganda were specifically chosen as they are low-income and their public and private
47 health facilities are strongly committed to providing services for NCD. However, their health systems
48 struggle to scale-up provision for diabetes and hypertension in the face of competing health demands,
49 including HIV-infection. See **Table One**. Tanzania and Uganda also share relevant characteristics
50 with other low-income countries, especially in sub-Saharan Africa. The process evaluation has the
51 potential to enhance the generalisability of integrated care to other similar settings by providing
52 understanding of the determinants and mechanisms of the implementation process.
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58 Insert **Table One ‘Key data on the country settings’** about here
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3 Our programme is underpinned by a participatory, multi-actor approach which supports dialogue,
4 knowledge exchange, fosters mutual understanding and provides input in policy agendas around
5 diagnosis and treatment of DM, hypertension and HIV in an integrated clinic. The INTE-AFRICA
6 conceptual framework is illustrated in **Figure Two**.
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11 Insert **Figure Two ‘INTEAFRICA Conceptual Model’** about here
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14 INTE-AFRICA will test integrated health services at primary care centres for HIV-infection, diabetes
15 and hypertension, by providing a “*One stop shop*” integrated care clinic for these conditions (the
16 intervention). We will conduct a pragmatic parallel arm cluster-randomised trial: 32 urban health
17 facilities in the two countries will be randomised, with 16 facilities allocated to deliver the
18 intervention immediately (intervention arm), and 16 facilities to continue with usual care (control
19 arm). In both arms, the clinic staff will receive refresher training in DM and hypertension
20 management to enable all healthcare staff to deliver the same standard of care to all patients. At each
21 selected facility, cohorts of approximately 220 patients; 110 HIV infected and 110 NCD patients, will
22 be enrolled to evaluate the primary outcomes. Both integrated and vertical health delivery approaches
23 will run concurrently. The primary care facilities will initiate and stabilise patients on treatment,
24 manage complications (including referral to higher facilities) and conduct clinical and laboratory
25 monitoring of patients for all three conditions. Specific characteristics of integrated care in each clinic
26 are: ‘*One stop shop*’ with concurrent management of HIV, hypertension and DM in the same facility;
27 management of patients with HIV, hypertension and DM by the same clinician or team of clinicians
28 (nurses, counsellors other staff); integrated training of clinicians; single waiting area and queue;
29 integrated health education about all three conditions; one pharmacy with a single drug dispensing
30 point; similar testing, and cross-testing, for diagnosis and monitoring with requisition of laboratory
31 tests in the same place; and similar format of paper medical records for each condition kept in the
32 same patient folder. Patients who decline to participate in the research and trial participants in control
33 arm clinics will continue to receive standard vertical health care delivery. Inclusion criteria for
34 participation are: being over 18 years old; having confirmed HIV-infection, diabetes or hypertension;
35 living within the catchment population of the health facility; likely to remain in the catchment
36 population for six months and willing to provide written informed consent. Very ill patients requiring
37 in-patient care will be excluded. Participants will be observed by the research team during clinic visits
38 with additional reviews at six and 12 months. Further details are provided in the trial protocol.
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54 ***Qualitative Process Evaluation of the INTE AFRICA trial***

55 Process evaluations typically evaluate how and whether interventions are delivered as intended and
56 whether such implementation is congruent with the theory underpinning the intervention.^{32 50-52}
57 Updated Medical Research Council (MRC) guidance for evaluation of complex health interventions
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3 has recently recognised the value of process evaluation within trials stating, “*it can be used to assess*
4 *fidelity and quality of implementation, clarify causal mechanisms and identify contextual factors*
5 *associated with variation in outcomes.*”³²The process evaluation in INTE-AFRICA is particularly
6 focused on context, description of the intervention and its causal assumptions, implementation,
7 mechanisms of impact and outcomes.³² Further we evaluate the extent to which resources and
8 activities supporting the intervention function to deliver intended outputs, with subsequent
9 improvements in outcomes. A central focus lies in identifying contextually relevant strategies for
10 successful implementation, and practical difficulties in adoption, delivery and maintenance to inform
11 wider implementation.⁵³ We recognise that outcomes (e.g. knowledge gained) of INTE-AFRICA are
12 dependent on understanding cultures and contexts of the stakeholders (i.e. service users, healthcare
13 providers, policy makers, community leaders/members, non-governmental organisations (NGO),
14 international organisations, and clinical researchers) involved and those surrounding service design
15 and delivery as well as care seeking practices. The role of social and behavioural science approaches
16 is central to this process evaluation. It aims to enhance understanding of issues related to the NCD and
17 HIV agendas and service delivery approaches from all perspectives and stakeholders along the
18 integration process. INTE-AFRICA will utilise a broad social behavioural approach to support
19 community engagement in research in Uganda and Tanzania, going beyond clinical trial recruitment
20 and retention to improve NCD/ HIV literacy. Behavioural and social science research strategies⁵⁴ will
21 allow NCD and HIV related research to place the needs and perspectives of people living with NCD
22 and/or HIV at the centre of the progression of clinical studies, such as INTE-AFRICA, and investigate
23 participant motivations and decision-making processes related to preferences for or participation in
24 different types of integrated and decentralised services.
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39 Process evaluation design, like healthcare interventions, requires a theoretical framework to structure
40 the evaluation across sites. We draw here on Bronfenbrenner’s ecological model of behaviour^{55 56} to
41 conceptualise integrated care as events that disrupt complex social systems⁵⁷ operating across multiple
42 contextual levels. We are interested in better understanding the importance of context, which becomes
43 especially relevant when comparing Tanzania and Uganda. According to the Bronfenbrenner model,
44 contextual factors are evaluated at the **macro** (universal vs partial coverage; free primary healthcare
45 and drugs, and users fees; fiscal policy); **meso** (drug ordering and drug delivery systems, health
46 worker education and employment, community understanding and perspectives on multi-morbidity);
47 and **micro** (clinic level management, resources, service user experience) levels. See **Figure Three**.
48 These contextual factors, likely to influence implementation and their effects, will be investigated to
49 capture variation in adoption, delivery and maintenance outcomes as well as responses to the
50 intervention. This will affect both reach and fidelity, which are hypothesised to be important factors in
51 outcome differences.
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3 Insert **Figure Three ‘Potential contextual influences on INTE AFRICA programme**
4 **implementation cascade’** about here
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8 To situate INTE-AFRICA within this theoretical framework, we will develop a logic model. This
9 model will set out contextual determinants of HIV and NCD illness management in SSA and assess
10 how integrated care components function to address these determinants to improve outcomes in the
11 management of patients. See **Table Two**.
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16 Insert **Table Two ‘Logic Model of programme inputs, processes and outcomes’** about here
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19 **METHODS**

20 ***Overall Design***

21 This protocol describes procedures for a qualitative process evaluation of the INTE-AFRICA
22 pragmatic parallel arm cluster-randomised trial comparing integrated health service provision for
23 HIV-infection, DM and hypertension with the current standard vertical care delivery model. The aims
24 of this qualitative process evaluation are to explore the experiences, attitudes and practices of a wide
25 variety of stakeholders during the process of programme implementation and to develop an
26 understanding of the impact of broader structural and contextual factors on the implementation
27 process. The process evaluation works in tandem with the collection of selected clinical outcomes
28 (e.g. clinical efficacy of different treatments) and health economic data (e.g. costs and benefits of
29 different approaches) to estimate the potential benefits to patients and health services at clinic and
30 country level (protocol reported elsewhere). It will use three qualitative research techniques: in-depth
31 interviews with stakeholders (service user, healthcare provider, policy maker, non-governmental
32 organisation (NGO)/international organisation, and clinical researcher); focus group discussions
33 (FGD) with community leaders and community members; and clinic-based observations in one site
34 per country. This design permits an assessment of the fidelity of INTE-AFRICA’s implementation, a
35 detailed description of the processes, relationships, and contexts involved in the delivery of integrated
36 care, and the identification of factors attributing to the failure or success of the programme. It thus
37 addresses the ‘black box’ problem in interpreting trial results by improving understanding of the
38 mechanisms that connect particular intervention components to particular outcomes.⁵⁸ The chosen
39 approach will enhance social construction and acceptability of chosen decentralised integrated
40 approaches, link outcomes to policy and advocacy and impact sustainability of HIV, DM and
41 hypertension chronic disease service integration in two LMIC countries. It provides the opportunity to
42 document and refine INTE-AFRICA activities prior to a larger pragmatic trial or scale-up by Uganda
43 and Tanzanian governments. These synergistic approaches to evaluate, understand and respond will
44 support integration, inform surveillance, policy and practice development and improve efforts to
45 involve and educate communities in Uganda and Tanzania. It will create a model and a platform of
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3 best practices and lessons learnt for other countries implementing integrated and decentralised
4 community health services for HIV and chronic disease. The process evaluation methods for each
5 objective are described in **Table Three**, including how each method maps onto the three different
6 contextual levels.
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11 Insert **Table Three: ‘Process Evaluation Design and data collection framework’** about here.
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14 ***Public and Patient Involvement***

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16 Public and patient involvement (PPI) throughout a programme of research enhances research quality
17 and relevance by providing different perspectives and a sense of ownership. This protocol will adhere
18 to the same principles, and will allow the voice of ‘service users’ and those affected to be heard, and
19 utilised. Key stakeholders such as service users and their families will be fully involved in guiding the
20 research, acting as research participants, and in implementation of change in health service delivery
21 and integrated care planning. All aspects of the process evaluation are underpinned by participatory
22 action health research and its success and usefulness will be grounded in PPI, participation and
23 engagement in the form of patient/professional identification of research priorities, collaborations and
24 partnerships, expert steering, community participation around health needs and optimal integrated
25 services, awareness raising activities, development of print materials, toolkits and training for
26 healthcare professionals.
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34 ***Data collection***

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36 We will use the Empirical Phenomenological Psychological (EPP) five-step method,⁵⁹ which
37 combines psychological, interpretative and idiographic components, to gain understanding of the
38 complex social processes, of social, aged, gendered and culturally/community specific meanings and
39 of incremental understanding of the distinct lived experience of policy makers, service users, health
40 care providers, researchers and communities. We will balance the description of phenomena with
41 interpretation of insights and are cognisant of participant experiential phenomena and authors’
42 interpretation of associated meanings. It will yield an in-depth socio-cultural understanding of service
43 user/participant reported outcomes, their motivations, preferences, beliefs, expectations, identities,
44 hopes and views on conditions, related stigma and of decision-making processes. This will provide
45 better understanding of stakeholder and community positioning during integration. This understanding
46 will inform policy and practice, ensure effective service user education, position service users and
47 their families to understand these conditions and interpret study outcomes and facilitate future HIV
48 and chronic disease clinical studies.
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58 Both descriptive patient level data and rich socio-behavioural qualitative data will be collected by a
59 team of trained researchers in Tanzania and Uganda. Data collection will entail exploring the
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3 experiences, attitudes and practices of a wide variety of stakeholders during the process of INTE-
4 AFRICA programme implementation and will develop an understanding of the impact of broader
5 structural and contextual factors on the implementation process.^{17 53}We will collect data on social
6 behavioural and cultural aspects impacting implementation (e.g. individual and community health
7 risks, protective behaviours and health responses) within the broader social and political frameworks,
8 the practicalities of accessing, providing and sustaining integrated services (e.g. staff time, resources,
9 equity of access, catchment area/populations, quality of care, waiting room dynamics, record keeping
10 and retention across multi/co-morbidities, training gaps); and process indicators (e.g. perceived
11 stigma, acceptability of vertical versus integrated service designs, lay knowledge and awareness and
12 bottlenecks to accessing services). We will also describe implementation of the intervention in terms
13 of fidelity to the intended model of care, adaptations to the intervention during implementation, and
14 dose and reach of intervention components actually delivered and received (such as numbers and
15 proportions of eligible staff who received integrated care training, numbers of proportions of patient
16 participants who received all or most of their care from integrated services, and frequency of drug
17 stock-outs)⁶⁹. The latter data will be complemented by routinely collected quantitative data such as
18 training attendance and medical records. We will document changes in healthcare provider roles,
19 attitudes and patient relationships.

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22 Interviews with service users and providers will include specific questions about their experience and
23 management of individuals with multi-morbid HIV, hypertension and/or diabetes. These include
24 service user, healthcare provider, and policymaker/senior manager perceptions of INTE-AFRICA;
25 impacts of INTE-AFRICA on the provision of integrated HIV/AIDS care and NCD care, and
26 relationships with NGO and international organisations; changes in health provider roles, attitudes,
27 and patient relationships; impacts of the INTE-AFRICA implementation context on trial and health
28 economic cost outcomes; impacts of the INTE-AFRICA intervention on an integrated health systems
29 approach to care (medicine supplies, record keeping, service user education, clinical care pathways,
30 data management, staff training); and barriers to and facilitators of change. The purposive samples of
31 service users and providers (**Table 3**) will include those who live with or manage multi-morbidity.
32 Selected patient outcomes will also be collected in order to estimate the potential benefits to patients
33 and to health services. We will assume a more pragmatic approach when garnering perspectives from
34 higher level stakeholders involved in health policy and practice generation, and NGO and
35 international organisations (e.g. WHO Country offices, UNAIDS, PEPFAR, CDC) providing
36 peripheral supports and guidance.

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39 The data, when combined and triangulated across these stakeholder perspectives, will provide a '*thick*
40 *description*', of how the intervention was delivered, maintained and experienced by stakeholders.^{17 53}
41 It will also offer explanations for observed variation over time and between countries, and detailed

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3 insight into the interaction between different contextual features and components of integration of
4 NCD or HIV/NCD services. It will also facilitate triangulation of information across stakeholders,
5 clinics and countries. We envisage returning to these two clinics in the future, four years and six
6 years after integration, to achieve a deeper understanding of processes and patient and provider
7 experiences.
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11 ***Setting, study populations, and recruitment***

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13 This will be a cohort study taking place in one site per country, with the same participants interviewed
14 at each time. 25 patients in each facility and 20 healthcare workers (10 in each facility) will be
15 purposely selected and invited; at six, 12 and 18 months after the start of the trial, to reflect
16 retrospectively on their experience of integration. See **Table Three**. These numbers are expected to
17 reach saturation (i.e. the point that further information does not provide any additional variation in
18 observed themes). We may replace participants if there is significant loss to follow up or refusal for
19 repeated interviews. For instance, if a participant drops out at 12 months, we still have their six-month
20 experience documented, and we can replace with a new participant, invited to reflect on their 12-
21 month retrospective experience. Where possible we will gender match interviewers with participants
22 (particularly patients). The following recruitment procedures will take place at each clinic.
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- 30 • Observations will be made in the *clinic* in consultation with the health facility and clinics in-
31 charges.
- 32 • Recruitment of *service users* will be supported by clinic nurses who will identify and
33 approach selected participants who have a minimum of six months experience of integration,
34 and will be asked to consent to partake in an in-depth interview on the day they attend the
35 clinic. INTE-AFRICA researchers will purposively sample women and men of different ages
36 and explore any age/gender and condition ((HIV/hypertensive/diabetic/multi/co-morbid)
37 related differences.
- 38 • *Health care providers* at the clinic (health facility managers and health professionals such as
39 physicians, nurses, public health nurses) will be approached at the clinic to participate in an
40 in-depth interview on the day the INTE-AFRICA team are scheduled to attend the clinic.
- 41 • *Ministerial policy makers and provincial/regional/district level clinical/health senior*
42 *management* (directors for NCD, HIV and curative services) will be identified and requested
43 to participate in a semi-structured interview (face to face or telephone).
- 44 • *NGO and international organisations* (for example WHO Country office, UNAIDS,
45 PEPFAR, CDC) will be identified and requested to participate in a semi-structured interview
46 (face to face or telephone).
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- *Community leaders* will be identified in the clinic catchment areas by virtue of their position while *community members* will be identified in consultation with the community leaders and invited to participate in a FGD.
- *Clinical researchers* will be invited to participate in an in depth interview at the 24 month end point.

Ethical considerations

Ethical approval for the evaluation has been granted by the research ethics committees of the Liverpool School of Tropical Medicine (UK), the National Institute of Medical Research (Tanzania) and Medical Research Council (Uganda). The key ethical principles of voluntary and informed participation, confidentiality and safety of participants will be used in all researcher and participant interactions. Written consent for interviews and observations will be obtained from all participants. All participants will be provided with written information about the research, this will be explained verbally, and informed that their participation is voluntary and that they may withdraw from participation at any time. Safety and confidentiality of all data will be ensured by: (1) encrypting all transcriptions with a password protected code; (2) storing all data in a secure, encrypted database accessible only to authorised persons on the research team; (3) de-linking all personal information of participants from the data collected and stored and each participant have a unique identification number.

Data analysis and synthesis

The analysis of qualitative data will be iterative, moving between data collection and analysis to test emerging theories. Field notes of observations will be analysed thematically to provide a description of the process and content involved in adapting and delivering the intervention. Audio recordings of interviews and FGDs will be transcribed verbatim by competent and experienced social scientists, with a subsample transcribed using conversation analytic conventions. Translation from local languages (e.g. Swahili, Luganda) into English will be performed for easy sharing with the study partners. Translation will occur using a back translation method for consistency. An electronic data management package (e.g. NVivo) will be used to manage the qualitative data analysis at the respective country levels. The analysis of the observational data will require knowledge obtained from health professional interviews at different levels to compare how reported experience, and different accounts of patient and professional perspectives relate to actual implementation of INTE-AFRICA scenarios: i) when DM and hypertension services are integrated with HIV-infection services; and ii) comparing countries. Care will be taken to identify and follow up deviant cases which do not fit into emerging theories. Reliability and validity of the analysis is optimised through iterative data collection, the use of a multi-method design incorporating interviews, FGD and observations and the ongoing discussion of findings within the research team for scrutiny and feedback.^{60 61}

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5 The chosen phenomenological approach (EPP), usually used in psychological research, reveals the
6 structures of subjective experience and meaning of a lived phenomenon (in first person point of view).
7 It follows to some extent Husserl's principle of active efforts to "bracket out" the researchers'
8 theoretical pre-understanding in the first steps of a text analysis⁵⁹. The "bracketing", however, does
9 not exclude an empathetic, psychological focus in the analysis on the experiences of the researched
10 phenomenon as it is lived by the informant and what it means is to her or him. In the context of INTE-
11 AFRICA, researchers in both countries will strive to get an empathetic understanding of the text, and
12 hence do not apply their professional prior knowledge about integration.
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19 We will conduct a stepwise analysis in five steps. **First**, the text will be read several times to get a
20 good grasp of how the informant spoke about the researched phenomenon of integration. In this step,
21 theoretical reflection will be withheld. **Second**, the whole text will be divided into meaning units of a
22 whole paragraph or a single word. **Third**, the informant's personal language will be transformed, unit-
23 by-unit, to the researchers' language. The researchers will discuss the transcription unit by unit. When
24 different interpretations occur, the researchers will return to the interview text and discuss in a free,
25 imaginative process until agreement can be reached through negotiated consensus. **Fourth**, the text
26 will be screened in a search for comprehensive themes. The text will be interpreted with connection to
27 the researchers' theoretical knowledge in an interchange between the original data, the transformed
28 units and the researchers' theoretical pre-understanding about integration. The meaning units will be
29 assorted into appropriate themes and thus constitute a general structure of the phenomenon of
30 integrated care. **Fifth**, this essential structure will penetrate all the revealed themes and thus the
31 meaning of the researched phenomenon of integrated care to the informant.
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41 We will add a further layer of triangulation of perspectives across stakeholders and across conditions
42 (HIV/hypertension/DM/multi/co-morbidity) when raising the abstraction level. Triangulation of
43 socio-behavioural qualitative and observational data, during analysis will occur in order to understand
44 how different types of evidence enhance the overall interpretation of how INTE-AFRICA was
45 implemented, and what the additional health economic and clinical data are, drawing case
46 comparisons across clinics, and across countries, and developing possible explanations for
47 implementation variation. This approach will help to identify factors which are plausibly and/or
48 consistently related to successful or unsuccessful delivery of intervention components. Emerging
49 theories and the relationship of the data to the conceptual literature underpinning the intervention will
50 be discussed and refined at INTE-AFRICA research team meetings throughout the project. The
51 analysis of the observational data will also require knowledge from health professional interviews to
52 compare how reported experience relates to actual implementation of integration at the clinic level.
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Beyond the EPP analysis of triangulated stakeholder narratives, the public understanding of science (PUS) theoretical framework⁶² will guide overall qualitative data collection and analysis during INTE-AFRICA. It will unpack how patients and their communities in Uganda and Tanzania understand and use different knowledge on HIV and NCDs in their lives by understanding how they create meaning from scientific findings relating to NCDs and HIV and if, how, and to what degree they incorporate these findings into their everyday lives. This theoretical framework has the capacity to shift public attitudes by connecting and communicating development of innovative scientific concepts in the medical field (in this instance integration of HIV/NCD services in Tanzania and Uganda) to the non-scientific public, and thereby enhance education, training cascade, health policy and practice, and ultimately public understanding of multi-morbidities and sustainable routes to care. Further, it will create a platform for the sharing of lessons learnt, best practices and context adaptation of the final integrated model of care in other African countries (clinical care policies and practice, staff cascade of training, service user education and community awareness raising).

Conclusion

This paper reports the design and methods for the planned process evaluation of the INTE-AFRICA cluster randomised, controlled trial in selected clinics in Tanzania and Uganda. It provides a unique opportunity to document implementation and collaboratively refine integrated care in two sub-Saharan African countries. The process evaluation protocol adheres to recommendations intended to facilitate the standardisation of process evaluation design and reporting⁵¹. This makes possible the synthesis of results of similar studies elsewhere in the SSA region in future.

Contributorship Statement

All authors contributed to the conceptualisation of the research and contributed to writing the manuscript.

MCVH, MB, JVL, SJ designed the process evaluation protocol.

SJ, MN, SM, JB led the development of the INTE-AFRICA trial.

MCVH drafted the manuscript and all co-authors edited and commented on subsequent drafts. All authors approved the final draft for submission. All authors agree to be accountable for all aspects of the work in ensuring that questions related to the accuracy or integrity of any part of the work are appropriately investigated and resolved.

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6 2019-2023” Programme (CEX2018-000806-S), and from the Government of Catalonia through the
7 CERCA Programme.
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11 12 13 14 **Ethical approval statement**

15 Ethical approval for the evaluation has been granted in 2019 at the Liverpool School of Tropical
16 Medicine (UK), the National Institute of Medical Research (Tanzania) and Medical Research Council
17 (Uganda).
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20 21 22 **Data sharing statement**

23 No additional data available.
24

25 **Competing interests statement**

26 None
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29 30 **Provenance and peer review**

31 Not commissioned; internally peer reviewed.
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34 35 **Open access**

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Table One 'Key data on the country settings'

	Tanzania	Uganda
Income level	Low	Low
Population size	58m (2018)	35m (2016)
Estimated prevalence of hypertension from STEPS survey	26%	26%
Estimated prevalence of diabetes from STEPS survey ⁴⁹ *	5-10%	2-5%
Estimated prevalence of HIV-infection	5.1% (2017)	6.2% (2017)
Doctors density /100,000 population	3 (2014)	0.8 (2005)

* diabetes estimate varies according to age and gender. Data are of variable quality but reference 11 shows that the overall median diabetes prevalence in 12 countries in Africa is 5%.

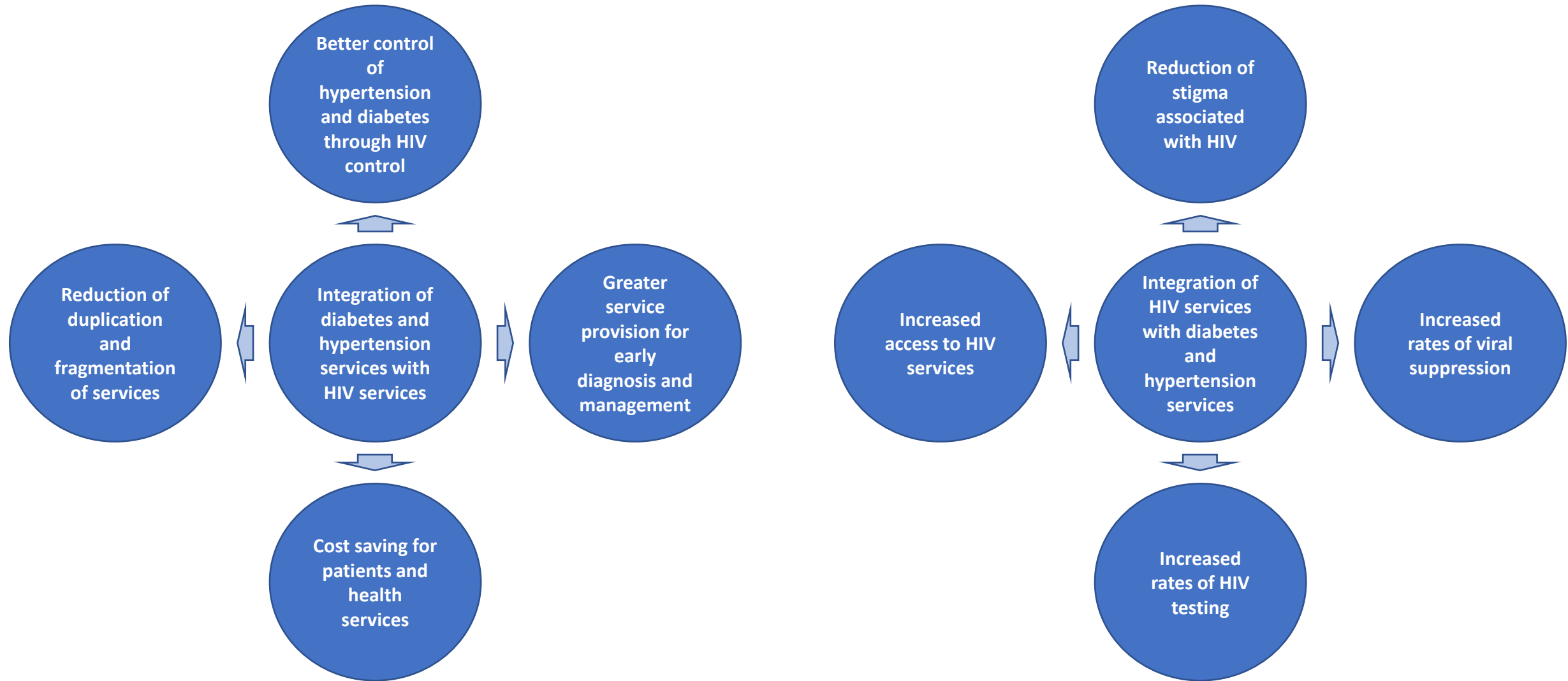
Table Two ‘Logic Model of programme inputs, processes and outcomes’

Intervention inputs	Changes in care processes	Outcomes
Negotiation with national, district and local government health departments, NGOs and funders	Agreement about and support for service model, including reorganisation of clinics and staff Commitment to ensure drug supply	<ul style="list-style-type: none"> • Reorganisation of clinics and staff to implement the model • An effective, quality, and sustainable funded drug supply chain
Negotiating lower drug prices Supporting and monitoring drug ordering in each clinic Providing buffer drug supplies to each clinic	Drugs always in stock	<ul style="list-style-type: none"> • Increased diagnosis of comorbid conditions • Increased retention and adherence • Increased viral suppression, better control of blood pressure and blood glucose
Engagement with and support for clinicians and managers in each clinic	Clinicians and managers enable and support integration, and find solutions to emerging problems	<ul style="list-style-type: none"> • Less AIDS, cardiovascular disease and diabetes complications • Lower patients costs (travel and absence from work)
Provision of integrated service in each clinic (alongside and additional to existing services)	Trial participants attend integrated service Avoid multiple visits for patients with multi-morbidity	<ul style="list-style-type: none"> • Less health service duplication and costs (health service costs might increase if more patients are diagnosed and are more adherent) • Increase patient satisfaction • Increased clinician satisfaction; less burn-out and absenteeism
Training clinicians about integrated clinical management	Better diagnosis and treatment including attention to comorbid conditions	<ul style="list-style-type: none"> • Reduce missed opportunities for improving care and health outcomes
Community engagement	Identify and enlist community organisations and resources to help with health education, tracing defaulters or patients who have difficulty attending clinic	
Providing standardised stationery for integrated medical records; training clinicians to use it	Increased awareness by clinicians and patients about disease severity, comorbidity, adherence and control in individual patients	
Improving monitoring and evaluation based on clinics registers and medical records	Regular data analysis and feedback to staff	Quality assurance and continuous improvement in the quality of care
Identifying effective health education	Improve health education at clinics	Healthier lifestyles Increased adherence

Table Three: 'Process Evaluation Design and data collection framework'

Post Integration * Numbers indicated are per country/. Data Collection at each Site	6 months	12 months	18 months	Contextual level
<i>Observations</i> of consultations, different processes and clinic flow at clinic levels and in non-clinical areas.	1 week	1 week	1 week	Micro context (facility and neighbourhoods)
<i>In depth phenomenological interviews</i> with service users	25	25	25	Micro context (facility and neighbourhoods)
<i>In depth phenomenological interviews</i> with health care providers at the clinic (health facility managers, and health professionals such as physicians, nurses, public health nurses)	10	10	10	Meso context (national to regional/city) Micro context (facility and neighbourhoods)
Semi-structured interviews with Ministerial policy makers and provincial/regional/district level clinical/health senior management (Director for NCD, HIV and curative services).	-	5	5	Macro context (Global) Meso context (national to regional/city)
<i>Semi-structured interviews</i> with NGO and international organisations (for example WHO Country office, UNAIDS, PEPFAR, CDC)	-	5	5	Macro context (Global) Meso context (national to regional/city)
<i>Focus group discussions</i> (FGD) with community leaders (8-12 participants)	1	1	1	Micro context (facility and neighbourhoods)
<i>Focus group discussions</i> (FGD) gender specific with community members(8-12participants)	2	2	2	Micro context (facility and neighbourhoods)
<i>In depth phenomenological interviews</i> with clinical researchers			4	Micro context (facility and neighbourhoods) Meso context (national to regional/city)

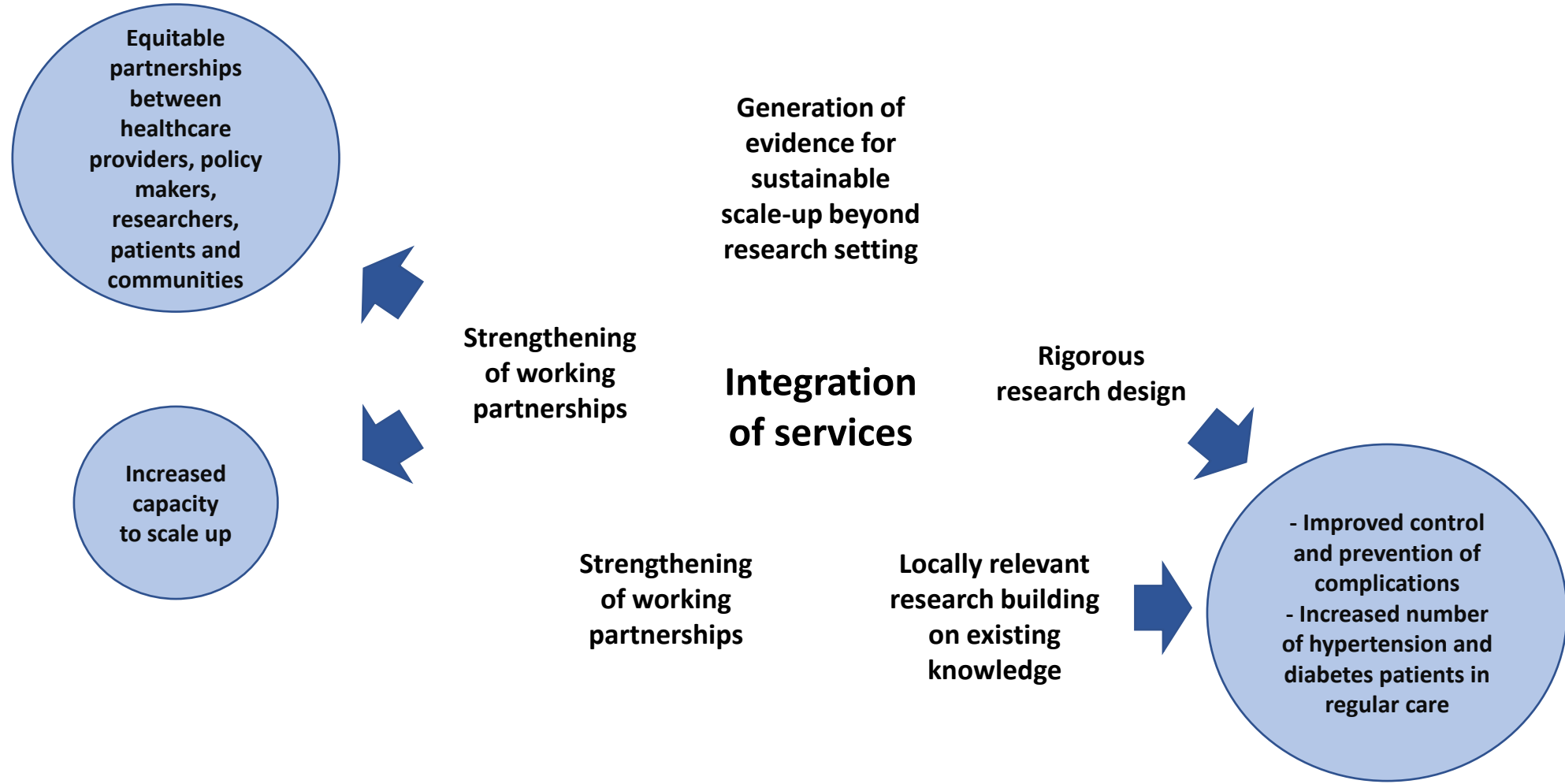
Figure One 'Potential benefits of integrating diabetes, hypertension and HIV services for a) DM and hypertension control, and b) HIV control'



a) Benefits for hypertension and diabetes control

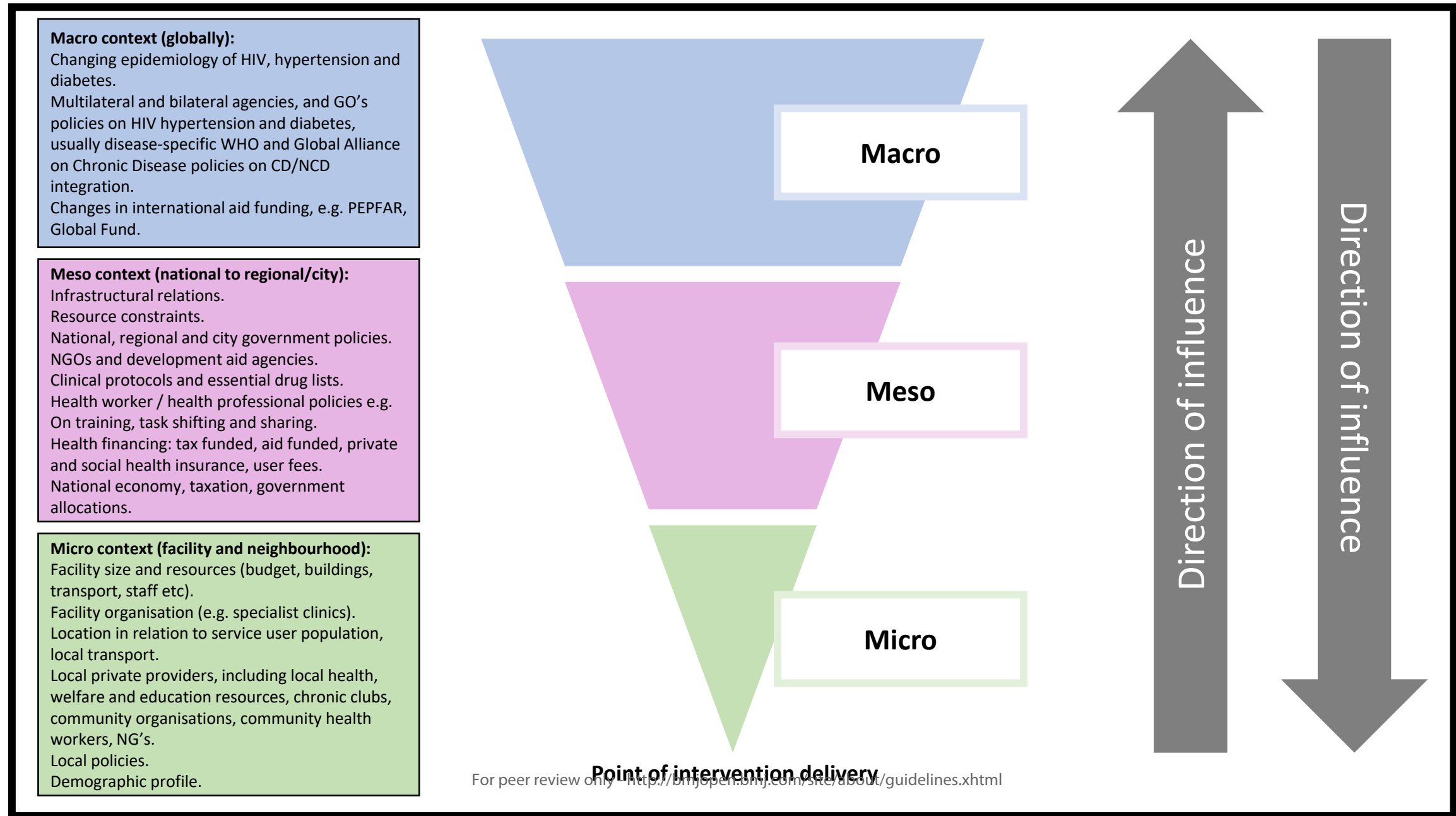
b) Benefits for HIV-control

Figure Two 'INTEAFRICA Conceptual Model'



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Figure Three 'Potential contextual influences on INTEAFRICA programme implementation cascade'



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Strengthening integration of chronic care in Africa: protocol for the qualitative process evaluation of integrated HIV, diabetes and hypertension care in a cluster randomised controlled trial in Uganda and Tanzania.

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Title

Strengthening integration of chronic care in Africa: protocol for the qualitative process evaluation of integrated HIV, diabetes and hypertension care in a cluster randomised controlled trial in Uganda and Tanzania

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Abstract

Introduction In sub-Saharan Africa (SSA), the burden of non-communicable diseases (NCDs), particularly diabetes mellitus (DM) and hypertension, has increased rapidly in recent years, although HIV infections remain a leading cause of death among young-middle aged adults. Health service coverage for NCDs remains very low in contrast to HIV, despite the increasing prevalence of co-morbidity of NCDs with HIV. There is an urgent need to expand healthcare capacity to provide integrated services to address these chronic conditions.

Methods and Analysis: This protocol describes procedures for a qualitative process evaluation of the INTE-AFRICA, a cluster-randomised trial comparing integrated health service provision for HIV-infection, DM, and hypertension, to the current stand-alone vertical care. Interviews, focus group discussions, and observations of consultations and other care processes in two clinics (Tanzania, Uganda) will be used to explore the experiences of stakeholders. These stakeholders will include health service users, policymakers, healthcare providers, community leaders and members, researchers, non-governmental (NGO) and international organisations. The exploration will be carried out during the implementation of the project, alongside an understanding of the impact of broader structural and contextual factors.

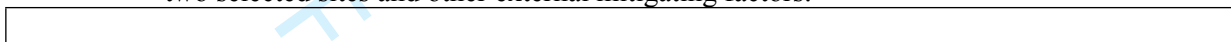
Ethics and Dissemination: Ethical approval has been granted by Liverpool School of Tropical Medicine (UK), the National Institute of Medical Research (Tanzania) and TASO Research Ethics Committee (Uganda). The evaluation will provide the opportunity to document the implementation of integration over several time points (six, 12 and 18 months) and refine integrated service provision prior to scale-up. This synergistic approach to evaluate, understand and respond will support service integration and inform monitoring, policy and practice development efforts to involve and educate communities in Uganda and Tanzania. It will create a model of care and a platform of best practices and lessons learnt for other countries implementing integrated and decentralised community health services.

Key Words

Health service delivery, Non communicable disease, HIV, integration, task-shifting, sub-Saharan Africa

Article Summary: Strengths and Limitations of this study

- The INTE-AFRICA trial will implement integration of HIV/NCD services in Tanzania and Uganda in response to an urgent need to respond to increased burden of NCDs, and expand capacity of healthcare systems to manage co-morbidity.
- The INTE-AFRICA trial is based on a partnership between African and European researchers, working closely with policy makers and other stakeholders.
- The process evaluation of INTE-AFRICA uses qualitative and observational methods at two facilities to explore and document stakeholder experiences of integration of services, alongside an understanding of the impact of broader structural and contextual factors.
- The process evaluation works in tandem with quantitative evaluation of clinical efficacy and cost effectiveness of the INTE-AFRICA trial.
- Limitations of the process evaluation may centre on patient drop out, characteristics of the two selected sites and other external mitigating factors.



BACKGROUND

Non-communicable diseases (NCDs) have risen rapidly in Africa, alongside a continuing high burden of HIV-infection. In the sub-Saharan Africa (SSA) region, HIV/AIDS remains a major cause of morbidity and mortality among young-middle aged adults, but the region is also experiencing a rapidly rising burden of NCDs (particularly DM and hypertension), giving rise to a dual HIV-NCD epidemic.¹⁻³ While lifestyle changes associated with urbanisation and globalization (such as eating habits and lack of physical exercise) underpin the ongoing demographic and epidemiologic transition toward increasing NCDs, these changes also affect chronic conditions (such as HIV).¹⁻³ The number of people in regular HIV care is rising⁴, alongside the rate of NCDs in the SSA region, with hypertension representing the single largest risk factor for death, and DM which has seen a massive increase in prevalence in a short period of time.^{2 5-7} Patient populations in SSA are increasingly demonstrating younger age of onset of NCDs, with co-morbidity of NCDs with HIV, and the impact of NCDs is particularly severe in populations affected by poverty.^{3 8-11}

Since 2003, significant global investment and development partner engagement has facilitated the establishment of HIV screening and treatment programmes as the first large-scale chronic disease initiatives in Africa. Health services for HIV are stand-alone and vertically delivered. They have also been combined with decentralisation and task-shifting, which has enabled primary health centres to treat large numbers of patients. Non-clinically qualified health workers play a major role in supporting patients on HIV treatment, with almost 70% of people living with HIV-infection in regular care. In contrast, health service coverage for NCDs remains very low.^{2 12} Coordinated national NCD control and care programmes are relatively new with significant gaps in funding and operational evidence for program implementation.^{11 13} For example, only about 5-10% of persons with DM are thought to be in regular diabetes care, and the figure is likely to be similar for persons with hypertension.^{2 8 11} Furthermore, those in care experience insufficient health service provision for the diagnosis and management of DM and hypertension (medicines supply is patchy).^{2 12 14-17} HIV populations at risk of developing NCDs, and presenting with co/multi-morbidities could potentially impact on the gains from the achieved scale-up of HIV care services.¹⁸

Hence, there is an urgent need to expand the capacity of healthcare systems in the SSA region to provide services for NCDs, either alongside, or integrated, with HIV.¹⁹ As chronic conditions, DM, hypertension and HIV-infection require lifelong care. Key challenges to chronic care in SSA are linkage and retention in care, access and medicines adherence.^{20 21} As such, the infrastructure and lessons learnt from the HIV chronic disease model can serve as important resources for the expansion of NCD prevention, care and treatment. HIV chronic care management pathways, resources and infrastructure can be leveraged to integrate with newly developing NCD services, ultimately to strengthen the platform for NCD services and improve health outcomes for people with NCDs.²²⁻²⁴

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3 Health systems have the developed experience managing HIV as a chronic disease, including linking
4 and retaining patients in care and supporting treatment adherence in drugs, diagnostics procurement
5 and other key health systems indicators.^{21 25-27} Integration can reduce duplication and fragmentation,
6 streamline services by treat those with co/multi-morbidities, and potentially offer patient benefits
7 relating to time and cost. See **Figure One**. It could however also threaten service capacity by
8 resulting in increased service demand and loss of clinical focus on one disease.
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14 Insert **Figure One ‘Potential benefits of integrating diabetes, hypertension and HIV services for**
15 **a) DM and hypertension control, and b HIV control’** about here
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19 Despite the increase in academic and clinical interest in HIV/NCD integration in SSA,^{9 26 28-33} little
20 evidence about integration in terms of both scope and generalizability exists. Extant evidence is
21 limited to small scale feasibility studies in largely different contexts³⁴⁻⁴⁰, despite suggesting that
22 integrated care is an efficient use of resources compared to the standard of care and beneficial for
23 patients’ NCD and HIV clinical outcomes.^{28 30 32} There is a lack of large scale or randomized and/or
24 controlled evaluations and context-specific clinical, cost effectiveness and process outcomes data
25 constrains policymaking and development of integrated care models, which could strengthen health
26 systems when tailored to the distinct needs of each specific SSA country.^{19 21 37} Such evidence is
27 paramount to inform policy, government resource prioritisation, and to develop integrated care
28 models which strengthen health systems best suited to the needs of that specific SSA country. The
29 INTE-AFRICA trial is conducted to respond to the insufficient existing evidence to substantiate the
30 benefits and sustainability of integrated care as well as implementation of such programmes in the
31 SSA setting. We present here the qualitative process evaluation protocol designed to evaluate INTE-
32 AFRICA, a European Commission Horizon 2020 funded implementation research project (protocol
33 number 19-100) operating in Uganda and Tanzania.
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44 ***The INTE-AFRICA Trial***

45 INTE-AFRICA aims to implement and assess the effectiveness of integration of HIV, DM and
46 hypertension services at the point of service delivery covering many health facilities where common
47 approaches to clinical decision-making, drug procurement and human resource management occur.
48 The project will generate the research evidence needed by health services in Africa, to scale-up and
49 sustain chronic disease management and services in an integrated manner. We are also interested to
50 observe changing dynamics pertaining to stigma and discrimination associated with HIV.⁴¹
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57 Tanzania and Uganda were specifically chosen by INTE-AFRICA as they are low-income countries
58 and their public and private health facilities are strongly committed to providing services for NCD.
59 However, their health systems struggle to scale-up provision for diabetes and hypertension in the face
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3 of competing health demands, including HIV-infection. See **Table One**. Tanzania and Uganda also
4 share relevant characteristics with other countries in SSA. As such, the process evaluation has the
5 potential to enhance the generalisability of integrated care to other similar settings by providing
6 understanding of the determinants and mechanisms of the implementation process.
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11 Insert **Table One ‘Key data on the country settings’** about here
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14 Our programme is underpinned by a participatory, multi-actor approach which supports dialogue and
15 knowledge exchange, fosters mutual understanding and provides input in policy agendas around
16 diagnosis and treatment of DM, hypertension and HIV in an integrated clinic. The INTE-AFRICA
17 conceptual framework is illustrated in **Figure Two**.
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22 Insert **Figure Two ‘INTEAFRICA Conceptual Model’** about here
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25 INTE-AFRICA will test integrated health services at primary care centres for HIV-infection, diabetes
26 and hypertension, by providing a “*One stop*” integrated care clinic for these conditions (the
27 intervention). We will conduct a pragmatic parallel arm cluster-randomised trial: 32 largely urban
28 health facilities offering primary care services in the two countries will be randomised, with 16
29 facilities allocated to deliver the intervention immediately (intervention arm), and 16 facilities to
30 continue with usual care (control arm). At each selected facility, cohorts of approximately 220
31 patients; 110 HIV infected and 110 NCD patients, will be enrolled to evaluate the primary research
32 outcomes.
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39 The primary care facilities will initiate and stabilise patients on treatment, manage complications
40 (including referral to higher facilities) and conduct clinical and laboratory monitoring of patients for
41 all three conditions. Specific characteristics of integrated care in each ‘*One stop*’ integrated care clinic
42 are: concurrent management of HIV, hypertension and DM in the same facility; management of
43 patients with HIV, hypertension and DM by the same clinician or team of clinicians (nurses,
44 counsellors other staff); integrated training of clinicians; single waiting area and queue; integrated
45 health education about all three conditions; one pharmacy with a single drug dispensing point; similar
46 testing, and cross-testing, for diagnosis and monitoring with the requisition of laboratory tests in the
47 same place; and similar format of paper medical records for each condition kept in the same patient
48 folder.
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57 Patients who decline to participate in the research and trial participants in control arm clinics will
58 continue to receive standard vertical health care delivery. Inclusion criteria for participation are: being
59 over 18 years old; having confirmed HIV-infection, DM or hypertension; living within the catchment
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3 population of the health facility; likely to remain in the catchment population for six months and
4 willing to provide written informed consent. Very ill patients requiring in-patient care will be
5 excluded. The research team will observe participants during clinic visits with additional reviews at
6 six and 12 months. Further details are provided in the full INTE-AFRICA trial protocol.
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10 11 ***Qualitative Process Evaluation of the INTE AFRICA trial***

12 The aim of the process evaluation of INTE-AFRICA is to explore the experiences, attitudes and
13 practices of a wide variety of stakeholders during the process of programme implementation and to
14 develop an understanding of the impact of broader structural and contextual factors on the
15 implementation process of service integration. Process evaluations typically evaluate how and
16 whether interventions are delivered as intended and whether such implementation is congruent with
17 the theory underpinning the intervention.^{25 42-44} Updated Medical Research Council (MRC) guidance
18 for evaluation of complex health interventions has recently recognised the value of process evaluation
19 within trials stating, “*it can be used to assess fidelity and quality of implementation, clarify causal*
20 *mechanisms and identify contextual factors associated with variation in outcomes.*”²⁵ Hence, the
21 process evaluation in INTE-AFRICA is particularly focused on context, description of the
22 intervention and its causal assumptions, implementation, mechanisms of impact and outcomes.²⁵
23 Further we evaluate the extent to which resources and activities supporting the intervention function
24 to deliver intended outputs, with subsequent improvements in outcomes.
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34 A central focus lies in identifying contextually relevant strategies for successful implementation of
35 service integration, and practical difficulties in adoption, delivery and maintenance to inform wider
36 implementation.⁴⁵ We recognise that outcomes (e.g. knowledge gained) of INTE-AFRICA are
37 dependent on understanding cultures and contexts of the stakeholders (i.e. patients, healthcare
38 providers, policy makers, community leaders/members, non-governmental organisations (NGO),
39 international organisations, and clinical researchers) involved and those surrounding service design
40 and delivery as well as care seeking practices.
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47 The role of social and behavioural science approaches to understanding individual experience, and the
48 role of such contextual dynamics is central to this process evaluation. It aims to enhance
49 understanding of issues related to the NCD and HIV agendas and service delivery approaches from all
50 perspectives and stakeholders along the integration process. INTE-AFRICA will utilise a broad social
51 behavioural approach to support community engagement in research in Uganda and Tanzania, going
52 beyond clinical trial recruitment and retention to improve NCD/ HIV literacy. Behavioural and social
53 science research strategies⁴⁶ will allow NCD and HIV related research to place the needs and
54 perspectives of people living with NCD and/or HIV at the centre of the progression of clinical studies,
55 such as INTE-AFRICA, and investigate participant motivations and decision-making processes
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3 related to preferences for or participation in different types of integrated and decentralised services.
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6 ***Theoretical Framework: Bronfenbrenner's ecological model of behaviour*** 7

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9 Process evaluation design, like healthcare interventions, requires a theoretical framework to structure
10 the qualitative and observational evaluation across sites. The chosen theoretical framework is
11 Bronfenbrenner's ecological model of behaviour^{47 48} used to conceptualise integrated care as events
12 that disrupt complex social systems⁴⁹ operating across multiple contextual levels. We are interested in
13 better understanding the importance of context, which becomes especially relevant when comparing
14 Tanzania and Uganda. For example, healthcare coverage and charging dynamics between countries
15 and between HIV as opposed to NCD care differs. In Tanzania, whilst HIV services and drugs for
16 HIV are free, patients are required to pay a direct user fee (unless elderly or very poor) or use their
17 health insurance to pay for NCD drugs. Currently there is a strategy to progress to single health
18 insurance to support universal health coverage in Tanzania. In Uganda, HIV services are also free to
19 all (public and private not for profit health facilities) and HIV drugs are always in stock. However, in
20 Uganda whilst NCD services are free in public facilities, stockouts of laboratory reagents and NCD
21 drugs are frequent, and patients have to pay a direct user fee to access them. There is also no national
22 insurance scheme in Uganda, only private insurance which is relatively expensive and optional.
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31 Using the Bronfenbrenner theoretical framework, contextual factors are evaluated at the ***macro***
32 (universal vs partial coverage; free primary healthcare and drugs, affordability and users fees; fiscal
33 policy, financial aspects at government level, funding barriers for chronic care management and
34 barriers to government scale-up of service integration); ***meso*** (HIV/NCD drug ordering, drug delivery
35 systems and continuity of supply, health care provider education and employment, community
36 understanding and perspectives on multi-morbidity); and ***micro*** (clinic and pharmacy level
37 management, resources, patient/service user experience) levels. See **Figure Three**. These contextual
38 factors, likely to influence implementation of integration and their effects, will be investigated to
39 capture variation in adoption, delivery and maintenance outcomes as well as responses to the
40 intervention. This will affect both reach and fidelity, which are hypothesised to be important factors in
41 outcome differences.
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51 Insert **Figure Three 'Potential contextual influences on INTE AFRICA programme**
52 **implementation cascade'** about here
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56 To situate INTE-AFRICA within the Bronfenbrenner theoretical framework, we will develop a logic
57 model. This model will set out contextual determinants of HIV and NCD care management in SSA
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3 and assess how integrated care components function to address these determinants to improve
4 outcomes in the management and support of patients. See **Table Two**.
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8 Insert **Table Two ‘Logic Model of programme inputs, processes and outcomes’** about here
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11 **METHODS**

12 ***Study Setting***

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14 This will be a cohort study taking place in one “*One stop*” integrated care clinic per country. In
15 Tanzania, the selected site is *Temeke Regional Referral Hospital* in Dar Es Salaam, a public tertiary
16 health facility, with 465 staff, and serving a population of over 1 million. In Uganda, the selected site
17 is the *Kasangati Health Centre IV*, Kasangati, a public district health facility located in the Wakiso
18 District serving a population of over 2 million. Both provide a range of services to the community
19 (primary care, HIV/AIDs, NCDs, surgical, maternal and child health, health education, dental and
20 pharmacy).
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26 ***Study Design***

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28 This protocol describes procedures for a qualitative process evaluation of the INTE-AFRICA
29 pragmatic parallel arm cluster-randomised trial comparing integrated health service provision for
30 HIV-infection, DM and hypertension with the current standard vertical care delivery model. The
31 process evaluation works in tandem with the collection of selected clinical outcomes (e.g. clinical
32 efficacy of different treatments) and health economic data (e.g. costs and benefits of different
33 approaches) to estimate the potential benefits to patients and health services at clinic and country level
34 (protocol reported elsewhere).
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41 ***Patient and Public Involvement***

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43 Patient and public involvement (PPI) throughout a programme of research enhances research quality
44 and relevance by providing different perspectives and a sense of ownership. This protocol will adhere
45 to the same principles, and will allow the voice of ‘*service users*’ and those affected to be heard, and
46 utilised. Key stakeholders such as patients as service users and their families will be fully involved in
47 guiding the research, acting as research participants, and in implementation of change in health
48 service delivery and integrated care planning. All aspects of the process evaluation are underpinned
49 by participatory action health research and its success and usefulness will be grounded in PPI,
50 participation and engagement in the form of patient/professional identification of research priorities,
51 collaborations and partnerships, expert steering, community participation around health needs and
52 optimal integrated services, awareness raising activities, development of print materials, toolkits and
53 training for healthcare professionals.
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3 It will use three qualitative research techniques: in-depth interviews with stakeholders (patients,
4 healthcare provider, policy maker, non-governmental organisation (NGO)/international organisation,
5 and clinical researcher); focus group discussions (FGD) with community leaders and community
6 members; and clinic-based observations in one site per country. This design permits an assessment of
7 the fidelity of INTE-AFRICA's implementation, a detailed description of the processes, relationships,
8 and contexts involved in the delivery of integrated care, and the identification of factors attributing to
9 the failure or success of the programme. It thus addresses the 'black box' problem in interpreting trial
10 results by improving understanding of the mechanisms that connect particular intervention
11 components to particular outcomes.⁵⁰ The chosen approach will enhance social construction and
12 acceptability of chosen decentralised integrated approaches, link outcomes to policy and advocacy
13 and impact sustainability of HIV, DM and hypertension chronic disease service integration in two
14 LMIC countries. It provides the opportunity to document and refine INTE-AFRICA activities prior to
15 a larger pragmatic trial or scale-up by Uganda and Tanzanian governments. These synergistic
16 approaches to evaluate, understand and respond will support integration, support affordability, address
17 barriers to government scale up and funding barriers for chronic care, inform surveillance, policy and
18 practice development and improve efforts to involve and educate communities in Uganda and
19 Tanzania. It will create a model and a platform of best practices and lessons learnt for other countries
20 implementing integrated and decentralised community health services for HIV and chronic disease.
21 The process evaluation methods for each objective are described in **Table Three**, including how each
22 method maps onto the three different contextual levels.
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36 Insert **Table Three: 'Process Evaluation Design and data collection framework'** about here.
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39 ***Study Population and Recruitment***

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41 25 patients and 10 health care providers in *Temeke Regional Referral Hospital* in Dar Es Salaam,
42 Tanzania and *Kasangati Health Centre IV*, Kasangati, Uganda will be purposely selected and invited;
43 at six, 12 and 18 months after the start of the trial, to reflect retrospectively on their experience of
44 integration. Health care providers include the hospital/health centre overall in charge and pharmacist,
45 and the 'One stop' medical officers in-charge, trained clinicians managing HIV, diabetes and
46 hypertension patients, pharmacist, laboratory technician, counsellors or nurses providing health
47 education and counselling, and nurses in the registration desk who are also responsible in taking vital
48 signs from patients. We will also collect qualitative data from interviews with Ministerial policy
49 makers and provincial/regional/district level clinical/health senior management (directors for NCD,
50 HIV and curative services); NGO and international organisations (for example WHO Country office,
51 UNAIDS, PEPFAR, CDC) and clinical researchers; and conduct FGD with community leaders and
52 community members. These numbers are expected to reach saturation (i.e. the point that further
53 information does not provide any additional variation in observed themes). We may replace
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3 participants, for example patients if there is significant loss to follow up or refusal for repeated
4 interviews. For instance, if a participant drops out at 12 months, we still have their six-month
5 experience documented, and we can replace with a new participant, invited to reflect on their 12-
6 month retrospective experience. Where possible we will gender match interviewers with participants
7 (particularly patients). Participants (patients, healthcare providers and others) will not be directly
8 compensated but rather they will be compensated for incurred transport costs to attend the
9 interview/FGD, and provided with refreshments during the interview/FGD.
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15 The following recruitment procedures will take place at each 'One stop' integrated care clinic;

- 16 • Observations will be made in the integrated clinic in consultation with the hospital/health
17 centre and 'One stop' clinic in-charges.
- 18 • Recruitment of patients will be supported by clinic nurses who will identify and approach
19 selected participants who have a minimum of six months experience of integration, and will
20 be asked to consent to partake in an in-depth interview on the day they attend the clinic.
21 INTE-AFRICA researchers will purposively sample women and men of different ages and
22 explore any age/gender and condition ((HIV/hypertensive/DM/multi/co-morbid) related
23 differences.
- 24 • *Health care providers* at the integrated clinic will be approached to participate in an in-depth
25 interview on the day the INTE-AFRICA team are scheduled to attend.
- 26 • *Ministerial policy makers and provincial/regional/district level clinical/health senior
27 management* will be identified and requested to participate in a semi-structured interview
28 (face to face, online using Zoom or telephone).
- 29 • *NGO and international organisations* will be identified and requested to participate in a
30 semi-structured interview (face to face or telephone).
- 31 • *Community leaders* will be identified in the clinic catchment areas by virtue of their position
32 while *community members* will be identified in consultation with the community leaders and
33 invited to participate in the FGDs.
- 34 • *Clinical researchers* will be invited to participate in an in depth interview at the 24 month end
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51 **Data collection**

52 We will use the Empirical Phenomenological Psychological (EPP) five-step method,⁵¹ which
53 combines psychological, interpretative and idiographic components, to collect data. The data will
54 garner an understanding of the complex social processes, of social, aged, gendered and
55 culturally/community specific meanings and broaden the incremental understanding of the distinct
56 lived experience of policy makers, patients, health care providers, researchers and communities. We
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3 will balance the description of phenomena with the interpretation of insights and are cognisant of
4 participant experiential phenomena and authors' interpretation of associated meanings. It will yield an
5 in-depth socio-cultural understanding of patient /participant reported outcomes, their motivations,
6 preferences, beliefs, expectations, identities, hopes and views on conditions, related stigma and of
7 decision-making processes. This will provide better understanding of stakeholder and community
8 positioning during integration. This understanding will inform policy and practice, ensure effective
9 patient/service user education, position service users and their families to understand these conditions
10 and interpret study outcomes and facilitate future HIV and chronic disease clinical studies.
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17 Both descriptive patient level data and rich socio-behavioural qualitative/observational data will be
18 collected by a team of trained researchers in Tanzania and Uganda. Data collection will entail
19 exploring the experiences, attitudes and practices of a wide variety of stakeholders during the process
20 of INTE-AFRICA programme implementation and will develop an understanding of the impact of
21 broader structural and contextual factors on the implementation process.^{10 45}We will collect data on
22 social behavioural and cultural aspects impacting implementation (e.g. individual and community
23 health risks, protective behaviours and health responses) within the broader social and political
24 frameworks (government resources and barriers to sustaining integration), the practicalities of
25 accessing, providing and sustaining integrated services (e.g. staff time, resources, equity of access,
26 supply chain dynamics and pharmacy components pertaining to drug types, drug/reagent availability
27 and costs for integrated patients, catchment area/populations, quality of care, waiting room dynamics,
28 record keeping and retention across multi/co-morbidities, training gaps); and process indicators (e.g.
29 perceived stigma, acceptability of vertical versus integrated service designs, lay knowledge and
30 awareness, the dynamics of public versus private sector integration (where relevant to the participant),
31 and bottlenecks to accessing services). We will also describe implementation of the intervention in
32 terms of fidelity to the intended model of care, adaptations to the intervention during implementation,
33 and dose and reach of intervention components actually delivered and received (such as numbers and
34 proportions of eligible staff who received integrated care training, numbers of proportions of patient
35 participants who received all or most of their care from integrated services, and frequency of drug
36 stock-outs). The latter data will be complemented by routinely collected quantitative data such as
37 training attendance and medical records. We will document changes in healthcare provider roles,
38 attitudes and patient relationships.
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54 Interviews with patients/service users, healthcare provider and policymaker/senior manager, will
55 include specific questions about their experience and management of individuals with multi-morbid
56 HIV, hypertension and/or diabetes. These include their perceptions of INTE-AFRICA; impacts of
57 INTE-AFRICA on the provision of integrated HIV/AIDS care and NCD care, and relationships with
58 NGO and international organisations; changes in health provider roles, attitudes, and patient
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relationships; impacts of the INTE-AFRICA implementation context on trial and health economic cost outcomes; impacts of the INTE-AFRICA intervention on an integrated health systems approach to care (medicine supplies, record keeping, service user education, clinical care pathways, data management, staff training); and barriers to and facilitators of change and future sustainability of integrated care provision. We will assume a more pragmatic approach when garnering perspectives from higher level stakeholders involved in health policy and practice generation, and NGO and international organisations (e.g. WHO Country offices, UNAIDS, PEPFAR, CDC) providing peripheral supports and guidance. We are especially interested in better understanding the complexities around government scale up and resource allocation for chronic care (for example decentralisation, financial planning, identification of potential funding sources at ministry levels, subsidised NCD drugs, and by international donors (CDC, PEPFAR, UNAIDS). See **Table Three**.

Data analysis and synthesis

The analysis of qualitative data will be iterative, moving between data collection and analysis to test emerging theories. Field notes of observations will be analysed thematically to provide a description of the process and content involved in adapting and delivering the intervention. Audio recordings of interviews and FGDs will be transcribed verbatim by competent and experienced social scientists, with a subsample transcribed using conversation analytic conventions. Translation from local languages (e.g. Swahili, Luganda) into English will be performed for easy sharing with the study partners. Translation will occur using a back translation method for consistency. An electronic data management package (e.g. NVivo) will be used to manage the qualitative data analysis at the respective country levels. The analysis of the observational data will require knowledge obtained from health professional interviews at different levels to compare how reported experience, and different accounts of patient and professional perspectives relate to actual implementation of INTE-AFRICA scenarios: i) when DM and hypertension services are integrated with HIV-infection services; and ii) comparing countries. Care will be taken to identify and follow up deviant cases which do not fit into emerging theories. Reliability and validity of the analysis is optimised through iterative data collection, the use of a multi-method design incorporating interviews, FGD and observations and the ongoing discussion of findings within the research team for scrutiny and feedback.^{52 53}

The chosen phenomenological approach (EPP) to collecting and analysing data, usually used in psychological research, reveals the structures of subjective experience and meaning of a lived phenomenon (in first person point of view). It follows to some extent Husserl's principle of active efforts to "bracket out" the researchers' theoretical pre-understanding in the first steps of a text analysis.⁵¹ The "bracketing", however, does not exclude an empathetic, psychological focus in the analysis on the experiences of the researched phenomenon as it is lived by the informant and what it means is to her or him. In the context of INTE-AFRICA, researchers in both countries will strive to

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3 get an empathetic understanding of the text, and hence do not apply their professional prior
4 knowledge about integration. The analysis of the observational data will also require knowledge from
5 health professional interviews to compare how reported experience relates to actual implementation of
6 integration at the clinic level.
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11 We will conduct a stepwise EPP analysis in five steps. *First*, the text will be read several times to get
12 a good grasp of how the informant spoke about the researched phenomenon of integration. In this
13 step, theoretical reflection will be withheld. *Second*, the whole text will be divided into meaning units
14 of a whole paragraph or a single word. *Third*, the informant's personal language will be transformed,
15 unit-by-unit, to the researchers' language. The researchers will discuss the transcription unit by unit.
16 When different interpretations occur, the researchers will return to the interview text and discuss in a
17 free, imaginative process until agreement can be reached through negotiated consensus. *Fourth*, the
18 text will be screened in a search for comprehensive themes. The text will be interpreted with
19 connection to the researchers' theoretical knowledge in an interchange between the original data, the
20 transformed units and the researchers' theoretical pre-understanding about integration. The meaning
21 units will be assorted into appropriate themes and thus constitute a general structure of the
22 phenomenon of integrated care. *Fifth*, this essential structure will penetrate all the revealed themes
23 and thus the meaning of the researched phenomenon of integrated care to the informant.
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33 *Credibility and transferability*

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35 The process evaluation protocol adheres to recommendations intended to facilitate the standardisation
36 of process evaluation design and reporting⁴³. It provides a unique opportunity to document
37 implementation and collaboratively refine integrated care in two sub-Saharan African countries. This
38 makes possible the synthesis of results of similar studies elsewhere in the SSA region in future. In
39 order to ensure credibility, whilst we utilise different methods of data collection
40 (qualitative/observational), and operate concurrently with clinical outcomes data and health
41 economics analysis, we will also add a further layer of triangulation of sources in terms of
42 perspectives across stakeholders and across conditions (HIV/hypertension/DM/multi/co-morbidity)
43 when raising the abstraction level. Triangulation of socio-behavioural qualitative and observational
44 data during analysis will occur in order to understand how different types of evidence enhance the
45 overall interpretation of how INTE-AFRICA was implemented, and what the additional health
46 economic and clinical data are, drawing case comparisons across clinics, and across countries, and
47 developing possible explanations for implementation variation. The data, when combined and
48 triangulated across these multi stakeholder perspectives, will provide a '*thick description*', of how the
49 intervention was delivered, maintained and experienced by stakeholders.^{10 45} It will also offer
50 explanations for observed variation over time and between countries, and detailed insight into the
51 interaction between different contextual features and components of integration of NCD or HIV/NCD
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3 services. It will also facilitate triangulation of information across stakeholders, clinics and countries.
4 We envisage returning to these two clinics in the future, four years and six years after integration, to
5 achieve a deeper understanding of processes and patient and provider experiences. This approach will
6 help to support transferability to other settings, by identifying factors which are plausibly and/or
7 consistently related to successful or unsuccessful delivery of intervention components.
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12 Emerging theories and the relationship of the data to the conceptual literature underpinning the
13 intervention will be discussed and refined at INTE-AFRICA research team meetings throughout the
14 project. We envisage utilising the public understanding of science theory ⁵⁴ to unpack how patients
15 and their communities in Uganda and Tanzania understand and use different knowledge on HIV and
16 NCDs in their lives. This could be facilitated by understanding how they create meaning from
17 scientific findings relating to NCDs and HIV and if, how, and to what degree they incorporate these
18 findings into their everyday lives. This theory has the capacity to shift public attitudes by connecting
19 and communicating the development of innovative scientific concepts in the medical field (in this
20 instance integration of HIV/NCD services in Tanzania and Uganda) to the non-scientific public, and
21 thereby enhance education, training cascade, health policy and practice, and ultimately public
22 understanding of multi-morbidities and sustainable routes to care. Further, it will create a platform for
23 the sharing of lessons learnt, best practices and context adaptation of the final integrated model of care
24 in other African countries (clinical care policies and practice, staff cascade of training, service user
25 education and community awareness raising).
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36 ***Ethical considerations***

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38 Ethical approval for the evaluation has been granted by the research ethics committees of the
39 Liverpool School of Tropical Medicine (UK), the National Institute of Medical Research (Tanzania)
40 and TASO Research Ethics Committee (Uganda). The key ethical principles of voluntary and
41 informed participation, confidentiality and safety of participants will be used in all researcher and
42 participant interactions. Written consent for interviews and observations will be obtained from all
43 participants. All participants will be provided with written information about the research, this will be
44 explained verbally, and informed that their participation is voluntary and that they may withdraw from
45 participation at any time. Safety and confidentiality of all data will be ensured by: (1) encrypting all
46 transcriptions with a password protected code; (2) storing all data in a secure, encrypted database
47 accessible only to authorised persons on the research team; (3) de-linking all personal information of
48 participants from the data collected and stored. Each participant will have a unique identification
49 number.
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Contributorship Statement

All authors contributed to the conceptualisation of the research and contributed to writing the manuscript.

MCVH, MB, JVL, SJ, ES, DB, CP, JO designed the process evaluation protocol.

SJ, MN, SM, JB led the development of the INTE-AFRICA trial.

MCVH drafted the manuscript and all co-authors edited and commented on subsequent drafts. All authors approved the final draft for submission. All authors agree to be accountable for all aspects of the work in ensuring that questions related to the accuracy or integrity of any part of the work are appropriately investigated and resolved.

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Ethical approval statement

Ethical approval for the evaluation has been granted in 2019 at the Liverpool School of Tropical Medicine (UK), the National Institute of Medical Research (Tanzania) and TASO Research Ethics Committee (Uganda).

Data sharing statement

No additional data available.

Competing interests statement

None

Provenance and peer review

Not commissioned; internally peer reviewed.

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For peer review only

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Table One 'Key data on the country settings'

	Tanzania	Uganda
Income level	Low	Low
Population size	58m (2018)	35m (2016)
Estimated prevalence of hypertension from STEPS survey	26%	26%
Estimated prevalence of diabetes from STEPS survey ¹⁵ *	5-10%	2-5%
Estimated prevalence of HIV-infection	5.1% (2017)	6.2% (2017)
Doctors density /100,000 population	3 (2014)	0.8 (2005)

* diabetes estimate varies according to age and gender. Data are of variable quality but reference 11 shows that the overall median diabetes prevalence in 12 countries in Africa is 5%.

Table Two ‘Logic Model of programme inputs, processes and outcomes’

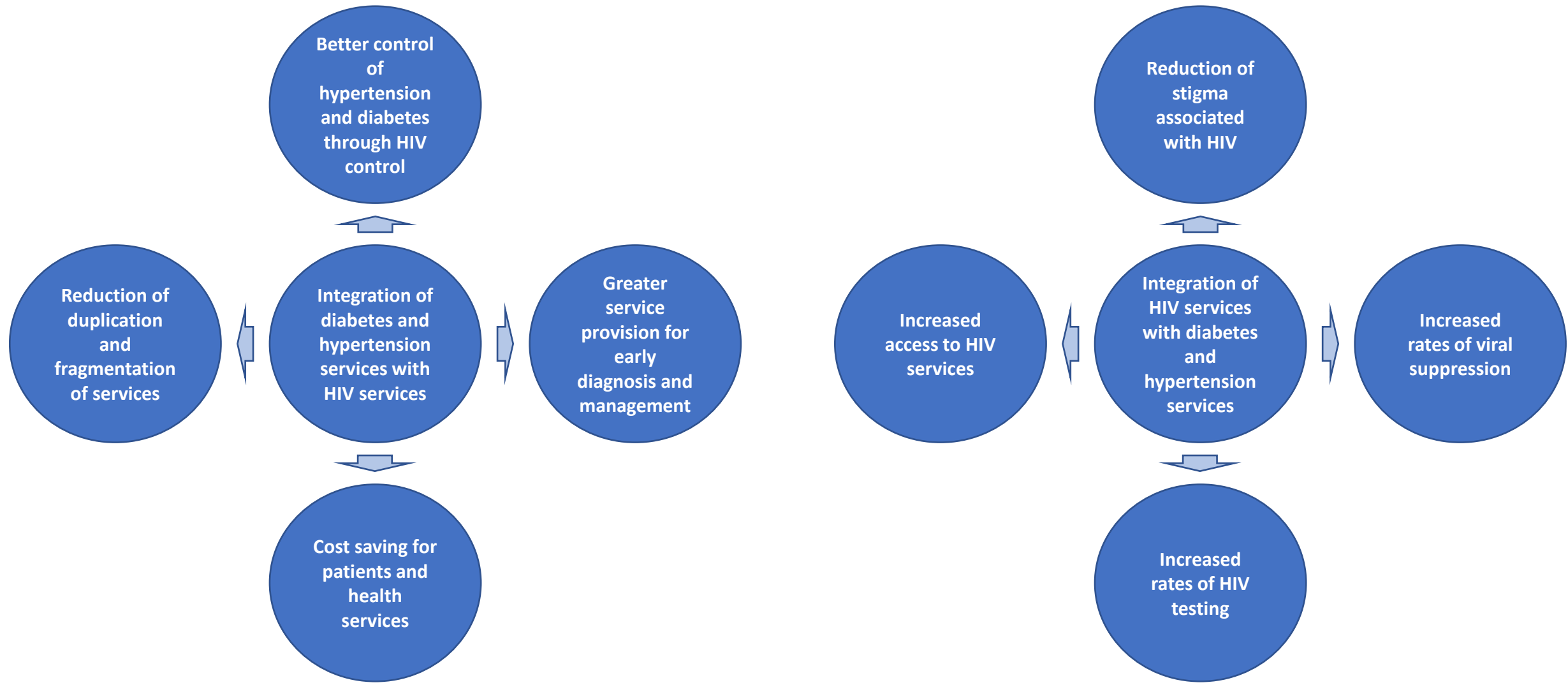
Intervention inputs	Changes in care processes	Outcomes
Negotiation with national, district and local government health departments, NGOs and funders	Agreement about and support for service model, including reorganisation of clinics and staff Commitment to ensure drug supply	<ul style="list-style-type: none"> • Reorganisation of clinics and staff to implement the model • An effective, quality, and sustainable funded drug supply chain
Negotiating lower drug prices Supporting and monitoring drug ordering in each clinic Providing buffer drug supplies to each clinic	Drugs always in stock	<ul style="list-style-type: none"> • Increased diagnosis of comorbid conditions • Increased retention and adherence • Increased viral suppression, better control of blood pressure and blood glucose
Engagement with and support for clinicians and managers in each clinic	Clinicians and managers enable and support integration, and find solutions to emerging problems	<ul style="list-style-type: none"> • Less AIDS, cardiovascular disease and diabetes complications
Provision of integrated service in each clinic (alongside and additional to existing services)	Trial participants attend integrated service Avoid multiple visits for patients with multi-morbidity	<ul style="list-style-type: none"> • Lower patients costs (travel and absence from work)
Training clinicians about integrated clinical management	Better diagnosis and treatment including attention to comorbid conditions	<ul style="list-style-type: none"> • Less health service duplication and costs (health service costs might increase if more patients are diagnosed and are more adherent)
Community engagement	Identify and enlist community organisations and resources to help with health education, tracing defaulters or patients who have difficulty attending clinic	<ul style="list-style-type: none"> • Increase patient satisfaction • Increased clinician satisfaction; less burn-out and absenteeism
Providing standardised stationery for integrated medical records; training clinicians to use it	Increased awareness by clinicians and patients about disease severity, comorbidity, adherence and control in individual patients	<ul style="list-style-type: none"> • Reduce missed opportunities for improving care and health outcomes
Improving monitoring and evaluation based on clinics registers and medical records	Regular data analysis and feedback to staff	Quality assurance and continuous improvement in the quality of care
Identifying effective health education	Improve health education at clinics	Healthier lifestyles Increased adherence

Table Three: 'Process Evaluation Design and data collection framework'

Post Integration * Numbers indicated are per country/. Data Collection at each Site	6 months	12 months	18 months	Contextual level
<i>Observations</i> of consultations, different processes and clinic flow at clinic levels and in non-clinical areas.	1 week	1 week	1 week	Micro context (facility and neighbourhoods)
<i>In depth phenomenological interviews</i> with patients/service users	25	25	25	Micro context (facility and neighbourhoods)
<i>In depth phenomenological interviews</i> with health care providers at the clinic (hospital overall in charge, hospital pharmacist, the medical officers in-charge of the integrated clinic, trained clinicians managing HIV, diabetes and hypertension patients, pharmacist, laboratory technician, counsellors or nurses providing health education and counselling and nurses in the registration desk who are also responsible in taking vital signs)	10	10	10	Meso context (national to regional/city) Micro context (facility and neighbourhoods)
Semi-structured interviews with Ministerial policy makers and provincial/regional/district level clinical/health senior management (Director for NCD, HIV and curative services).	-	5	5	Macro context (Global) Meso context (national to regional/city)
<i>Semi-structured interviews</i> with NGO and international organisations (for example WHO Country office, UNAIDS, PEPFAR, CDC)	-	5	5	Macro context (Global) Meso context (national to regional/city)
<i>Focus group discussions</i> (FGD) with community leaders (8-12 participants)	1	1	1	Micro context (facility and neighbourhoods)
<i>Focus group discussions</i> (FGD) gender specific with community members(8-12participants)	2	2	2	Micro context (facility and neighbourhoods)
<i>In depth phenomenological interviews</i> with clinical researchers			4	Micro context (facility and neighbourhoods) Meso context (national to regional/city)

Figure One 'Potential benefits of integrating diabetes, hypertension and HIV services for a) DM and hypertension control, and b) HIV control'

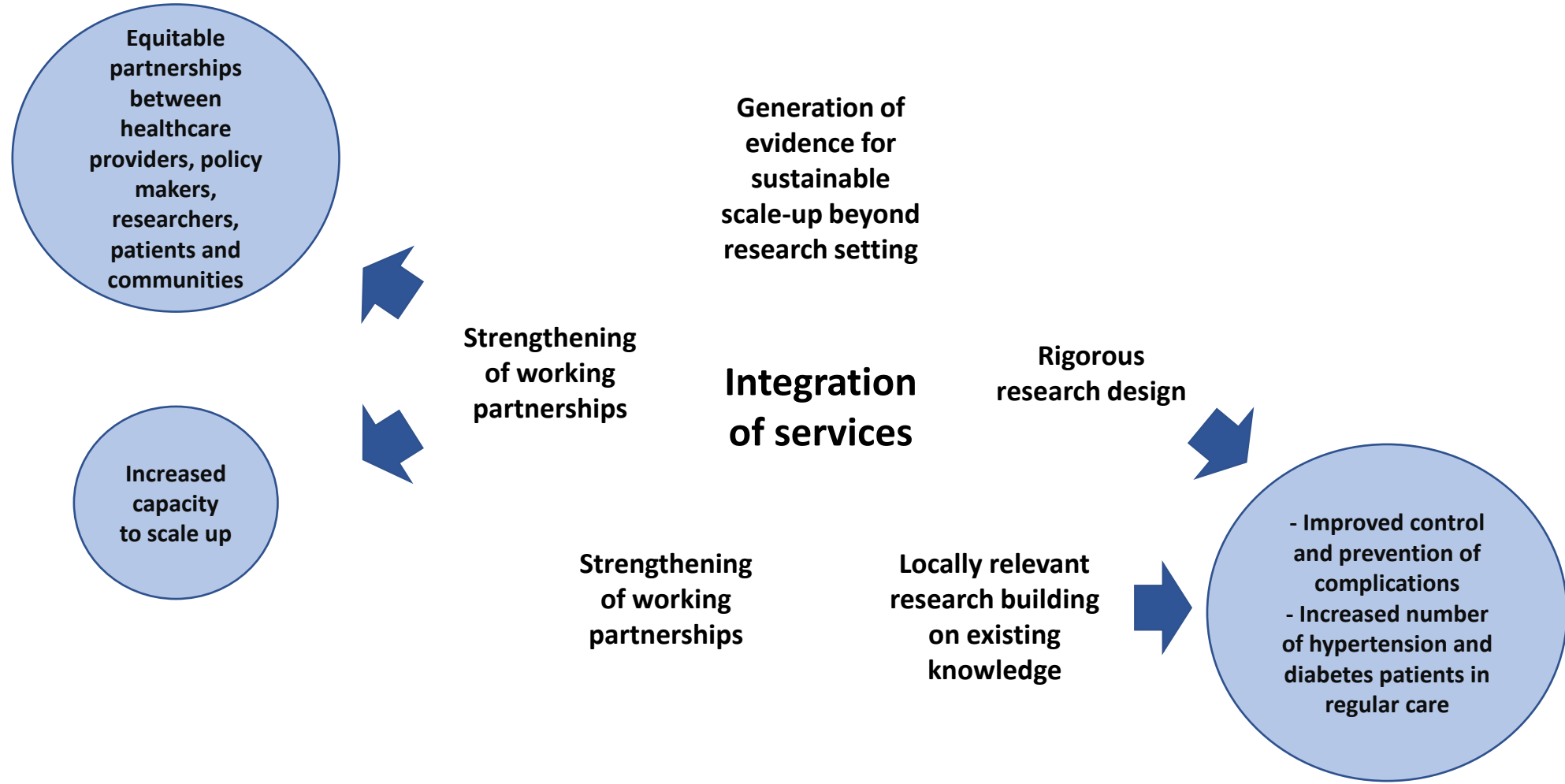
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a) Benefits for hypertension and diabetes control

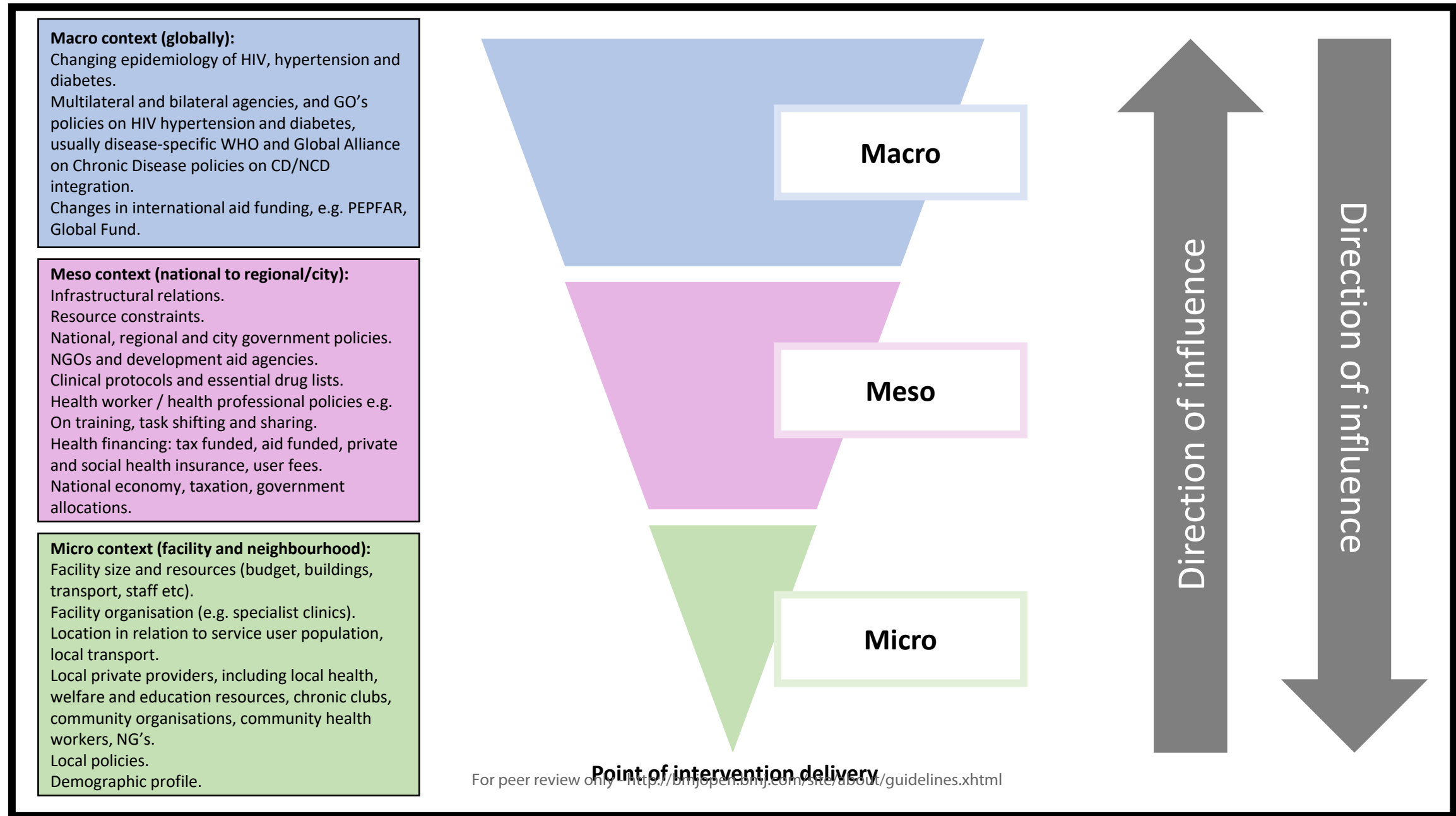
b) Benefits for HIV-control

Figure Two 'INTEAFRICA Conceptual Model'



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Figure Three 'Potential contextual influences on INTEAFRICA programme implementation cascade'



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Strengthening integration of chronic care in Africa: protocol for the qualitative process evaluation of integrated HIV, diabetes and hypertension care in a cluster randomised controlled trial in Tanzania and Uganda.

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Title

Strengthening integration of chronic care in Africa: protocol for the qualitative process evaluation of integrated HIV, diabetes and hypertension care in a cluster randomised controlled trial in Tanzania and Uganda.

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Abstract

Introduction In sub-Saharan Africa (SSA), the burden of non-communicable diseases (NCDs), particularly diabetes mellitus (DM) and hypertension, has increased rapidly in recent years, although HIV infection remains a leading cause of death among young-middle-aged adults. Health service coverage for NCDs remains very low in contrast to HIV, despite the increasing prevalence of comorbidity of NCDs with HIV. There is an urgent need to expand healthcare capacity to provide integrated services to address these chronic conditions.

Methods and Analysis: This protocol describes procedures for a qualitative process evaluation of INTE-AFRICA, a cluster-randomised trial comparing integrated health service provision for HIV-infection, DM, and hypertension, to the current stand-alone vertical care. Interviews, focus group discussions, and observations of consultations and other care processes in two clinics (in Tanzania, Uganda) will be used to explore the experiences of stakeholders. These stakeholders will include health service users, policy-makers, healthcare providers, community leaders and members, researchers, non-governmental (NGO) and international organisations. The exploration will be carried out during the implementation of the project, alongside an understanding of the impact of broader structural and contextual factors.

Ethics and Dissemination: Ethical approval was granted by the Liverpool School of Tropical Medicine (UK), the National Institute of Medical Research (Tanzania) and TASO Research Ethics Committee (Uganda) in 2020. The evaluation will provide the opportunity to document the implementation of integration over several timepoints (6, 12 and 18 months) and refine integrated service provision prior to scale-up. This synergistic approach to evaluate, understand and respond will support service integration and inform monitoring, policy and practice development efforts to involve and educate communities in Tanzania and Uganda. It will create a model of care and a platform of good practices and lessons learnt for other countries implementing integrated and decentralised community health services.

Key Words

Health service delivery, Non communicable disease, HIV, integration, task-shifting, sub-Saharan Africa

Article Summary: Strengths and Limitations of this study

- The INTE-AFRICA trial will implement integration of HIV/NCD services in Tanzania and Uganda in response to an urgent need to respond to increased burden of NCDs, and expand capacity of healthcare systems to manage comorbidity.
- The INTE-AFRICA trial is based on a partnership between African and European researchers, working closely with policy-makers and other stakeholders.
- The process evaluation of INTE-AFRICA employs qualitative and observational methods at two facilities to explore and document stakeholder experiences of integration of services, alongside an understanding of the impact of broader structural and contextual factors.
- The process evaluation works in tandem with quantitative evaluation of clinical efficacy and cost-effectiveness of the INTE-AFRICA trial.
- Limitations of the process evaluation may centre on patient drop-out, characteristics of the two selected sites, selection, information and social desirability bias and other external mitigating factors.



BACKGROUND

Non-communicable diseases (NCDs) have risen rapidly in Africa, alongside a continuing high burden of HIV-infection. In sub-Saharan Africa (SSA), HIV/AIDS remains a major cause of morbidity and mortality among young-middle aged adults, but the region is also experiencing a rapidly rising burden of NCDs (particularly DM and hypertension), giving rise to a dual HIV-NCD epidemic.¹⁻³ While lifestyle changes associated with urbanisation and globalization (such as eating habits and lack of physical exercise) underpin the ongoing demographic and epidemiologic transition toward increasing NCDs, these changes also affect chronic conditions (such as HIV).¹⁻³ The number of people in regular HIV care is rising⁴, alongside the rate of NCDs in the SSA region, with hypertension representing the single largest risk factor for death, and DM which has seen a massive increase in prevalence in a short period of time.^{2 5-7} Patient populations in SSA are increasingly demonstrating younger age of onset of NCDs, with comorbidity of NCDs with HIV, and the impact of NCDs is particularly severe in populations affected by poverty.^{3 8-11}

Since 2003, significant global investment and development partner engagement has facilitated the establishment of HIV screening and treatment programmes as the first large-scale chronic disease initiatives in Africa. Health services for HIV are stand-alone and vertically delivered. They have also been combined with decentralisation and task-shifting, which has enabled primary health centres to treat large numbers of patients. Non-clinically qualified health workers play a major role in supporting patients on HIV treatment, with almost 70% of people living with HIV-infection in regular care. In contrast, health service coverage for NCDs remains very low.^{2 12} Coordinated national NCD control and care programmes are relatively new with significant gaps in funding and operational evidence for program implementation.^{11 13} For example, only about 5-10% of persons with DM are thought to be in regular diabetes care, and the figure is likely to be similar for persons with hypertension.^{2 8 11} Furthermore, those in care experience insufficient health service provision for the diagnosis and management of DM and hypertension (medicines supply is patchy).^{2 12 14-17} HIV populations at risk of developing NCDs, and presenting with co/multi-morbidities could potentially impact on the gains from the achieved scale-up of HIV care services.¹⁸

Hence, there is an urgent need to expand the capacity of healthcare systems in the SSA region to provide services for NCDs, either alongside, or integrated, with HIV.¹⁹ As chronic conditions, DM, hypertension and HIV-infection require lifelong care. Key challenges to chronic care in SSA are linkage and retention in care, access and medicines adherence.^{20 21} As such, the infrastructure and lessons learnt from the HIV chronic disease model can serve as important resources for the expansion of NCD prevention, care and treatment. HIV chronic care management pathways, resources and infrastructure can be leveraged to integrate with newly developing NCD services, ultimately to strengthen the platform for NCD services and improve health outcomes for people with NCDs.²²⁻²⁴ Health systems have the developed experience

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3 managing HIV as a chronic disease, including linking and retaining patients in care and supporting
4 treatment adherence in drugs, diagnostics procurement and other key health systems indicators.^{21 25-27}
5 Integration can reduce duplication and fragmentation, streamline services by treat those with co/multi-
6 morbidities, and potentially offer patient benefits relating to time and cost. See **Figure 1**. It could
7 however also threaten service capacity by resulting in increased service demand and loss of clinical
8 focus on one disease.
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14 **Figure 1 ‘Potential benefits of integrating diabetes, hypertension and HIV services for a) DM and**
15 **hypertension control, and b HIV control’**
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19 Despite the increase in academic and clinical interest in HIV/NCD integration in SSA,^{9 26 28-33} little
20 evidence about integration in terms of both scope and generalizability exists. Extant evidence is limited
21 to small scale feasibility studies in largely different contexts³⁴⁻⁴⁰, despite suggesting that integrated care
22 is an efficient use of resources compared to the standard of care and beneficial for patients’ NCD and
23 HIV clinical outcomes.^{28 30 32} There is a lack of large scale or randomized and/or controlled evaluations
24 and context-specific clinical, cost effectiveness and process outcomes data constrains policymaking and
25 development of integrated care models, which could strengthen health systems when tailored to the
26 distinct needs of each specific SSA country.^{19 21 37} Such evidence is paramount to inform policy,
27 government resource prioritisation, and to develop integrated care models which strengthen health
28 systems best suited to the needs of that specific SSA country. The INTE-AFRICA trial is conducted to
29 respond to the insufficient existing evidence to substantiate the benefits and sustainability of integrated
30 care as well as the implementation of such programmes in the SSA setting. We present here the
31 qualitative process evaluation protocol designed to evaluate INTE-AFRICA, a European Commission
32 Horizon 2020 funded implementation research project (protocol number 19-100) operating in Tanzania
33 and Uganda.
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44 ***The INTE-AFRICA Trial***
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46 INTE-AFRICA aims to implement and assess the effectiveness of the integration of HIV, DM and
47 hypertension services at the point of service delivery covering many health facilities where common
48 approaches to clinical decision-making, drug procurement and human resource management occur. The
49 project will generate the research evidence needed by health services in Africa, to scale-up and sustain
50 chronic disease management and services in an integrated manner. We are also interested in observing
51 changes in dynamics pertaining to stigma and discrimination associated with HIV.⁴¹
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57 INTE-AFRICA team specifically chose Tanzania and Uganda as they are low-income countries and
58 their public and private health facilities are strongly committed to providing services for NCD.
59 However, their health systems struggle to scale-up provision for diabetes and hypertension in the face
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3 of competing health demands, including HIV-infection. See **Table 1**. Tanzania and Uganda also share
4 relevant characteristics with other countries in SSA. As such, the process evaluation has the potential
5 to enhance the generalisability of integrated care to other similar settings by providing understanding
6 of the determinants and mechanisms of the implementation process.
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10 11 **Table 1 ‘Key data on the country settings’**

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14 Our programme is underpinned by a participatory, multi-actor approach which supports dialogue and
15 knowledge exchange, fosters mutual understanding and provides input in policy agendas around
16 diagnosis and treatment of DM, hypertension and HIV in an integrated clinic. The INTE-AFRICA
17 conceptual framework is illustrated in **Figure 2**.
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20 21 22 **Figure 2 ‘INTEAFRICA Conceptual Model’**

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25 INTE-AFRICA will test integrated health services at primary care centres for HIV-infection, diabetes
26 and hypertension, by providing a “one-stop” integrated care clinic for these conditions (the
27 intervention). We will conduct a pragmatic parallel arm cluster-randomised trial: 32 largely urban health
28 facilities offering primary care services in the two countries will be randomised, with 16 facilities
29 allocated to deliver the intervention immediately (intervention arm), and 16 facilities to continue with
30 usual care (control arm). At each selected facility, cohorts of approximately 220 patients; 110 HIV
31 infected and 110 NCD patients, will be enrolled to evaluate the primary research outcomes.
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38 The primary care facilities will initiate and stabilise patients on treatment, manage complications
39 (including referral to higher facilities) and conduct clinical and laboratory monitoring of patients for all
40 three conditions. Specific characteristics of integrated care in each ‘one stop’ integrated care clinic are:
41 concurrent management of HIV, hypertension and DM in the same facility; management of patients
42 with HIV, hypertension and DM by the same clinician or team of clinicians (nurses, counsellors other
43 staff); integrated training of clinicians; single waiting area and queue; integrated health education about
44 all three conditions; one pharmacy with a single drug dispensing point; similar testing, and cross-testing,
45 for diagnosis and monitoring with the requisition of laboratory tests in the same place; and similar
46 format of paper medical records for each condition kept in the same patient folder.
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54 Patients who decline to participate in the research and trial participants in control arm clinics will
55 continue to receive standard vertical health care delivery. Inclusion criteria for participation are: being
56 over 18 years old; having confirmed HIV-infection, DM or hypertension; living within the catchment
57 population of the health facility; likely to remain in the catchment population for six months and willing
58 to provide written informed consent. Very ill patients requiring in-patient care will be excluded. The
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3 research team will observe participants during clinic visits with additional reviews at six and 12 months.
4 Further details are provided in the full INTE-AFRICA trial protocol.
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8 ***Qualitative Process Evaluation of the INTE AFRICA trial***

9 The aim of the process evaluation of INTE-AFRICA is to explore the experiences, attitudes and
10 practices of a wide variety of stakeholders during the process of programme implementation and to
11 develop an understanding of the impact of broader structural and contextual factors on the
12 implementation process of service integration. Process evaluations typically evaluate how and whether
13 interventions are delivered as intended and whether such implementation is congruent with the theory
14 underpinning the intervention.^{25 42-44} Updated Medical Research Council (MRC) guidance for
15 evaluation of complex health interventions has recently recognised the value of process evaluation
16 within trials stating, “it can be used to assess fidelity and quality of implementation, clarify causal
17 mechanisms and identify contextual factors associated with variation in outcomes.”²⁵ Hence, the
18 process evaluation in INTE-AFRICA is particularly focused on context, description of the intervention
19 and its causal assumptions, implementation, mechanisms of impact and outcomes.²⁵ Further we
20 evaluate the extent to which resources and activities supporting the intervention function to deliver
21 intended outputs, with subsequent improvements in outcomes.
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31 A central focus lies in identifying contextually relevant strategies for successful implementation of
32 service integration, and practical difficulties in adoption, delivery and maintenance to inform wider
33 implementation.⁴⁵ We recognise that outcomes (e.g. knowledge gained) of INTE-AFRICA are
34 dependent on understanding cultures and contexts of the stakeholders (i.e. patients, healthcare
35 providers, policy-makers, community leaders/members, non-governmental organisations (NGO),
36 international organisations, and clinical researchers) involved and those surrounding service design and
37 delivery as well as care seeking practices.
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44 The role of social and behavioural science approaches to understanding individual experience, and the
45 role of such contextual dynamics is central to this process evaluation. It aims to enhance understanding
46 of issues related to the NCD and HIV agendas and service delivery approaches from all perspectives
47 and stakeholders along the integration process. INTE-AFRICA will utilise a broad social behavioural
48 approach to support community engagement in research in Tanzania and Uganda, going beyond clinical
49 trial recruitment and retention to improve NCD/ HIV literacy. Behavioural and social science research
50 strategies⁴⁶ will allow NCD and HIV related research to place the needs and perspectives of people
51 living with NCD and/or HIV at the centre of the progression of clinical studies, such as INTE-AFRICA,
52 and investigate participant motivations and decision-making processes related to preferences for or
53 participation in different types of integrated and decentralised services.
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Theoretical Framework: Bronfenbrenner's ecological model of behaviour

Process evaluation design, like healthcare interventions, requires a theoretical framework to structure the qualitative and observational evaluation across sites. The chosen theoretical framework is Bronfenbrenner's ecological model of behaviour^{47 48} used to conceptualise integrated care as events that disrupt complex social systems⁴⁹ operating across multiple contextual levels. We are interested in better understanding the importance of context, which becomes especially relevant when comparing Tanzania and Uganda. For example, healthcare coverage and charging dynamics between countries and between HIV as opposed to NCD care differs. In Tanzania, whilst HIV services and drugs for HIV are free, patients are required to pay a direct user fee (unless elderly or very poor) or use their health insurance to pay for NCD drugs. Currently there is a strategy to progress to single health insurance to support universal health coverage in Tanzania. In Uganda, HIV services are also free to all (public and private not for profit health facilities) and HIV drugs are always in stock. However, in Uganda whilst NCD services are free in public facilities, stockouts of laboratory reagents and NCD drugs are frequent, and patients have to pay a direct user fee to access them. There is also no national insurance scheme in Uganda, only private insurance which is relatively expensive and optional.

Using the Bronfenbrenner theoretical framework, contextual factors are evaluated at the *macro* (universal vs partial coverage; free primary healthcare and drugs, affordability and users fees; fiscal policy, financial aspects at government level, funding barriers for chronic care management and barriers to government scale-up of service integration); *meso* (HIV/NCD drug ordering, drug delivery systems and continuity of supply, health care provider education and employment, community understanding and perspectives on multimorbidity); and *micro* (clinic and pharmacy level management, resources, patient/service user experience) levels. See **Figure 3**. These contextual factors, likely to influence implementation of integration and their effects, will be investigated to capture variation in adoption, delivery and maintenance outcomes as well as responses to the intervention. This will affect both reach and fidelity, which are hypothesised to be important factors in outcome differences.

Figure 3 'Potential contextual influences on INTE AFRICA programme implementation cascade'

To situate INTE-AFRICA within the Bronfenbrenner theoretical framework, we will develop a logic model. This model will set out contextual determinants of HIV and NCD care management in SSA and assess how integrated care components function to address these determinants to improve outcomes in the management and support of patients. See **Table 2**.

Table 2 'Logic Model of programme inputs, processes and outcomes'

METHODS

Study Setting

This will be a cohort study taking place in one “one stop” integrated care clinic per country. In Tanzania, the selected site is *Temeke Regional Referral Hospital* in Dar Es Salaam, a public tertiary health facility, with 465 staff, and serving a population of over 1 million. In Uganda, the selected site is the *Kasangati Health Centre IV*, Kasangati, a public district health facility located in the Wakiso District serving a population of over 2 million. Both provide a range of services to the community (primary care, HIV/AIDs, NCDs, surgical, maternal and child health, health education, dental and pharmacy).

Study Design

This protocol describes procedures for a qualitative process evaluation of the INTE-AFRICA pragmatic parallel arm cluster-randomised trial comparing integrated health service provision for HIV-infection, DM and hypertension with the current standard vertical care delivery model. The process evaluation works in tandem with the collection of selected clinical outcomes (e.g. clinical efficacy of different treatments) and health economic data (e.g. costs and benefits of different approaches) to estimate the potential benefits to patients and health services at clinic and country level (protocol reported elsewhere).

Patient and Public Involvement

Patient and public involvement (PPI) throughout a programme of research enhances research quality and relevance by providing different perspectives and a sense of ownership. This protocol will adhere to the same principles, and will allow the voice of ‘service users’ and those affected to be heard, and utilised. Key stakeholders such as patients as service users and their families will be fully involved in guiding the research, acting as research participants, and in implementation of change in health service delivery and integrated care planning. All aspects of the process evaluation are underpinned by participatory action health research and its success and usefulness will be grounded in PPI, participation and engagement in the form of patient/professional identification of research priorities, collaborations and partnerships, expert steering, community participation around health needs and optimal integrated services, awareness raising activities, development of print materials, toolkits and training for healthcare professionals.

It will use three qualitative research techniques: in-depth interviews with stakeholders (patients, healthcare provider, policy-maker, non-governmental organisation (NGO)/international organisation, and clinical researcher); focus group discussions (FGD) with community leaders and community members; and clinic-based observations in one site per country. This design permits an assessment of the fidelity of INTE-AFRICA’s implementation, a detailed description of the processes, relationships, and contexts involved in the delivery of integrated care, and the identification of factors attributing to

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3 the failure or success of the programme. It thus addresses the 'black box' problem in interpreting trial
4 results by improving understanding of the mechanisms that connect particular intervention components
5 to particular outcomes.⁵⁰ The chosen approach will enhance social construction and acceptability of
6 chosen decentralised integrated approaches, link outcomes to policy and advocacy and impact
7 sustainability of HIV, DM and hypertension chronic disease service integration in two LMIC countries.
8 It provides the opportunity to document and refine INTE-AFRICA activities prior to a larger pragmatic
9 trial or scale-up by Tanzanian and Ugandan governments. These synergistic approaches to evaluate,
10 understand and respond will support integration, support affordability, address barriers to government
11 scale up and funding barriers for chronic care, inform surveillance, policy and practice development
12 and improve efforts to involve and educate communities in Tanzania and Uganda. It will create a model
13 and a platform of best practices and lessons learnt for other countries implementing integrated and
14 decentralised community health services for HIV and chronic disease. The process evaluation methods
15 for each objective are described in **Table 3**, including how each method maps onto the three different
16 contextual levels.
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27 **Table 3: 'Process Evaluation Design and data collection framework'**

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30 ***Study Population and Recruitment***

31 25 patients and 10 health care providers in *Temeke Regional Referral Hospital* in Dar Es Salaam,
32 Tanzania and *Kasangati Health Centre IV*, Kasangati, Uganda will be purposely selected and invited;
33 at six, 12 and 18 months after the start of the trial, to reflect retrospectively on their experience of
34 integration. Health care providers include the hospital/health centre overall in charge and pharmacist,
35 and the 'one stop' medical officers in-charge, trained clinicians managing HIV, diabetes and
36 hypertension patients, pharmacist, laboratory technician, counsellors or nurses providing health
37 education and counselling, and nurses in the registration desk who are also responsible in taking vital
38 signs from patients. We will also collect qualitative data from interviews with Ministerial policy-makers
39 and provincial/regional/district level clinical/health senior management (directors for NCD, HIV and
40 curative services); NGO and international organisations (for example WHO Country office, UNAIDS,
41 PEPFAR, CDC) and clinical researchers; and conduct FGD with community leaders and community
42 members. These numbers are expected to reach saturation (i.e. the point that further information does
43 not provide any additional variation in observed themes). We may replace participants, for example
44 patients if there is significant loss to follow up or refusal for repeated interviews. For instance, if a
45 participant drops out at 12 months, we still have their six-month experience documented, and we can
46 replace with a new participant, invited to reflect on their 12-month retrospective experience. Where
47 possible we will gender match interviewers with participants (particularly patients). Participants
48 (patients, healthcare providers and others) will not be directly compensated but rather they will be
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3 compensated for incurred transport costs to attend the interview/FGD, and provided with refreshments
4 during the interview/FGD.
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7 The following recruitment procedures will take place at each 'one-stop' integrated care clinic;
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- 9
- 10 • Observations will be made in the integrated clinic in consultation with the hospital/health centre
11 and 'one stop' clinic in-charges.
12
 - 13 • Recruitment of patients will be supported by clinic nurses who will identify and approach
14 selected participants who have a minimum of six months experience of integration, and will be
15 asked to consent to partake in an in-depth interview on the day they attend the clinic. INTE-
16 AFRICA researchers will purposively sample women and men of different ages and explore
17 any age/gender and condition ((HIV/hypertensive/DM/multi/co-morbid) related differences.
18
 - 19 • *Health care providers* at the integrated clinic will be approached to participate in an in-depth
20 interview on the day the INTE-AFRICA team are scheduled to attend.
21
 - 22 • *Ministerial policy-makers and provincial/regional/district level clinical/health senior*
23 *management* will be identified and requested to participate in a semi-structured interview (face
24 to face, online using Zoom or telephone).
25
 - 26 • *NGO and international organisations* will be identified and requested to participate in a semi-
27 structured interview (face to face or telephone).
28
 - 29 • *Community leaders* will be identified in the clinic catchment areas by virtue of their position
30 while *community members* will be identified in consultation with the community leaders and
31 invited to participate in the FGDs.
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 - 33 • *Clinical researchers* will be invited to participate in an in depth interview at the 24 month end
34 point.
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41 **Data collection**

42 We will use the Empirical Phenomenological Psychological (EPP) five-step method,⁵¹ which combines
43 psychological, interpretative and idiographic components, to collect data. The data will garner an
44 understanding of the complex social processes, of social, aged, gendered and culturally/community
45 specific meanings and broaden the incremental understanding of the distinct lived experience of policy-
46 makers, patients, health care providers, researchers and communities. We will balance the description
47 of phenomena with the interpretation of insights and are cognisant of participant experiential
48 phenomena and authors' interpretation of associated meanings. It will yield an in-depth socio-cultural
49 understanding of patient /participant reported outcomes, their motivations, preferences, beliefs,
50 expectations, identities, hopes and views on conditions, related stigma and of decision-making
51 processes. This will provide better understanding of stakeholder and community positioning during
52 integration. This understanding will inform policy and practice, ensure effective patient/service user
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3 education, position service users and their families to understand these conditions and interpret study
4 outcomes and facilitate future HIV and chronic disease clinical studies.
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8 Both descriptive patient level data and rich socio-behavioural qualitative/observational data will be
9 collected by a team of trained researchers in Tanzania and Uganda. Data collection will entail exploring
10 the experiences, attitudes and practices of a wide variety of stakeholders during the process of INTE-
11 AFRICA programme implementation and will develop an understanding of the impact of broader
12 structural and contextual factors on the implementation process.^{10 45}We will collect data on social
13 behavioural and cultural aspects impacting implementation (e.g. individual and community health risks,
14 protective behaviours and health responses) within the broader social and political frameworks
15 (government resources and barriers to sustaining integration), the practicalities of accessing, providing
16 and sustaining integrated services (e.g. staff time, resources, equity of access, supply chain dynamics
17 and pharmacy components pertaining to drug types, drug/reagent availability and costs for integrated
18 patients, catchment area/populations, quality of care, waiting room dynamics, record keeping and
19 retention across multi/co-morbidities, training gaps); and process indicators (e.g. perceived stigma,
20 acceptability of vertical versus integrated service designs, lay knowledge and awareness, the dynamics
21 of public versus private sector integration (where relevant to the participant), and bottlenecks to
22 accessing services). We will also describe implementation of the intervention in terms of fidelity to the
23 intended model of care, adaptations to the intervention during implementation, and dose and reach of
24 intervention components actually delivered and received (such as numbers and proportions of eligible
25 staff who received integrated care training, numbers of proportions of patient participants who received
26 all or most of their care from integrated services, and frequency of drug stock-outs). The latter data will
27 be complemented by routinely collected quantitative data such as training attendance and medical
28 records. We will document changes in healthcare provider roles, attitudes and patient relationships.
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43 Interviews with patients/service users, healthcare provider and policy-maker/senior manager, will
44 include specific questions about their experience and management of individuals with multi-morbid
45 HIV, hypertension and/or diabetes. These include their perceptions of INTE-AFRICA; impacts of
46 INTE-AFRICA on the provision of integrated HIV/AIDS care and NCD care, and relationships with
47 NGO and international organisations; changes in health provider roles, attitudes, and patient
48 relationships; impacts of the INTE-AFRICA implementation context on trial and health economic cost
49 outcomes; impacts of the INTE-AFRICA intervention on an integrated health systems approach to care
50 (medicine supplies, record keeping, service user education, clinical care pathways, data management,
51 staff training); and barriers to and facilitators of change and future sustainability of integrated care
52 provision. We will assume a more pragmatic approach when garnering perspectives from higher level
53 stakeholders involved in health policy and practice generation, and NGO and international organisations
54 (e.g. WHO country offices, UNAIDS, PEPFAR, CDC) providing peripheral supports and guidance. We
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3 are especially interested in better understanding the complexities around government scale up and
4 resource allocation for chronic care (for example decentralisation, financial planning, identification of
5 potential funding sources at ministry levels, subsidised NCD drugs, and by international donors (CDC,
6 PEPFAR, UNAIDS). See **Table 3**.
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10 ***Data analysis and synthesis***

11 The analysis of qualitative data will be iterative, moving between data collection and analysis to test
12 emerging theories. Field notes of observations will be analysed thematically to provide a description of
13 the process and content involved in adapting and delivering the intervention. Audio recordings of
14 interviews and FGDs will be transcribed verbatim by competent and experienced social scientists, with
15 a subsample transcribed using conversation analytic conventions. Translation from local languages (e.g.
16 Swahili, Luganda) into English will be performed for easy sharing with the study partners. Translation
17 will occur using a back-translation method for consistency. An electronic data management package
18 (e.g. NVivo) will be used to manage the qualitative data analysis at the respective country levels. The
19 analysis of the observational data will require knowledge obtained from health professional interviews
20 at different levels to compare how reported experience, and different accounts of patient and
21 professional perspectives relate to actual implementation of INTE-AFRICA scenarios: i) when DM and
22 hypertension services are integrated with HIV-infection services; and ii) comparing countries. Care will
23 be taken to identify and follow up deviant cases which do not fit into emerging theories. Reliability and
24 validity of the analysis is optimised through iterative data collection, the use of a multi-method design
25 incorporating interviews, FGD and observations and the ongoing discussion of findings within the
26 research team for scrutiny and feedback.^{52 53}
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39 The chosen phenomenological approach (EPP) to collecting and analysing data, usually used in
40 psychological research, reveals the structures of subjective experience and meaning of a lived
41 phenomenon (in first person point of view). It follows to some extent Husserl's principle of active
42 efforts to "bracket out" the researchers' theoretical pre-understanding in the first steps of a text
43 analysis.⁵¹ The "bracketing", however, does not exclude an empathetic, psychological focus in the
44 analysis on the experiences of the researched phenomenon as it is lived by the informant and what it
45 means is to her or him. In the context of INTE-AFRICA, researchers in both countries will strive to get
46 an empathetic understanding of the text, and hence do not apply their professional prior knowledge
47 about integration. The analysis of the observational data will also require knowledge from health
48 professional interviews to compare how reported experience relates to actual implementation of
49 integration at the clinic level.
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58 We will conduct a stepwise EPP analysis in five steps. **First**, the text will be read several times to get a
59 good grasp of how the informant spoke about the researched phenomenon of integration. In this step,
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3 theoretical reflection will be withheld. **Second**, the whole text will be divided into meaning units of a
4 whole paragraph or a single word. **Third**, the informant's personal language will be transformed, unit-
5 by-unit, to the researchers' language. The researchers will discuss the transcription unit by unit. When
6 different interpretations occur, the researchers will return to the interview text and discuss in a free,
7 imaginative process until agreement can be reached through negotiated consensus. **Fourth**, the text will
8 be screened in a search for comprehensive themes. The text will be interpreted with connection to the
9 researchers' theoretical knowledge in an interchange between the original data, the transformed units
10 and the researchers' theoretical pre-understanding about integration. The meaning units will be assorted
11 into appropriate themes and thus constitute a general structure of the phenomenon of integrated care.
12 **Fifth**, this essential structure will penetrate all the revealed themes and thus the meaning of the
13 researched phenomenon of integrated care to the informant.
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22 ***Credibility and transferability***

23 The process evaluation protocol adheres to recommendations intended to facilitate the standardisation
24 of process evaluation design and reporting ⁴³. It provides a unique opportunity to document
25 implementation and collaboratively refine integrated care in two sub-Saharan African countries. This
26 makes possible the synthesis of results of similar studies elsewhere in the SSA region in future. In order
27 to ensure credibility, whilst we utilise different methods of data collection (qualitative/observational),
28 and operate concurrently with clinical outcomes data and health economics analysis, we will also add a
29 further layer of triangulation of sources in terms of perspectives across stakeholders and across
30 conditions (HIV/hypertension/DM/multi/comorbidity) when raising the abstraction level. Triangulation
31 of socio-behavioural qualitative and observational data during analysis will occur in order to understand
32 how different types of evidence enhance the overall interpretation of how INTE-AFRICA was
33 implemented, and what the additional health economic and clinical data are, drawing case comparisons
34 across clinics, and across countries, and developing possible explanations for implementation variation.
35 The data, when combined and triangulated across these multi stakeholder perspectives, will provide a
36 'thick description', of how the intervention was delivered, maintained and experienced by
37 stakeholders.^{10 45} It will also offer explanations for observed variation over time and between countries,
38 and detailed insight into the interaction between different contextual features and components of
39 integration of NCD or HIV/NCD services. It will also facilitate triangulation of information across
40 stakeholders, clinics and countries. This approach will help to support transferability to other settings,
41 by identifying factors which are plausibly and/or consistently related to successful or unsuccessful
42 delivery of intervention components. We recognise the potential for selection and information bias as
43 limitations of the trial itself, and mitigate by using a random sampling approach, defining characteristics
44 in a cohort, using a standardised approach to collecting data with continual assessment of information
45 bias, and ensuring that research personnel are unaware of participant disease status. We will address
46 social desirability in the process evaluation by only providing brief information at the outset of the
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3 evaluation in order to avoid priming, using an interview schedule approved by a panel of INTE-
4 AFRICA experts in terms of sensitivity, conducting qualitative research using skilled interviewers with
5 limited power relationship between interviewer and participant, conducting the interviews in a safe and
6 secure setting where the participant feels comfortable, briefing them that there is no right and wrong
7 answer, and finally by encouraging them to use anecdotes and experiential evidence to support their
8 views.
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14 Emerging theories and the relationship of the data to the conceptual literature underpinning the
15 intervention will be discussed and refined at INTE-AFRICA research team meetings throughout the
16 project. We envisage utilising the public understanding of science theory⁵⁴ to unpack how patients and
17 their communities in Tanzania and Uganda understand and use different knowledge on HIV and NCDs
18 in their lives. This could be facilitated by understanding how they create meaning from scientific
19 findings relating to NCDs and HIV and if, how, and to what degree they incorporate these findings into
20 their everyday lives. This theory has the capacity to shift public attitudes by connecting and
21 communicating the development of innovative scientific concepts in the medical field (in this instance
22 integration of HIV/NCD services in Tanzania and Uganda) to the non-scientific public, and thereby
23 enhance education, training cascade, health policy and practice, and ultimately public understanding of
24 multi-morbidities and sustainable routes to care. Further, it will create a platform for the sharing of
25 lessons learnt, best practices and context adaptation of the final integrated model of care in other African
26 countries (clinical care policies and practice, staff cascade of training, service user education and
27 community awareness raising).
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38 ***Ethical considerations***

39 Ethical approval for the evaluation has been granted by the research ethics committees of the Liverpool
40 School of Tropical Medicine (UK), the National Institute of Medical Research (Tanzania) and TASO
41 Research Ethics Committee (Uganda). The key ethical principles of voluntary and informed
42 participation, confidentiality and safety of participants will be used in all researcher and participant
43 interactions. Written consent for interviews and observations will be obtained from all participants. All
44 participants will be provided with written information about the research, this will be explained
45 verbally, and informed that their participation is voluntary and that they may withdraw from
46 participation at any time. Safety and confidentiality of all data will be ensured by: (1) encrypting all
47 transcriptions with a password protected code; (2) storing all data in a secure, encrypted database
48 accessible only to authorised persons on the research team; (3) de-linking all personal information of
49 participants from the data collected and stored. Each participant will have a unique identification
50 number.
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Contributorship Statement

All authors contributed to the conceptualisation of the research and contributed to writing the manuscript.

MCVH, MB, JVL, SJ, ES, DB, CP, JO designed the process evaluation protocol.

SJ, MN, SM, JB led the development of the INTE-AFRICA trial.

MCVH drafted the manuscript and all co-authors edited and commented on subsequent drafts. All authors approved the final draft for submission. All authors agree to be accountable for all aspects of the work in ensuring that questions related to the accuracy or integrity of any part of the work are appropriately investigated and resolved.

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Ethical approval statement

Ethical approval for the evaluation was granted in 2020 at the Liverpool School of Tropical Medicine (UK), the National Institute of Medical Research (Tanzania) and TASO Research Ethics Committee (Uganda).

Data sharing statement

No additional data available.

Competing interests statement

None

Provenance and peer review

Not commissioned; internally peer-reviewed.

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Table 1 ‘Key data on the country settings’

	Tanzania	Uganda
Income level	Low	Low
Population size	58m (2018)	35m (2016)
Estimated prevalence of hypertension from STEPS survey	26%	26%
Estimated prevalence of diabetes from STEPS survey ¹⁵ *	5-10%	2-5%
Estimated prevalence of HIV-infection	5.1% (2017)	6.2% (2017)
Doctors density /100,000 population	3 (2014)	0.8 (2005)

* diabetes estimate varies according to age and gender. Data are of variable quality but reference 11 shows that the overall median diabetes prevalence in 12 countries in Africa is 5%.

Table 2 'Logic Model of programme inputs, processes and outcomes'

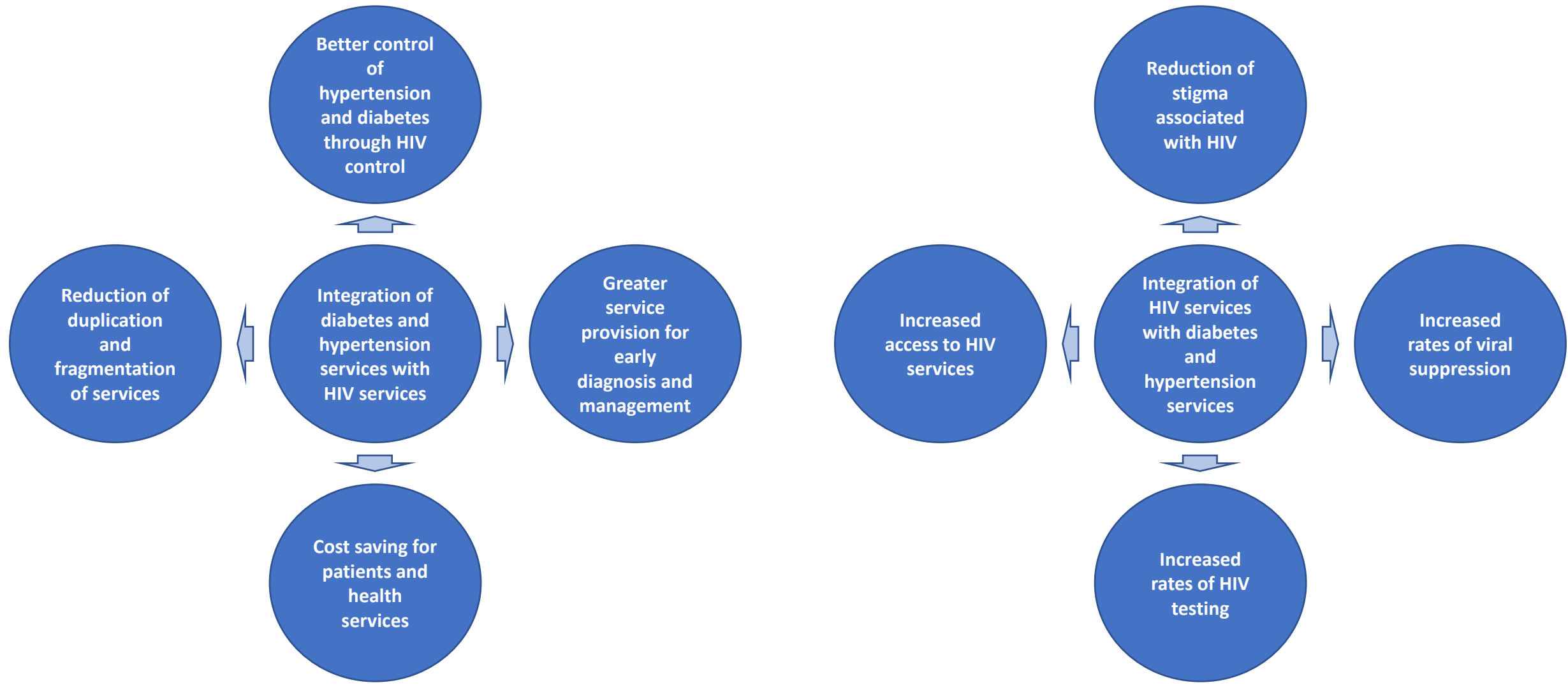
Intervention inputs	Changes in care processes	Outcomes
Negotiation with national, district and local government health departments, NGOs and funders	Agreement about and support for service model, including reorganisation of clinics and staff Commitment to ensure drug supply	<ul style="list-style-type: none"> • Reorganisation of clinics and staff to implement the model • An effective, quality, and sustainable funded drug supply chain
Negotiating lower drug prices Supporting and monitoring drug ordering in each clinic Providing buffer drug supplies to each clinic	Drugs always in stock	<ul style="list-style-type: none"> • Increased diagnosis of comorbid conditions • Increased retention and adherence • Increased viral suppression, better control of blood pressure and blood glucose • Less AIDS, cardiovascular disease and diabetes complications • Lower patients costs (travel and absence from work) • Less health service duplication and costs (health service costs might increase if more patients are diagnosed and are more adherent) • Increase patient satisfaction • Increased clinician satisfaction; less burn-out and absenteeism • Reduce missed opportunities for improving care and health outcomes
Engagement with and support for clinicians and managers in each clinic	Clinicians and managers enable and support integration, and find solutions to emerging problems	
Provision of integrated service in each clinic (alongside and additional to existing services)	Trial participants attend integrated service Avoid multiple visits for patients with multi-morbidity	
Training clinicians about integrated clinical management	Better diagnosis and treatment including attention to comorbid conditions	
Community engagement	Identify and enlist community organisations and resources to help with health education, tracing defaulters or patients who have difficulty attending clinic	
Providing standardised stationery for integrated medical records; training clinicians to use it	Increased awareness by clinicians and patients about disease severity, comorbidity, adherence and control in individual patients	
Improving monitoring and evaluation based on clinics registers and medical records	Regular data analysis and feedback to staff	Quality assurance and continuous improvement in the quality of care
Identifying effective health education	Improve health education at clinics	Healthier lifestyles Increased adherence

Table 3: 'Process Evaluation Design and data collection framework'

Post Integration * Numbers indicated are per country/. Data Collection at each Site	6 months	12 months	18 months	Contextual level
<i>Observations</i> of consultations, different processes and clinic flow at clinic levels and in non-clinical areas.	1 week	1 week	1 week	Micro context (facility and neighbourhoods)
<i>In depth phenomenological interviews</i> with patients/service users	25	25	25	Micro context (facility and neighbourhoods)
<i>In depth phenomenological interviews</i> with health care providers at the clinic (hospital overall in charge, hospital pharmacist, the medical officers in-charge of the integrated clinic, trained clinicians managing HIV, diabetes and hypertension patients, pharmacist, laboratory technician, counsellors or nurses providing health education and counselling and nurses in the registration desk who are also responsible in taking vital signs)	10	10	10	Meso context (national to regional/city) Micro context (facility and neighbourhoods)
Semi-structured interviews with Ministerial policy-makers and provincial/regional/district level clinical/health senior management (Director for NCD, HIV and curative services).	-	5	5	Macro context (Global) Meso context (national to regional/city)
<i>Semi-structured interviews</i> with NGO and international organisations (for example WHO Country office, UNAIDS, PEPFAR, CDC)	-	5	5	Macro context (Global) Meso context (national to regional/city)
<i>Focus group discussions</i> (FGD) with community leaders (8-12 participants)	1	1	1	Micro context (facility and neighbourhoods)
<i>Focus group discussions</i> (FGD) gender specific with community members(8-12participants)	2	2	2	Micro context (facility and neighbourhoods)
<i>In depth phenomenological interviews</i> with clinical researchers			4	Micro context (facility and neighbourhoods) Meso context (national to regional/city)

Figure One 'Potential benefits of integrating diabetes, hypertension and HIV services for a) DM and hypertension control, and b) HIV control'

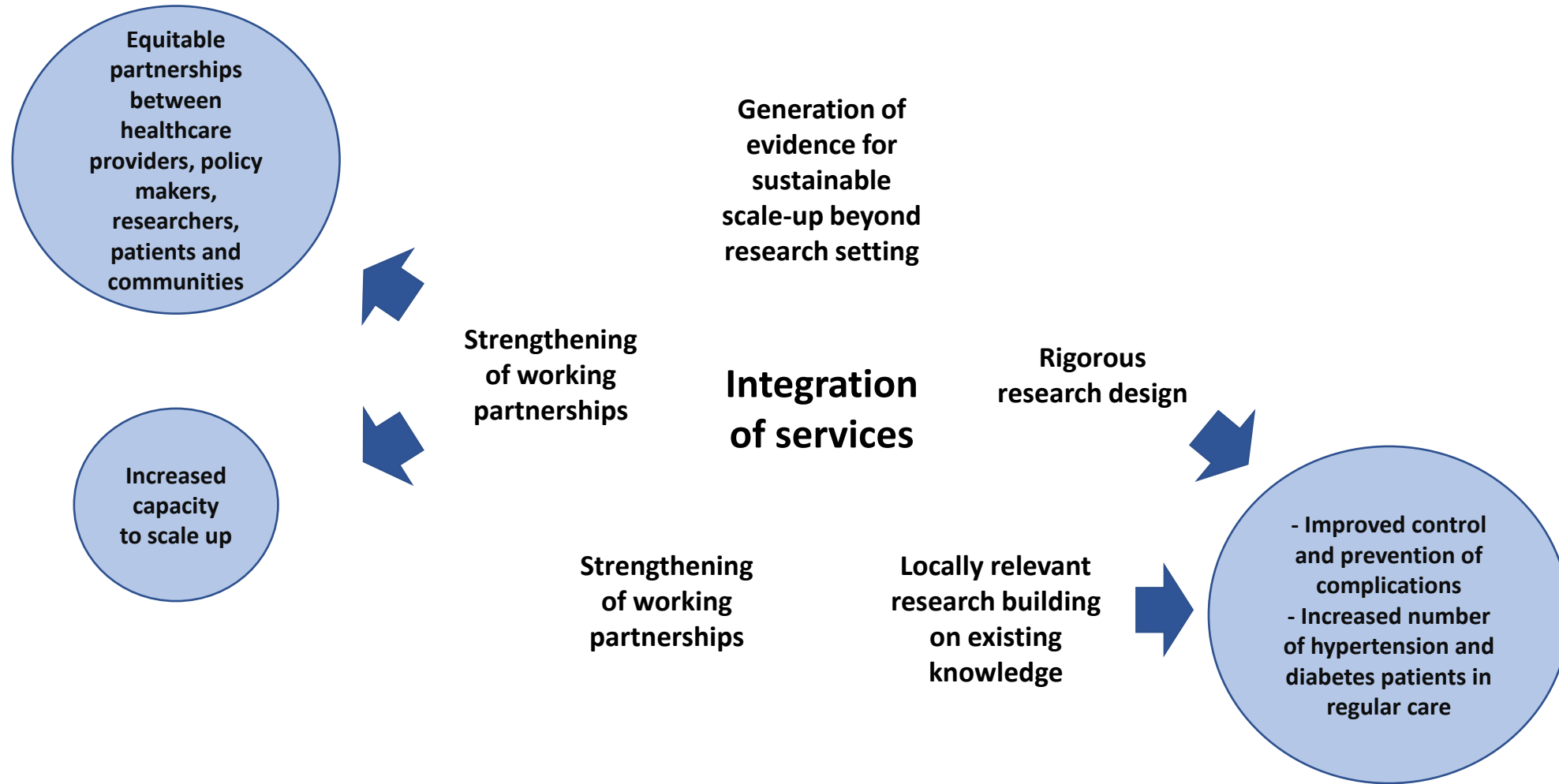
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a) Benefits for hypertension and diabetes control

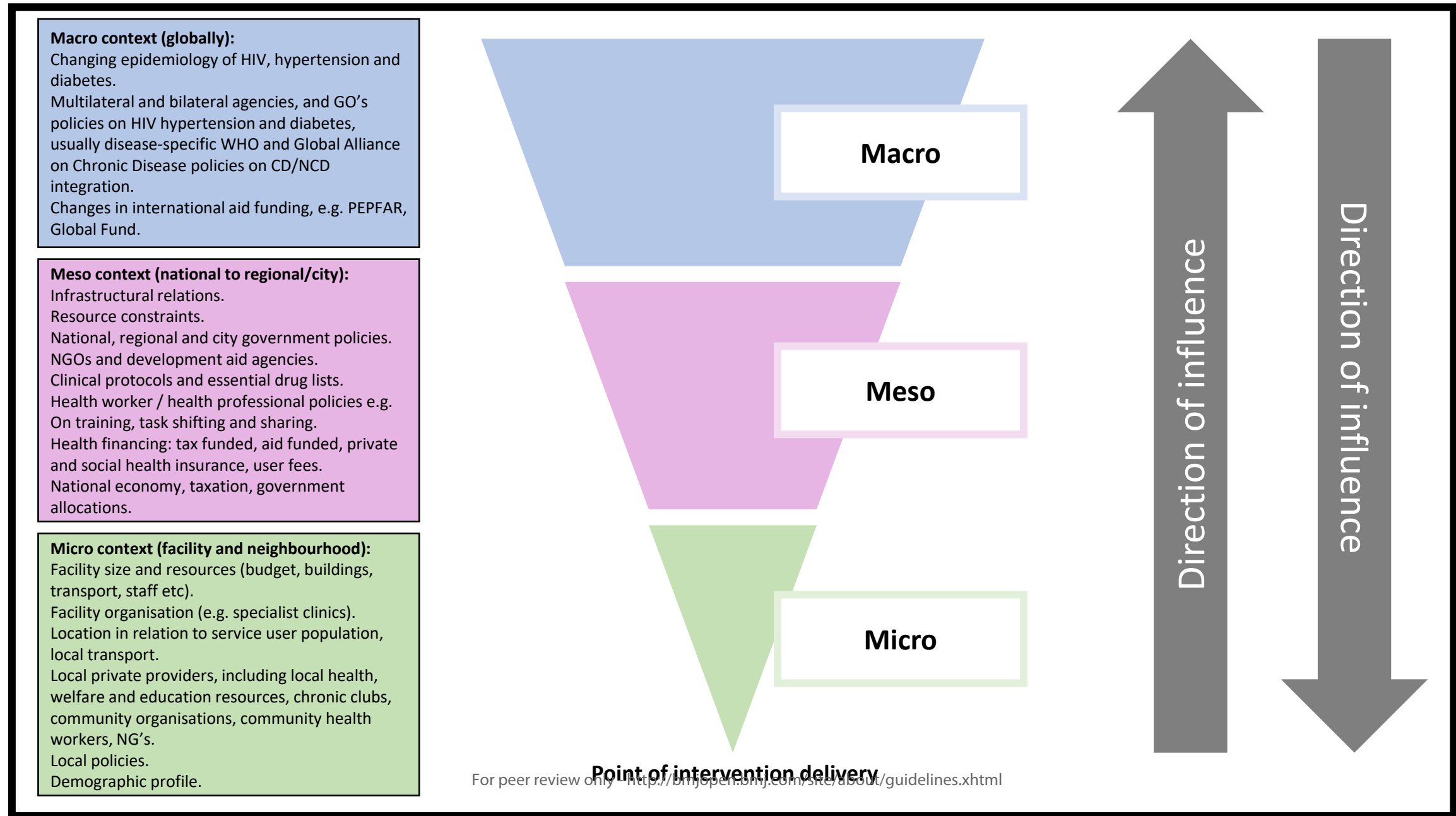
b) Benefits for HIV-control

Figure Two 'INTEAFRICA Conceptual Model'



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Figure Three 'Potential contextual influences on INTEAFRICA programme implementation cascade'



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