PROTOCOL for Work Package (WP) 2

Development and piloting of knowledge tests for people who provide primary clinical care in Nigeria and Kenya

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1. Study Summary

1.1. Purpose

This protocol describes one work package in a programme of work that aims to reduce the time interval between presentation to the formal health sector with a cancer symptom and receiving treatment for cancer (NIHR158242 – Reducing Delays in Cancer Care in sub-Saharan Africa). In this work package, we will develop and psychometrically validate a knowledge test for primary care clinicians. In subsequent work packages, we will develop a complementary method to assess clinician performance by means of standardised patients, then we will develop and pilot an educational intervention to improve recognition and referral of people with cancer symptoms before conducting a cluster randomised trial to evaluate the package. We hope to show that, as a result of the intervention, knowledge will increase (measured by the test developed in this work package), consultations will be more effective in identifying high risk patients (measured by standardised patients) and patient delay will be reduced. The entire programme will be underpinned by a further work package dedicated to understanding the system level factors that are necessary for the success and sustainability of service interventions. The test we develop in this work package will be made available to others and incorporated in Continuing Professional Development in Low- and Middle-Income Countries.

1.2. Development of knowledge test: Summary of process

1. We will develop a knowledge test which comprises two question formats:
    - Patient vignettes which describe a patient presentation and which will be followed by interactive questions on our five knowledge domains of history taking, clinical examination, differential diagnosis, treatment/management and next steps.
    - Stand-alone very short answer questions (VSAQs) which provide a short patient presentation and a single question focusing on one of our five knowledge domains.
2. Test content will be based on evidence and national guidelines.
3. Following piloting and psychometric assessment (below) we will trim our question pool.

1.3. Development process

The development will be overseen by Yakasai, (member of the recently formed Nigerian Federal Government Committee on guidelines for cancer referral), Omigbodun (past president of the West African College of Surgeons) and Asiki (Medical doctor and senior research fellow at the African Population and Health Research Centre in Nairobi). Technical expertise will be provided by Hamilton (who has experience in testing knowledge of cancer diagnosis in primary care), Brown (expert in the design and psychometric evaluation of clinical knowledge tests) and Lilford (who will ensure that the production of knowledge tests in this WP are co-ordinated with the production of scripts for the standardised patients in

WP3). The process will be governed by the local and international advisory structure for the grant and progress will be reported at the monthly programme management meeting.

1.4. Piloting and psychometrics of the knowledge test

1. In each of the three sites we will recruit 80 clinicians drawn from 40 large / small clinics, urban / rural areas, and different cadres representing their proportions in each site.
2. Each clinician will take part in two tests, three months apart in which some questions are repeated, and some are not.
3. This design allows us to calibrate the effect of prior exposure to a test on performance, net of any educational programme.
4. We will measure completion rates and question / test scores and how these vary by site, cancer type, risk level and knowledge domain. These observations will enable us to design the educational intervention to address knowledge gaps and to refine our sample size calculations for the cluster RCT.
5. We will use a one-parameter Rasch model to evaluate question difficulty across tests.
6. We will use Classical Test Theory item analysis to calculate question discrimination and identify poorly performing questions.
7. Data will also be analysed for internal consistency across questions (Cronbach alpha), and concurrent validity (correlating scores with those from the SP assessment).

Following the second test, a clinically trained researcher in each site will use a semi-structured tool to guide ten participating clinicians through a cognitive walk-through, discussion on indications for referral, and barriers to optimal practice.

2. Background

2.1. Delayed treatment of cancer in sub-Saharan Africa (SSA)

Delayed treatment is associated with reduced cancer survival and quality of life.[1-4] However, less than a quarter of common curable cancers in SSA present early (Stages I and II);[5] a figure we recently confirmed in Nigeria[6] and Kenya.[7]

A recent paper in Nature Medicine[8] on priorities for all cancer research in LMIC assigned the highest priority to “reduce the burden of patients presenting with advanced-stage disease” and the second highest priority to “solution-oriented research including overcoming health system barriers to accessing cancer care”.

2.2. Tackling causes of delay

There are many models of stages of delay, both generic[9] and cancer specific,[10 11] all separating pre-presentation delay from delay following presentation to the formal health system. Previous work by our team and others shows that over half the delay to treatment occurs *after* presentation to formal health services[12 13] – the delay we tackle in this study. [14]

More specifically we will tackle failure to refer or investigate patients who should be referred according to evidence and current guidelines. Poor diagnostic and communication skills are a major cause of delay[15-18] in SSA. After referral, emotional support, attitudes in the community (e.g., faith groups), access to resources, and responsiveness of specialist services all play a role in modulating 'churn' as patients return to the same and different clinics without progress towards resolution. [12] Across both the clinic and the subsequent pathway, our interventions will aim to strengthen health systems,[19] and evaluations will examine system-level factors that support or limit intervention effectiveness.

2.3. Overview

This protocol details a work package that aims to develop and pilot tests of applied knowledge of cancer symptoms in primary care. It is part of a wider study to develop, implement and evaluate methods to reduce delays in cancer care within the health service in Kenya and Nigeria. The knowledge tests will identify common gaps to be addressed in a clinician education intervention and function as an outcome measure in evaluation of the intervention.

The objectives of this work package are:

1. Develop knowledge tests
2. Pilot the tests
3. Undertake psychometric analysis of the pilot results
4. Identify common knowledge gaps

In a further Work Package, we will develop a protocol for deployment of Standardised Patients ('mystery shoppers') to make direct observations of the quality of care when a patient presents with symptoms of cancer. Some of the vignettes we develop for the Work Package described here will mirror the scripts used by the Standardised Patients. This will enable us to measure the knowledge to practice gap that has been described in previous studies of the quality of primary health care. Thus, in terms of Kirkpatrick's classification of educational outcomes, this Work Package will measure level two attainment (knowledge) while the Standardised Patient observations in the next Work Package observe how well participants apply what they have learned (level three).

2.4. Setting

The study is set in Nigeria and Kenya. Nigeria has a population of 219 million, larger than the population of the UK, France and Germany combined. Kenya, on the other hand, has a population of 53 million. Like much of SSA, these are lower middle-income countries that are introducing Universal Health Coverage through a system of public and private providers across primary, secondary and tertiary care. Typical of SSA, these countries all provide basic

diagnostic and surgical services.[20] Together these sites will enable us to take advantage of a wide geographic and socio-cultural spread.

In Nigeria, our study sites are in the North (Kano) and Southwest (Ibadan), purposively selected to cover ethnic, religious and culturally diverse populations. Kano, the second largest city in Nigeria with over 4 million people is predominantly Muslim and mainly inhabited by people of Hausa ethnicity. Ibadan is the third largest city with a population of 3.7 million with Christianity and Islam being the dominant religions. In Kenya, our study site is Nairobi County. Nairobi is the capital and largest city of Kenya, with a predominantly Christian population of 4.7 million.

3. Work programme

3.1. Topics studied

The knowledge test will focus on symptom types relating to cancers of the breast, uterus, colo-rectum, oesophagus and stomach, head-and-neck, urinary system, and lung. These cancers present recognisable symptom clusters where a competent clinician should consider cancer. They are also common cancers with the added advantage that some share symptoms of other serious diseases (e.g., lung cancer and tuberculosis; colon cancer and inflammatory bowel disease). This is an advantage since clinicians will learn about other diseases as a side-effect of learning about cancer diagnosis.

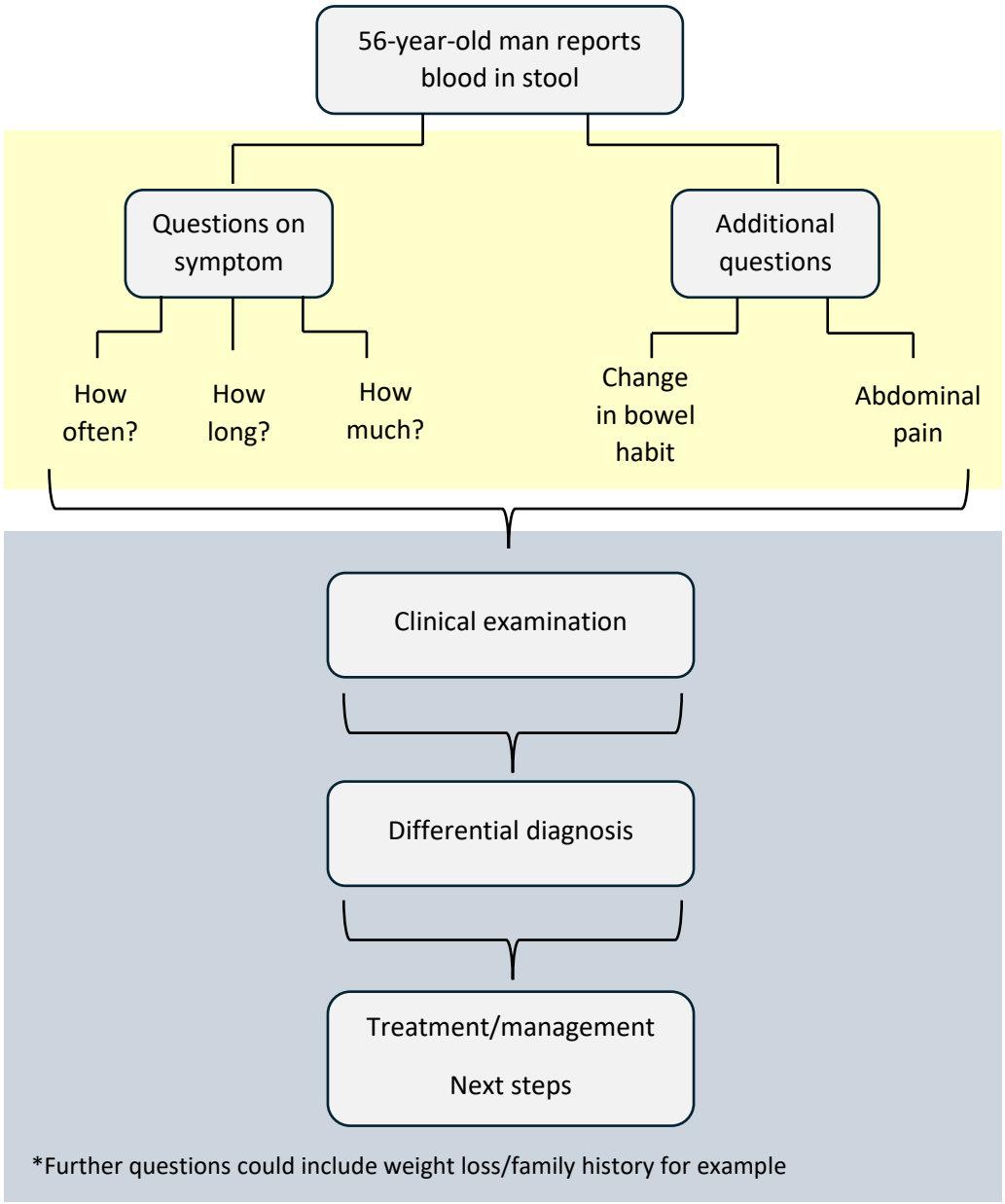
3.2. The knowledge test

Drawing from existing studies[21 22] and national guidelines,[23] we are in the process of developing two question formats to use in the knowledge test. Using a combination of question formats enables us to test knowledge across all included cancers at different levels of risk, as well as mirror the scenarios used in the simulated patient work package so we can evaluate the knowledge to practice gap. We seek to assess applied knowledge across five domains: additional questions (history taking), clinical examination, differential diagnosis, treatment/management and next steps/other knowledge about the cancer.
The question formats are:

1. Patient vignettes. The assessor will guide the clinician through a patient presentation, starting with a typical “opening statement” and following this up by asking about 1) questions the clinician would ask (and answering these), 2) clinical examinations the clinician should perform (and giving the results), 3) the differential diagnosis, and 4) treatment/management plan (e.g. investigations and/or referral). This scheme is shown diagrammatically in Figure 1.

2. Stand-alone very short answer questions (VSAQs). We will give the clinician a brief patient presentation and ask a single question related to one of the five knowledge domains. A VSAQ is designed to be answered in 5-10 words [24 25]

Figure 1: Flow diagram for vignettes for the knowledge test



Examples of each type of question are shown in the Supplementary Material.

Each clinician will answer four patient vignettes and 14 stand-alone VSAQs at each testing time point (there will be two tests, with an interval of approximately three months between tests). We will develop 10 vignettes (one for each cancer plus three control – 'non-cancer' – vignettes) and 27 VSAQs. We will focus on high-risk cancer symptoms in the vignettes, and a mix of risk levels in the VSAQs.

It is not possible for each clinician to answer each question in a single sitting. Therefore, to enable us to pilot sufficient questions (for psychometric purposes) whilst keeping test length acceptable, we will use an innovative sampling approach to determine which questions a

particular clinician will be asked. Figure 2 summarises our test specification. Repeating scenarios (anchor questions) across and between tests enables us to link the data across all scenarios and to determine the impact of testing on knowledge acquisition[26].

Scenarios describing cancer symptoms that should clearly trigger a referral (according to local guidelines) will be interposed with control scenarios. These control scenarios will be of two types. The first type will be cases with symptoms strongly suggestive of a condition (like post-viral sinusitis) that does not warrant referral. The second type of control will be a serious non-cancer condition (like hyperthyroidism or rheumatoid arthritis) where active management by the clinician is required (according to local guidelines). The reason for including these 'non-cancer' conditions is to reduce the probability of selection by default of cancer options through unvarying repetition of cancer scenarios. Our findings, though motivated by cancer diagnosis, will have beneficial effects beyond cancer.

We are working in collaboration with the Standardised Patient work package (see above) to ensure that our seven cancer vignettes mirror the scripts the Standardised Patients will follow when they make visits to clinical facilities. Thus, they will be initiated by the same patient presentation which should be followed by the same series of actions (Figure 1). Since the test vignettes (this protocol) and the standardised patient scripts (forthcoming protocol) are mirror images of each other, we will be able to estimate the knowledge-practice gap. This gap will inform the design of the educational intervention. The control conditions, unlike the cancer symptom scenarios, will not have mirror image equivalents in the Standardised Patient protocol.

Figure 2: Test specification

	Test @time point 1	**Test @time point 2**
3 cancer vignettes – covering all domains of knowledge High risk of cancer	3 vignettes randomly selected from the 7 created (one for each cancer).	1 vignette randomly selected from the 3 used at time point 1, plus 2 vignettes randomly selected from the 4 NOT selected at time point 1.
1 non-cancer vignette	1 vignette randomly selected from the 3 created.	1 vignette randomly selected from the 2 NOT selected at time point 1.
The positioning of the non-cancer vignette will be random in the complete set of 4 vignettes.		
14 Stand-alone VSAQs: per test form 4 Ctrl, 4 Low, 4 Med, 2 High risk, presented in a random order	Test form A, B or C randomly selected.	1 test form randomly selected from the 2 NOT selected at time point 1.

	Test form A	**Test form B**	**Test form C**
Breast	***Med***, High	Low, ***Med***	Ctrl, ***Med***
Urinary	Low, Med	**Ctrl**, Low	**Ctrl**, Med
Head & Neck	*Ctrl*, Low	*Ctrl*, High	Low, High
Lung	Ctrl, High	**Low**, Med	Ctrl, **Low**
Oesophageal/Stomach	*Low,* Med	*Low,* High	Ctrl, Med
Uterus	Ctrl, Low	Ctrl, **Med**	Low, **Med**
Recto-Colon	Ctrl, *Med*	Ctrl, *Med*	Low, High

Notes:
Anchor questions between test forms A and B are shown in italics, between test forms A and C are underlined, between test forms B and C are in bold and between all three test forms are in bold, underlined italics.
Ctrl refers to non-cancerous conditions, Low, Med and High refer to the risk of cancer given the presenting symptoms.
VSAQs will be spread across knowledge domains per test form as follows: 3 x additional questions, 3 x clinical examination, 3 x differential diagnosis, 3 x treatment/ management and 2 x next steps/other. At least one question per knowledge domain will be an anchor question.

3.3. Piloting (beta-testing) and sign off

The scenarios/questions to be used in the test for the RCT evaluation will be selected following piloting using formal psychometric analysis described below. Before we reach the piloting stage two further 'pre-clinical testing' procedures will be followed.

First, we will ask work colleagues (n > 4 in each site) to feedback on simulated test interviews as the tests develop. They will be asked for feedback on the understandability

and verisimilitude of the questions, and we will identify questions with likely ceiling or floor effects (too easy or too hard).

Second, all questions will undergo formal ratification from the Partnership Advisory Committees described below.

The above will be iterative processes, whereby we will improve our product before the formal pilot testing described below.

We enclose a selection of example *draft* questions as Supplementary Material A, to provide an idea of the form that the various questions will take.

3.4. Clinical implementation of the pilot knowledge tests

The knowledge tests will be implemented by direct interaction between the questioner and the participating clinician (either face-to-face or on-line). We select this method instead of written testing on the basis of our previous experience from the World Bank's eleven-country study in sub-Saharan Africa [27]. Data will be collected directly onto tablets and these tablets will also perform the randomisation of question order described above (Figure 2). This program will be thoroughly beta tested before it is deployed.

3.5. Selection of participating clinics for the pilot

We will recruit 40 clinics at each site (Kenya, Ibadan, Kano). Clinics will be selected purposively to include large / small clinics, urban / rural areas, and different cadres representing their proportions in each site. The clinics will be selected from a sampling frame of registered primary healthcare care facilities in each site with their geographic information system (GIS) coordinates. A diverse sample of clinics will be selected in each site from regions that that fall outside the areas demarcated for the main trial that will follow (WP5 in our overall programme of work). We aim to recruit a mean of at least two clinicians per site. By clinician we mean doctors, nurses and medical/clinical officers.

3.6. Recruitment of participants

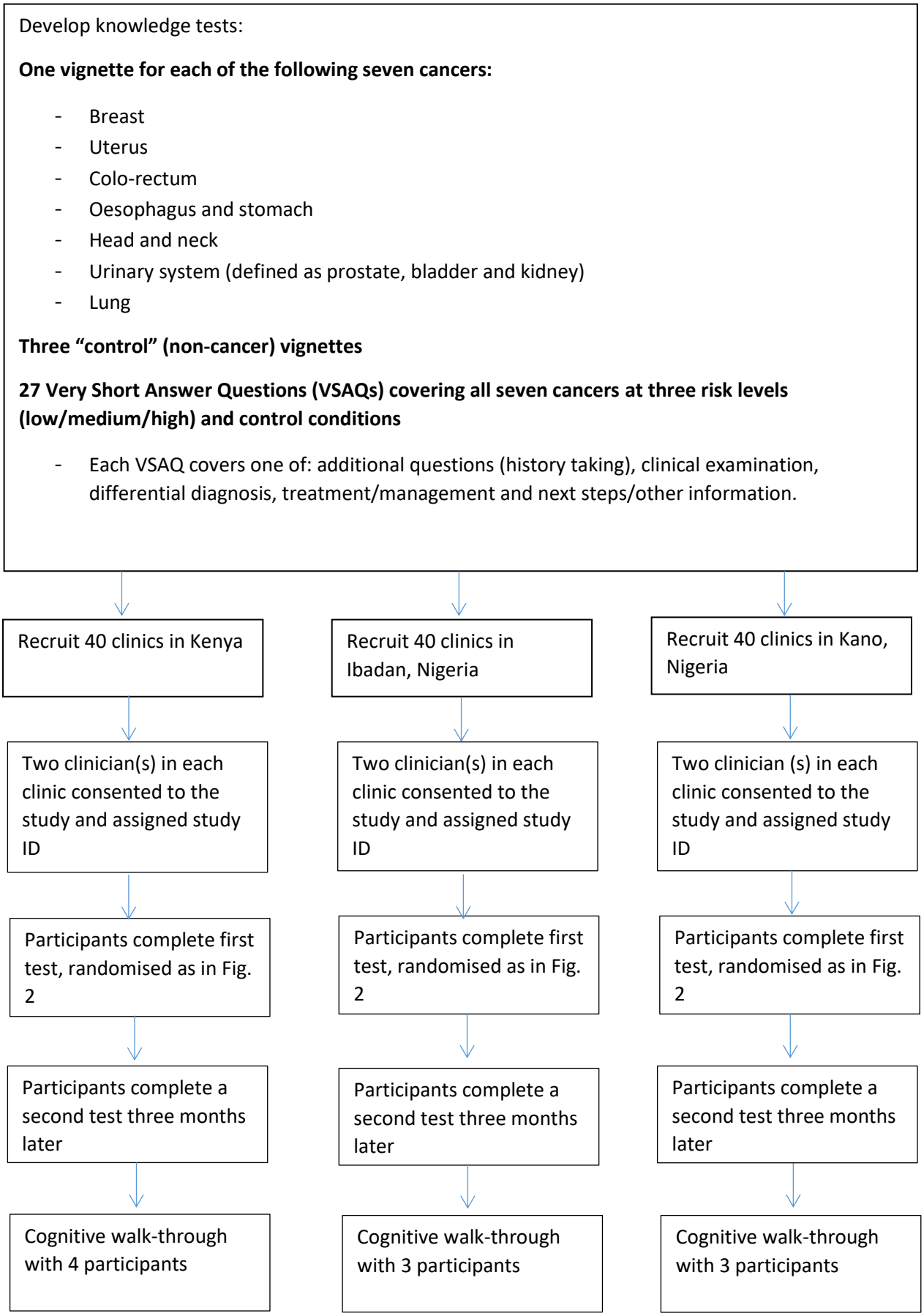
Clinicians will be randomly recruited from each of the 40 clinics to participate in the pilot knowledge test. We therefore expect to recruit at least 80 clinicians per site or a total of 240 clinicians across sites. The randomly selected clinicians will be sent a participant information sheet and consented to participate by a member of the research team. The participant information sheet will not mention cancer in order not to prime clinicians to make this response.

3.7. Test rollout (Figure 3)

Following consent participants will be asked whether they prefer a face-to-face or on-line knowledge test. Participants will receive a random selection of vignettes and VSAQs as shown in Figure 2. Participants will receive an invitation three months later to do the second test.

The tests will be recorded (voice only) unless the participant refuses. The recordings will be destroyed after the data have been analysed.

Figure 3: Developing and piloting of knowledge tests



3.8. Cognitive walkthrough

Ten out of the 240 clinicians will be randomly selected to participate in a cognitive walk-through (4 in Nairobi, 3 in Ibadan and 3 in Kano); this distribution will allow appropriate country-level representation. The cognitive walkthrough will be conducted by a clinical trained researcher at each site.

We are experienced in such a process[21]. There are four broad areas encompassing delays in investigation/referral of possible cancer: attitudinal (including views about the benefits of earlier cancer diagnosis/ harms from over-investigation); knowledge (including of the risks of cancer with specific presentations, and of how to investigate); practice factors (particularly access to and duration of appointments); and financial (including patient and health system costs)[21]. A grid capturing these will be used to structure the interviews. Although we have a ratification process from the local and international advisory committees, the cognitive walk though will seek views on the workability of national/local recommendations locally, to ensure our questions reflect the reality of current clinical practice.

This iterative process will generate a final, locally relevant question bank for the next stage.

3.9. Data analysis

From our total sample of 240 clinicians (80 at each site), we expect 222 clinicians to respond to each vignette and 213 to respond to each VSAQ. However, as we will use Item Response Theory (IRT) for analysis, we will be able to predict the scores that each clinician would have achieved on each vignette and VSAQ. Our quantitative analysis will include:

- Completion rates and question / test scores and how these vary by site, cancer type, risk level and knowledge domain. These observations will enable us to design the educational intervention to address knowledge gaps and to refine our sample size calculations for the cluster RCT.
- A one-parameter Rasch model to evaluate question difficulty across tests, using the anchor questions to enable fair comparisons.
- Classical Test Theory item analysis to calculate question discrimination (Pearson's item-rest correlation) and identify poorly performing questions.
- Internal consistency across questions (Cronbach alpha) and consideration of optimal test length for the main study.
- Concurrent validity (correlating scores with those from the SP assessment).

Our sample size of 240 clinicians will be sufficient for us to estimate the level of knowledge of the clinician cohort and to identify areas for development for inclusion in the educational intervention, which is a key aim of the pilot. Because we have had to make a trade-off between reliability and practicality (time constraints), the level of precision for each

individual clinician's level of knowledge might be modest at the piloting stage. However, we will be able to use the information obtained to determine the optimal mix and number of questions thereby maximising precision at the individual level and providing precise estimates of improvements in knowledge over time, allowing for a degree of correlation between clinicians within clinics.

4. Study organisation and oversight

The overall programme management structure is shown in supplementary material B.

4.1. Study oversight

The study will be overseen in each country by the country lead:

- Dr Gershim Asiki – Nairobi, Kenya
- Prof Olufunke Fayehun – Ibadan, Southwest Nigeria
- Prof Ibrahim Yakasai – Kano, North Nigeria

The final version of the knowledge test will be ratified by each country Partnership Advisory Group (Supplementary Material B).

4.2. Timeline

The study will be implemented over 12 months from February 2025 until January 2026. The 6 initial months will be spent on developing the templates and local adaption. The following 6 months will be spent on piloting and psychometrics of the knowledge tests. Specific deliverables and timelines are indicated in the Gantt chart below.

Table 1: Timeline of Activities

	2024					2025												2026
	Aug	Sep	Oct	Nov	Dec	Jan	Feb	Mar	Apr	May	Jun	Jul	Aug	Sep	Oct	Nov	Dec	Jan
Stakeholder engagement																		
Ethics application and approval																		
Recruitment of field researchers																		
Training																		
Recruit pilot clinics																		
Develop templates and local adaption																		
Piloting and psychometrics of knowledge tests																		
Data Analysis																		
Report writing and dissemination																		

5. Ethics

As stated in section 3.6, each participant will complete a consent form after agreeing verbally to take part. They will be able to select whether to be recorded and all recordings will be destroyed at the end of the study.

6. Dissemination and outputs

The study protocol will be published in a peer-reviewed journal. The referral guidelines, vignettes and scoring system on clinical knowledge will also be disseminated through publication, targeted mailing and through attendance at selected high impact meetings and through contacts with organisations such as WHO.

References

1. Neal R, Tharmanathan P, France B, et al. Is increased time to diagnosis and treatment in symptomatic cancer associated with poorer outcomes? Systematic review. *British journal of cancer* 2015;112(1):S92-S107.
2. Hamilton W, Walter FM, Rubin G, et al. Improving early diagnosis of symptomatic cancer. *Nature Reviews Clinical Oncology* 2016;13(12):740-49.
3. Richards M. The size of the prize for earlier diagnosis of cancer in England. *British journal of cancer* 2009;101(2):S125-S29.
4. Jensen H, Tørring ML, Vedsted P. Prognostic consequences of implementing cancer patient pathways in Denmark: a comparative cohort study of symptomatic cancer patients in primary care. *BMC cancer* 2017;17:1-10.
5. Jedy-Agba E, McCormack V, Adebamowo C, et al. Stage at diagnosis of breast cancer in sub-Saharan Africa: a systematic review and meta-analysis. *The Lancet Global Health* 2016;4(12):e923-e35.
6. Omigbodun AO, Agboola AD, Fayehun OA, et al. Trends in Clinical Stage at Presentation for Four Common Adult Cancers in Ibadan, Nigeria. *medRxiv* 2023:2023.09. 22.23295952.
7. Karagu A, Ng'ang'a A, Kibachio J, et al. Developing a national cancer control plan through effective partnerships: a case of Kenya national cancer control strategy 2017-2022: American Society of Clinical Oncology, 2018.
8. Pramesh C, Badwe RA, Bhoo-Pathy N, et al. Priorities for cancer research in low-and middle-income countries: a global perspective. *Nature medicine* 2022;28(4):649-57.
9. Organisation WH. World Health Organisation: Guide to cancer early diagnosis. *Geneva, Switzerland* 2017
10. Walter F, Webster A, Scott S, et al. The Andersen Model of Total Patient Delay: a systematic review of its application in cancer diagnosis. *Journal of health services research & policy* 2012;17(2):110-18.
11. Coxon D, Campbell C, Walter FM, et al. The Aarhus statement on cancer diagnostic research: turning recommendations into new survey instruments. *BMC health services research* 2018;18:1-9.
12. Makene FS, Ngilangwa R, Santos C, et al. Patients' pathways to cancer care in Tanzania: documenting and addressing social inequalities in reaching a cancer diagnosis. *BMC Health Services Research* 2022;22(1):189.
13. Brand NR, Qu LG, Chao A, et al. Delays and barriers to cancer care in low-and middle-income countries: a systematic review. *The oncologist* 2019;24(12):e1371-e80.
14. Petrova D, Špacírová Z, Fernández-Martínez NF, et al. The patient, diagnostic, and treatment intervals in adult patients with cancer from high-and lower-income countries: A systematic review and meta-analysis. *PLoS Medicine* 2022;19(10):e1004110.
15. Mutebi M, Wasike R, Mushtaq A, et al. The effectiveness of an abbreviated training program for health workers in breast cancer awareness: innovative strategies for resource constrained environments. *Springerplus* 2013;2:1-10.
16. Kisuya J, Wachira J, Busakhala N, et al. Impact of an educational intervention on breast cancer knowledge in western Kenya. *Health education research* 2015;30(5):786-96.
17. Ngugi CW, Boga H, Muigai AW, et al. Factors affecting uptake of cervical cancer early detection measures among women in Thika, Kenya. *Health care for women international* 2012;33(7):595-613.

18. Surgery NGHRUoG. Quality and outcomes in global cancer surgery: protocol for a multicentre, international, prospective cohort study (GlobalSurg 3). *BMJ open* 2019;9(5):e026646.
19. Rowe AK, Rowe SY, Peters DH, et al. Effectiveness of strategies to improve health-care provider practices in low-income and middle-income countries: a systematic review. *The Lancet Global Health* 2018;6(11):e1163-e75.
20. Knight S, Shaw C, Pius R. GlobalSurg Collaborative and National Institute for Health Research Global Health Research Unit on Global Surgery. Global variation in postoperative mortality and complications after cancer surgery: a multicentre, prospective cohort study in 82 countries. *Lancet* 2021;397(10272):387-97.
21. Rose PW, Hamilton W, Aldersey K, et al. Development of a survey instrument to investigate the primary care factors related to differences in cancer diagnosis between international jurisdictions. *BMC family practice* 2014;15:1-8.
22. Sheringham J, Sequeira R, Myles J, et al. Variations in GPs' decisions to investigate suspected lung cancer: a factorial experiment using multimedia vignettes. *BMJ quality & safety* 2017;26(6):449-59.
23. Health Mo. National Guidelines for Cancer Management. 2013 doi: Available from https://knh.or.ke/wp-content/uploads/2017/08/National-Cancer-Treatment-Guidelines2.pdf
24. Sam AH, Hameed S, Harris J, et al. Validity of very short answer versus single best answer questions for undergraduate assessment. *BMC Medical Education* 2016;16:1-4.
25. Sam AH, Westacott R, Gurnell M, et al. Comparing single-best-answer and very-short-answer questions for the assessment of applied medical knowledge in 20 UK medical schools: Cross-sectional study. *BMJ open* 2019;9(9):e032550.
26. Bala L, Westacott RJ, Brown C, et al. Twelve tips for introducing very short answer questions (VSAQs) into your medical curriculum. *Medical Teacher* 2023;45(4):360-67.
27. Daniels B, Yi Chang A, Gatti R, et al. The medical competence of health care providers in sub-Saharan Africa: Evidence from 16 127 providers across 11 countries. *Health Affairs Scholar* 2024;2(6)

Supplementary Material A – Question examples

Question 1: Vignette (a condition where the clinician should consider and exclude Cancer/Tuberculosis. They should either arrange a chest x-ray or refer.)

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Case I : A 45-year old woman comes to you and says they have a cough and they are losing weight

Question Number	Type of Questions	Provider Response Asked 1 Did not Ask 0	Client Record
START TIME	H H : M M		
I. History Which questions would you ask?			
Any question gets 1 mark [maximum 4 marks]			
H1	Duration?		
H2	Cough productive?		
H3	Any blood in cough?		
H4	Hungry/Appetite?		
H5	How much weight loss?		
H6	Fatigue/Tiredness?		
H7	Night sweat?		
H8	Smoker? How many?		
H9	Pain? Back, chest?		
H10	Short of breath?		
H11	Any contact with person with T.B?		
Record others for quality improvement			
H12	*Additional:*		
H13	*Additional:*		
H14	*Additional:*		
H15	*Additional:*		
H16	*Additional:*		

II. Examinations What would you look for?			
Any question gets 1 mark [maximum 5 marks]			
E1	General appearance/Signs emaciation?		
E2	Blood pressure		
E3	Pulse rate		
E4	Neck/Lymph Nodes		
E5	Pallor/Mucus membrane		
E6	Chest examination (auscultation and percussion)		
Please note any additional examinations mentioned by the provider below (text)			
E7			
E8			
E9			
E10			
E11			
III. Differential diagnosis			
D1	**What is your differential diagnosis?**	**Answer** 1. Lung cancer [2 marks] 2. TB [2 marks]	= 4 marks
IV. Management What actions would you take?			
Either refer to specialist OR chest x-ray [maximum 4 marks – full marks] 1 mark for TB test (e.g. Mantoux)			
Record open format			

Question 2: Vignette (a non-cancer control condition; symptoms classic for hyperthyroidism)

.

Case I: A 29-year old man comes to you saying that he has palpitations (fast heart beat), heat intolerance and is losing weight

Question Number	Type of Questions	Provider Response Asked 1 Did not Ask 0	Client Record
START TIME	☐☐ H H : ☐☐ M M		
I. History Which questions would you ask?			
Any question gets 1 mark [maximum 4 marks]			
H1	Duration?		
H2	Any pain?		
H3	Fainting?		
H4	Hungry/Appetite?		
H5	Diarrhoea?		
H6	Fatigue/Tiredness?		
H7	Frequent bowel movement?		
H8	Insomnia/Can't sleep?		
H9	Family history?		
H10	Sweating/Fever?		
H11	Cough?		
Record others for quality improvement			
H95	*Additional:*		
H96	*Additional:*		
H97	*Additional:*		
H98	*Additional:*		
H99	*Additional:*		
II. Examinations What would you look for?			
Any question gets 1 mark [maximum 5 marks]			

E1	General appearance/Signs emaciation?		
E2	Blood pressure		
E3	Pulse rate		
E4	Neck/Lymph Nodes		
E5	Pallor/Mucus membrane		
E6	Eyes/Bulging eyes		
E7	Neck/Thyroid gland		
E8	Abdominal mass		
Please note any additional examinations mentioned by the provider below (text)			
E9			
E10			
E11			
E12			
E13			
III. Differential diagnosis			
D1	**What is your first diagnosis on the differential?**	**Answer** **1. Hyperthyroidism [1 mark]** **2. Thyrotoxicosis [1 mark]** **3. Graves' disease [1 mark]** **4. Premature menopause [1 mark]**	=4 marks
III. Management **What actions would you take?**			
2 marks for thyroid analysis; 1 mark for ECG [maximum 2 marks] 1 mark for no treatment or symptomatic pending test			
Record open format			

Question 3: VSAQ

Lung, medium risk, differential diagnosis

A 50-year-old man tells you that he is worried as he has lost a lot of weight over the last 3 months. He tells you that he hasn't been particularly hungry or thirsty, but he has been more tired than usual. He has smoked 10 cigarettes a day for 30 years and has had a cough for over three months, which has recently started to give him chest pain.

What is your differential diagnosis? List up to THREE potential diagnoses, including any that it is imperative to rule in/out.

Answers: Lung cancer, COPD, TB, Sarcoidosis, GERD

Question 4: VSAQ

Breast, medium risk, clinical examination

A 75-year-old woman tells you her left nipple retracted quite suddenly two months ago. She tells you that this has never happened before and that she has not had any previous surgery. The woman looks well.

Assuming the woman consents, list THREE signs that it would be important to look for during clinical examination.

Answers: Check if unilateral, any lump, features of infection, skin changes (dimpling/tethering)

Supplementary Material B – Study Organisation

The study will be organised according to the project monument structure for the wider study, served by a network of committees, advisory groups and in-country groups as detailed below.

The Executive Steering Committee (ESC)

The ESC provides overall decision-making and strategic direction to ensure good governance holding the Joint Leads and in-country leads to account for progress against milestones. The Committee will have an independent chair, and will be supported by the following external members: Professor Zulfiqar Bhutta (Centre for Global Child Health, Toronto, Canada and Center of Excellence in Women & Child Health and Aga Khan University), Professor Mike

English (Centre for Tropical Medicine and Global Health, University of Oxford), Dr Modupe Odunsi (Medical director of cancer hospital in Lagos), Professsor Paula Griffiths (Professor of Population Health at Loughborough University), Dr Miriam Mutebi TBC. and at least two Community representatives from our Partnership Advisory Group (see below). Faculty members will be the PI, in-country leads, training lead, and cross-cutting group leads. The committee will meet at 0, 6, and 12 months.

The International Strategic Advisory Group (ISAG)

The ISAG provides advice on scientific and policy strategy and the scope of the overall direction of the programme covering research, health systems strengthening, capacity building, societal impact, and dissemination. The ISAG will meet at least once during this work package and TBC will chair. TBC will be supported by external members including national and international policymakers and stakeholder representatives from each collaborating country (Partnership Advisory Group below), including community representatives. The committee will help distil generalisable lessons and develop theoretical insights into health systems.

Partnership Advisory Groups (PAG)

A local PAG in each study site will bring together key stakeholders, including community representatives, local policymakers and formal and voluntary sectors. They will contribute throughout the research process and specifically to developing the vignettes. They will meet monthly and more frequently over periods of maximum activity. They will have representation on the ISAG. They will co-opt additional people for specific purposes e.g., people with expertise in referral practice for design of knowledge tests.

Programme Management and Finance Committee (PMC)

The PMC is chaired by the Joint Leads and held virtually monthly to discuss operational and financial issues; KPIs/performance; risk management; track impact; promote collaboration; support capacity building; and encourage follow-on applications. At least two community representatives and all researchers are invited to contribute. Leads for Training (Owoaje / Fayehun), Community Engagement and Involvement (Mohammed), Monitoring, Evaluation and Learning (Omigbodun) and Data Management and Governance (Watson) will attend.

Financial Monitoring Committee (FMC)

The FMC will meet quarterly to produce financial reports for the funder, and monitor budgets and spend against activities within each site.

Cross-cutting groups

Different countries will have responsibility for co-ordination activities across the collaborating centres (section 6). Working groups (including community representatives) will be formed as follows:

a. Training and Capacity Strengthening led by Owoaje/Fayehun, University of Ibadan.
b. Community and policy engagement led by Mohamed, APHRC and Muthoni.
c. Evidence synthesis led by Lilford.
d. Economics led by KEMRI.
e. Systems research and health sociology led by Williams / Griffiths / Fayehun.

These groups will meet face-to-face at the yearly International Strategic Advisory Group meeting, and then virtually as required.

In-Country Research Teams

In-country research teams will meet weekly to operationalise their activities.

Meeting formats

To reduce our carbon footprint and to encourage camaraderie meeting formats will be based on the method used by patient cafes in Kenya, where some people (selected at random) attend meetings face to face, while others attend virtually.