

PROTOCOL for Work Package (WP) 3

Development of the standardised patient method to assess quality of cancer 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, WP3, we will develop, and test a method to evaluate the quality of diagnosis and referral utilizing Standardised Patients (SPs). Standardised Patients have been used for research in all parts of the world to assess the quality of care delivered. They simulate real patient encounters and have been used before in both Kenya and Nigeria. They have also been used in well-publicized World Bank studies. In subsequent work packages, we will develop and pilot an intervention to improve recognition and referral of people with cancer symptoms. We hope to show that, because of the intervention, knowledge will increase, 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 intervention we develop will be made available to others and incorporated in Continuing Professional Development in Low- and Middle-Income Countries (LMICs).

For several reasons (described in detail in this protocol as well as the informed consent waiver request in Section 5), we are requesting a waiver of informed consent for the pilot. We have received funding from NIHR to conduct this project. The funding agency has peer-reviewed the grant proposal and thus the project has undergone scientific review. The study will be conducted contingent on and upon ethical clearance.

1.2. Objectives

The SP method will help identify common gaps to be addressed in clinical practice (including asking history questions, making referrals, requesting lab tests, and dispensing or prescribing medicines) for cancer-related conditions in primary care settings. This information will inform the intervention and function as an outcome measure in evaluation of the intervention.

The objectives of this WP are:

- (1) Develop SP cases
- (2) Trial SP cases
- (3) Analyse results for validating the SP method for developed cases
- (4) Measure clinical performance, variation of performance overall, by clinical condition and provider characteristics and the knowledge practice gap

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), Kwan and Das (experts in the design and evaluation of SP deployment), Daniels and Watson (statistical expertise), and Lilford (who will ensure that the production of knowledge tests in WP2 are coordinated with the production of scripts for the SPs in WP3). The process will be governed by the local and international advisory structure for the grant. Progress will be reported at the monthly programme management meeting.

- We will develop a series of SP cases to describe a patient presentation and to guide responses over five knowledge domains of: history taking, clinical examination, differential diagnosis, treatment/management and next steps.
- Following the consultation, the SP will complete a form that forms the basis for assessment over the above five domains; did the clinician ask the appropriate questions, do or offer the correct examination, explain the possible causes clearly, take the correct action in terms of testing or referring and explain what would happen next and why.
- SPs will then be recruited and trained following a process with which we are familiar.

2. Introduction and Rationale

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

There is extensive evidence that delayed cancer treatment drives worse outcomes in LMICs. More than half of the delay takes place after the patient has presented to the formal health sector.¹ Patients with worrying symptoms are often not referred for diagnosis and treatment. There is extensive evidence that primary care is generally of low quality in sub-Saharan Africa; the World Bank eleven country study (using clinical vignettes) found that less than half of patients with clear-cut symptoms are currently diagnosed and referred.² Except for lung disease (where symptoms of cancer and Tuberculosis overlap), there have been no direct measurements of the quality of referral in patients with cancer symptoms according to a survey of patients with cancer.¹ The purpose of this Work Package is to develop a method to measure the quality of diagnosis and referral for patients who should be referred according to local and international guidelines.

2.2. Use of standardised patients & other approaches to quality measurement

A variety of methods are available to measure quality of care, or clinical performance and they have different advantages and disadvantages^{3,4} Table 1 below summarizes different quality measures by assessing (A) the extent to which they measure knowledge versus practice; (B) the extent to which they can provide estimates that account for confounders; and (C) the extent to which they are able to provide information on a broad set of illnesses, highlighting the advantages and disadvantages of different measures.⁴

Clinical performance when presented with patients with cancer symptoms is the focus of this WP. This will be the first step for measuring and improving quality of cancer care in sub-Saharan Africa

(SSA). If successfully implemented, this work package will produce critical data to understand a key bottleneck in the provision of care. Generated knowledge can lead to recommendations on how to improve quality and reduce diagnostic delays, which is a high priority of the control and management of non-communicable diseases, especially in LMIC settings undergoing an epidemiological transition and seeing increased prevalence and incidence in different types of cancer. Collecting and documenting this information in the settings of our interest is particularly important since they account for the majority of “first contacts” in primary care.

Table 1. Types of quality-of-care measures

Measure of Quality	Measures Knowledge	Measures Practice	Accounts for Case-Mix	Accounts for Patient-Mix	Hawthorne Effects (<i>i.e., providers may change their behaviour because of the study</i>)	Illnesses Covered
Knowledge Vignettes	Yes	No	Yes	Yes	Yes	All
Clinical Observation	No	Yes	No	No	Yes	Limited in two ways. First, “serious” illnesses like unstable angina will show up on a sporadic basis. Second, the observer never knows what the patient has—and doctors frequently make incorrect diagnoses.
Chart Abstraction	No	Yes	No	No	No	Similar to clinical observation, but providers rarely keep patient charts. Even when they exist, charts tend to be incomplete and don’t accurately reflect patient-provider interactions.
Standardised Patients	No	Yes	Yes	Yes	No	Limited to (A) adults only with some exceptions for non-adult presentations; (B) diseases that don’t have any obvious physiological symptoms (which cannot be mimicked) and (C) conditions that don’t require invasive exams—particularly in LMICs.

While knowledge vignettes and provider observation methods generate insight into specific components of quality of care, these methods have significant limitations for understanding quality.^{5,6} Vignettes provide an accurate picture of provider knowledge for a wide range of illnesses and can control for case and patient-mix, but they do not reflect clinical practice, as large “know-do” gaps (*i.e., the difference between what is known by a health care provider and what the same health care provider does in practice*) have been documented in a variety of settings.^{4,5,7,8}

Clinical observation (either direct or videotaped) can provide information about clinical practice, but this method is limited in four ways. First, observed differences in quality may be confounded

with differences in patients and illnesses presented. Although it is possible to control for case and patient mix using vignettes, observed measures of what happens in practice are subject to the usual confounders of severity and patient characteristics. Second, because most patients on any given day present with self-limiting or “minor” illnesses, it is very difficult to assess process quality for patients with severe or life-threatening illnesses. For example, it is likely that several weeks of observation would be required before an individual with a specific type of cancer is observed in the practice of a regular provider to observe the type of care that is provided. Third, the presence of an observer in the clinic may itself change the provider’s behaviour (i.e. the “Hawthorne effect”).^{7,8}

The indicator of the quality of clinical practice in this study will be based on the use of SPs. Formally, an SP is an individual who is recruited, hired, and extensively coached to portray the historical, physical, and emotional features of an actual patient accurately and in a standardised, consistent manner. They come from all walks of life and need to be emotionally mature, affable, and intelligent and have flexible schedules (since assignments are rarely regularly scheduled).

There are two components of the SP approach: standardization and simulation. The objective of standardization is to present a case in a clinically accurate and consistent manner while the objective of simulation is to imitate the natural environment in which clinical encounters happen in any given social context. The goal is to “pass” as a normal patient without being detected by the medical service provider. All the SPs portraying a particular scenario are meticulously trained and rehearsed to ensure that the clinical presentation as well as the emotional, physical and psychosocial aspects of the patient they represent — speech, body language, dress, reactions to physical examinations — are standardised thus ensuring that each provider, when meeting an SP, will face the same clinical challenge. An ideal SP can also be coached to accurately recall details of his or her encounter with health care providers, thus providing an opportunity to generate data on quality of care (e.g. to what degree a task is done or not done, whether a question is asked) and to provide feedback about the process including the patient centeredness of the provider.

The SP methodology thus presents an opportunity to control the case mix and the patient presentation, enabling us to obtain a measure of quality that is comparable across all providers. It also provides a measure of clinical performance uncontaminated by Hawthorne effects and recall bias. Compared to provider observation and vignettes, the use of SPs should give a more “real-world”, and hence more accurate, portrayal of a doctor’s effort and expertise. With the appropriate design of clinical cases and carefully trained SPs, it is possible to detect both errors of omission and commission. For all these reasons, SPs are the “gold standard” method of assessing provider communication skills and behaviour.

However, SP-based studies also have their limitations. Perhaps the most restricting concern the kinds of cases that can be used in LMIC settings. Due to ethical concerns, case presentations that require invasive examinations are by necessity eliminated. Although intimate examinations do not preclude the use of SPs in medical education in high-income countries, we will train SPs to provide a realistic explanation to avoid them if they are offered. SPs will also be trained to document what they were offered as this information contributes to the quality score - see below.

2.3. 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. Together these sites will enable us to take advantage of a wide geographic and socio-cultural spread.

In Kenya, our study site is Kiambu County. Kiambu is a municipality of Kenya, with a population of 2.4 million. 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.

3. **Work Package 3 (WP3)**

Overall, we will implement our SP study based on protocols from previous SP studies, including studies conducted in Nairobi in 2014, across Kenya in 2018, and in the Nigerian states of Lagos and Kano in 2019.^{4,9–12}

3.1. SP case development

For this study, individuals who are hired to portray as SPs will present SP cases. Each SP case is comprised of a narrative script and an exit survey. The script describes the social milieu of the presenting case as well as the situation that motivates the individual to access health care services the day of the visit. The script will specify a standard opening statement (complaint), an appropriate sociodemographic background, and a series of responses to a variety of clinical inquiries. The responses will be designed to allow clinicians to rule out alternative causes for the initial complaint and indicate a serious underlying cause, after sufficient questioning. Corresponding to the script, the exit survey will collect information from the visit with a sampled provider. This information will become quality of care data for the analysis. **Appendix A** includes an SP case with its corresponding script (A1) and exit questionnaire (A2).

We will develop SP cases for different symptom complexities across seven main cancer symptom groups and three control cases, described in Table 2. They are 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. Three “control” cases (early rheumatoid arthritis, acute asthma, and hyperthyroidism) will also be developed. The inclusion of these control cases will help differentiate whether observed levels of quality of cancer-related care are specific to cancer symptoms or simply reflect more general provider practice, improve generalizability across SP presentations, offers further observations for power

calculations, and provides a more stable baseline for comparison than a single control case when implementing SPs for monitoring in subsequent WPs.

Number	SP Case	Potential SP Implementation Risks
SP Case 1	Early Rheumatoid Arthritis	None
SP Case 2	Acute Asthma	None
SP Case 3	Suspected Colorectal Cancer	Declines if offered a rectal examination
SP Case 4	Suspected Head & Neck Cancer #1	None
SP Case 5	Suspected Head & Neck Cancer #2	None
SP Case 6	Suspected Lung Cancer	None
SP Case 7	Hyperthyroidism	None
SP Case 8	Suspected Gastric Cancer	None
SP Case 9	Suspected Uterine Cancer	Patient asks if she may return if offered internal examination
SP Case 10	Suspected Urinary Cancer (haematuria - high risk)	Patient asks if he may return if offered internal examination

SP scripts and exit questionnaires corresponding to the 10 case groups above will be developed by our research team. A Partnership Advisory Group (PAG) in each study site will be convened to, among other things, advise our team on case development to ensure local guidelines are captured and contextual content is incorporated, while also maintaining the ability to assess key outcomes across study sites. The PAG will bring together key stakeholders, including community representatives, local policymakers and formal and voluntary sectors. We will finalize the cases before the initiation of the pilot. SPs participating in training (and the subset who will be selected and hired for fieldwork) will also contribute to the development of standardised narratives in the scripts. Members of the PAG will also advise on outcome measures for each case, ensuring that they are contextually relevant for the study site.

3.2. SP recruitment and training

For the 10 SP case groups listed in Table 2, we will aim for 2 SPs assigned to each case group, or a total of 20 SPs (with the potential for 2-3 additional substitutes), to conduct the study. The process to reach the final SP cohort at each study site is as follows:

- A fieldwork position will be advertised, leveraging existing networks with survey and research entities
- Applications will be reviewed and availability throughout the project schedule will be assessed.
 - o 50-60 individuals will be invited for a 2-day interview
- The research team and supervisors will conduct a 2-day interview which introduces an SP script and exit survey, offers opportunities for groups of interviewees to discuss the content of the scripts and exit surveys, and has each interviewee to act out the case in a mock scenario. Interviewees will be graded for strong work ethic, punctuality, ability to work on a team, adaptable, strong attitude, commitment to good data quality, and ability to portray the case realistically and accurately based on the written script. It will also be important to ensure that interviewees can express whether they have strong feelings and/or opinions for or against the health system, health facilities, or providers, or if they have worked or have close family/friends in health facilities that may be a part of the sample. Such factors could interfere with responsibilities of being an SP.
 - o The team will then invite 28-35 individuals (from the original 50 to 60) as recruits to participate in the training, which will serve as a further selection process for the final SP cohort for the pilot.
- SP recruits will be extensively trained over the course of three weeks. The recruits will be graded by supervisors and the research team over the course of training based on similar criteria as the 2-day interview, as well as by training exercises and quizzes.
 - o Over the course of the three-week training, the research team will aim to identify the best 20 candidates (with 2-3 additional substitutes) for the final SP cohort for the pilot.

Table 3 shows the SP training agenda. SP recruits will be extensively trained over the course of three weeks. Following Kwan et al. (2018), recruits first focus on learning the cases while simultaneously helping in the evolution of the scripts, as described under 3.1. At the beginning of the 1st week, all recruits will gain familiarity with all cases, but by the middle of the 1st week, recruits will be allocated to a single case group for exercises for the remainder of the week.

Table 3. SP training agenda

	Week 1						Week 2						Week 3					
	MONDAY	TUESDAY	WEDNESDAY	THURSDAY	FRIDAY	SATURDAY	MONDAY	TUESDAY	WEDNESDAY	THURSDAY	FRIDAY	SATURDAY	MONDAY	TUESDAY	WEDNESDAY	THURSDAY	FRIDAY	
9.00 - 9.30	SP Introduction	Introduction to Group Work	Group work: Script and Narrative Development	Group reenactment of scripts and SP cases	Introduction to Exit Questionnaire	Exit Questionnaire	Introduction to Mock Interviews	Mock interviews	Mock interviews for SP cases with practice recall questions	Mock interviews	Quality of care introduction	Mock interviews	Mock interviews to practice recall questions	Dry runs for the team	Dry runs for the team	Dry runs for the team	Final debriefing of the team	
10.00 - 10.30	Review of SP cases	Review of SP cases in groups			Exit Questionnaire		Mock interviews				Mock interviews							Mock interviews
10.30 - 11.00																		
11.00 - 11.30																		
11.30 - 11.44	TEA/ COFFEE BREAK	TEA/ COFFEE BREAK	TEA/ COFFEE BREAK	TEA/ COFFEE BREAK	TEA/ COFFEE BREAK	TEA/ COFFEE BREAK	TEA/ COFFEE BREAK	TEA/ COFFEE BREAK	TEA/ COFFEE BREAK	TEA/ COFFEE BREAK	TEA/ COFFEE BREAK	TEA/ COFFEE BREAK	TEA/ COFFEE BREAK	TEA/ COFFEE BREAK	TEA/ COFFEE BREAK	TEA/ COFFEE BREAK	TEA/ COFFEE BREAK	
11.44 - 12.00	Review of SP cases	Review of SP cases in groups	Group work: Script and Narrative Development	Risk Mitigation Strategies (Thermometers, invasive exams, lab tests, treatments given, avoiding detection)	Exit Questionnaire	Exit Questionnaire	Mock interviews	Mock interviews	Mock interviews for SP cases with practice recall questions	Mock interviews for SP cases	Mock interviews	Mock interviews	Mock interviews to practice recall questions	Dry runs for the team	Dry runs for the team	Dry runs for the team	Final debriefing of the team	
12.00 - 12.30																		
12.30 - 13.00																		
13.00 - 13.30	LUNCH	LUNCH	LUNCH	LUNCH	LUNCH	LUNCH	LUNCH	LUNCH	LUNCH	LUNCH	LUNCH	LUNCH	LUNCH	LUNCH	LUNCH	LUNCH	LUNCH	
13.30 - 13.44																		
13.44 - 14.00	Review of SP cases	Group work: Script and Narrative Development	Group work: Script and Narrative Development	Risk Mitigation Strategies	Exit Questionnaire	Exit Questionnaire	Mock interviews	Mock interviews	Mock interviews for SP cases with improvisation questions practice	Mock interviews for SP cases	Training on audio recorders	Mock interviews to practice recall questions	Mock interviews to practice recall and improvisation questions	Debriefing of the teams after dry runs	Debriefing of the teams after dry runs	Debriefing of the teams after dry runs	Last round of mock interviews practice recall and improvisation questions	
14.00 - 14.30											Mock interviews to practice recall questions							
14.30 - 14.00																		
14.00 - 14.30																		
14.30 - 14.44	TEA/ COFFEE BREAK	TEA/ COFFEE BREAK	TEA/ COFFEE BREAK	TEA/ COFFEE BREAK	TEA/ COFFEE BREAK	TEA/ COFFEE BREAK	TEA/ COFFEE BREAK	TEA/ COFFEE BREAK	TEA/ COFFEE BREAK	TEA/ COFFEE BREAK	TEA/ COFFEE BREAK	TEA/ COFFEE BREAK	TEA/ COFFEE BREAK	TEA/ COFFEE BREAK	TEA/ COFFEE BREAK	TEA/ COFFEE BREAK	TEA/ COFFEE BREAK	
14.44 - 16.00	Review of SP cases	Group work: Script and Narrative Development	Group work: Script and Narrative Development	Risk Mitigation Strategies	Exit Questionnaire	Exit Questionnaire	Mock interviews	Mock interviews	Mock interviews for SP cases with improvisation questions practice	Mock interviews for SP cases	Mock interviews to practice recall questions	Mock interviews to practice recall questions	Mock interviews to practice recall and improvisation questions	Debriefing of the teams after dry runs	Debriefing of the teams after dry runs	Debriefing of the teams after dry runs	Last round of mock interviews practice recall and improvisation questions	
16.00 - 16.30																		
16.30 - 17.00																		

Exercises toward the end of the 1st week include proceeding to memorization and appropriate role-playing, as well as techniques to perfect recall of the questions asked and examinations completed during a visit with a health care provider.

Recruits will brainstorm potential risks and options for mitigating them. The team will formally ensure that the recruits know how to step aside if an emergency occurs or if a real patient needs urgent care, or to avoid invasive exams or procedures without raising suspicion. For example, certain cancer symptom types may provoke the offer of an intimate examination, which the SP will defer on the grounds that they are not ready or wish to be accompanied (a method we have used before). In addition to harm-avoidance measures that are developed from experience and based on SP experiences during the pilot, all SPs will be trained to record any evidence of bias qualitatively in an open-ended narrative for each interaction. Finally, SPs will learn how to report quantitative measures of objective and subjective non-medical performance.

Recruits will also meet with health care providers working with our team to provide feedback on their presentation and realistic depiction of the cases. Finally, dry runs will be completed with visits to providers working with our team to help build the confidence of the SPs and take them through several “real-life” situations, including how to find, approach, and exit a health facility all while staying in character.

3.3. Pilot design

Although our project builds on prior work with SPs, given that this is a new exercise with protocols for cancer-related health conditions that had to be developed from the ground up (with the exception of Tuberculosis which covers for lung cancer – see above), and because we did not have preliminary data on spread/variance of cancer-related quality outcomes with SPs that we could use for sample size/power calculations, we will devise a staged approach to address uncertainty. We plan to conduct a SP pilot study in Kiambu (after ethics approvals) to develop SP cases, train SP recruits, and pilot test the SP method and cases out in a small number of providers/health facilities, with a waiver of informed consent (requested in this protocol). We will then repeat this pilot in the two Nigerian settings.

The study will be designed to ensure that we can obtain upper-bound estimates on the detection rate and key clinical performance outcomes to inform the main SP study. All visits during the pilot will be compressed into a two-month period with larger providers receiving up to 6 SPs within a month. This means that some providers will receive visits from 5-6 SPs within a month.

Each SP will be assigned to simulate only one type of clinical scenario. Two SPs will be assigned to each clinical scenario. There are 10 different types of clinical scenarios, and therefore we will train 20 SPs (plus 2-3 additional SPs as a buffer) to allow for two SPs to present one clinical scenario. Each SP will make two visits per working day. For the pilot, 25 health facilities have

been recruited in each of the three sites (Kiambu, Kenya; Ibadan, Nigeria; Kano, Nigeria) with the following breakdown based on facility type:

- 6 large public
- 6 small public
- 6 large private
- 6 small private
- 1 hospital

The total number of SP visits will range from a minimum of 214 to a maximum 250 visits per site. The minimum assumes that each large facility and hospital will receive 10 SP visits (one per SP case with 10 cases) and each small facility will receive 7 SP visits (4 cancer cases and 3 control cases). The maximum assumes that all facilities in the sample will receive 10 SP visits each in total (all 10 cases). The final number of visits will be determined during training and pilot as we learn more regarding the risk of SP detection for later visits in smaller facilities across a small period of time (for example, if there is only one health provider at a small facility, we should not send seven SPs portraying cancer-related cases within a two-week duration). Given 214-250 visits per site, 2 SPs assigned to each case, an SP is able to conduct 2 visits per day, and that each facility may receive more than one (but not the same) SP in the pilot, we estimate that data collection for the pilot will be carried out over two weeks amounting to 12.5 days of data collection.

3.4. Data collection

For all cases, providers will be assessed on 4 dimensions: the fraction of essential checklist history, examinations, testing/referral and personal aspects such as politeness and privacy. We will adapt international standards for local contexts as described under 3.1.

Main outcomes include average visit length; essential history questions asked; correct diagnosis suspected or given; appropriate referral; essential lab investigations/X-rays ordered; appropriateness of treatment regimens prescribed; amount of money paid by SP, and an assessment of kind and informative (patient-centred) behaviour.

To collect each of these measures, SPs will be debriefed with a structured questionnaire within one hour of the interaction with the healthcare provider. Medicines and prescriptions dispensed in the clinic will be saved (and photographed), and the medicine names will be recorded when a label is present. The questionnaire will be programmed on a tablet.

The exit questionnaire in Appendix A2 shows the type of key variables we will be including for each SP case. Our approach to coding of medicines/pills follow previous SP studies.^{15,16} Coding of prescriptions will be done by two members of our technical advisory group of health care providers. Unlabelled pills will be coded as unlabelled and not analysed further.

We will also measure risk of SP detection through unmasking rates (usually < 2%), where unmasking refers to a whether the provider suspects that the SP is not a real patient.

Unmasking rates will be measured through open-ended written debriefs from SPs detailing any issues that occurred during interactions. We will also measure mean scores (overall and on different parts (e.g., technical quality and patient centeredness) collected from the survey. Key examples of mean scores will include: (a) total completion of pre-specified relevant history-taking for each case; (b) total referral frequency for each case; (c) performance on SP-observed objective indicators of medical performance over history taking, examinations offered, and correct clinical actions such as testing and/or referral; and (d) performance on SP-completed subjective indicators of patient experience such as satisfaction and security plus a general rating. Estimation of mean care quality and variation in quality of care will be used to estimate the likely power the main project will have to detect meaningful differences in quality.

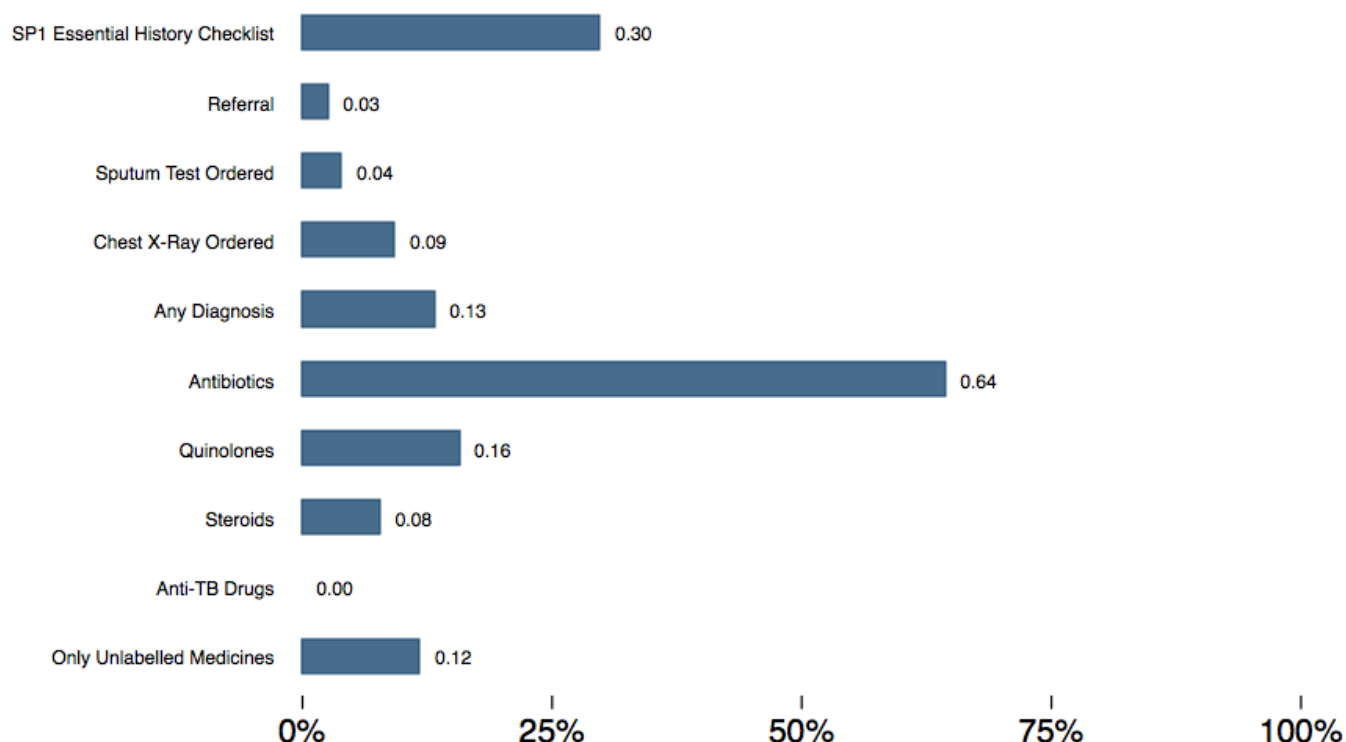
Example pilot results:

Below is an example figure of key results, showing data from SPs presenting a case scenario of a naïve TB suspect case scenario in Delhi, India.^{12,17}

Figure 1. Naïve TB suspect case scenario in Delhi, India

SP1: Naïve TB suspect case

N=75



Note: Sources: Das et al. (2014) and Kwan et al. (2018). Based on the above data, most (~90%) cases of suspected TB receiving no tests. Instead, the majority receive broad-spectrum antibiotics and non-specific therapies. Empiric therapy and polypharmacy (about 3.5 to 5 drugs per patient per visit) seems to be widespread. Essential history

questions were asked in less than a third of the SP visits, and diagnosis was rarely given (<20%).

We will elicit the power of tests with different sample sizes and effect sizes. We will vary the size of the overall sample, the size of the treatment group (for instance, education training) and the effect size. For the effect size, we will use low numbers to begin with (for instance, a 5-percentage point increase in checklist completion, 6 percentage point increase in diagnostic tests or referral for a specific SP case, etc.) and then introduce greater effect sizes.

4. Research Team

Leadership: Joint-Lead

- **Prof Omigbodun** at the University of Ibadan, Nigeria
- **Prof Lilford** at the University of Birmingham.

They will provide overall leadership and management with support from **Sartori**, a Senior Programme Manager

- **Muthoni** (CEI Co-applicant) will lead CEI activities across the collaboration and is founding director of the Cancer Café that supports and empowers people with cancer and represents community voices as a member of the National Cancer Institute, Kenya.

Research Team:

- We have an extensive network of patients and community groups (led by **Muthoni** (CEI Lead), Cancer Café and **Mugo-Siati** (collaborator), Executive Director of Kenya Network of Cancer Organisations).
- Health systems support includes:

Asiki, Mohamed and Wilunda will lead delivery of research activities in Kenya.

- o **Asiki** leads APHRC Non-Communicable Diseases (NCDs) unit and member of the inter-agency NCD technical working group Kenya Ministry of Health.
- o Working with **Mwenda** (collaborator), Head of Kenya National Control Programme, **Mohamed**, Associate Research Scientist in Chronic Disease Management at APHRC supports the Kenya National Cancer Strategy, and **Wilunda** (APHRC) is a cancer epidemiologist.
- o **Nyongesa** (collaborator) leads the cancer treatment centre and programme leader of the American Cancer Society (ACS) Patient Navigation Program at Kenyatta National Hospital and will provide advice and support on intervention development and pilot. **Williams**, Prof of Health Policy and Management at University of Birmingham, has expertise in priority setting, decision making in healthcare, intervention development and implementation studies. **Griffiths**, Prof of Medical Sociology at University of Warwick, is an experienced qualitative researcher and has led successful qualitative work packages across multiple global health grants on access to and quality of healthcare in LMIC. Williams and Griffiths will co-lead qualitative research.

- **Omigbodun** and **Fayehun** will also co-lead delivery of activities in Ibadan, Nigeria.
 - o **Fayehun**, Head of Department Sociology at University of Ibadan, has expertise in intervention development and process evaluation and is immediate past Chair for the Consortium for Advanced Research Training in Africa, one of Africa's largest doctoral training networks.
 - o **Owoaje**, Prof of Community Medicine at University of Ibadan, has a track record in educational theory and research management and will co-lead training and capacity strengthening with Fayehun.
 - o **Yakasai** former Director General with Hospital Board, Kano state and Provost, College of Health Sciences, Bayero University will lead all activities in Kano and ensure input from the Federal Ministry of Health Nigeria. **Umar** is Head of Gynaecological Oncology Unit, Bayero University/Aminu Kano Teaching Hospital^{18,19} and will support Yakasai in ensuring delivery of activities in Kano state.
 - o **Harrison** (collaborator), Prof of Surgery/Data Science at University of Edinburgh, surveyed facilities for cancer surgery in LMICs, providing scientific advice across the programme.²⁰
- Expert consultation on standardised patient methodologies
 - o **Das**, at Georgetown University, will lead WP3 and will be supported by **Kwan** at University of California San Francisco and **Daniels** at Harvard University. This team has a wide variety of expertise on quality of care measurement, including Standardised Patient (SP) methodology and clinical competence vignettes,²¹ including vignettes incorporated in World Bank Service Delivery Indicators (Das, Daniels), a SP-based quality of care surveillance project during the scale-up of TB programs in urban India (Das, Kwan, Daniels), a large scale RCT in quality improvement in primary care (Das)²², and many other SP studies in both urban and rural India (Das), Nairobi (Das, Kwan, Daniels), nationwide Kenya (Das, Kwan), Nigeria (Kwan), South Africa (Kwan, Daniels), Rwanda (Kwan) and other settings.

5. Ethical Considerations

5.1. Ethics approvals

This study will be conducted according to ethical principles stated in the Declaration of Helsinki (2008). This research protocol will be submitted to the research ethics committee(s) appropriate to each centre.

5.2. Informed consent – waiver

With this submission, we are seeking approval for the WP3, for which we are requesting a waiver for provider informed consent. *[Any governmental, governing board support/approvals/MOUs or documentation – should note here]. In addition, we will require the [anyone else's support to get explicit approvals from local governments or governing bodies –*

should note here]. With this and taking into account previous studies involving the SP method for which informed consent has been waived (described below, including for two SP studies conducted in Kenya), we believe that demonstrating a scientifically valid answer to our research questions is not possible unless the requirement of individual provider informed consent is waived.

Previous SP studies conducted by Das and Kwan and other colleagues from our team have requested and received waivers of provider informed consent from ethics committees at Harvard University, Duke University, McGill University, Innovations for Poverty Action, the Kenya Medical Research Institute, and the Government of Rwanda. We will share the IRB protocols and approvals, if requested, of this precedent. Another SP study conducted at the Universidad Peruana Cayetano Heredia has also received waiver of informed consent.²³ These waivers have been granted under the provisions for waiver or alteration of the informed consent requirements under the United States Department of Health and Human Services regulations 45 CFR 46.116(d) (Office for Human Research Protections (OHRP). Accessed at: <http://www.hhs.gov/ohrp/policy/consentckls.html>).

This research will involve no more than minimal risk to participants. We have documented in prior studies that the SP method is minimally intrusive and can be piloted and conducted with no risks or harms to the providers participating in the project, and in the next section, we discuss the maintenance of strict confidentiality of our research data involving several mechanisms to protect confidentiality of participating healthcare providers in the study. In an SP detection survey conducted in India during a pilot, colleagues from our team (Das, Kwan, Daniels) elicited provider opinions on whether participation in the study had adversely affected their practice in any way.¹² The results were stark: of the 98 responding providers, not a single one replied with the affirmative. From the point of view that sending SPs to providers can be harmful, authors of the study described how the view of the participants of the pilot unanimously demonstrated that it did not.¹²

The lack of participant consent is unlikely to adversely affect the welfare of the participants. Based on the extensive experience conducting SP studies by members of our team, we predict that the lack of the participant's consent is unlikely to adversely affect the welfare of the providers for several reasons that have also been published.^{12,24} Firstly, no financial losses will be incurred by providers as the SPs, like real patients, will pay them whatever they charge in the clinics. There will be no added inconvenience to other patients as we will train the SPs on how to immediately step aside if there is an emergency that demands the doctor's attention. From observations from previously published SP studies, including those conducted in Kenya and Nigeria where we plan this study, average consultation times are between 3 and 8 minutes, so this will only inconvenience other patients only by that time.^{6,9,11,12,14,17,25–29} None of the identities of the providers or their health facilities will be compromised since we will maintain strict anonymity in the information collected. At no time during or after the project (or in any publications or presentations) will the providers or health facilities be identified.

Additionally, the ethics guidelines on health services audit studies state that SPs should be used in cases where the person being sent the SP is providing a service to other people and where

other options have been carefully studied, but cannot answer the research questions required.^{21,24,30} For our study, we have made the educated decision to select the SP approach after more than two decades of research, during which we were unable to find adequate ways to answer the research questions about quality of health care that can be answered by using SPs. Reasons for not observing real patients are stated above.

It is also of note that in previous work we have successfully implemented SP case scenarios within SP pilots and larger SP studies in Nairobi, nationwide in Kenya, and in the Nigerian states of Lagos and Kano. We do not recommend any changes to the approach of SP implementation and believe that the combination of spacing SP visits and the waiver of provider informed consent will bring detection rates to below 1 -2 percent.

This research does not involve any therapeutic interventions or other clinical or diagnostic interventions. As part of their training, SPs will be fully informed and trained on how to recognize and avoid harmful situations, such as avoiding blood draws and injections. In prior SP studies conducted by members of our team, these have been successfully avoided with proper training and debriefing. Following the event of any potential harmful situation, a full debriefing will be conducted with the entire field team, and SPs will be led through a refresher on avoiding all invasive examinations. The next section discusses this further.

Lastly, we cite a recent study by Rhodes et al. on ethical aspects of simulated patient studies, commissioned by the US Department of Health and Human Services.³⁰ The review found “several relevant considerations” that both favour and oppose soliciting consent for simulated patient studies. Making research participation conditional on informed consent protects the autonomy of research subjects and shields them from unreasonable exposure to research risks. However, scientific validity is also an important ethical principle of human subjects research, as the net risks to subjects must be justified by the value to society of the knowledge to be gained. The use of simulated patients to monitor access is a naturalistic and scientifically sound experimental design that can answer important policy-relevant questions, with minimal risks to human subjects. As interaction between researchers and subjects increases, however, so does the need for consent”.³⁰

The report concluded: “As long as adequate protections of confidentiality of research data are in place, minimally intrusive simulated patient research that gathers policy-relevant data on the health system without the consent of individuals working in that system can be ethically justified when the risks and burdens to research subjects are minimal and the research has the potential to generate socially valuable knowledge”.³⁰

To fully use the potential of this “mystery client” approach and maximize its impact, SPs must present themselves as regular patients to health providers, who therefore cannot be informed ahead of time that they will be visited by trained SPs posing as patients. We request that the requirement for provider informed consent be waived to ensure that health providers will treat the SPs as they would any regular patient.

When it is appropriate at the end of the study, a simple and straightforward disclosure letter will be sent to debrief any provider who received an SP, following other SP studies which have received ethical approval for a waiver of provider informed consent.^{17,21,24,25,29} The letter will inform them that they received an SP for this study, along with the context and importance of our study, the necessity of having to use deception, and contact details of the study investigators in the case they wish to know more and the contact details for *[insert name of ethics board]* in the event there is a concern about the conduct of this project. We will also make it clear to them that their confidentiality will be maintained through the procedures described. In the event where any misconception may have arisen, we seek to re-establish any trust that may have been lost by explaining why these research procedures were necessary to obtain scientifically valid findings.

5.3. Risks to healthcare providers

As the pilot study confirmed, there are no obvious risks perceived risk by health care providers who will be involved in the study. Doctors will receive their usual consultation fees because SPs will be instructed to pay the charges, like any other patient in such settings. There is therefore no economic loss for the providers to participate.

Also, we do not anticipate any risks to the real patients of the health care providers for two reasons. First, these are facilities that see on average 22 patients a day (private facilities) or 113 patients a day (public facilities), with the providers spending 3-8 minutes per patient on average (as shown in our previous SP study in Nairobi, Kenya).⁹ Therefore, it is not the case that our study is going to add substantially to the waiting time for any of the patients. We estimate the additional waiting time to be at most 10 minutes. In addition, our protocol also dictates that if there is a medical emergency in the clinic, our SP will immediately step aside.

5.4. Risks to standardised patients

The Nairobi SP study documented that the SP method is minimally intrusive with no risks or harms to the providers participating in the project.⁹ More specifically, Daniels et al. (2017) reports the following from the Nairobi study:

There were no adverse events reported by SPs during the fieldwork. The most common invasive treatment that SPs had to avoid was being given an injection, which was offered in 38 of 126 non-diarrhoea interactions (30%; 95% CI 23 to 39). To assess detection rates, each provider was administered a structured questionnaire within 2 weeks of the completion of fieldwork asking whether an SP had visited the clinic, and, if so, the characteristics of the SP. Providers claimed to have detected an SP in nine instances, but on further elicitation of the characteristics and presentations of the suspected cases, there was no match between the SPs we had sent and the presentation of the patient that the

provider suspected to be an SP. We therefore conclude that detection rate for the SPs was zero in this study.

We want to emphasize that this research does not involve any therapeutic interventions, such as those involved in randomized clinical trials that compare the effects of drugs among individuals. Researchers of the Nairobi SP study, who are investigators in this study, have verified that all 38 events in which injections were offered were successfully avoided by the SPs, as a result of thorough risk mitigation strategy training. As part of the Nairobi study and the subsequent nationwide SP study, SPs were fully informed and trained on how to recognize and avoid harmful situations, such as avoiding blood draws and injections. Further, members of our team who have participated in these previous studies will also be present and participate as trainers in the SP training for this study – therefore, we propose and can ensure that the Nairobi SP training protocol and best practices from other SP studies will be followed and implemented for this study. Following any potential event, the team will plan a full debriefing and SPs will be led through a refresher on avoiding all invasive examinations. Consideration to drop any SP case that presents more than minimal risk to participants will also be carefully made with ethical considerations and protocol.

During each week of data collection for the SP pilot, supervisors will additionally hold two meetings with all the SPs to review the dos and don'ts with regard to SP safety and risk mitigation strategies. During these meetings, supervisors will go over instructions for the SPs on how to avoid invasive or potentially unclean examinations (e.g. thermometers) and interventions (e.g. injections), such as avoiding the placement of their arms on the table and always asking the provider what he intends to do if he moves toward the SP for any examination.

Additionally, there will be a review once a week during which SPs will be asked to describe any situation that arose with regard to invasive procedures and what tactics were used to avoid or refuse such events. SPs will be reminded in these weekly meetings that rather than risk invasive procedures, they should reveal their identities and give the supervisor's phone number to the provider if they feel that the provider is aggressively pursuing an invasive procedure. Any such a case will be recorded as an adverse event with clear documentation of the circumstances that led to the disclosure.

5.5. Potential benefits

There are no direct benefits for the providers/doctors involved in the study. However, this study will serve to assess the usefulness and impact of the standardised patient strategy to evaluate quality of cancer care, which can in turn inform policy and decision makers, and further the goal of cancer detection and management in LMICs. Thus, there is an important public health/societal benefit. Our project will be first-ever study of quality of cancer care using the SP method, and it can offer valuable insights for the remaining work package as well as broader interventions and policies.

5.6. Confidentiality

We have documented that our project will maintain strict confidentiality of our research data involving several mechanisms to protect the confidentiality of participating healthcare providers in the study. All study data will be kept confidential. The identity of providers who participate in the study will be anonymized through the process described below. This process will be communicated explicitly to those involved.

During training and throughout data collection, all SPs participating in the study will be debriefed on their critical duty to restrain themselves from discussing SP and fieldwork experiences with individuals outside of the research team (e.g., family members, friends, neighbours). SP individuals and supervisors will conduct the exit questionnaires and debrief sessions in spaces where they cannot be overheard from others and away from the location of the SP-provider visit.

All exit questionnaires will be completed on electronic tablets. To ensure the confidentiality and the safety of the information gathered, all data will be accessed through REDCap password-protected secure servers, which provides industry-leading security sockets layers with encryption, including SOC-2 certification, GDPR compliance, and a wide array of security features (Dobility, Inc., Cambridge, Massachusetts and Washington DC, USA). After data from the SP-provider visits are uploaded securely, they will be retrieved through the secure server by the study investigators. Study investigators will then strip all provider identifiers (for this study, the term “provider identifiers” means: provider name, GPS codes, street address, workplace and address if applicable, mobile or fixed telephone numbers, other contact information) and assign numerical code IDs to each provider as the first step in receiving data. Each provider in the study will have their own numerical code ID, and the access to the file that matches provider numerical code IDs to provider identifiers will be restricted to the study investigators only. The list that associates provider identifiers with code ID will be kept in a password-protected secure server. Datasets will be constructed from these de-identified data and will be used in analysis. This also pertains to any future use of data generated from this study.

Experts who may participate in treatment coding will at no time receive any data that contain identifiable characteristics for providers, supervisors, or SPs. This will protect participants and maintain their anonymity, in addition to eliminating any coding bias.

Additionally to minimize the likelihood of identifying providers or their institutions in this study,³¹ data used by the PIs to generate reports and manuscripts will report data aggregated at large group level (e.g., study site, provider type). Participant names and other identifying information will not be used in any reports or manuscripts related to this research, and any quote used will be anonymized.

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Appendices

A1. Script

Standardised Case: Classic Case of Suspected Tuberculosis

WILSON

Wilson is 35 years old and has studied up to diploma level. He is the owner of a small tea shop. Today, in the morning like any other day, when he leaves for work, his wife Jane asks, “Lately you barely finish your tea and today you have had only one slice of bread.” Wilson replies, “I have cough and seem to have lost my appetite.” Wilson’s family is small. It consists of his wife and two children, aged six (daughter) and four (son) and they live in a two room house which he rents. His business at the tea stall is doing well as he is able to earn on average Ksh 8000– Ksh 10000 per month. Generally Wilson keeps good health and has not had any major health problems or any chronic illnesses.

But for the last 2-3 weeks he is suffering from a cough which is present all day and it also has expectoration though that does not have any unusual color in it and is clear. He also has some occasional fever and chills as well as night sweats. Since this problem started he feels a bit tired and also has lost some weight, as his clothes have gotten a bit loose. He has noted that his belt needed a new hole as it was too loose. He does not suffer from any associated chest or body pain. Around 1 week ago, he had visited a local chemist who gave him a cough syrup and some pills for the fever. He smokes 4-5 cigarettes per day for the last 8-10 years and drinks alcohol once or twice a month.

His relationship with his wife is good. He loves her very much. He has a cheerful and an easy going personality but today his face bears a tense look as he is worried about his cough and fever and plans to visit a doctor nearby.

Wilson ana umri wa miaka 35 na amehitimu shahada ya diploma. Anamiliki mkahawa wa chai. Leo asubuhi kama kwa kawaida, aendapokazini, mkewe Jane anauliza, "siku hizi hata humaliza kunywa chai yako na leo umekula kipande kimoja tu cha mkate." Wilson anajibu, "Ninakohoa na ni kama nimepoteza hamu ya chakula." Familia ya Wilson ni ndogo. Ambapo ni mkewe, watoto wake wawili (msichana mwenye umri wa miaka sita na mvulana wa miaka minne) na wanaishi katika nyumba yenye vyumba viwili anayoikodisha. Biashara yake kwenye mkahawa imenawiri kwa kuwa anapata kati ya shilingi 8000 na 10000 kila mwezi. Kijumla Wilson analida afya bora na hajawahi kuwa na magonjwa yoyote sugu.

Lakini kwa wiki mbili au tatu amekuwa akikohoa na kutoa kikohozi kisichokuwa na rangi yoyote ile. Pia wakati mwingine yeye huhisi joto jingi na kibaridi mwilini. Tangu shida hii ilipoanza, Wilson anahisi uchovu mwilini na amepunguza uzani. Isitoshe, mavazi yake hayamtoshi vyema, yamelegea. Amegundua kwamba mshipi wake unahitaji tundu mpya kwa vile umelegea. Haugui maumivu ya kifua au mwili. Kama wiki moja iliyopita, alienda kwenye duka la dawa akapewa dawa ya kunywa ili kutuliza kikohozi na tembe za kupunguza joto mwilini. Yeye huvuta kati ya

sigara nne hadi tano kwa siku kwa muda wa miaka 8-10 na pia hunywa pombe mara moja au mbili kwa mwezi.

Uhusiano wake na mkewe ni mwema. Anampenda sana. Ni mtu mchangamfu na mcheshi lakini leo uso wake unadhihirisha wasiwasi kutokana na kikohozi na joto mwilini na ana mpango wa kumtembelea daktari aliye karibu.

JANE

Jane is 30 years old and has studied up to form four. She supplements her family income by knitting sweaters and table cloths for her neighbours at the estate. She is a little worried today as she has a cough and running mild fever and thus does not feel like doing work. Her husband suggests that she should go and see a doctor today about it. He leaves for work at his tea stall. Jane's family is small with her husband and two children aged six (daughter) and four (son) and they live in a two room house. She has been stitching clothes since a few years as her husband's work does not generate enough income and with her work she is able to earn an extra 2000 – 3000 shillings in a month. Generally Jane has been in good health and has not had any major health problems or any chronic illness. Her husband and children too have good health.

But for the last 2-3 weeks she has been having a cough and also has expectoration that does not have any color, it is clear. She is also running a mild fever, on and off, she feels tired and also has lost some weight, as her clothes have gotten a bit loose. She does not suffer from any associated chest or body pain. Around 1 week ago, she had visited a local chemist who gave her cough syrup and some pills for the fever. Jane has a cheerful nature and she abstains from alcohol and smoking.

Her relationship with her husband is good and she loves him very much. But today she is worried about her cough and fever and visits a nearby doctor.

Jane ana miaka 30 na amesoma hadi kidato cha nne. Anachangia mapato ya familia yake kwa kushona sweta na vitambaa vya meza na kuwauzia majirani wake mtaani. Leo ana wasiwasi kidogo kwa vile ana kikohozi na joto kiasi mwilini na hajihisi kufanya kazi. Mumewe anamshauri ya kwamba yafaa aende akamwone daktari leo. Halafu anaenda kazini kwenye mkahawa. Familia ya Jane ni ndogo. Ambapo ni mumewe, watoto wake wawili (msichana mwenye umri wa miaka sita na mvulana wa miaka minne) na wanaishi katika nyumba yeye vyumba viwili. Amekuwa akishona nguo kwa miaka michache iliyopita kwa kuwa kazi ya mumewe haileti mapato ya kutosha na kwa kazi yake anaweza kupata kati ya shilingi 2000 hadi 3000 kwa mwezi. Kujumla Jane amekuwa na afya njema na hajapatwa na magonjwa yoyote sugu. Mume wake na watoto wana afya njema.

Lakini kwa wiki mbili au tatu amekuwa na akikohoa na kutoa kikohozi kisichokuwa na rangi yoyote ile. Pia anahisi joto kiasi na mara kwa mara hutokwa na jasho usiku. Tangu shida hii ianze anahisi uchovu mwilini na pia amepunguza uzani kama inavyodhihirishwa na mavazi yake ambayo hayambani kama vile hapo awali. Haugui ugonjwa wa kifua ama maumivu mwilini. Kama wiki moja hivi iliyopita, alienda kwenye duka la dawa akapewa dawa ya kutuliza kikohozi na tembe za kupunguza joto. Jane ni mchangamfu na hanywi pombe wala kuvuta sigara.

Uhusiano wake na mumewe ni mwema na anampenda sana. Lakini leo ana hofu kuhusu kikohozi na joto mwilini na anaenda kwa daktari wa karibu.

Opening statement: “Doctor, I have been having cough for a while.”

“Daktari, nimekuwa nikikohowa kwa muda”

History questions asked by the provider and their answers:

1. Q: Anything else?
Kuna kitu kingine
A: And sometimes I have fever.
Na wakati mwingine nina joto jingi mwilini
2. Q: What is the duration of the cough?
Umekohoa kwa muda gani?
A: 2-3 weeks.
Wiki 2 hadi 3.
3. Q: Are you producing sputum?
Unatoa kohozi nzito?
A: Yes.
Ndio.
4. Q: Does the sputum contain blood?
Je kohozi lina damu?
A: No.
La.
5. Q: How long have you had fever?
Umehisi joto jingi kwa muda gani?
A: For 2 to 3 weeks.
Kwa wiki 2 hadi 3.
6. Q: What is the pattern of the cough?
Hiyo joto ikoje?
A: It rises in the evening.

Huzidi jioni.

7. Q: Have you taken any medicines for your illness?

Je, umetumia dawa yoyote kwa shida hii?

A: Yes

Ndio

8. Which medicines?

Madawa gani?

A: Went to a local chemist who gave cough syrup and some pills for fever.

Nilienda kwenye duka ya dawa nikanunua dawa ya kunywa na tembe za kupunguza joto.

9. Q: Do you know the names of medicines you were given?

Je, wajua majina ya madawa ambazo ulipewa?

A: No

La

10. Q: For how long did you take the medicine?

Je, ulitumia madawa hayo kwa muda gani?

A: I only used them for three days, then stopped.

Nilitumia madawa kwa siku tatu tu.

11. Q: Do you get any chest pain?

Unahisi maumivu kifuani?

A: No.

La.

12. Q: Any loss of appetite?

Hamu ya chakula imepotea?

A: Yes, loss of appetite.

Ndio, hamu imepotea.

13. Q: Have you lost weight?

Umepunguza uzani?

A: I think so; my clothes have become a bit loose.

Nadhani; Nguo zangu hazinitoshi vilivyo tena.

14. Q: Any wheezing or difficulty in breathing?

Kuna mlio toka kifuani au ugumu katika kupumua?

A: No.

La.

15. Q: Do you smoke?

Je unavuta sigara?

A: Yes, some [in case of male SP]. No [in case of female SP].
Ndio, wengine [mume]. La [mke].

16. Q: How many cigarettes a day?
Unavuta sigara ngapi kwa siku?

A: 4-5 cigarettes, I guess.
Nakisia sigara 4 hadi 5.

17. Q: Since when have you been smoking?
Tangu lini umekuwa ukivuta sigara ?

A: For the last 8-10 years.
Kwa miaka 8 hadi kumi zilizopita.

18. Q: Do you drink alcohol?
Unakunywa pombe?

A: Yes [in case of male]. No [in case of female].
Ndio [mume]. La [mke].

19. Q: How often do you drink?
Wewe hunywa pombe mara ngapi?

A: Once or twice in a month.
Mara moja au mbili kwa mwezi.

20. Q: Have you ever been treated for TB in the past?
Umewahi tibiwa juu ya homa ya mapafu hapo awali?

A: No.
La.

21. Q: Does anyone in your household have similar symptoms?
Je kuna mtu katika nyumba unayoishi aliye na dalili kama hizi?

A: No.
La.

22. Q: Do you have diabetes?
Je unaugua kisukari?

A: I don't know.
Sijui.

23. Q: Do you have hypertension?
Je unahisi moyo kupiga sana?

A: I don't know.
Sijui.

24. Q: Do you have HIV-AIDS?
Je unaugua ukimwi?

A: I don't know.

Sijui.

25. Q: Have you ever been tested for these diseases?

Ushawahi pimwa juu ya haya magonjwa?

A: No.

La.

Allergies: No known drug allergies.

Alaji: hakuna dawa inayojulikana kutibu alaji.

A2. Exit questionnaire**SP EXIT QUESTIONNAIRE: TB****COVER PAGE**

formid	Form ID	
CP1	City Name	NAIROBI
CP2	Area ID	
CP3	Facility Name	
CP4	Facility ID	
CP5	Physical Address	

In the following section, Visit 2 should only be filled if Visit 1 was unsuccessful, and Visit 3 should only be filled if the first two visits were unsuccessful.

Visits		Visit-1		Visit-2		Visit-3	
CP6	Date of survey for each visit	___/___/___ DD/MM/YY		___/___/___ DD/MM/YY		___/___/___ DD/MM/YY	
CP7	SP Name						
CP8	SP ID						
CP9	Total time spent at the provider clinic (24hr time)	Time In Hrs Min	Time Out Hrs Min	Time In Hrs Min	Time Out Hrs Min	Time In Hrs Min	Time Out Hrs Min
CP10	Completion of the case (1=Yes, 2=No)						
CP10 a	If no, give reason:						
Reason for non-completion of the case: 1 = Waited 7 hours, 2 = No providers available, 3 = Facility closed for the day, 4=Turned back at registration, 5 = Other, specify:							
CP11	How many patients were waiting when you reached the clinic?						
CP12	How many patients were waiting when you left the clinic?						
CP13	In which age group do you think the provider falls? (1=Under 30, 2=Between 30 and 50, 3=Above 50)		CP14	Provider Gender (1=Male, 2=Female)			

CP15	Do you know the name of the provider you saw? (1=Yes, 2=No; If no, skip to CP16)	☐	CP15 a	If yes, provider's name:		CP15 b	Did SP ask for the provider's name? (1=Yes, 2=No)	☐
CP16	Do you know the provider's qualification? (1=Yes, 2=No; If no, skip to CP17)	☐	CP16 a	If yes, select qualification. (1=Doctor, 2=CO, 3=Nurse, 4=Pharmacist, 5 = Lab tech, 6=Other, Specify)	☐	CP16 b	Did SP ask for the provider's qualification? (1=Yes, 2=No)	☐
CP17	Interviewer Name				CP18	Interviewer ID	☐ ☐	

HISTORY INFORMATION (ESSENTIAL) ASKED BY THE PROVIDER			Asked YES (1) NO (2)	If not asked, given by SP? YES (1) NO (2)
	KISWAHILI	ENGLISH		
H1	<i>Je, mhudumu alikuuliza muda wa kukohoa?</i>	Did the provider ask about duration of cough?	☐	☐
H2	<i>Je, mhudumu alikuuliza kama unatoa makohozi?</i>	Did the provider ask whether sputum is produced?	☐	☐
H3	<i>Je, mhudumu alikuuliza kama kuna damu kwa makohozi?</i>	Did the provider ask about blood in the sputum?	☐	☐
H4	<i>Je mhudumu aliuliza jinsi unavyokohoa (siku nzima, asubuhi au usiku)?</i>	Did the provider ask about any pattern with the cough (throughout the day, morning and night)?	☐	☐
H5	<i>Je, mhudumu alikuuliza kuhusu joto?</i>	Did the provider ask about fever?	☐	☐
H6	<i>Je, mhudumu alikuuliza kama unauchungu kifuani?</i>	Did the provider ask about chest pain?	☐	☐
H7	<i>Je, mhudumu alikuuliza kama unatoa jasho usiku?</i>	Did the provider ask about night sweats?	☐	☐
H8	<i>Je mhudumu alikuuliza kama umepoteza hamu ya chakula?</i>	Did the provider ask about any loss of appetite?	☐	☐
H9	<i>Je, mhudumu alikuuliza kama umepunguza kilo?</i>	Did the provider ask if you have lost weight?	☐	☐
HISTORY INFORMATION (RECOMMENDED) ASKED BY THE PROVIDER			Asked YES (1) NO (2)	If not asked, given by SP? YES (1) NO (2)
	KISWAHILI	ENGLISH		

H10	<i>Je, mhadumu aliuliza kama umewahi kuwa na shida ya kifua kikuu?</i>	Did the provider ask if you had TB in the past?	☐	☐
H11	<i>Je, mhadumu aliuliza kuhusu familia yako na kama kuna yeyote amekuwa na dalili kama hizo kwa familia yenu?</i>	Did the provider ask if anyone in the household or family has similar symptoms?	☐	☐
H12	<i>Je mhadumu aliuliza kama unatoa sauti kama ya paka ukipumua?</i>	Did the provider ask about any wheezing?	☐	☐
H13	<i>Je, mhadumu alikuuliza kuhusu shida ya kupumua?</i>	Did the provider ask about any difficulty in breathing?	☐	☐
H14	<i>Je, mhadumu aliuliza kama unavuta sigara ama umewahi vuta sigara?</i>	Did the provider inquire if you smoke or have smoked in the past?	☐	☐
H15	<i>Je, mhadumu aliuliza kama unakunywa pombe ama kama umewahi kunywa pombe?</i>	Did the provider inquire if you take alcohol or have taken alcohol in the past?	☐	☐
H16	<i>Je mhadumu aliuliza kama una magonjwa mengine yoyote?</i>	Did the provider ask if you have any other illness?	☐	☐
H17	<i>Je, mhadumu aliuliza kuhusu ugonjwa wa sukari?</i>	Did the provider ask about diabetes?	☐	☐
H18	<i>Je, mhadumu aliuliza kuhusu ugonjwa wa ukimwi?</i>	Did the provider ask about HIV-AIDS?	☐	☐
H19	<i>Je, mhadumu aliuliza kuhusu shinikizo la damu?</i>	Did the provider ask about high blood pressure or hypertension?	☐	☐
H20	<i>Je, mhadumu aliuliza kama una mizio ya dawa yoyote?</i>	Did the provider ask about allergies to any medications?	☐	☐
H21	<i>Je, mhadumu aliuliza kama kuna tembe unazomeza kwa sasa?</i>	Did the provider ask if you are taking other medications currently?	☐	☐
EXAMINATIONS (CLINICAL) CONDUCTED			Yes (1) No (2)	
E1	Pulse rate		☐	☐
E2	Blood pressure		☐	☐
E3	Auscultation front		☐	☐
E4	Auscultation back		☐	☐
E5	Temperature attempted with thermometer?		☐	☐
E6	Temperature taken by touch?		☐	☐
E7	Throat examination		☐	☐
E8	Weight		☐	☐

E9	Any other examinations attempted? (If yes, list in E9a. If no, skip to E10)		☐				
E9a	Specify if other:						
EXAMINATIONS (INVESTIGATIONS) ORDERED BY THE PROVIDER Write the name of the lab or facility where the provider			Yes (1) No (2)	Cost (Enter -99 if cost is not specified. Enter 0 if free.)			
	Investigation Name	Name of referral site					
E10	Sputum smear examination (Sputum AFB)		☐	KSh			
E11	Sputum culture test and drug susceptibility test		☐	KSh			
E12	Sputum – GeneXpert test		☐	KSh			
E13	Blood – Total Count, Differential Count – FSR		☐	KSh			
E14	Chest X-Ray		☐	KSh			
E15	Mantoux test		☐	KSh			
E16	Blood – HIV test		☐	KSh			
E17	Blood – Diabetes test		☐	KSh			
E18	Blood – General		☐	KSh			
E19	Any other investigations ordered? (1=Yes, 2=No. If yes, list below. If no, skip to E20)		☐				
	Investigation Name	Name of referral site		KSh			
	1.			KSh			
	2.			KSh			
	3.			KSh			
	4.			KSh			
	5.			KSh			
E20	Total cost of investigations. Sum of investigations costs or lump sum, if lump sum is given. Enter -99 if not specified. Enter 0 if free.			KSh			
DIAGNOSIS				1=Yes, 2=No			
D1	Did the provider mention any suspicion of cancer in the whole conversation?			☐			
D2	Did the provider give or mention a diagnosis?			☐			
D2a	If yes, what was the diagnosis? (If one or more diagnosis given, then write all of them)						

MEDICINES (Enter -66 in frequency if to be taken SOS)									
M1	Total time taken by provider				: : HH MM SS				
M2	Did the provider dispense/prescribe any medicine? (1=yes, 2 = No. If no, skip to T1)								☐
M3	Medicines Dispensed at the facility=1, Elsewhere =2	(a) Name (If unlabeled, write unlabeled in Brand)	(b) Types of medicine Tablet =1, Capsules =2, Syrups =3, Injectable =4, Powder=5	(c) Dose	(d) Frequency	(e) Duration (Enter -99 if not specified)	(f) How many days in a week (Enter -99 if not specified)	(h) Drug classification on code	(i) Price paid (Enter -99 if cost is not specified. Enter 0 if free.)
	1. ☐	Brand	☐						Ksh
		Generic							
	2. ☐	Brand	☐						Ksh
		Generic							
	3. ☐	Brand	☐						Ksh
		Generic							
	4. ☐	Brand	☐						Ksh
		Generic							
	5. ☐	Brand	☐						Ksh
		Generic							
	6. ☐	Brand	☐						Ksh
		Generic							

M4	Total cost of treatment <i>Sum of treatment costs or lump sum, if lump sum is given. Enter 0 if free. Enter -99 if not specified.</i>	KSh
Annex to M3 (h) Drug classification code: Antimalarials =1 ; Antibiotics =2 ; Anti-TB medicines =3; Analgesics/antipyretics =4; Cough preparations =5 ; Gastrointestinal medicines =6; Steroids =7 ; Antihistamines/non-steroidal anti-allergy medicines =8 ; Cardiovascular medicines =9 ; Central Nervous System (CNS) medicines =10 ; Anti-asthmatics (bronchodilators) =11 ; Vitamins and minerals =12 ; Non-allopathic medicines (herbals,		

TREATMENT		1=Yes, 2=No
T1	Did the provider ask the patient to come back? (If yes, mark from T1a to T1h, If no, skip to T2)	☐
T1a	If symptoms persist	☐
T1b	If symptoms become worse	☐
T1c	To get medicines	☐
T1d	For diagnostic tests or test results	☐
T1e	After so many days (If yes, fill T1f. If no, skip to T1g)	☐
T1f	If yes, enter number of days. If no, leave blank. If asked to come back on same day, enter 0.	
T1g	Other	☐
T1h	Specify if other:	
T2	Cost of consultation/registration If given, write cost. If there is not a separate	KSh
T3	Other costs Enter -99 if not applicable.	Specify if other: KSh
T4	Total amount paid: Sum of treatment, investigations, consultation/registration and other costs, or lump sum, if lump sum is given. Enter 0 if free.	KSh
T5	Any other questions asked that were not on the	☐ 1=Yes, 2=No 1. 2. 3. 4. 5. 6. 7. 8.
T6	Did the provider offer an injection?	☐

T7	Did the provider offer IV fluid?	☐
T8	Did the provider inform about any danger signs of the disease?	☐
T9	Did the provider inform about any side effects of drugs (nausea, vomiting, red discoloration of the urine)?	☐
T10	Did the provider speak about cough hygiene?	☐
T11	Did the provider speak about smoking cessation?	☐
REFERRAL		1 = yes 2 = no
R	Did the provider ask the patient to go anywhere for further management? <i>(If yes fill R1 to R4a, if no, go to G1)</i>	☐
R1	Private Provider/Private Hospital	☐
R2	Government Hospital	☐
R3	Other	☐
R4	<i>Specify if other:</i>	

GLOBAL ASSESSMENT SCALE			
G1	Did the provider use a cell phone at any point during the whole conversation?	Yes =1, No =2	☐
G2	Were there other people in the room besides clinic staff?	Yes =1, No =2	☐
G3	Was there a TV on in the room?	Yes =1, No =2	☐
G4	Did you like this provider?	Yes =1, No =2	☐
G5	Would you go to this provider again?	Yes =1, No =2	☐
G6	How well did the provider create an environment in which you could convey your symptoms and concerns easily?	Definitely =3 Somewhat =2 Not at all=1	☐
G7	How well did the provider appear to be knowledgeable about your illness?	Very knowledgeable =3 Somewhat knowledgeable =2 Not at all =1	☐
G8	How well did the provider address your worries seriously?	Very seriously =3 Somewhat seriously =2 Not at all =1	☐
G9	How well did the provider explain anything about your illness?	Very well 3 Somewhat =2 Not at all =1	☐
G10	How well did the provider explain your treatment plan?	Very well =3 Somewhat =2 Not at all =1	☐
G11	Provider Assessment Note: The SP will give a rank to the provider from 1-10, where 10 is the highest and 1 is the lowest.		☐

Errors and Detection		
ED1	Did you think you made any mistakes in the presentation of the case? If yes, please note them down.	☐ (1=Yes, 2=No)

ED2	Do you think the provider detected you as an SP? If yes, how were you detected?	☐ (1=Yes, 2=No)

Comments:

[illegible]