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Using flow cytometry for paediatric leukaemia diagnosis in Kenya: a protocol for mixed methods study

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ABSTRACT

Introduction Each year, an estimated 1700 children should be diagnosed with cancer in western Kenya, with leukaemia making up nearly one-third of cases. However, far fewer are actually diagnosed, highlighting significant delays or errors in diagnosis. Flow cytometry, which the WHO considers essential for leukaemia diagnosis, remains underused across sub-Saharan Africa due to high costs, outdated equipment and a lack of trained personnel. In Kenya, decades-old cytometers have been adapted for leukaemia detection, but these systems are now outdated. Newer platforms, such as simplified single-tube multiparametric assays, provide a scalable and sustainable alternative. This study presents a protocol to evaluate the accuracy of diagnosis and the potential for implementing a streamlined flow cytometry assay using peripheral blood, supported by a regional educational initiative.

Methods and analysis This prospective, mixed-methods implementation study has three aims: (1) to assess the concordance between the Beckman Coulter ClearLLab 10C gold standard 4-tube assay and the streamlined ClearLLab LS 1-tube assay using paired bone marrow and peripheral blood samples; (2) to evaluate the feasibility of peripheral facility referrals and transport logistics with couriered peripheral blood samples from referring sites across western Kenya; and (3) to measure training effectiveness and knowledge gain through a multimodal educational programme using the Project ECHO (Extension for Community Healthcare Outcomes) model.
Up to 300 patients at Moi Teaching and Referral Hospital in Eldoret, Kenya, will be enrolled in Aim 1. A separate sample of 100 patients from peripheral facilities will be included in Aim 2. Surveys, knowledge assessments and structured interviews will be used to evaluate training impact under Aim 3. Diagnostic concordance, sensitivity, specificity and knowledge gain will be measured through appropriate quantitative and qualitative methods.

Ethics and dissemination The protocol has received approval from institutional ethics committees at Moi University, MTRH and Indiana University. De-identified data will be analysed and shared through peer-reviewed publications, stakeholder presentations and educational platforms.

STRENGTHS AND LIMITATIONS OF THIS STUDY

⇒ This study introduces a simplified flow cytometry assay for low-resource settings.
⇒ The diagnostic comparison evaluates a single-tube multiparametric assay against the standard 4-tube method, using both peripheral blood and bone marrow samples.
⇒ The protocol integrates a national Project ECHO (Extension for Community Healthcare Outcomes) education model to support knowledge dissemination and long-term sustainability.
⇒ The results from peripheral facilities may be influenced by variability in sample quality, transportation logistics and clinician engagement in training programmes.
⇒ The findings from a single regional centre may limit generalisability to other resource-limited countries in sub-Saharan Africa and beyond.

INTRODUCTION

Western Kenya has approximately 24 million residents, including around 12 million children up to age 19.[1] Based on global estimates of cancer rates in similar populations, approximately 1700 children should be diagnosed with paediatric cancer each year in western Kenya, with up to 400 having acute lymphoblastic leukaemia (ALL). However, the number of children seeking cancer treatment is much lower than expected according to epidemiology and treatment records at major referral centres in lower- and middle-income countries (LMIC), including Kenya.[2–4] Curative treatments, especially for children with ALL and lymphoma, are available, but due to factors like cost and travel distance, fewer than 20% of children with leukaemia in the catchment area are diagnosed. When children do not receive proper diagnosis and treatment, they often do not survive.

Diagnosing and classifying leukaemias and lymphomas beyond just routine Wright-stained or H&E-stained, glass slide-based morphology faces challenges in most of sub-Saharan Africa. Flow cytometers available at several hospital sites in western Kenya are

used to monitor treatment response in patients infected with HIV. The first public health facility in Kenya to implement flow cytometry for diagnosing haematologic malignancies is the Academic Model Providing Access to Healthcare (AMPATH) Reference Laboratory (ARL) at Moi University School of Medicine and Moi Teaching and Referral Hospital (MTRH) in Eldoret. A significant gap in cancer care is the absence of affordable early detection or diagnostic tests for children showing signs or symptoms of leukaemia and lymphoma. For suspected cases, patients must travel to Eldoret to access costly diagnostic services that exceed US$200. Although immunohistochemistry is supported by the Social Health Authority, flow cytometry or genetic testing is not covered.

The WHO considers flow cytometry an essential diagnostic test for identifying leukaemia and lymphoma in LMICs.[5] The process of counting CD4 and CD8 T-lymphocyte subsets using flow cytometry has been established at the ARL for decades to monitor HIV treatment responses. In the ARL and other centres across sub-Saharan Africa, older flow cytometers used for T-cell subset counting were later adapted for diagnosing leukaemia and lymphoma. Early studies demonstrated that using flow cytometry in LMICs is feasible for diagnosing lymphoid and myeloid leukaemia.[6] However, relying on outdated equipment is costly, inefficient and increasingly obsolete, especially as manufacturers no longer provide technical support for older instruments. Now, next-generation flow cytometry, typically defined to include at least 8-colour to 10-colour methodology, offers solutions to these issues with improved workflows that make testing faster and more affordable for patients' families.

In high-income countries, flow cytometry is a key tool in diagnosing leukaemia, often using multitube assays that require advanced equipment, highly trained staff and, in many laboratories, cold chain-dependent reagents. One standard is the ClearLLab 10C assay, which includes four separate tubes targeting B-cell, T-cell/natural killer (NK)-cell and myeloid populations. Although this method is very effective and has the advantage of being cold chain-independent, its high cost, and to some extent its complexity, limit its use in low-resource settings. In contrast, flow cytometry platforms that employ single-tube multiparametric assays have been developed to simplify workflows, cut reagent costs and make testing more accessible. These streamlined systems have the potential to expand diagnostic capacity in areas where traditional methods are still not feasible.

Given the large gap between expected diagnoses based on epidemiological data and the actual number of patients diagnosed in the referral region, as well as the availability of curative treatments for ALL, urgent efforts should focus on improving diagnostic processes for paediatric patients. Using and optimising flow cytometry provides a practical way to increase the number of leukaemia diagnoses and speed up the initiation of treatment.

Aims and objectives

This study aims to develop a testing algorithm to maximise the cost-effective screening of blood for ALL using the ClearLLab LS screening tube and to facilitate the enrolment and treatment of children with leukaemia. Additionally, for flow cytometry to be a sustainable diagnostic tool, we need reliable methods to train staff to perform these tests routinely over the long term. Adapting flow cytometry technology to use peripheral blood samples that can be couriered to the ARL for testing will speed up diagnosis and treatment, ultimately increasing impact. Specifically, this study intends to address and accomplish the following aims:

1. To validate and measure the concordance of flow cytometry testing comparing bone marrow aspiration and peripheral blood samples from patients hospitalised at MTRH with suspected leukaemia.
2. To develop and validate an adapted flow cytometry assay for diagnosing acute lymphoblastic leukaemia using peripheral blood samples from patients in peripheral facilities in Kenya.
3. To develop a comprehensive educational model for training and implementing flow cytometry in the region, covering both short-term and long-term needs.

As a result of the data gathered by this study, we hypothesise that we can develop a cost-effective system (under US$200) using a single ClearLLab LS tube that can be stored dry and at room temperature to screen for leukaemia with a very high degree of sensitivity and specificity, and only extending the testing to one or more of the lineage-specific ClearLab 10C tubes when such additional testing is medically indicated. This approach should be suitable for screening and diagnosis in patients with suspected leukaemia in LMICs. This advanced diagnostic platform will enable earlier and more effective treatment, ultimately improving survival rates in LMIC settings.

METHODS AND ANALYSIS

Study design

This study will use a prospective, observational design to assess the initial implementation, clinical usefulness and long-term sustainability of flow cytometry as a diagnostic tool for paediatric leukaemia in an LMIC setting. The research will be carried out at MTRH and will include patients from local and peripheral health facilities throughout the region. The main goal of this study is to evaluate the clinical impact and feasibility of implementing flow cytometry in this environment and to create a scalable framework for its integration into routine leukaemia diagnostic procedures in resource-limited settings.

Setting

The AMPATH is a global health partnership linking North American medical institutions with a regional tertiary care centre in Eldoret, Kenya, MTRH and an academic medical institution, Moi University College of Health

Sciences.[7 8] It also includes the ARL, an advanced diagnostic testing facility located within the hospital complex. For more than 30 years, Indiana University has been a partner in this collaboration, with a proven track record of addressing disparities in infectious and chronic disease outcomes such as tuberculosis and HIV in Kenya.[9 10] Over the past decade, care for patients with cancer has gained increased focus within AMPATH, leading to greater awareness, improved diagnosis and a better understanding of various types of cancer, including childhood cancers.[11–19]

Although ALL in children, adolescents and young adults is the most common childhood cancer in the world, the same efforts to diagnose and care for these patients in high-income countries have not been replicated in Kenya. ALL is a highly curable cancer with available treatments in Kenya. To help address this disparity, additional partners from The Burkitt's Lymphoma Fund for Africa, Beckman Coulter and the University of Missouri have joined the efforts to improve leukaemia and lymphoma diagnostics by adapting new technology to address this problem and ultimately improve patient care.

Study planning

Before any patients are consented to the study or any study samples are collected, staff at all participating hospitals, clinical laboratories and clinics will be trained on the study procedures. These brief training sessions will be held weekly initially and then shift to monthly as clinical staff become comfortable with the study processes. These trainings will be led by the programme manager, education coordinator and data manager, with input from the study oncologists.

Patients and recruitment

Aim 1: concordance of flow cytometry testing

Participants will include children and young adults aged 0–19 admitted to MTRH with clinical suspicion of leukaemia. Eligible patients will have signs or symptoms indicating leukaemia or a clinical need for a diagnostic bone marrow aspiration, as determined by the primary medical team at the hospital. Patients with a prior confirmed diagnosis of leukaemia will be excluded. Eligible patients will be prospectively identified from both the paediatric and adult wards at MTRH, and study personnel will obtain informed consent before data and specimen collection. Patient enrolment began in April 2025 with anticipated completion in December 2027.

Aim 2: feasibility of conducting flow cytometry assays using blood samples transported from peripheral facilities

This arm will include patients with suspected leukaemia who have been presented in the Paediatric Oncology Project ECHO (Extension for Community Healthcare Outcomes) sessions or through consultation with the MTRH study team. These patients will be prospectively enrolled from peripheral facilities across western Kenya within the referral region of MTRH. Patients deemed eligible will be consented by study personnel via telephone and will then have 4–5 mL of peripheral blood drawn into an EDTA tube, which will be transported to MTRH via contracted courier for further testing. Patients with findings suggestive of leukaemia will be offered immediate referral to MTRH for continued workup and treatment. Enrolment is projected to begin in July 2027 with anticipated completion in 2028.

Aim 3: developing a comprehensive educational framework for sustainable flow cytometry implementation

Participants in this arm will include clinical and laboratory staff involved in diagnosing paediatric leukaemia at participating facilities. This includes pathologists, laboratory scientists, haematologists and medical officers. A structured recruitment approach will be used to enrol eligible personnel in the Flow Cytometry Project ECHO training series. Participants will complete standardised pre-intervention and post-intervention surveys assessing knowledge, confidence and the perceived feasibility of flow cytometry in leukaemia diagnosis. The initial training session occurred in January 2025 with the launch of the ECHO programme in February 2025. Additional training sessions are planned for January 2028 and again in 2030 while the ECHO programme is expected to run through the duration of the study period.

Data collection

Aim 1: diagnostic accuracy of peripheral blood flow cytometry

For all eligible patients at MTRH with suspected leukaemia, clinical and laboratory data will be collected prospectively at enrolment. Informed consent will be obtained before specimen collection. As part of routine clinical care, the primary medical team will perform a bone marrow aspirate (BMA). In addition to standard diagnostic smears, an extra bone marrow sample (up to 5 mL in an EDTA tube) will be collected for flow cytometry analysis. Bone marrow aspirates will be analysed using both the comprehensive 4-tube ClearLLab 10C assay and the single LS tube, with the samples acquired on a 3-laser Beckman Coulter flow cytometer—either the CytoFlex or DxFlex—and evaluated with the Kaluza software. At the same time, a peripheral blood sample (up to 5 mL in EDTA) will be taken for complete blood count (CBC), peripheral smear and flow cytometry testing with an LS tube (table 1).

Clinical data collected during enrolment will include demographic information, presenting symptoms, CBC results and the presence or absence of blasts on peripheral smear review. Flow cytometry results from both peripheral blood and bone marrow aspirates will be analysed and compared with the final clinical diagnosis.

For patients diagnosed with leukaemia, care will be transferred to the paediatric oncology service for standard treatment and assessments (figure 1). Participation in the study offers a direct benefit to patients, as all flow cytometry testing will be provided at no cost to families.

Table 1 This table shows the five commercial ClearLLAb tubes used in the study, along with their corresponding part numbers

	LS tube	B-cell tube	T-cell tube	M1 cell tube	M2 cell tube
Part #	B74073	B96805	B96806	B96807	B96808
FITC	κ/CD8	Kappa	TCRγδ	CD16	CD15
PE	λ/CD4	Lambda	CD4	CD7	CD123
ECD	CD19	CD10	CD2	CD10	CD117
PC5.5	CD56	CD5	CD56	CD13	CD13
PC7	CD10	CD200	CD5	CD64	CD33
APC	CD34	CD34	CD34	CD34	CD34
APC-A700	CD5	CD38	CD7	CD14	CD38
APC-A750	CD20	CD20	CD8	HLA-DR	HLA-DR
PB	CD3	CD19	CD3	CD11b	CD19
KrO	CD45	CD45	CD45	CD45	CD45

The five blue fluorochromes, three red fluorochromes and two violet fluorochromes with their associated surface markers for each individual tube are shown.

Aim 2: feasibility of conducting flow cytometry assays using blood samples transported from peripheral facilities

Medical providers at peripheral facilities in the MTRH referral region will identify patients with suspected leukaemia during case-based teleECHO sessions or through direct clinician consultation with the paediatric oncology team at MTRH. On verbal consent obtained by study personnel, peripheral facilities will draw 4–5 mL of peripheral blood into an EDTA tube and send the sample via courier to the ARL for testing (figure 2).

Haematopoietic samples are stable in EDTA for up to 48 hours, and all testing will be completed within 36 hours of collection. On receipt, samples will be logged, tracked and processed according to established laboratory protocols. CBC and peripheral blood smear review will be performed alongside flow cytometry testing.

Results will be shared with patients and the referring providers. Patients with findings concerning for leukaemia will be offered a referral to MTRH for further evaluation and treatment (figure 2). For patients whose flow cytometry results and peripheral testing are not suggestive of malignancy, follow-up contact will occur at 30 days to assess symptom resolution and determine whether additional testing is necessary. Turnaround time, sample integrity and diagnostic concordance will be recorded as part of the study evaluation metrics.

Aim 3: developing a comprehensive educational framework for sustainable flow cytometry implementation

As an educational programme, a vital step will involve using a virtual needs assessment. The first part will assess self-perceived knowledge and comfort with flow cytometry, using a Likert scale for more effective analysis at later evaluation points. The second part will evaluate motivation for learning about flow cytometry, assess resources and support and clarify the programme's expectations. This required survey information and assessment will be collected in the weeks leading up to the in-person training (figure 3) for those 10 participants, and again for all virtual participants before the ECHO launch (figure 4). As additional participants enrol in the ECHO programme, they will also be asked to complete an electronic survey at the time of entry.

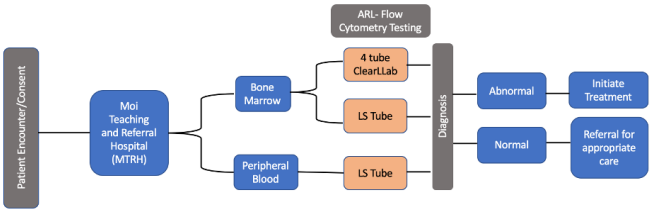

Figure 1 Schematic depicting sample collection by type and subsequent flow cytometry testing for Aim 1. Based on testing outcomes, patients will either be treated for their leukaemia or taken off study and cared for at the discretion of their primary team. ARL, Academic Model Providing Access to Healthcare Reference Laboratory.

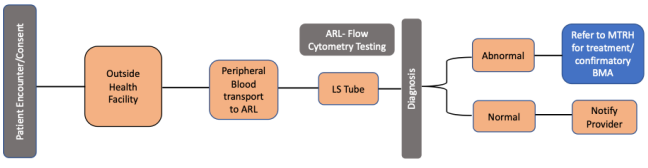

Figure 2 Schematic depicting sample collection and referral workflow for satellite (outside) health facility for Aim 2. Patients will be seen at the outside facility, and PB samples will be obtained for further flow cytometry testing. The outcome of the testing will then determine whether a patient is discharged, treated or referred to MTRH from the outside facility. ARL, Academic Model Providing Access to Healthcare Reference Laboratory; MTRH, Moi University School of Medicine and Moi Teaching and Referral Hospital; PB, peripheral blood.

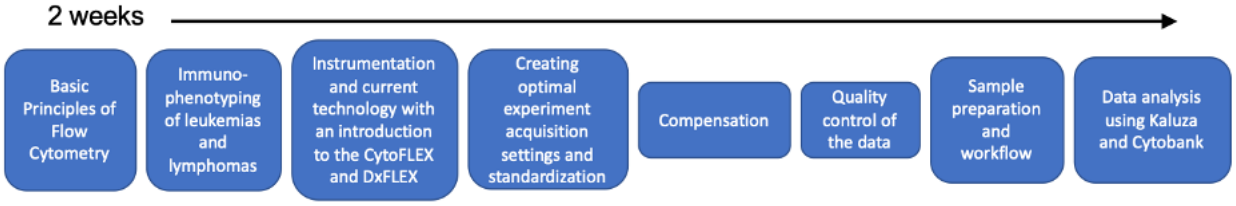

Figure 3 The curriculum for the 2-week hands-on training is outlined per the blocks above.

A final post-intervention survey will be conducted at the end of the ECHO series to evaluate changes in knowledge, diagnostic confidence and perceived feasibility of incorporating flow cytometry into clinical practice. Participants will be assigned unique study identifiers to protect their anonymity, and survey completion will be optional. A subset of participants may be invited to take part in brief, structured interviews to offer qualitative feedback on the educational content and its relevance to clinical practice.

Data management

All study data will be stored securely in a password-protected Research Electronic Data Capture database hosted at MTRH and Indiana University. Clinical data and flow cytometry results will be entered by trained study personnel using standardised electronic case report forms. All identifying information will be removed before analysis. For the educational assessments, survey responses will be collected automatically and participants will be assigned a unique identifier to compare pre-assessment and post-assessment results.

Flow cytometry data will be analysed using Beckman Coulter Kaluza software at the ARL. De-identified flow cytometry files will be uploaded to the Cytobank cloud platform to enable external expert consultation and advanced analysis. Appropriate cases may also be used for teaching during ECHO sessions. All programmes used comply with institutional data security protocols.

Data analysis

Aim 1: flow cytometry concordance

For all patients enrolled at MTRH, BMA samples will be analysed using both the 4-tube ClearLLab 10C assay and the 1-tube ClearLLab LS assay. The 10C assay includes four tubes that separately evaluate B-cell, T/NK-cell and two myeloid lineage populations (M1 and M2), providing a comprehensive diagnostic panel that serves as the current gold standard. The LS tube, a 10-colour/12-antibody assay, is designed to streamline the diagnostic process (table 1). Comparative analysis will assess diagnostic concordance between the LS tube and the 10C assay. The goal is to determine whether the simplified LS assay can reliably identify cases of leukaemia and serve as a practical and sustainable alternative to the more complex multitube panel in this setting.

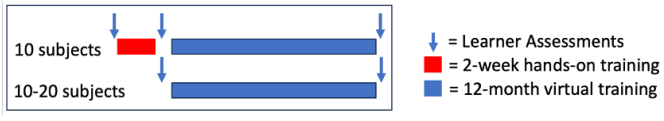

Figure 4 The five assessments of the learners receiving in-person or virtual training are shown.

A total of 300 hospital patients enrolled in the study will provide a width of 0.053 (ie, 0.919–0.972 for a proportion of 0.95) for the Clopper-Pearson asymmetric exact two-sided 95% CI surrounding the proportion of patients who demonstrate results (negative, positive) that show agreement between two methods. Two bone marrow methods (4-tube vs 1-tube) will be compared. In a separate comparison, the 1-tube peripheral blood method will be compared with the 1-tube bone marrow method. Since a 95% or higher agreement is expected, 0.95 will be used as the proportion in the CI width calculation. Error rates will be measured by reporting sensitivity (1—false negative rate) and specificity (1—false positive rate). Proportions and 95% CIs will be calculated for agreement, sensitivity and specificity for the two comparisons (4-tube bone marrow vs 1-tube bone marrow; 1-tube peripheral blood vs 1-tube bone marrow). The 95% CIs will reflect the precision of these estimates. Success will be indicated by agreement >95%, sensitivity >95% and specificity >95%, as seen in paediatric literature.[15 16]

Aim 2: peripheral facility validation

This aim seeks to determine whether flow cytometry testing can be reliably used for patients presenting at peripheral health facilities. These patients will be identified through Project ECHO sessions or direct consultations and will have their peripheral blood samples collected and transported to MTRH for centralised flow cytometry testing. This approach evaluates the feasibility of a decentralised referral network supported by remote diagnostic infrastructure, which is a critical step toward increasing access to leukaemia diagnostics in resource-limited regions.

A sample of 100 patients from other community clinics (outside MTRH) will provide a width of 0.127 (ie, 0.824–0.951 for a proportion of 0.90) for the Clopper-Pearson asymmetric exact two-sided 95% CI surrounding the proportion of patients whose peripheral blood (tested with 1 tube) is successfully transported to the main hospital.[20] It is anticipated that ≥90% of patients with leukaemia by flow cytometry will be referred and begin treatment. The analyses will involve calculating the proportion and 95% CI for the transportation success rate. Success for this aim

will be indicated by a transportation success rate of 90% or higher.

Aim 3: analysis of training success

This aim assesses the effectiveness of a multimodal educational strategy to train healthcare providers and laboratory personnel in the use and interpretation of flow cytometry for leukaemia diagnosis. Participants will include clinicians and laboratory staff from across the region engaged through an in-person training programme and a year-long Project ECHO telehealth series. This training aims to build foundational knowledge, boost confidence and support sustainable implementation of flow cytometry at both central and peripheral sites. Measuring knowledge gains and perceived utility will be essential to understanding the programme's impact and guiding future replication.

A two-sided paired t-test will be used to evaluate pre-training versus post-training gains separately for participants in in-person and virtual training (three assessments) and those only in virtual training (two assessments). Specifically, for participants who undergo the initial in-person training (10 individuals), the study team will compare their pre-training and 2-week post-training assessments. After completing their 2-week post-assessment, this group will also be evaluated on their progress during ongoing virtual ECHO education by comparing pre-education and 1-year post-education assessments. These tests will focus on the performance scale score (primary outcome) and secondary scale scores (self-perceived knowledge and flow cytometry comfort).

For the different groups of people who do not participate in initial in-person training but do take part in virtual ECHO ongoing education (10–20 individuals), the study team will compare pre-education measurements with those taken 1 year after virtual education (figure 4). A sample of 10 individuals receiving both in-person and virtual training will provide 80% power (at 0.05 alpha) for a two-sided paired t-test to detect a 1.0 SD change in scale scores. Power will exceed 80% for the separate analysis of the group receiving only virtual training if the enrolled sample approaches 20 instead of 10. In-person training in years 3 and 5, followed by the year-long virtual ECHO training, will allow the opportunity to repeat assessments of new groups of learners on two additional occasions, helping to verify the reliability of the method.

ETHICS AND DISSEMINATION

Overall, the risk associated with the diagnostic aspect of this study is minimal. Specimen collection will adhere to the standard of care and will not involve additional procedures. To safeguard patient confidentiality, each sample will be labelled with an accession number that is not linked to their medical record or other patient identifiers. The key to all identifiers will be stored securely. All samples will be analysed in a blinded manner.

Flow cytometry assays will use validated reagents and protocols provided by Beckman Coulter, and all testing will include appropriate positive and negative controls to ensure reliability and reduce non-specific signals. Strict adherence to scientific methods and rigorous experimental design will be employed to produce clear and unbiased results.

The study protocol, consent forms and related documents have been reviewed and approved by the Institutional Research and Ethics Committee of MTRH and Moi University (Ref - ELD/MTRH/R&P/10/2/V.2/2010), as well as the Indiana University Institutional Review Board (Protocol #22183).

Results will be shared through peer-reviewed publications, local and international scientific conferences and stakeholder meetings within Kenya and the larger AMPATH network. A summary of key findings will be provided to participating sites to inform clinical practice. The dissemination strategy will focus on the accuracy, cost-effectiveness and potential sustainability of peripheral blood flow cytometry as a diagnostic tool for paediatric leukaemia in low-resource settings. By demonstrating a testing model that remains below the cost threshold of common insurance programmes, this academic-industry partnership aims to increase diagnostic access and enable more children to receive accurate diagnoses and curative treatment. De-identified datasets may be available on reasonable request after publication.

PATIENT AND PUBLIC INVOLVEMENT

Patients, parents and caregivers were not directly involved in designing, conducting or reporting this study. Given the focus on diagnostics and implementation science, the expected burden on participating patients and families is minimal. The AMPATH research team will handle the consent process for each patient enrolled in Aim 1. All results will be shared with patients and caregivers once available through written materials and verbal discussions, and updates to clinical care pathways will be communicated via the paediatric oncology division. Findings from Aims 2 and 3 will be shared with regional stakeholders, including referring providers and healthcare facilities, through direct outreach, medical conferences and feedback sessions.

DISCUSSION

The strength of this comprehensive academic-industry partnership study will combine expertise in immunology, oncology and education through the use of a low-cost and sustainable multiparametric flow cytometry approach. If successful, this programme provides a scalable solution to enhance early leukaemia diagnosis and address a critical gap in cancer care for children in Kenya and the region.

We expect successful implementation of the LS tube assay at ARL based on prior published studies and institutional experience.[21 22] However, if the LS assay has

limited utility, we will consider reflex testing with one or more tubes from the more comprehensive 4-tube ClearLLab 10C assay, or consider increasing the number of screening tube markers to ensure adequate diagnoses. Sample transport to MTRH may prove challenging, which could affect the quality of the samples arriving at the clinical laboratory. If necessary, we are ready to bring patients from outside clinics to MTRH for screening tests. Ultimately, the strengths of this study will maximise the development and implementation of a reliable, affordable and scalable method for leukaemia diagnosis in a resource-limited setting.

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Contributors TV led the conceptualisation and served as Principal Investigator. TV, SK, FN and TS collaborated on protocol planning. Methodology design involved TV, TS, PM, FN, EH, SK, TL, VR and TB. PM led the statistical analysis. An investigation was conducted by BM, ES, MO, RT, GO, RK, VR and NK. FN, BM, GO and TV contributed key resources. Data curation was supported by ES, MO and RK. TS drafted the original manuscript. All authors participated in review and editing. Visualisations were developed by EH and TS. TV, FN, SK and TL supervised the study. Project administration was led by FN and TL. Funding acquisition was supported by TV and SK. All authors reviewed and approved the final manuscript and remain involved in the ongoing implementation of the study protocol. TV is the Guarantor for this study protocol. In addition to the spelling and grammar evaluation tools within Microsoft Word, the authors used ChatGPT on the completed manuscript to help identify and mitigate potential cultural bias in phrasing and content. However, the initial versions of the manuscript were created without the use of AI and represent the independent thought of the authors.

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Competing interests SK and VR are employees of PhenoPath, A Quest Diagnostics Company. SK is also a consultant for Beckman Coulter Life Sciences. All other authors have no competing interests to declare.

Patient and public involvement Patients and/or the public were not involved in the design, or conduct, or reporting, or dissemination plans of this research.

Patient consent for publication Not applicable.

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