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Bridging the Gap Through Research

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Conflicts of Interest

• None





- Cancer disparities between LMIC vs HIC
- Role of research in improving access and outcomes in LMIC
- The ARGO Experience
- Conclusion





• Cancer disparities between LMIC vs HIC

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Cancer incidence in LMIC is increasing

- Most LMICs are experiencing the double burden of diseases
- Growing crisis in cancer incidence and mortality
- Incidence increases most significantly in LMICs
 - 400% in LMICs, 168% in MICs, 53% in HICs
- Factors responsible for the increase include
 - Rising population
 - Highest fertility rate
 - Epidemiological transition dietary change and expanding urbanization
 - Demographical transition life expectancy
 - Increase awareness and diagnostic facilities
 - Genetic factors?



Ngwa et al. Lancet Oncol. 2022 Jun;23(6):e251-e312. Bray et al. CA Cancer J Clin. 2024 May-Jun;74(3):229-263. Soerjomataram & Bray . Nat Rev Clin Oncol. 2021 Oct;18(10):663-672





Cancer mortality in LMIC is increasing

- The mortality/incidence ratio for cancers in LMIC is high
- Mortality is estimated to rise from 520,348 in 2020 to 1 million deaths per year by 2030
- Late presentation & advanced disease
- Outcome of cancer care
 - HIC improving
 - LMICs static or getting worse



Bray et al. CA Cancer J Clin. 2024 May-Jun;74(3):229-263.

The Institution of Cancer Control Program has reduced the mortality in most HICs







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Factors responsible for improving cancer care outcome

- Early detection
- Accurate diagnosis
- Advancements in treatment options
- Improved patient experience
- Value-based care
- Social innovations that focus on community engagement, patient navigation
- Survivor networks

• Most innovations come from research conducted in HICs



Mooney K, et al. Am Soc Clin Oncol Educ Book. 2017;37:695-704. Wells JC, et al.. JAMA Oncol. 2021





- Research in HIC does not always place priority on diseases peculiar to LMIC
 - SCD
 - Burkitt lymphoma
 - Esophageal cancer
 - Hepatobiliary cancer



Pramesh *et al. Nat Med.* 2022 Apr;28(4):649-657.

GBD 2021 Sickle Cell Disease Collaborators.. Lancet Haematol. 2023





- Disease-specific control strategies that are effective in HICs may not be effective in LMICs
 - Differences in disease characteristics,
 - Health systems capacities
 - Sociocultural factors,
 - Available treatment options
 - Treatment completion rates,
 - Pharmacokinetic and biological variation associated with ethnicity

Positive predictive values at colonoscopy (95% Cl)		
Advanced neoplasia	8.1% (5.3–12.0)	
Advanced adenoma	7.0% (4.5–10.8)	
Colorectal cancer	1.1% (0.3-3.3)	
Detection rate, per 1000 participants screened with a fecal immunochemical test		
Colorectal cancer	1·4 per 1000 participants	
Advanced neoplasia	10∙9 per 1000 participants	

Alatise OI, et al. Lancet Glob Health. 2022 Pramesh *et al. Nat Med.* 2022 Apr;28(4):649-657.





- Health systems research is highly context-specific.
 - Social Determinants
 - Access to Resources
 - Geographic Location
 - Systemic Issues







- The high costs of many interventions developed in HICs render them nonimplementable in LMICs
 - The world has a lot to learn from SSA and other LMICs!

5FU/LV	\$162
FLOX	\$30,618
FOLFOX	\$40,506
FOLFOX/cetuximab	\$100,074
FOLFOX/bev 6 m	\$67,902
FOLFOX/bev 12 m	\$95,298
Immunotherapy	\$XXXXXX



Importance of Research in Sub-Saharan Africa (SSA)

- Generate evidence
 - Physician and patient decision making
 - Generate practice guidelines
 - Generate quality measurement and improvement,
 - Baseline information for product approval, organization and management decisions, and
 - Program financing and priority setting





Importance of Research in SSA

- Provides academic and professional development opportunities that will improve career satisfaction, probably reducing brain drain
- Brings everybody to the table
- Greater access to advanced care and associated resources
- Job and training opportunity





Factors that makes research suitable and necessary in LMIC

- Different disease burdens
- Unique molecular biology
- Population size



• Willingness of people (patients/researchers)





Challenges of the Research in LMIC

- Lack of an environment conducive to research in academic institutions
- Inadequate research infrastructure and trained human resources, with protected time
- Funding
- Scarcity of reliable data





Challenges of the Research in LMIC

- Paucity of clinical trials
- Lack of functional leadership capacity and competencies of political leaders to drive development initiatives
- Poor people's attitudes towards innovative ideas





Research priority in LMICs

- Reduce the burden of patients with advanced disease
- Improve access and affordability, and outcomes of cancer treatment
- Value-based care and other quality improvement strategies
- Implementation research
- Leveraging technology to improve cancer control





Research priority in LMICs

- Better quantification of the NCD burden;
- Aetiologic evidence for locally important risk factors;
- Molecular characterization of cancers, which can guide precision medicine in LMIC contexts
 - Biomarker-directed care
- De-escalation of treatment and appropriate treatment sequence





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How it all started

- Mammadi Soudavar Traveling Fellowship at Memorial Sloan Kettering Cancer Center
- Professional relationship and personal friendship established between OIA and TPK
- Reciprocal trip to OAU by TPK































- Founded in 1962 as the University of Ife but rechristened as the Obafemi Awolowo University on May 12, 1987, in honour of one of its most distinguished founding fathers, Chief Jeremiah Obafemi Awolowo.
- Has
 - 2 Colleges
 - 13 Faculties
 - 92 Departments
 - 19 Research centers
 - 32,000 students



Obafemi Awolowo University Teaching Hospital Complex (OAUTHC)

- Established in 1975
- Hospital beds 832
- Surgical beds 150
- Catchment over 15 million
- Center of excellence in Cardiac and HPB surgery







First visit of Peter Kingham



- The uniqueness of cancer seen in Nigeria was obvious from the first day
- Mutual interest in improving the outcome of the patient was evident



Observed differences between US and Nigerian CRC patient populations

- Nigerian CRC patients
 - Younger
 - Later stage
 - More rectal tumors
 - More peritoneal metastases
 - Worse outcomes
- This prompted further discussions about research questions, needs, and priorities...
- Model must include research and training







African Research Group for Oncology (ARGO)

- Founded in 2013
- **Mission:** To improve cancer outcomes in Nigeria and the wider sub-Saharan African region through <u>research</u> and <u>training</u>

• Goals:

- 1. Improve outcomes for cancer patients
- 2. Perform clinically meaningful research data are power!
- 3. Create a model that can be replicated elsewhere
- 4. Career development



Early Priorities: Clinical Relevance and Feasibility

- Focus on cancers that are
 - Common
 - Outcomes requiring improvement
 - Treatable by surgeons

- Start small
 - 5 sites in South-West Nigeria
 - 1 US







Expanding beyond South-West Nigeria



Geopolitical Zone	ARGO Sites
South West	17
South South	5
South East	4
North West	6
North Central	5
North East	2

+ collaborators in the US - 5, Canada -2, South Africa, Ghana, Kenya, and Tanzania

Dare et al, J Surg Oncol. 2023 Nov;128(6):1011-1020.





Other Collaborators





International Agency for Research on Cancer







Africa Research Group for Oncology (ARGO)







Colorectal Cancer





Colorectal Cancer Database

- Over 1300 patients
 - Mean age: 54.5 ±14.7yrs
 - 53.7% male
 - Over 500 data points collected per patient
- 10 contributing sites
- Prospectively maintained
- Regular QA of the data
- Biospecimens collected
- 10 research assistants
COLORECTAL STUDIES

Unknown what modifiable risk factors exist for Nigerian CRC pts	75% of patients present with Stage III or IV colorectal cancer		1-year survival < 50%
EPIDEMIOLOGY/BIOLOGY	EARLY DETECTION	DIAGNOSIS	TREATMENT
Case-control study evaluating modifiable risk factors for CRC Funding - NCI R01 PI- Alatise, Kingham	Point-of-care methylation blood test for CRC in high-risk patients Funding - <i>R01 pending</i> PI- Sukumar, Alatise, Kingham	Capacity building for colonoscopy skills Funding - CIRGO Grant PI- Alatise, Murthy	Phase II Immunotherapy trial for MSI-H colorectal cancer PI- Balogun
Determining sporadic and germline mutations in Nigerian CRC Funding - NCI R01 PI- Alatise, Kingham	Urine metabolite point-of-care test Funding - NCI UG3/UG3 PI- Kingham, Alatise	Establishing the feasibility of a deep- learning imaging classification network PI- Matteo DiBernardo	Improving outcomes in CRC cancer treatments: SCAMPS PI- Doyle
Environmental risk factors for CRC in Nigeria Funding - NCI R01 supplement PI- Alatise, Kingham	FIT stool testing Funding - Thompson Family Foundation; Prevent Cancer Foundation PI- Alatise, Kingham		
Cryptosporidium association with CRC PI- Alatise	Early diagnosis bowel cancer project Funding - Thompson Family Foundation PI- Alatise, Kingham		
	Delays in diagnosis for GI cancers PI- Alatise		





Nigerian CRC patients present with advanced disease and have worse outcomes







Nigerian CRC patients have mostly rectal cancer and present in the emergency department

	Elective	Emergency		All patients	Elective	Emergency	p-value
	N =371 (%)	N = 164 (%)	# Patients	535	371 (69.3)	164 (30.7)	
Cecum (A)	8 (2.2)	3 (1.8)	Median OS, months (95% CI)	13.3 (10.5–15.5)	17.4 (14.1–21.5)	6.4 (4.8–9.5)	< 0.001
Right colon (B) 71 (19.1)	71 (19.1)	51 (31.1)	30 day perioperative mortality (%)	51 (14.7)	19 (9.1)	32 (23.2)	< 0.001
Transverse colon (C)	10 (2.7)	15 (9.2)	Median OS by clinical stage, months (95% CI)		× /		
Left colon (D)	17 (4.6)	11 (6.7)	Stage I/II	34.3 (19.5-NR)	NR (24.0-NR)	16.9 (5.4-48.8)	0.008
Sigmoid colon (E)	59 (15.9)	24 (14.6)	Stage III	19.1 (13.9-28.2)	26.8 (17.2-40.8)	9.5 (3.7–16.4)	0.003
Rectum (F)	203 (54.7)	63 (38.4)	Stage IV	7.0 (5.3–9.2)	9.4 (6.9–11.5)	4.8 (3.0-6.5)	0.002

Aderibigbe AS, Dare AJ,Alatise OI; J Surg Oncol. 2025 Feb;131(2):170-182





Early diagnosis strategies are vital

- FIT: 2,330 asymptomatic patients; high false positives¹
- A bundle of clinical signs and symptoms²
- Piloted the effectiveness of the bundle of symptoms in the community
- Urine metabolite point of care testing (Co-PI NCI UG3/UH3)
- Blood methylation marker point of care testing (Co-PI NCI R01)
- Planned step wedge randomized pragmatic trial of a bundle of clinical signs and symptoms with patient navigation in each of the 30 districts in Osun State, Nigeria, with the Nigerian MOH

Alatise......Kingham TP. Lancet Glob Health 2022.
Alatise...Kingham TP. Cancer 2018

Biosensor POC device to identify 3 urine metabolites

- Smartphone connects to biosensor
- Impedance measured in biosensor



Biosensor Housing Unit





Disposable Chip and Biosample

Cellphone or Tablet





Inserting a chip into the housing unit

Sending measured data to a smartphone

Courtesy Jai Chen, PhD, U. Alberta

Sensitivity when specificity is fixed at 50%



cMethDNA Assay on 5-gene Panel



To identify a minimal marker subset of the 8-gene panel, cMethDNA results were re-analyzed using a subset of 5 of 8 plasma markers after selecting for individual plasma markers with the least background in normal and the highest methylation in CRC plasma

Klein Kranenbarg et al. Clinical Epigenetics (2021) 13:218 <u>https://doi.org/10.1186/s13148-021-01206-2</u>



Box–whiskers plot. Comparing CRC versus normal control plasma, significantly higher cumulative methylation of the 5-gene panel was observed in stage IV CRC



Receiver operating characteristic (ROC). The 5-gene panel, with negligible methylation in normal plasma identified samples from patients with stage IV CRC versus normal controls with a sensitivity of 100% and specificity of 100%



Rate of microsatellite instability is significantly higher among Nigerian CRC patients



Alatise et al, Nat Commun. 2021 Nov 24;12(1):6821.





Local research demonstrating high MSI-H rate leading to a Phase II CRC immunotherapy trial

- Primary Objective:
 - To evaluate the overall response rate (ORR) of MMRd metastatic CRC and locally advanced rectal patients treated with PD-1 blockade in Nigeria.
- Secondary Objective:
 - Evaluate progression-free survival (PFS), overall survival (OS), and germline mutation rate
 - Demonstrate that immunotherapy trials can be successfully performed in Nigeria (will be first of its kind trial in sub-Saharan Africa)
- Treatment
 - PD-1 checkpoint blockade for up to 24 months in cohort 1 (mCRC); up to 6 months in cohort 2 (locally advanced rectal cancer)









Unique pathways are found in microsatellite stable Nigerian CRC patients



Alatise et al, Nat Commun. 2021 Nov 24;12(1):6821.



Using silicone wristbands, we examined the chemical exposure profile of 25 cases and 26 controls in our ongoing colorectal cancer study in South West Nigeria.



Control

Colorectal Case

OAU HE HE



We examined the association between the number of chemical compounds in a class a participant was exposed to and colorectal cancer risk in exploratory analyses



Associations between chemical compound classes and colorectal cancer					
Compound Class	N Cases	N Controls	OR	95% CI	
Brominated Flame Retardants					
Low	22 (88%)	22 (85%)	Ref	Ref	
High	3 (12%)	4 (15%)	0.76	0.11.4.95	
Organosphates					
Low	9 (36%)	17 (65%)	Ref	Ref	
High	16 (64%)	9 (35%)	4.74	1.34, 19.5	
Polycyclic Aromatic Hydrocarbons					
Low	10 (40%)	17 (65%)	Ref	Ref	
High	15 (60%)	9 (35%)	6.12	1.58, 29.1	
Polychlorinated Biphenyls					
Low	18 (72%)	20 (77%)	Ref	Ref	
High	7 (28%)	6 (23%)	1.15	0.29, 4.60	
Pesticides					
Low	11 (44%)	19 (73%)	Ref	Ref	
High	14 (56%)	7 (27%)	3.24	0.85, 13.5	
Phthalates					
Low	19 (76%)	22 (85%)	Ref	Ref	
High	6 (24%)	4 (15%)	2.07	0.46, 10.5	

*A sum score was created to reflect the number of chemicals within a compound class that a participant was exposed to. We split exposures using the median value for each chemical compound class.



Dietary Patterns (DP) and Colorectal Cancer (CRC)

Background

- Studies on diet and CRC have mostly been carried out in HIC
- The few studies in sub-Saharan Africa focused on isolated nutrients/food types, but people tend to eat in patterns

Methods

- Case-control study with 507 cases and 1114 controls in Nigeria, West Africa
- 3 empirical DPs (using principal component analysis):
 - Diversified: Wide range of food groups
 - African traditional: Fruits and vegetables dominated
 - Westernized: Processed/red meat dominated
- 3 Index-based DPs: DASH, AMED and AHEI-2010







Westernized DP consistently increased the risk of CRC in all the models and stratifications of our analysis

DASH, AMED and AHEI-2010 had a protective relationship with CRC, though only AHEI-2010 was statistically significant





Breast Cancer

2024 Breast Cancer Research (34)

Early Detection	Radiology	Pathology	Treatment
Triple mobile assessment and patient navigation model	Ultrasound-guided core biopsy training program>Validation expansion	Biomarker/IHC testing	Pyschosocial barriers to BC surgery
Primary school-based intervention pilot	ECHO RAD-PATH assessment	Breast pathology synoptic templates	Improving adherence to BC guidelines
Addressing global inequities in breast cancer genetic testing	Mammography QA and ultrasound BIRADS re-evaluation	Global pathology academy: Online fellowship	Guideline Concordance Restrospective Analysis
Pt. reported barriers to screening and early presentation of breast cancer	Artificial Intelligence Decision Support for Timely Breast Cancer Diagnosis in Nigeria	Prevalence/magnitude of TILS	Post-Mx prophylactic compression sleeve
Understanding the experiences, perceptions and health seeking behaviors of relatives of breast cancer patients at Obafemi Awolowo University Teaching Hospital Complex	Perceptions of Radiation Workers to Mammography Screening in Nigeria	Pathology Perspective in early breast cancer diagnosis	Evaluating the Impact of Financial Navigation on Financial Toxicity and Treatment Adherence for Cancer Care: A Randomized Control Trial - COST-FIN
Delay in breast cancer presentation and treatment in Nigeria: Evaluating health systems and structures	Comprehensive Multi-center Oncologic imaging survey	National snapshot of IHC in Nigeria	De-escalating mastectomy to facilitate breast conservation
Integrating Cervical and Breast Cancer Screening into Family Planning Services in a Nigerian Suburban Population: A Pilot		Improving hormone receptor testing in Tanzania	Factors responsible for inadequate restriction margins of mastectomies
Impact of patient navigation in cancer patients		Pathology capacity building scoping review	De-escalating auxiliary surgery
			Mastectomy review/seroma
			QoL in elderly women with breast cancer

Correlation between body composition and toxicity grading in chemotherapy

Barriers to breast reconstruction in Nigeria: HCP and patients' perspective





Breast Cancer Database

- Over 2,000 patients
 - Over 1000 data points collected per patient
- 7 contributing sites
- Prospectively maintained
- Biospecimens collected
- 20 research assistants

Ultrasound-guided breast biopsy training for Nigerian Radiologists



Blended Learning

Simulation Biopsy

Patient Biopsy



LOW-COST BREAST BIOPSY TECHNIQUE

Core-Needle Biopsy Kit (\$15.6)

Low-Cost Vacuum-Assisted Core Needle Biopsy Kit (\$1.1)



Ultrasound images and photomicrographs of the standard Core-Needle Biopsy technique and the low-cost Vacuum-Assisted Core-Needle Biopsy technique for the same breast mass. Note the similar histological findings.





Improving access to breast cancer screening and treatment in Nigeria: The triple mobile assessment and patient navigation model

- Community level interventions using mobile technology
 - Handheld iBreast Exam device
 - Mobile breast ultrasound
 - Mobile mammography
 - Patient navigation
- Outcomes of interest
 - Screening participation rate
 - Cancer detection rate
 - Stage at diagnosis
 - Timeline from detection to initiation of treatment





Mango *et al*. Lancet Glob Health. 2022 Apr;10(4):e555-e563. Omisore *et al. PLoS One*. 2023 Jun 13;18(6):e0284341.







De-escalating axillary after neoadjuvant chemotherapy in node positive breast cancer patients in Nigeria

- Target population:
 - Breast cancers converted from cN1 to cN0 disease after neoadjuvant chemotherapy
- Goal:
 - Determine the feasibility and efficacy of pre-op axillary US and single agent SLNB for axillary staging
 - Reduce unnecessary axillary dissection and its concomitant morbidity
- Accrual ongoing





De-escalation of breast and axillary surgery using USS and Conventional Xrays



De-escalation of breast and axillary surgery using USS and Conventional X-rays







HPB Cancers





Delay in presentation of HPB cancers in Nigeria







HPB Capacity and Infrastructure Needs Assessment

Surgeons

- HPB surgeons 14.3%
- General surgeons 85.7%
- Anaesthesiologists
 - HPB anesthesiologists 20.0%
- Nurses
 - HPB nurses 5.7%
- IR 25.7%
- ICU capacity 87%

- Pretested blood 86%
- Radiology services
 - CT scan 82.8%
 - MRI 60.0%
 - Intraoperative ultrasound 20.0%
- Surgical instruments
 - LigaSure 25.7%
 - Vascular staplers 22.8%
 - Ultrasonic scalpels 8.6%
 - Liver retractors 14.3%

Alatise et al. HPB (Oxford). 2024;26(9):1123-1130.





Starting a HPB Surgery Program from scratch: closing the gap in West Africa

- 2015: First hepatectomy performed at OAUTHC
 - Performed 69 liver resections from 2015 to 2023
 - Anesthesiology training, low CVP protocol
- 2018: Started ERCP program
 - Performed over 1,200 ERCPs for over 800 patients since March 2018
 - Remains the only ERCP program for Nigerian 220 million people
- ERCP has changed the HPB practice in Nigeria









Financial Toxicity





The out-of-pocket cost of breast cancer care in Nigeria: A prospective analysis

- 71 patients
 - 66% ≥ Stage III at presentation
 - 96 % received systemic chemotherapy
 - 23.9 % received adjuvant radiotherapy
- Over 70% of breast cancer patients experienced a <u>catastrophic health expenditure</u> due to out-of-pocket costs associated with accessing care.
- 66% of patients had **no form of health insurance**









Evaluating the Impact of **Financial** Navigation on Financial Toxicity and Treatment Adherence for Cancer Care: A Randomized Control Trial (COST-FIN)

- Comprehensive baseline assessment
 - Financial and health literacy
 - Social determinants of health
 - Clinical parameters
- Patients randomized to financial navigation (vs standard of care)
 - Paired with financial navigator
 - Assistance with NHIS enrollment
 - Funding from donors



"I'm tired of researching the problem. I want to find the solution."

- Dr. Juliet Lumati









Capacity-Building





Multidisciplinary Project ECHO Meetings

- Colorectal Cancer Management ECHO, 2020
- ARGO Pathology ECHO, 2020
 - Checklist reporting
- Breast ECHO, 2021
- Histology ECHO, 2021
 - Automation of immunohistochemistry processing
- RADPath ECHO, 2022
- HPB ECHO HPBridge iHPBA initiative
- Improved clinical care + generate research ideas



Online Breast Pathology Fellowship Program

- 9 pathologists trained
 - Nigeria, Mozambique, Tanzania
- Program evaluation
 - Increased confidence in pathology skills
 - Improved collaboration across departments
 - Mentorship + professional development
- Analysis of mastectomy reports
 - Improved reporting using synoptic templates
- Success is motivation for other fellowships
 - GI Medical Oncology Fellowship














Colonoscopy Training Program

- ~15 physicians per cohort
 - Recruiting 3rd cohort
- Low- and high-fidelity simulation + experience with live patients
- Free colonoscopies for participating patients





ons: colonoscopy trainers







Nigerian CAncer research Training (NCAT) Program

- Multi-pronged longitudinal program
- Goal: build national cancer research capacity
- ~12 scholars per cohort
 - The 4th cohort is in session
- Program evaluation
 - High satisfaction among scholars
 - Valued mentorship relationships

















Biostats Training Program

- ~15 trainees per cohort
 - Recruiting 3rd cohort
- Access to statistical software
- One-on-one instruction
- Perform analyses for ARGO studies included as authors











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Bridging the Gap

- Advancing knowledge transfer
- Improving health outcomes through training
- Advancing research by fostering collaboration
- Building sustainable research funding models, which should include both local, philanthropic, and international funding





Bridging the Gap

- Need to continue to invest in
 - Preventive efforts
 - Cancer diagnostic tests
 - System-friendly treatment paradigm
 - Quality of care
 - Workforce training
 - Developing cancer registries





The Legacy of ARGO

- Trainings across all levels
- Novel research ideas
- Grant funding

We cannot scale elite, but we can scale access.

- Research outputs that have influenced practice
- Peer to peer relationships + a growing network

You are welcome to be part of the team





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 - SOS
 - Cancer Prevent
 - Pfizer









Thank You

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