COUNTY FEEDBACK

NOVARTIS ACCESS PROGRAM KENYA

MARCH 2020

Contents

ABBREVIATIONS

CHVs	Community Health Volunteers
CHWs[1]	Community Health Workers
KEML	Kenya Essential Medicines List
KEMSA	Kenya Medical Supplies Authority
MEDS	Mission for Essential Drug and Supplies
NCD	Non-Communicable Diseases
NHIF	National Hospital Insurance Fund
UHC	Universal Health Coverage
STGs	Standard Treatment Guidelines

[1] In Samburu County they have shifted from this terminology to CHAs (Community Health Assistants)

INTRODUCTION

In 2016, Novartis launched the program Novartis Access in Kenya, to provide a basket of 14 medicines (Furosemide, Amlodipine, Bisoprolol, Valsartan, Ramipril, Hydrochlorothiazide, Simvastatin, Vildagliptin, Glimepiride, Metformin, Salbutamol, Letrozole, Anastrozole, and Tamoxifen) for NCDs at a cost of $1 per month. They commissioned a team of researchers at Boston University (BU) to evaluate the program. A randomized control trial in which four counties received the medicines and four control counties did not receive the medicines was undertaken to measure whether the program had an effect on the availability and the price of medicines at health facilities and households. After two years a mid-term evaluation was undertaken. After this interim evaluation Novartis changed their distribution strategy to include the private sector and provided their medicines to all eight counties. A final evaluation was conducted in November 2019. A key part of these evaluations were mixed methods (quantitative and qualitative) surveys at baseline, midline and endline of households with NCDs and of public and private facilities diagnosing and providing treatment for NCDs. In addition, continuous surveillance was done by making regular phone calls to the households and facilities to collect data on NCD medicines availability and prices. The BU evaluation team has created a web site at http://sites.bu.edu/evaluatingaccess-novartisaccess/ where many documents and publications about the evaluations and the project have been posted.

Following the completion of the data collection for the evaluation of the Novartis Access Program in Kenya, Boston University – the evaluators, along with their partners Innovations for Poverty Action (IPA) organized a series of meetings with county government officials from the 8 study counties in Kenya participating in the evaluation. The purpose of these meetings was to discuss the quantitative and qualitative findings and get their feedback and suggestions before the evaluation report was finalized. The meetings took place in Nyeri, Kakamega, Narok and Kwale between March 10th 2020 and March 13th 2020. Mr. Meshack Ndolo – in his capacity as technical advisor for Boston University - facilitated the meetings on the first two days, bridging the conversation around the program to the other activities happening at the county and national level. Boston University researchers attended the first two days of these meetings in Nyeri County, and met with county officials from Embu, Nyeri, Makueni and Samburu, but they had to return to the US due to the COVID-19 pandemic and related travel restrictions. Researchers from the evaluation partner IPA continued with the remaining meetings in Kakamega, Narok and Kwale and met with county officials from Kakamega, West Pokot, Narok and Kwale.

This report was written by Zana Kiragu based on her notes and those of Veronika Wirtz and Monica Onyango (BU researchers), John Mungai, John Mboya, Jemima Okal and Kelvin Gichia (IPA researchers) and Meshack Ndolo (BU consultant). The draft report was provided to all county officials who attended the meetings for their review and comments.

Boston University gratefully acknowledges active involvement and most valuable contributions of all county officials who provided feedback and input into this evaluation.

Meeting outcomes

Comments on Evaluation Findings

- All counties expressed surprise at the medicines in the Novartis Access basket - as many of those selected did not align with the essential medicines list or standard treatment guidelines and were more expensive than generic competitors.
- Many counties expressed appreciation of the NCD prevalence data from baseline[2]- in view of the fact that prevalence is difficult to measure due to information systems challenges including reporting and lack of a unique identifier to track patients in the health system.
- Some counties also appreciated the health insurance data, since the health insurance landscape in the country has been changing rapidly.

What could Novartis have done differently?

- Medicines selection requires adjustment: All county officials expressed that an understanding of the health systems landscape and consultation with technical experts on the ground is crucial to a program's success. The fact that healthcare is devolved and counties may vary in care delivery further highlights the importance of consultations to understand the landscape. For example, the officials reported that the basket of Novartis Access medicines included simvastatin which is not part of any of the counties' procurement list.
- The basket approach hindered program penetration: when the program was launched the 14 medicines of the program had to be purchased as a joint offer by wholesalers. This was not permitted by KEMSA, the main wholesaler service for county health facilities. KEMSA's policies do not allow the purchase of a group of products. Since counties have to purchase the majority of medicines from KEMSA they felt that offering medicines through MEDS may have resulted in better penetration of Novartis Access products.
- Price per month was seen as an access barrier: Market surveillance to determine prices and set a competitive price was also echoed across counties - as the Novartis Access price was high for some of the medicines - such as furosemide and hydrochlorothiazide. One county mentioned that for some of the medicines in the basket - tamoxifen, letrozole and salbutamol - the 1US dollar per month price was competitive, and these could successfully penetrate the market if supplied through KEMSA.

What are counties doing to address availability and affordability of NCD medicines?

- Community health volunteers: Counties face different challenges and have different capabilities, thus they are at different stages of addressing NCD management. Capacity building for community health volunteers to increase screening for NCDs and follow up of NCD patients was mentioned.
- Training health providers: Some counties such as Nyeri have successfully trained health workers, namely community health volunteers, and have equipped them with blood pressure machines and glucometers. Other counties such as Samburu are at the planning stage and have a budget allocation for NCD training.
- Strengthening information systems: All counties face the challenge of establishing robust information systems and having a means of tracking patients as they move through the health

[2] See http://sites.bu.edu/evaluatingaccess-novartisaccess/files/2019/12/Turpin-et-al-EAMJ-2019-Print-version.pdf

system to facilitate accurate capture of NCD prevalence data. Many counties have a monitoring and evaluation/research official, and they expressed interest and need for support from academic institutions, e.g. Boston University, to build capacity for research.

- Health insurance: While health insurance was not a main focus of the Boston University evaluation, this is a rapidly changing landscape in Kenya at the moment. All counties reported efforts to increase uptake of health insurance through patient education or increased accreditation of health facilities, and in some cases incentives or special enrollment schemes, for example the *"one mbuzi for one year of NHIF ''* initiative in Narok.

Originally, the team from Boston University planned a workshop with national and county officials to take place after the county workshops to discuss the findings from the Novartis Access evaluation at national level. However, due to the COVID19 pandemic the national workshop had to be cancelled.

The findings from the 8 county meetings will be used to revise the agenda for the proposed national meeting to disseminate findings to allow more county presentations than originally envisioned.

The detailed outcomes of each of the county meetings in March 2020 can be found in the Annex.

Annex:

Annex 1: MEETING AGENDA

7:00AM – 8:00AM	**Registration + Breakfast**
8:00AM – 8:15AM	**Welcome Remarks and Introduction** ● **Mr. Newton Wambugu, County Chief Officer of Health, Nyeri County** ● **Boston University** ● **Innovations for Poverty Action**
8:15AM- 8.30AM	**Introduction and Overview of the Novartis Access Study:** ***Veronika Wirtz – Boston University***
8.30AM-9.00AM	**Quantitative Results:** ***Zana Kiragu – Boston University***
9.00AM- 9:30AM	**Qualitative Results:** ***Monica Onyango – Boston University***
10.00AM – 10.30 PM	**Tea Break/Networking**
10.30AM – 1 PM	**Group Discussion/Feedback** ***Veronika Wirtz & Meshack Ndolo – Co-facilitators*** **Questions addressed during discussion:** **a) What are your questions and comments about the findings of Novartis Access? Are there any findings that particularly surprised you?** **b) What do you think Novartis Access could have done differently to achieve its program goals of increasing availability and affordability?** **c) What are your counties currently doing to address availability and affordability of NCD medicines?** **a. What recommendations do you have for your county relating to access and affordability?** **b. What is the role of research and evaluation in these efforts**

1.00PM – 2.00 PM	**Lunch/Networking**

Note takers: John Mungai, Jemima Okal, Kelvin Gichia, Veronika Wirtz, Monica Onyango, Zana Kiragu

Annex 2: DAY ONE - NYERI COUNTY AND EMBU COUNTY

Date: March 10TH 2020

Location: White Rhino Hotel, Nyeri County

Nyeri County Participants:

	Name	Title
1.	Newton Wambugu	County Chief Officer for Health
2.	Nelly Muiruri	Chief Nurse
3.	Dr. Ndegwa John	County pharmacist
4.	Dr. Marion Gituanja	UHC Coordinator
5.	Dr. Martin Mwangi	NCD Coordinator

Embu County Participants:

	Name	Title
1	Elizabeth Kiende	NCD Coordinator
2	Rose Nancy Murithi	Chief Nurse
3	Dr. Jediel Kiria	Representing CDH Embu
4	Dr. Dedan Mathenge	County Pharmacist
5	Rosalyne Kaugi	Director of Public health

Comments on Evaluation Findings

- Nyeri County was surprised at the difference in price paid for medicines between wealth quintiles - where the patients in the first and fifth wealth quintiles reported paying more for medicines.
    - Their main concern with this finding was that medicine prices are usually the same regardless of one's social class, thus the discrepancy should not exist.
    - Additional arguments against this finding were:
        - Even if the poorer individual were to go to the rural chemists, they would not pay less than the richer person as the variance in price may not be significant
        - Even if the rich are getting their medicine from the children out of town, then out of pocket payment cost reduces but is transferred to someone else who transfers funds to them
    - The Boston University team explained some reasons for higher price observed among the poor:
        - No insurance cover
        - No regulation of prices so prices in the rural setup could take advantage of patients without other options
- Nyeri officials were also surprised that diagnosis of NCDs happens in the public sector while treatment generally occurs in the private sector. This is because they have made efforts to ensure that NCD medicines and other commodities are available and affordable at lower level public health facilities by taking the following measures:
    - Introduced medicines for diabetes and hypertension to be available at Level 3 facilities.
    - Provided lab testing facilities at Level 3 for monitoring biochemical profiles and appropriate referrals.
    - Trained and introduced the role of Community Health Volunteers (CHVs) to test blood sugar and provided requisite CHV kits at the Level 2 and 3 facilities for basic NCD screening services and referral.

- Moving towards the introduction of NCDs score cards with the goal of ensuring NCDs medicines obtained at health facility do get to the households and are used by the patient.

- The County pharmacist expounded on these effort:
  - There is Kshs 400 million (USD 4m) on the county budget for the financial year 2019/2020 and the lowest levels of the facilities have been included as beneficiaries of these funds.
  - Supply is based on an *"ask and it shall be given"* basis – therefore even smallest of the facilities should still be restocked in time.
  - Nyeri County has a buffer store – this helps them to restock before the next ordering cycle. The buffer stores were specifically intended for the lower level facilities, thus having any drug being out of stock in the public sector is unexpected.
  - Nonetheless officials recognized that they had not conducted household surveys to establish if the NCD medicines reached the households.
- Embu officials were surprised that Novartis did not consult with leaders and health professionals on the ground before program design, agreement on the list of medicines, communication through a circular from the Ministry of Health and rolling out the program.
- Embu officials also pointed out failure to use KEMSA as the supplier of Novartis Access products was surprising considering KEMSA was the main source of medicines for counties.
- Embu officials were also surprised at the qualitative data finding that health care providers were not fully aware how NHIF functions. The NCD Coordinator stated that they have made efforts to provide guidance on the benefit of NHIF, so this finding was unexpected.
- Embu officials also commented on how out of pocket payments can trigger corrupt practice – referring to the qualitative finding that patients in Kakamega County reported barter trade to get medicines. Questions arose around who in reality received the goods traded in for the medicine supply.
- Embu County director of public health thought that the sample size for households was too small relative to the number of households in the county - they expressed interest in Boston University coming back to do more research in the county.

What could Novartis have done differently?

- Officials from both counties had a lot to say about this topic. They found Boston University's evaluation results which showed no substantial impact very plausible. Some had predicted the outcome from the start when they heard about the Novartis Access program.
- The Nyeri NCD Coordinator asserted that while the Novartis Access products may have been better quality than what was on the market, the Novartis approach was wrong.
- Nyeri County officials highlighted some issues with the Novartis Access program:
  1. Lack of consultation with the Ministry of Health
     - Novartis either failed to consult and reason with ministry officials or failed to follow guidance from ministry officials
     - On this point, the NCD Coordinator stated that one of the biggest challenges with pharmaceutical company initiatives is that their approach does not incorporate checking in with the people on the ground for their input. There was a lack of interaction with the technical officials who understand the situation on the ground and how the system operates. The directives issued to these technical officials without their consultation leaves them without any control or mandate over the access programs.
  2. Lack of understanding of the Kenya Health Systems Landscape at the program design and commencement stage

- They never looked at the health system landscape in terms of how public sector facilities work, their strengths and gaps, particularly with respect to the procurement cycle, and the fact that this may vary by county.
    - ✓ They did not understand the role KEMSA plays, its regional depots and distribution networks. There are counties that do not purchase from KEMSA. Some counties rely on MEDS due to their capacity to offer drugs on credit. For instance in Murang'a county Novartis Access program could have worked.
    - ✓ Novartis had public sector facilities in their sample, but they used MEDS for supply. They should have anticipated that this would not have an impact in the public sector facilities since KEMSA is the main supplier to government facilities. Facilities were only allowed to obtain products outside of KEMSA if commodity was not available. In addition, the penetration that KEMSA has in terms of access to hard to reach areas is important to note.
    - ✓ Note: Technical advisor Meshack Ndolo informed the officials that the KEMSA Act was amended in May 2019 making it mandatory for all counties and national government facilities to procure health products only from KEMSA and there is a legal penalty for procurement done elsewhere. It is also worth noting that KEMSA orders are never fully supplied, and receive 60 to 70% compared to MEDS which always has a 100% order fill rate.

3. Over-Ambitious
    - They should not have selected 15 medicines at once - these were too many.
    - An alternative approach that may have worked would have been to focus on one medicine for each disease state, try to get them into KEMSA with support of some partners to facilitate buy in and then demonstrate the economic impact. They could then scale up based on the results from the pilot phase.
    - Ideally having a simple structured program that can be easily scaled up would work best.
4. Poor visibility
    - The visibility of Novartis was commercial, they never shared it in another light. Other companies have used different approaches that ensure visibility and framing of products such that the government and partners around the government are able to support and push the products through.
    - There was resistance from the ministry officials who felt they were not adequately involved and MOU issues deterred lots of progressive movement of the products.
    - It is unclear whether prescriber behaviors were considered as they tend to have pronounced effect on health spending. They also mentioned that prescriber behavior may not necessarily be for the patients' benefits, highlighting the importance of training and sensitization on the guidelines.

- Embu County cited similar issues with the Novartis Access Program:
    1. Lack of consideration of the supply cycle.
        - The County Pharmacist explained the challenges with supply cycles due to KEMSA not having sufficient stock.
    2. Poor Pricing model

    - Embu officials would have preferred cheaper alternatives. They would still select the generic over Novartis Access due to price challenges and preferences. Novartis' prices were not competitive.
3. Lack of consultation prior to medicine selection.
    - There was no consideration of treatment guidelines or revised protocols, and no interaction with the technical officials on the ground.
    - There was no consideration of prescriber preferences; the County Pharmacist explained that prescriber preferences are used to inform procurement to avoid dead stock.
    - Embu officials went through the list of medicines in the portfolio and stated that with the exception of salbutamol, furosemide, hydrochlorothiazide and metformin – the other products were not typically used on the ground.
    - The issue of resistance to change was highlighted. The Embu County pharmacist used a food analogy *"If you come to me with chapati, I will not take it because once you leave with your chapati I will have to go back to my githeri."*
    - There is a need for sensitization immediately after product selection. When there has been a change in recommended antiretroviral medicines for ARVs for instance, there is a circular from *Afya House* (MoH) – the same approach should be taken with NCD medicines.

- Both counties came to similar conclusions on what Novartis could have done differently.
    1. Involvement of the local technical experts in all aspects of program design including selection of medicines which was not aligned with the KEML and STG. In addition, the technical officials understand the loopholes and gaps which were not taken into consideration at the beginning of the project.
    2. Learning the health systems including how counties function, the level of care at which NCDs are available and understanding of the pricing models used by the Ministry of Health. (Check MSL guideline 2018-2019)
    3. Being less ambitious by introducing only a few medicines first and doing a pilot in two to three counties, followed by a scale up based on lessons from the pilot, instead of launching 15 medicines at the same time in eight counties.
    4. Better understanding of the supply landscape including taking into consideration the tendering roles of KEMSA, its network of sub-depots and delivery across the country and new legislation in KEMSA. Perhaps a parallel supply of Novartis Access products through both KEMSA and MEDS would have worked well.

What are counties doing to address availability and affordability of NCD medicines?

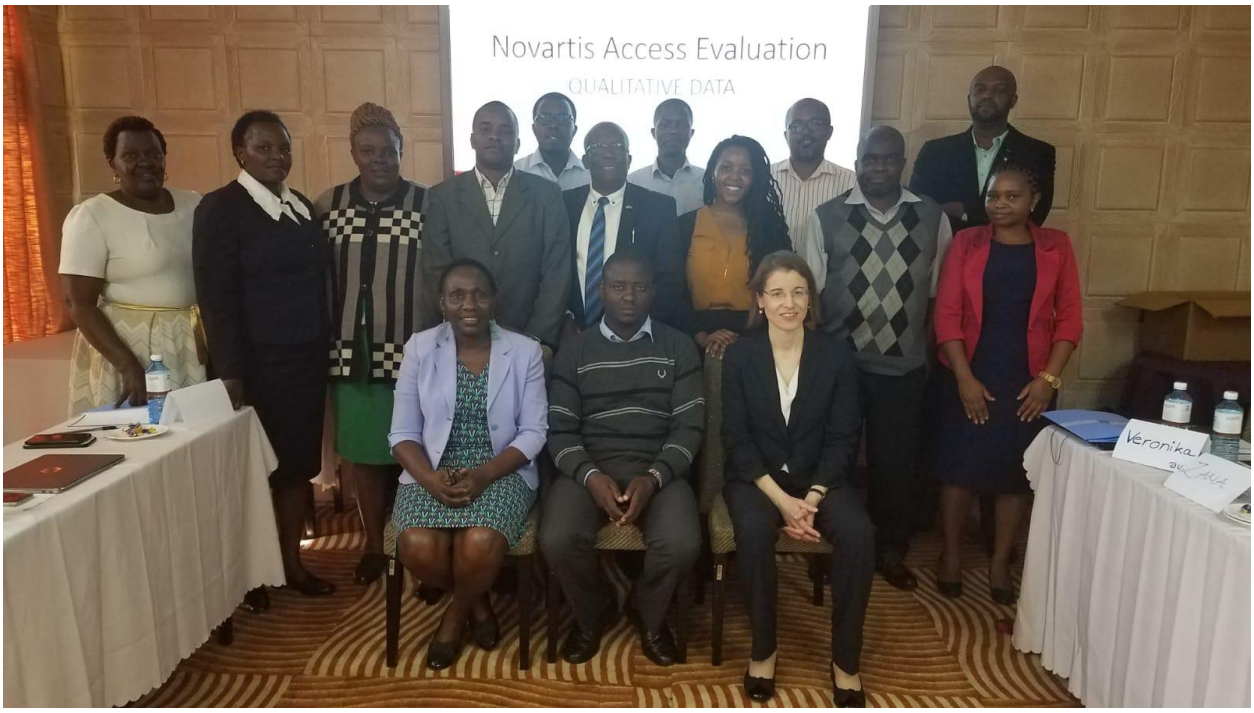
- Nyeri has been working on strengthening patient level data – they have standardized tools for diabetes and hypertension care and they are working on one for cancer. These tools have been introduced into the DHIS2 form MoH 740 under 'pilot tools'. The goal is to give a full holistic view of patients and their care, replace unstructured clinician notes and facilitate timely review for clinical decisions.
- Nyeri County mentioned efforts towards a surveillance system for medicines, but this is yet to be strengthened. They have a weekly tracer medicines list that was intended to curb issues of stock outs. Level 4 and 5 facilities submit weekly reports on stock levels of insulin, metformin and amlodipine. Based on these reports other facilities are informed where stock is available and they can reach out for redistribution. This is helpful since KEMSA recently struck off NCD medicines for Level 2 and 3 facilities.

- Novartis Access provides an opportunity for counties to reflect on what they can do differently when working with an external partner and how they can address some of the existing challenges e.g. an MSF program where NCD medicines are supplied for free to 11 facilities in Embu is due to end in 2021. There is no clear continuity plan - raising concerns around sustainability of intervention programs by external partners.
- Community health volunteers and workers are used to link patients to care. Nyeri has included community health volunteers in screening for hypertension and diabetes. They have glucometers and blood pressure machines. This has reduced the need for "medical camps", which tend to be arranged by politicians, where patients are never linked to health facilities to improve access to medicines.
- Nyeri recognizes Medtronic as a promising way to build an information system that maps patient needs, linkage to care and retention in care.
- HACK (Health Attack Concern Kenya) are delivering training to some health professionals in Embu. HACK has worked closely with the Council of Governors in reaching other counties.
- Beyond the scope of this program, but there is a Mental Health Technical Working Group (TWG) in the final stages of formation in Embu County
- Even though there is ongoing research, counties require more support and asked Boston University to help catalyze research projects.
- While counties are doing a lot of important work to restructure and refine their current approach to delivering care including availability of NCD medicines, they also reported some challenges faced in these efforts:
    - **National vs County government:** There is a difference of opinion between the national and county government on the level of care at which NCD medicines are offered. Counties feel that refills at Level 3 facilities will improve access. Before the national guidelines were changed (KEMSA ordering form also changed in line with this) to restrict certain medicines to certain levels, Nyeri county had introduced these medicines to lower levels of care.
    - **Procurement policies:** Policies around tendering and procurement of medicines that are not in line with devolution and what is felt to be more appropriate in organizing care at primary care level. For example, there is a new law being put in place that the counties can only order medicines from KEMSA failure to which they may be prosecuted/fined. Discussions regarding this are ongoing, but the law stands for now.
    - **Human resource:** Addressing human resource tasks, training and support supervision and mentoring is a challenge. Incentives and accreditations need to be aligned and gaps in the health workforce addressed.
    - **Education of the population and patients:** Education needs to be adapted for appropriateness in the local context, for instance there is no fast food in Nyeri, and hence guidelines should not talk about fast food.
    - **Retention in care:** Linkage to care and retention is a challenge and the practice of medical camps may do more harm than good as there is no follow-up of patients. It is therefore importance to continue strengthening community health volunteers/workers.

Additional Comments

- Nyeri NCD coordinator stated that they have realized there are gaps in translating what is available in the health facilities and what is happening with patients at the household level.
- Both counties found it enlightening to hear about the other county's experience.

- Both counties reported information systems challenges (e.g. creating unique identifiers is a major challenge and has become political). This made it difficult for them to have accurate numbers for NCD prevalence – double-counting was a common issue.
    - A Nyeri official stated they needed to have an NCD scorecards approach to strengthen screening and avoid screening the same people repeatedly.
    - Different models to address this have been tried over the years, and with the introduction of *huduma number* county officials thought they would have a permanent solution, but this has not come to pass yet since *huduma number* is not yet operational.
- Meshack Ndolo on devolution in health:
    - Health services in Kenya are 90% devolved and Counties are best placed to lead in the implementation of a program to increase quality and coverage of care. Novartis Access has the full potential to address NCD treatment gaps once all potential trouble spots are adequately thought through and addressed.
    - For instance, UHC came with a protocol where the majority of components were centralized and decisions on the design of UHC Pilot in 4 Counties were made in the Ministry of Health. To date, there remain challenges of rolling out UHC and intergovernmental consultations are required on all aspects. Some mechanics of handling information and data, health financing, supply chain of medical products have not been addressed due to the persistent challenges of realizing the full benefits of devolution.
    - There is hope that the new Cabinet Secretary of health will address these issues and the reforms at NHIF and KEMSA will be shared at the next intergovernmental engagements processes towards strengthening county facilities and undertaking joint assessments for improvements.
- Everyone had a chance to share some final words in terms of what they learned during the meeting and what they would like BU to incorporate in their final report.



Nyeri and Embu County Officials with the Boston University team, Technical Advisor Meshack Ndolo and the IPA team.

Annex 3: DAY TWO: MAKUENI COUNTY AND SAMBURU COUNTY

Date: March 11TH 2020

Location: White Rhino Hotel, Nyeri County

Samburu County Participants:

	Name	Title
1	Dr. Alex Mungai	County pharmacist
2	Dr. Martin Thuranira	County Director of Health
3	James Kiptoon	Sub-county public health officer
4	James Mwangi	County clinical officer rep NCD coordinator

Makueni County Participants:

	Name	Title
1	Dr. Steven Ndolo	County Director of Health
2	Anthony Mathulu	Assistant to the County Director
3	Stanislous Ndeto	County NCD Officer
4	Dr. James Kanyange	Director Health Commodities & Technologiesrep County pharmacist

Introductory comments were shared by the Samburu County Director of Health:

- There is an increasing importance of NCDs in the county due to lifestyle changes occasioned by the side effects of devolution and monies more available at sub-national levels.
- Medicines are an important component of NCD care. The issue of affordability and adherence go hand in hand which then leads to worsening of the condition and ultimately early mortality.
- The scale-up of UHC requires paying attention to NCDs, as they are the next huge burden of disease.
- NCDs touch everyone's life. The Samburu CDH used his own mother who suffers from an NCD and illustrated that NCDs often exert financial and social demands with family member support to facilitate access to services.

Comments on Evaluation Findings

- Overall, the findings of Novartis Access were not surprising and in line with what county officials expected.
- Once county officials knew about the program they predicted that it would not be successful given the procurement systems of medicines (mainly through KEMSA, on an item-by-item base, based on KEML) and the current level of care at which NCDs services are offered (mainly Level 4 and higher).
- Prices at facilities Level 4-6 are fixed by the county finance bill. Facilities at Level 2-3 are not supposed to charge for medicines. However, our findings show that some facilities at level 2-3 charge.
- Samburu County officials agreed with the finding that NCD diagnosis happens in the public sector while treatment in the private sector. They confirmed that chemists are filling a niche in the market where the public sector fails to deliver.

What could Novartis have done differently?

- There was lack of consultation with county officials about the roll out of Novartis Access. There was also no consultation process with prescribers. It was felt that the prescribers need to be involved to identify medicines that are most frequently used for these conditions. For instance, nifedipine was most commonly used at the time but amlodipine was chosen in the Novartis Access basket.
- There are some items in the basket that are attractive to counties: tamoxifen, letrozole and amoxicillin. Novartis Access offers these at a much lower cost than other competitors. It was felt that if these would be offered in a reliable fashion with no stock out problems at KEMSA, it would be a great win for the counties. In other words fewer medicines that are offered at competitive prices in a reliable fashion through KEMSA would be helpful to counties.
- The current model (14 NCD medicines, mostly higher priced than competitors) is more suitable for the private sector - in particular chemists - which would not reach the poorest people.
    - It would have been difficult for counties to justify the selection of Novartis Access medicines since the cost of generic drugs is relatively cheaper. Procuring Novartis Access medicines may have caused audit complications. *"There would have been no justification to the auditor as to why we were ordering an expensive drug when there are cheaper ones in the market"* [Health official Makueni]
    - *"Makueni is doing well, in fact the private chemists are complaining that they are out of business"* [Health official Makueni]
- Superiority of Novartis Access medicines over other medicines was not demonstrated. Considering the fact that Novartis Access medicines were not cheap, failure to demonstrate better quality further ruled against procurement of these medicines.
- KEMSA is the first point of reference for county health medicines and prices. Novartis engagement with KEMSA first prior to roll out may have had some influence on access and affordability.

What are counties doing to address availability and affordability of NCD medicines?

- Specific to Makueni County, *"differential care"* was seen as the touchstone of NCD care, where patients can get one or two refills in their community clinic (clinic assigned to them) but have to go for a check-up at least three or four times per year at Level 4 facilities. An information system should capture all levels and track patients. It should trigger a call to those patients who have not picked up their medicines. Plans for this system of care are underway and yet to be implemented.
- Partnerships facilitating improved NCD care were mentioned in Makueni County. The County Director of Health of Makueni felt that Medtronic/MSH/Novartis project being developed could be an *"optimal model of NCD care"* where patients are screened and possibly monitored by CHWs. Health facilities dispense medicines and monitor patients. An information system sends data in real time to management units at a higher level showing patients volume and performance.
- Both counties have a dedicated monitoring and evaluation staff member who can retrieve and analyze county specific data.
- Samburu County has made efforts to increase NHIF coverage through patient education. These efforts are directed at patients attending the Diabetes and Hypertension clinic at the county referral hospital.

- Samburu has plans to train CHVs on NCDs – particularly diabetes and hypertension. CHVs have successfully mapped pregnant mothers and HIV patients in the county and follow up their clinic visits – the county wants to leverage this to facilitate NCD patient tracking.
- Samburu County has included NCD prevention and control in their budget, Kshs 2.25million of the Kshs 38million budget is dedicated to capacity building/training healthcare workers on NCD management.
- Part of the 2018 to 2022 health plan in Samburu includes sensitization of Level 2 and 3 staff on NCD management and quantification of commodities required – these efforts are yet to begin.
- Health care workers at the Diabetes and Hypertension clinic in Samburu County referral hospital were taken for a training at the well-established NCD clinic in Moi Teaching and Referral Hospital in Eldoret. They expressed the importance of having the appropriate medical personnel for specific medicines made available e.g. oncologists for cancer medicines and cardiologists for cardiovascular medicines.
- UHC in Makueni is strengthening the primary care network, capturing what works and what doesn't and facilitating linkage to patient care.
- The counties also mentioned the challenges they face in NCD care delivery:
    - **Procurement cycles:** Counties order in March, May and December, which means that there are times when there are no medicines at the facilities since there is insufficient financing to buy the volumes needed. Samburu has not found a solution to the problem of stock-outs.
    - **NCD care at lower levels:** Counties have multiple challenges offering NCD services at level 2-3:
        - Lack of sufficiently trained, mentored and supervised human resources
        - Minimal lab services
        - Referrals from and to higher levels of care
        - EML and KEMSA restricting their offer of NCD medicines at lower levels of care
    - **Information systems:** The Makueni team felt that not knowing the *case load*, the number of people with NCDs in their county, is the most important barrier to effective NCD service planning.
    - **Cultural factors:** These play a huge role in addressing NCDs which have not been tackled by programs, particularly in Samburu where men often do not seek health care due to preconceived notions that these services are only for women and taking tablets could be perceived as *"weak".* They are therefore diagnosed at a late stage which makes effective treatment less likely.
    - **Pilferage:** There is a spill of public sector medicines into the private sector even though the package is unique to the public sector. Prevention of spill over and diversion was seen as a challenge.
        - Barcoding of medicines/batching has been introduced at KEMSA but this has not trickled down to the facilities therefore allowing infiltration of medicines intended for public facilities into privately owned chemists.
    - **Consideration of the health insurance benefits package:** Makuenicare provides a complete health benefit packet where everything is covered but because of the low price of the annual subscription fee relative to the benefits package, the government is denied revenue where they could have recovered some costs. Consultations have been done

with the government on the contents of a benefit package and this should be included in intergovernmental partnership conversation.

- **Human resource and equipment:** This is a big issue in Samburu, where some facilities are operating with only one health worker (usually a nurse or clinical officer) and they may not have the basic equipment such as glucometers. The expansive nature of the county with households and facilities being very far from each other makes service delivery to increase access to NCD care more difficult.
- **Procurement Law change:** Both counties mentioned challenges with the new law to purchase only from KEMSA since some medicines are not available at KEMSA – they felt the law would need to be reviewed and a change considered to allow for alternative suppliers such as MEDS.

- The county officials made some recommendations for their counties to address availability and affordability:
  - **Information systems:** DHIS-2 currently only captures HIV, TB and malaria medicines. The county officials felt that all programs with donor oversight and interest have the best information systems. *"There is a tunnel vision in which investment is only happening in very specific areas"*. In theory there is nothing that hinders using DHIS-2 as a routine information system of stock availability for NCD medicines; the resource limitations are currently the main barriers (who enters information and updates the software). This would support quantification – since quantification should go beyond consumption data and include case-loads as well.
  - **Policy Issues:** The Director of Health Commodities highlighted the importance of policies on pricing for services at different levels of care. The availability of medicines for free at the lower level facilities while they need to be paid for at level 4 and above results in patients never going for clinical diagnosis/review. They prefer to go directly for free medicines to avoid fees at higher levels. To address this challenge the following was highlighted as an area of improvement
    - Capacity building and need to invest in human resources
    - Diversity of services and getting input of the community and service providers.
  - **Public communication:** importance of communication for the public to be engaged was highlighted. This will be helpful to win their confidence over and increase uptake and utilization of services at Level 2 and 3 facilities.

Makueni and Samburu County officials in team discussions about the findings from the evaluation

Annex 4: DAY THREE: KAKAMEGA COUNTY AND WEST POKOT COUNTY

Date: March 12TH 2020

Location: Golf Hotel Kakamega, Kakamega County

Kakamega County Participants:

	Name	Title
1	Gaudencia Onyango	County Nursing officer
2	Erick Wanyama	County NCD coordinator
3	Dr. Levina Ndubi	Representing County Pharmacist
4	James Wachuga	Health Standards Coordinator representing Director of public health
5	Dr. John Otieno	Deputy Director, Clinical services, & M&E Coordinator

West Pokot County Participants:

	Name	Title
1	Dr. Peter Oduor	County Pharmacist
2	Samuel Lopar	County Nursing Officer
3	Wilson Tarus	County public health officer
4	James Rita	Representative of the County Director of Health

Comments on Evaluation Findings

- Requests for Additional Analyses
    - A correlation analysis between wealth quintiles and ability to purchase NCD medicines.
        - The West Pokot County Pharmacist had some thoughts on how this analysis could be interpreted: *"This comparison may be skewed a bit since the wealthy are majorly insured while the poor are predominantly out of pocket. So from the start, the poor will definitely spend more on the purchases."* He went on to explain the potential value Novartis Access could have brought: *"But of more significance is that heavy price reduction would have meant that the poor were able to afford their medication, and from good quality the condition was better controlled. The affordability would mean constant medication, controlled conditions. This at the end would avoid the hospitalization due to patients not taking medicines due to cost constraint. Moreover, this would in long term delay the long term complication of chronic illnesses like retinopathy, heart failure etc."*
    - An analysis by level of care to get accurate availability by levels of facilities.
        - The West Pokot County Pharmacist asserted the rationale behind such an analysis: *"Initially, the availability of medicines as reported was not very informative because the uptake of chronic illness medicines is in higher level facilities. This is because these conditions are managed by senior health workers (doctors, specialists). But we know chronic illness are found in all areas across the community. In the case of West Pokot, the county pharmacist had to train health workers to increase awareness such that the patients go to hospitals to see the doctor but get their prescription refills at the nearest dispensaries. This reduces the cost of travel and increased the uptake of access medicines."*

    - An assessment of the quality of Novartis drugs and other drugs in the market would be good.
        - The West Pokot County Pharmacist's recognized that while quality testing may be possible, it could be a time consuming and expensive endeavor. *"This is possible however may be expensive and time consuming. This is because it may involve carrying out bioavailability studies of the access program medicines vs. the other brand in the market."*
        - He also asserted that despite the lack of quality testing, the perspective and experience of West Pokot patients with access medicines were a testament to the quality of these products. *"But from the practice perspective and patient experience. The verdict is very much clear. The access program medicines had superior quality and therapeutic outcome. This was observed from the fact that fewer medicines were able to control blood sugar or hypertension as opposed to others brands where up to six drugs were given. A case in point here is amoxicillin, amlodipine and metformin. Secondly, was the feedback from patients on how better they felt after taking access program medicines compared to previously other brands? In fact many insisted on the access using the packing as the identifier for the medicines even when they go to buy from the private chemist. For example the amoxicillin DT had very good outcome to the extent that it came to be used by adult as well though the formulation was primarily made for children."*
- Perception on findings:
    - The difference reported in place of diagnosis and place of treatment is reflective of what is happening on the ground in both counties.
    - Diabetes prevalence in Kakamega could be higher than the results from the study; though they do not have any accurate data to prove as much.
    - Kakamega officials appreciated the data on hypertension since they still have no data on hypertension prevalence for Kakamega.
    - West Pokot thought the basket of medicines could have been different. From their perspective it would have been important to include other competitors when conducting such evaluations in the future to ensure results reflect the true picture. They proposed inclusion of alternative medicines that were cheaper than Novartis access products and are preferred or popular with the local communities but are from other pharmaceutical companies such as: Merck Serono, GSK, Novo Nordisk, SANOFI.
    - West Pokot officials were surprised by the inequity in prices paid for medicines.
    - They expected a big impact from the program especially in West Pokot given that the county procured medicines from MEDS. According to the county pharmacist, from February 2017 through 2019 they have been exclusively procuring from MEDS which was supplying them with medicines from Novartis, Merck and other companies. They only moved to sourcing medication from KEMSA in 2019 when parliament passed the law requiring purchase from KEMSA. *"This ensured almost 99% fill rate with our order from supplier and almost 100% prescription fill rate to the patient. Ordering from MEDS was a great achievement for our health system strengthening."* West Pokot County Pharmacist

What could Novartis have done differently?

- West Pokot reported the following:
    - **Awareness/Visibility:** They felt that lack of impact of Novartis Access may be attributed to lack of awareness about the program in the population. *"There should have been some*

ground preparation for the health workers to expect the access program commodities." West Pokot County Pharmacist
    - **Distribution approach:** The county pharmacist thought that MEDS could have started the distribution from the private facilities instead of the public ones which are the majority. This would have sorted the stocked out days due to non-payment by the counties to KEMSA or MEDS.
    - **Pricing:** Most of the generic drugs are cheaper for NCD patients compared to the Novartis medicines thus leading to facilities going on to order for more generics. *"Medicines are prescribed by generic and not by brands"* County Pharmacist. However, he went on to add: *"Although through the access program, the Novartis drugs were cheaper, and where they were higher, the difference were insignificant. Coupled by the health worker and patient preference, the access program would win."*
- Kakamega County reported the following about the Novartis Access approach:
    - Novartis should have used the standard treatment guidelines for product selection.
    - They should have undertaken market surveillance on the prices of similar products. The access commodities were still high in price compared to the other brands – they should have considered the price of other products on the market. For example, the price of Glucophage from Merck Pharmaceuticals is much lower compared to the Novartis brand.
    - MEDS should have been engaged to facilitate analysis of consumption frequencies and the procurement cycles for the counties before rolling out the intervention.
    - Prescribing patterns should have been considered: they prescribe by generic name and not by brand so they might have avoided Novartis Access products.
    - Patients also have preferences of certain medicines prescribed.
    - There should have been proper communication to the counties on the program.
    - They should have looked at the medicine's consumption patterns first.
    - They should have used KEMSA.

What are counties doing to address availability and affordability of NCD medicines?

- The Kakamega County referral hospital is currently developing a program where they negotiate with patients who cannot pay hospital bills to instead pay the money to NHIF and get covered.
- Kakamega County is providing free insulin for patients under 21 years of age with Type I diabetes through a partnership with Novo-Nordisk and PATH.
- Kakamega is planning to do more outreaches to sensitize the communities on the need for screening.
- Kakamega is enrolling patients for NHIF. This is a programme by the County Government targeting poor households. 8840 beneficiaries were enrolled into NHIF last financial year. This financial year close to 5000 beneficiaries will be enrolled into NHIF.
- Some private health facilities in Kakamega allow clients to trade in goods and assets in order to get medicines.
- The Kakamega Team recommended the following for their county:
    - That there should be an Electronic medical Records system (EMR) to track and monitor the NCD patients from all the levels of the facilities.
    - They are also proposing to NHIF to give refill medicines for 3 months instead of the current 2 weeks.
    - Need for an inclusive stakeholders meeting on NCDs.
- There is an increased budgetary allocation towards NCDs in West Pokot

- To enhance affordability, West Pokot has a *"free for all policy"* for level 2 and 3 facilities where patients are treated for NCDs for free.
- West Pokot has introduced a subsidy program in level 2&3 by paying NHIF capitation for a whole year and are now working on the same for level 4 hospitals to improve on access and affordability.
- There is improved/strengthened inventory management in West Pokot through continuous training.
- West Pokot, in collaboration with NHIF has been working to get facilities accredited to enhance access
- In addition, West Pokot had some recommendations for their county relating to access and affordability of medicines:
    - Continue to allocate enough budget to tackle NCDs
    - Raise awareness and sensitization on the importance of enrolling in NHIF
    - Increase diagnostic services in county hospitals
- West Pokot reports that the role of research and evaluation in these efforts is:
    - Guiding policy making
    - Advocacy with leaders
    - Redesign and align projects and programs

Kakamega and West Pokot county officials with the IPA team

Annex 5: DAY FOUR: NAROK COUNTY

Date: March 13th 2020

Location: Mara Frontier Hotel, Narok County

Narok County Attendees:

	Name	Title
1	Dr. Dan Ngere	County pharmacist
2	Nancy Kamiti	Representing NCD coordinator
3	Edward Tankoi	County public health officer
4	Elizabeth Siamanta	Representing county Clinical officer and CHS

The County public health officer and the county pharmacist gave introductory remarks with emphasis on the importance of research to generate evidence for decision-making.

Comments on Evaluation Findings

- The team should have done analysis by level of health facilities since some medicines can only be prescribed and dispensed by certain cadres who are only found in level 4 and above. Some of the medicines such as simvastatin can only be found in level 5 and above in Narok County.
- With reference to the price and availability of amlodipine, metformin and hydrochlorothiazide - the County pharmacist said that they have been very much available at the Narok County Referral Hospital with prices lower than what we found.
- Additional points to note on the Narok context:
    - Asthma medicines are only allowed to be prescribed at level 4.
    - Furosemide use is currently going down due to availability of the alternative hydrochlorothiazide.
- Surprises for Narok County
    - They were surprised that NHIF insurance cover uptake is higher at midline and declining at endline.
    - They were also surprised that the prevalence of NCD was at 3%, they suspect it could be higher, but they do not have any accurate data from DHIS-2 to inform this.

What could Novartis have done differently?

- Novartis should have used the current treatment guidelines for Kenya when selecting the medicines.
- Novartis should have put price caps or ceiling on their products since the available alternatives were cheaper than their products. This could have improved the affordability and accessibility of the medicines.
    - Should have done price capping on their products even for retail prices.
    - In addition they should have done a market surveillance for both public and private facilities on the prices and available equivalents.
    - Price surveillance for their therapeutic equivalents.
- Sensitization of their products was not done in the counties.
    - Carry out sensitization to consumers to increase their uptake of their product.

- Between July and September, counties generally run out of stock due to the end of the financial year and budget cycle – supply cycle should be considered.
- KEMSA does not charge for deliveries while MEDs charges therefore they should have thought about using both channels or using KEMSA exclusively
    - They should have also collaborated with KEMSA to update the list of medicines and products to facilitate including their basket of medicines in KEMSA order forms.

What are counties doing to address availability and affordability of NCD medicines?

- To encourage NHIF enrollment, there is a one *mbuzi* for one-year initiative. This means you sell one goat to the county government for one-year NHIF coverage to improve on the uptake of health insurance.
- The county is subsidizing prices of medicines for the elderly, expectant women and persons living with disabilities.
- The county uses forecasting to increase availability.
- There is a demand-driven approach of sourcing medicines by the county pharmacist and his team
- The officials had some recommendations for the county:
    - Health education and awareness
    - Nutritional assessment (screening)
    - Provision of screening tools for diabetes and hypertension.
    - Providing reporting tools for the NCDs
    - Strengthening primary healthcare by training CHVs for screening
    - Capacity building
    - Have a research and M&E focal person to assess existing research gaps
    - Strengthen NCD support groups
    - Give priority to NCDs for budgetary allocation
    - Partnerships and collaboration
    - Timely procurement of NCD medicines
    - Strengthen the current technical working group in Narok county

Narok County officials with the IPA team

Annex 6: DAY FOUR: KWALE COUNTY

Date: March 13th 2020

Location: Pride Inn Express Hotel Ukunda, Kwale County

Kwale County Attendees:

	Name	Title
1	Dr. Fatihiyya Wangara	County Health Research coordinator
2	Charles Maina Kabonoki	sub-county clinical officer/ Representing county NCD coordinator
3	Chimako Kaddi	County health records & information Officer
4	Galole Dima	Sub-county public health nurse / Representing county nursing officer

Comments on Evaluation Findings

- Since health facilities of different levels were included in the sample, the effect level of care could have on availability of NCD medicines should have been considered.
    - The County Health Research Coordinator explained: *"The health facilities sampled were of mixed levels i.e. dispensaries (level 2), health centers (level 3), and hospitals (level 4). Policy dictates operational differences across these levels. For instance, level 2 & 3 facilities offer all services for free whereas clients are charged at level 4 & 5. Additionally, the Kenya Essential Medicines List (KEML) guides on essential drugs by level of health facility."* Consequently, the County Health Research Coordinator felt it would be important to consider these inherent factors when assessing availability and access to medicines; possibly conduct sub group analysis.
- There was agreement with the finding on differences between place of diagnosis and place of treatment. It was reported that this could be rampant in some urban parts of Kwale e.g. Msambweni sub county. The county officials recognize the need to improve triage and efficiency at the hospital to motivate patients to go for diagnosis, revisits and treatment.
- The inequity in price paid for medicines could possibly be because people of lower socio economic status may not clearly understand government directives, their rights and estimated cost of the health services (medicines) they seek, either from the health facilities or community pharmacies.
- The low uptake of health insurance in Kwale County was acknowledged. Contributors of this may include the high illiteracy levels and stock outs of some commodities as well as unavailability of all services that may be required by a client. Further, several grey areas exist as far as NHIF guidelines are concerned e.g. modalities of procuring rare medication for clients as well referring elsewhere for certain tests. This lack of guarantee of a "one stop shop" may make the residents reluctant to get health insurance.

What could have Novartis done differently?

- To improve access Novartis could have considered working with counties that rely more heavily on MEDS. At the time the Novartis Access program was implemented, this county procured primarily through KEMSA and only ordered from MEDS when items were unavailable at KEMSA.

- The objective of Novartis Access program was not clear, and it seemed to push a marketing and sales objective without selling the bigger picture to the players at the county level. Novartis Access should have done more to understand the prioritization of ordering and purchasing trends in the county to position themselves better.
- County officials were comfortable with the list of 15 medicines but emphasized the need to look at the county-specific landscape when determining the selection of the products. They should have based medicines selection on the NCD trends in Kwale County, thus allowing county officials to make orders of Novartis Access products that aligned with the needs of the people.
- Involving the County at the design stage of this evaluation would definitely have provided insight into possible confounding factors hence better accounting for the same.

What are counties doing to address availability and affordability of NCD medicines?

- The county uses 'Beyond Zero Mobile Clinic' as buffer stock – when making allocations to facilities they allocate to 'Beyond Zero' and use it as a contingency. Additionally, the Beyond zero mobile clinic is well stocked, active and used for outreaches in hard to reach areas within the County.
- Kwale County government is flexible ad prioritizes health
    - The county offers free health services as follows:
        i. At all level 2 and 3 health facilities
        ii. For certain cohorts e.g. children aged below 5 years
        iii. A case by case waiver system for persons who cannot afford health services
    - Provides certain otherwise expensive essential commodities for free e.g. antirabies vaccine, anti-snake
    - Kwale County is still advocating for health insurance for its people. Specifically, the County has embraced the "*linda mama*" cover for pregnant women at ANC, labour and delivery as well as postnatal.
        - The county has consistently experienced an increase in budget allocation to health over the years which implies that there is political good will to ensure availability of drugs i.e. Prequalification of drugs and payments to KEMSA is prioritized, and currently the County health budget stands at KES 2 billion, with 0.62% of this allocated to NCDs.
    - There is a community health policy that awaits approval by the County assembly, advocating to streamline community health services including remuneration for CHVs.
- A form designed to collect household level data on NCDs is available. However, challenges still exist as far as incorporating these variables to the routine household register is concerned. Additionally, even if the data is collected, it cannot be reported on Kenya Health Information System (KHIS). Design and development of standard MoH tools is a function of the national government.
- County officials recognized the utility of data to justify the need for more allocation of the health funds to NCDs. The number of patients presenting with NCDS at health facilities is usually captured in monthly reports and subsequently uploaded on Kenya Health Information System (KHIS) by sub county health records and information officers (SCHRIOs).
- Some challenges and areas for improvement in Kwale County include:
    - **NHIF coverage**: The Kwale County government continues to work towards increase NHIF uptake, including increased accreditation at private facilities to encourage uptake among individuals.
    - **Capacity to offer services at lower level hospitals:** Increasing human resources at Level 2 facilities and above is one of the county's goals to increase capacity for service delivery at lower levels. Meeting staffing needs will minimize referrals from lower cadre hospitals.

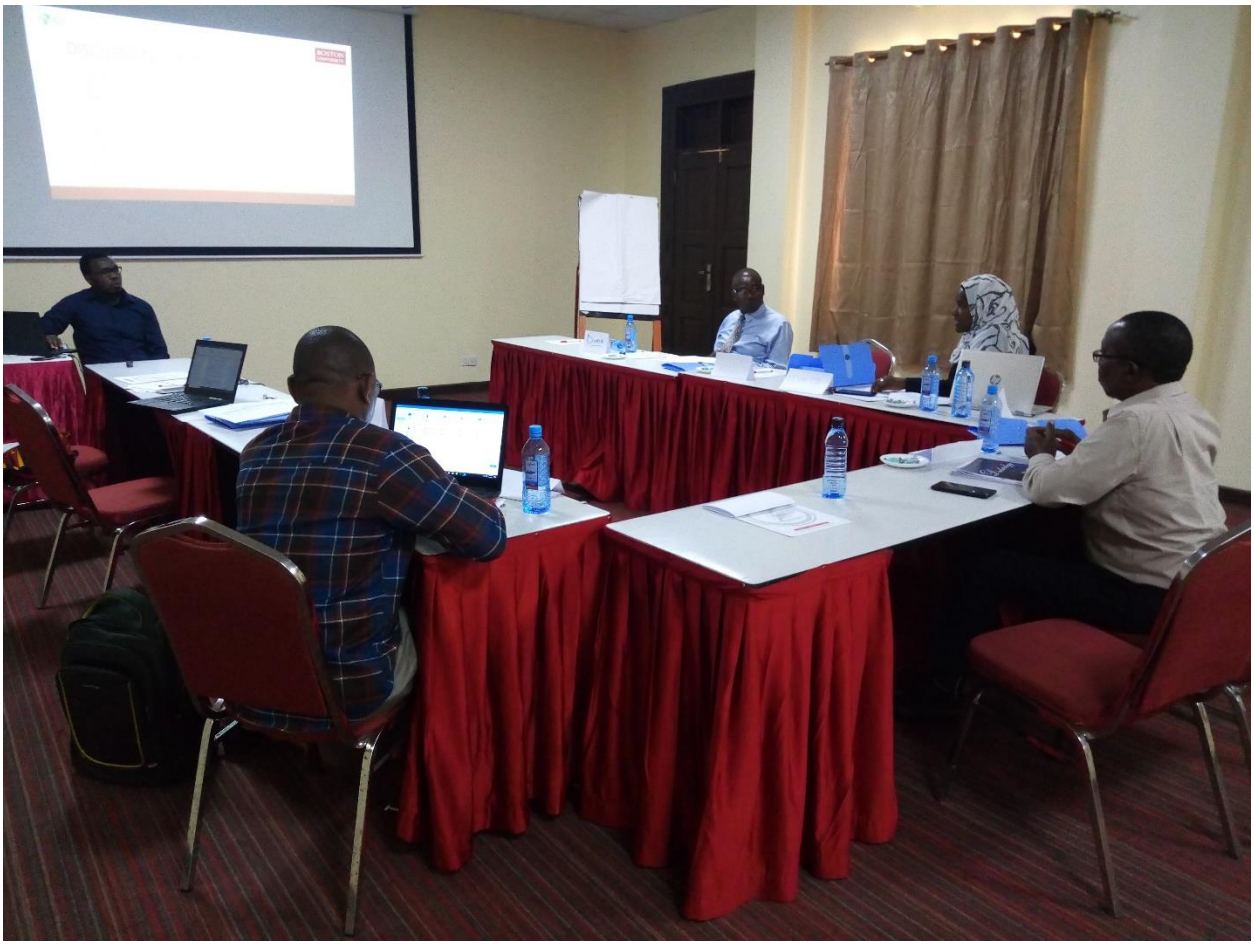
- **Affordability**: For patients with NHIF coverage, direct procurement of a drug that is out of stock is a challenge in that the public facility cannot rush to a chemist to buy it and then supply to the patient. This is because the facility will not get reimbursed by NHIF if they purchase in this manner. This leaves the patient in a position where they need to pay out of pocket at the chemist, where their NHIF may not cover the purchase.
- **Commodity management system**: there is need for an electronic inventory system with visibility across the county to improve accountability for health products and technologies.

- **National financial regulations:** revenue collected from all departments (including health) are centrally managed and reallocated. Spending at source is not allowed. Some health workers feel discouraged when revenue they collect does not directly dictate allocation to their health facilities.

- The Kwale officials had some recommendations for their county relating to access and affordability:
  - They highlighted the importance of understanding the costs associated with determining NCD burden and managing NCDs to inform the budget and justify reallocation of funds accordingly.
  - They proposed that Novartis should have an MOU with community pharmacies to regulate prices of the access products. While public facilities adhere to price lists, there is no regulation in the private sector.

Additional Comments

- The county recognized that feedback from research and evaluation is key in informing the allocation of resources.
- Kwale is flexible in implementing the KEML and has improved access of a variety of medicines at lower levels of care, with appropriate patient reviews by roving consultants.



Kwale County Officials with the IPA team