The MANGO Study

Measuring Adverse Pregnancy and Newborn Congenital Outcomes (MANGO) Study:

A hospital based-surveillance program for adverse pregnancy and birth outcomes in a resource-limited setting

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ampath Leading With Care

MTRH Moi Teaching and Referral Hospital Eldoret

An ISO 9001:2015 Certified Hospital

East Africa IeDE International Epidemiology Databases to Evaluate AIDS

Moi University Foundation of Knowledge

Indiana University

Background

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Purpose: MANGO is a pharmacovigilance study to assess pregnancy exposures and outcomes : examining the impact of HIV infection and ART exposure at conception and during pregnancy

Study design: mixed prospective and retrospective cohort

Implementation Period: Sept 2020 - Present

Site: Moi Teaching and Referral Hospital (MTRH), Kenya

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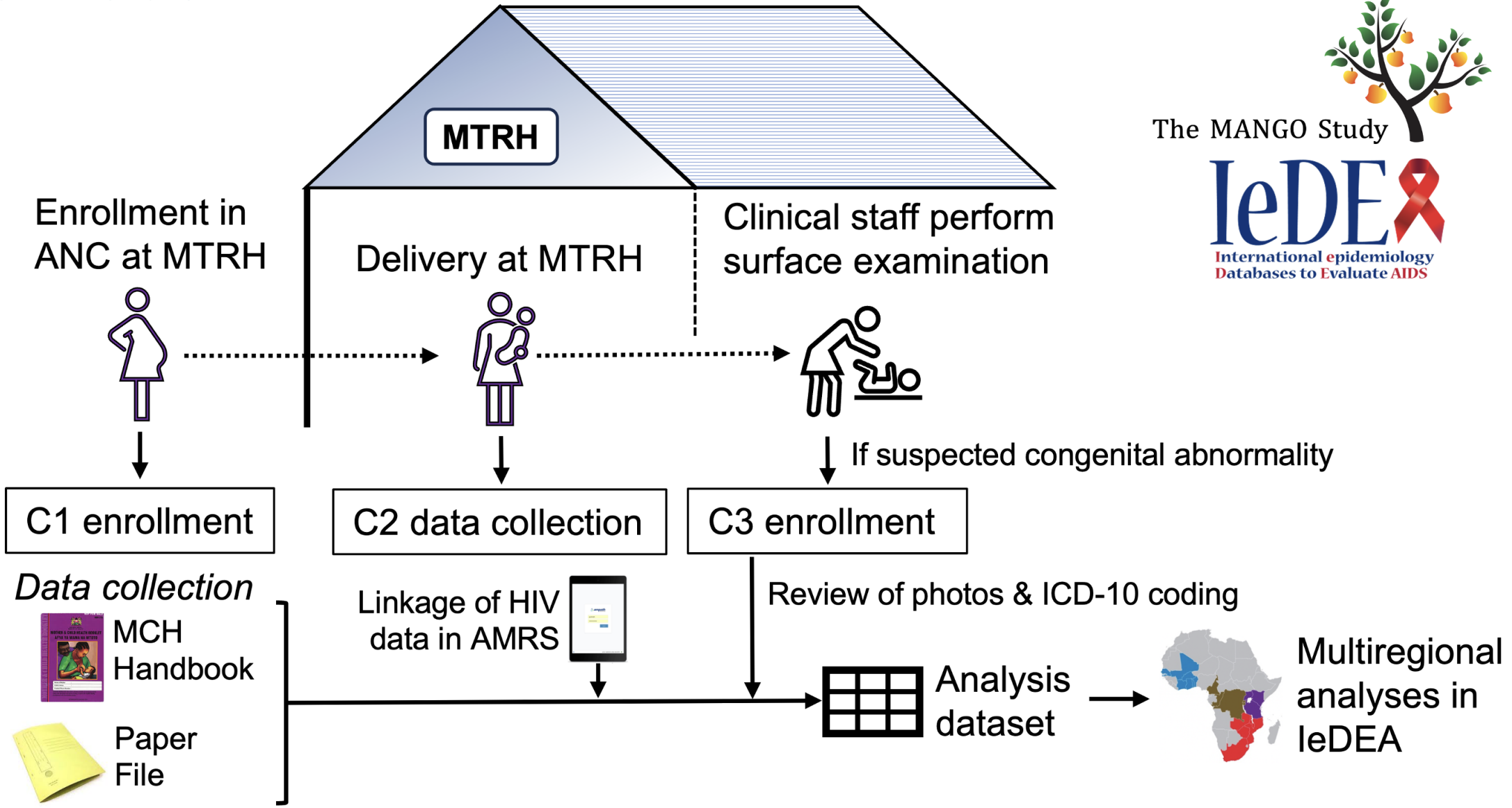
Methods



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IeDEA
International epidemiology Databases to Evaluate AIDS

Education / Training and QI program

The surveillance also involved :

a) **Healthcare worker training on**:

- comprehensive newborn surface exam
- birth defect identification
- **Improved documentation .**

- Training were done through :
  - Recurring in-person and zoom meetings in work areas
  - Structured Nurse Training Course
    - Offered CME credits

b) **Quality Improvement (QI) program in collaboration with hospital**

Training session on surface exam and birth defects

Enhanced NBSE and congenital abnormality documentation

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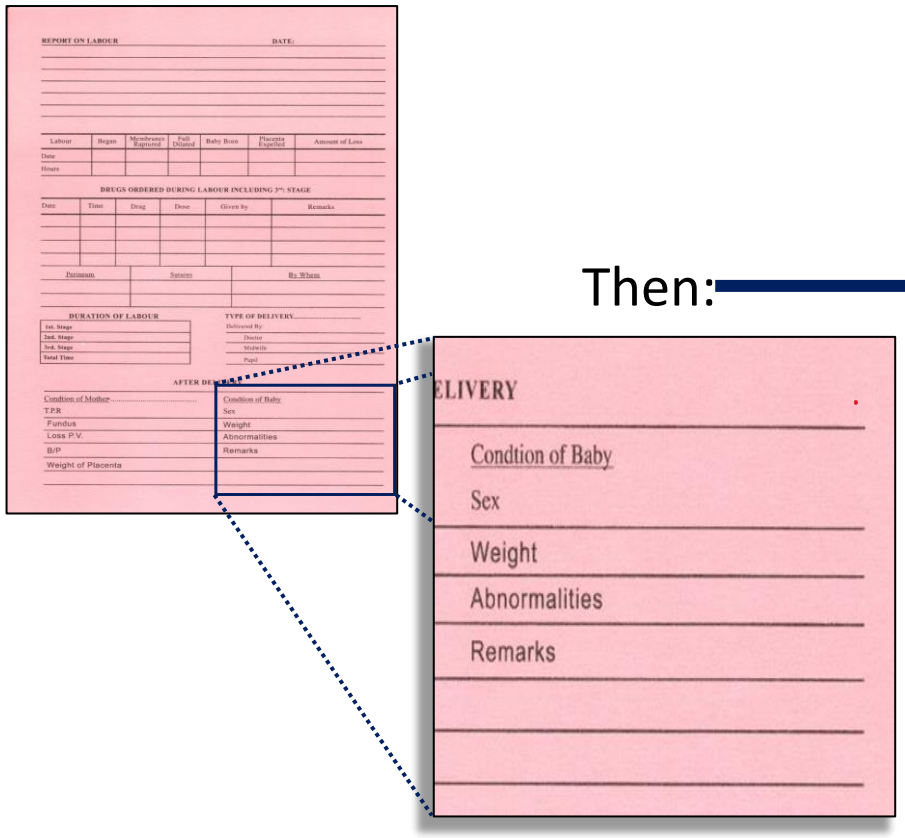
Delivery record “Pink Form” with limited documentation space

Then:



Now:

An ISO 9001: 2015 Certified Hospital

MOI TEACHING AND REFERRAL HOSPITAL

NEWBORN SURFACE EXAMINATION AND DOCUMENTATION FORM

Mothers Name..... HIV Status.....
Hospital Number. ..... CCC Number.....

Neonatal Data			
Time Of Delivery		Date of delivery	
Gender			
		Normal Ranges (For Term baby = >37 weeks Gestation)	
Birth Weight		≥2.5 < 4	
Head circumference		35 ± 2	
Birth Length		50 ± 2	
Foot Length		7cm ± 1	

Infant Physical Examination			
	Normal	Anomaly Present	Describe any anomaly identified (include side involved, location, size, extend, laterality, covering, extrusion of any organ, mobility)
Head			
Eyes			
Ears			
Nose and Mouth			
Neck and Clavicles			
Chest and Lungs			
Abdomen and Cord			
Genitalia			
Anus			
Back and Spine			
Limbs and Hip			
Skin			
Neonatal Reflexes			

Remarks	
Give baby to mother	
Admit to NBU	
Discharge through Clinic (Name of clinic)	

Name Signature

Some results from Audit-Based for Practice Improvement of Newborn Assessment

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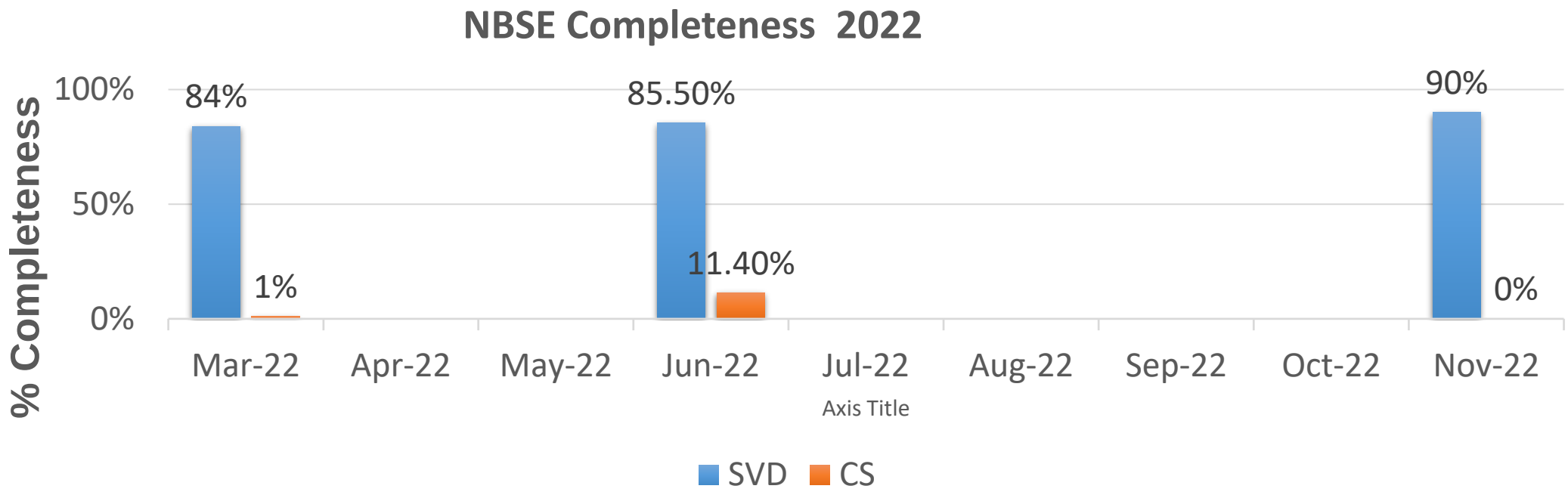
At baseline in 2021 of 8084 infants delivered, 1553(19.2%) infants had completed documentation of the NBSE from baseline audit

Results after 1 year of intervention



Currently – SVD NBSE is at 95-98% among SVD deliveries

Rop B., Matelong W., Kerich C., Muliro C., Were. E. Strengthening Routine Newborn Surface Exam in RMBH, MTRH: A Quality Improvement Project

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Characteristics of the MANGO cohort at delivery, October 2020 to September 2023.

Major congenital abnormality **Prevalence of 0.74% as of 2023**

Indicator	MANGO N=24,205	Kenya Aggregate Data (Ref.)
Maternal age at delivery (years), n (%)		
<20	1,947 (8.0)	13.0%[a]
20-34	**18,315 (75.7)**	**74.1%[a]**
35-49	3,892 (16.1)	12.9%[a]
Missing	51 (0.2)	--
Women living with HIV, n (%)	**1,084 (4.5)**	**5.2%[b]**
Transfer in for delivery, n (%)	1,754 (7.2)	n/a
Caesarian section delivery, n (%)	5,641 (23.3)	23.8%[c]
Missing	14 (0.06)	
Stillbirth, n (%)	**627 (2.6)**	**1.6%[d]**
Per 1000 births	**25.9**	**15.8**
Missing	16 (0.07)	
Premature birth (<37 weeks), n (%)	4,161 (17.7)[e]	12.3%[d]
Low birth weight (<2.5 kg), n (%)	3,643 (15.5)[e]	10.0%[f]
Major congenital abnormality, n (%)[g]		
C1 (n=839)	**4 (0.48, 95% CI 0.13-1.22)**	--
C2 (n=23,004)	**175 (0.76, 95% CI 0.65-0.88)**	--
Total (n=24,205)	**179 (0.74, 0.63-0.85)**	--
Total per 10,000 births		--
C1	47.7 (95% CI 13-122)	--
C2	76.1 (95% CI 65-88)	--
Total	73.9 (95% CI 63-85)	--

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All abnomalities (minor and major as of september 2024)

Abnromality	Total	Percentage n=27001
Extra digit	189	0.7%
Arm and leg	130	0.5%
Head and neck	115	0.4%
Toes and fingers	113	0.4%
Others	104	0.4%
Hip and genitalia	69	0.2%
Abdomenal and anal	64	64%
Hydrocephalus	40	0.1%
Mouth , lip and palate	38	0.1%
Spine	27	0.1%
Skull defect	24	0.1%
Skin	12	0.04%
Chest	7	0.03%
Total	**932**	**3.5%**

Prevalence major CA : 1% as of September 2024

Among infants born to women enrolled in C1, community-based surface examination identified some cases in which a major Cas was not reported by the mother via phone contact.

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Vital status at birth of neonates with major CA and results of the follow-up

October 2020 to September 2024 **N= 277**

Vita status at birth	
live birth	261(94.2%)
Fresh stillbirth	**9 (3.2%)**
Macerated stillbirth.	**6 (2.2%)**

Follow- up results : Among the live births

- At 1 month , **248** eligible infants
  - **24 (8.7%)** were already deceased before follow- up
  - **24 (8.7%)** had died
  - **18 (6.5%)** was unreachable by phone.
- At 6 months, **211.**eligible infants**,**
  - **4(1.7%)** had died
  - 42 (18.0%) were unreachable.
- At 1 year : 203 (85.7%) eligible
  - **7 (3.0%)** had died
  - 62 (26.2%) were unreachable.

Majority of the patient with CA died within 1 month of life 48(17.4%)

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"Diagnosis Done, Surveillance Ongoing—What's the Next Step?"

Hospital-based surveillance → Problem Identified →

- Service delivery gap for infants with CA and their families was identified.
- Critical gap in published data on the challenges faced by the 1-2% of infants with major CA in LMICs

↓

Grant Application: Applied for an NICHD supplement grant

Aim →

- **Assess Care Needs** of families with infants diagnosed with CA in resource-limited settings.
- **Develop Service Model to** optimized service delivery model tailored to these needs.

NICHD Supplement grant to East Africa IeDEA:

Study title: Development of a user-centered model of service delivery for families of infants with major congenital abnormalities in Kenya

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Development of a user-centered model of service delivery for families of infants with major congenital abnormalities in Kenya

Objectives

- **Aim 1.** Explore community perceptions, lived experiences and care needs of families with infants diagnosed with congenital abnormalities in resource-limited settings.

- **Aim 2.** Develop a service delivery model optimized to meet the needs of families with infants diagnosed with congenital abnormalities in resource-limited settings.

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Study design – Human centered - design

For the *discover* phase,

We conducted **in-depth interviews with 31 parents** of infants with major CAs delivered at MTRH to understand their experiences and care needs.

For the *define* and *develop* phases,

We conducted **HCD workshops with 19 healthcare providers** involved in the care of children with CAs at MTRH and **15 caregivers(parents)**

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Social-ecological model of factors influencing care needs of families of infants with major congenital abnormalities

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Domain	Themes	Sub- themes
Individual domain	**Psychological and emotional impact,** **Stigma** **Financial challenges**	**Initial Reactions** :fear, sadness, anxiety. **Self-Blame and denial ,** Maladaptation **Need for health Professional support** Importance of health insurance
Peer and family domain	**Psychological and emotional impact on the family** **Stigma** **Impact of family financial** **Partner involvement and shared responsibility**	Importance of family therapy and counselling **Role sibling ,extended family and community**
Healt care domain	Early diagnosis Support services Health education Intergrated care clinic Post discharge care	Affordability of specialized services Counselling and child life services Training of health care providers Crowding and long qeues Multidiplinary approach
Community and societal domain	**Community perceptions** Stigma Community support	Health educatiom

Example quotes from participants

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Sub themes	Quotes
Psychological and emotional impact	“I almost had a heart attack and I was very shocked. I used to arrive to the hospital sweating, at times I forgot what I was coming to do.”
Poverty	“I had to stop due to financial limitations.”
Community and interpersonal stigma	"I saw that I would be laughed at by people in the area, and then I came to know that is what made the father deny the child. Till today I don't know where he is."
Need for support and early diagnosis	"If the child is diagnosed early, you can get help early." "If I knew before, I could have aborted." ”It is like you have given birth to this child, you have been left to go and struggle on your own, but ... they should explain to you ….they don't tell you anything. “

Next steps

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1. Analyses of associations between HIV/ART exposure and adverse pregnancy/newborn outcomes
   - Mango-Kenya data
   - Bi-regional analysis of Kenya and South Africa data
2. Hospital transition to EMR
   - New challenges in improving surveillance , documentation and EMR utilization
   - Cleaning, harmonizing antenatal and perinatal EMR data
3. Interventions to provide more holistic care for families of infant with major congenital abnormalities

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Summary

- ✓Surveillance for CA requires a comprehensive approach
- ✓Majority of infants with CA die in the neonatal period
- ✓community-based surface examination and follow- up is feasible and can strength the surveillance process .

Beyond the numbers

- ✓Families with children born with CAs, face multifaceted challenges that require a comprehensive approach to address them .

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