USAID MEDICINES, TECHNOLOGIES, AND PHARMACEUTICAL SERVICES (MTaPS) PROGRAM

Improved Access. Improved Services. Better Health Outcomes.

Digital Tools for Pharmaceutical Systems

Global Digital Health Network

Webinar on 24th February 2021

Speakers
Francis Aboagye-Nyame, Project Director, Management Sciences for Health
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Moderator
Randy Wilson, Digital Health and Data Analytics Lead, Management Sciences for Health

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Agenda

Introduction	• Francis Abogye-Nyame
Needs for digital tools across the pharmaceutical systems regulatory landscape	• Javier Guzman
Overview of MSH tools designed to fit needs in the pharmaceutical system	• Kim Hoppenworth
Pharmadex and RxSolution - Progress, Challenges, Future plans and Link between potential tools and WHO Global Benchmarking Tool - GBT and strengthening standards	• Kim Hoppenworth & Deane Putzier
Q&A	• Randy Wilson

Introduction & Needs for digital tools

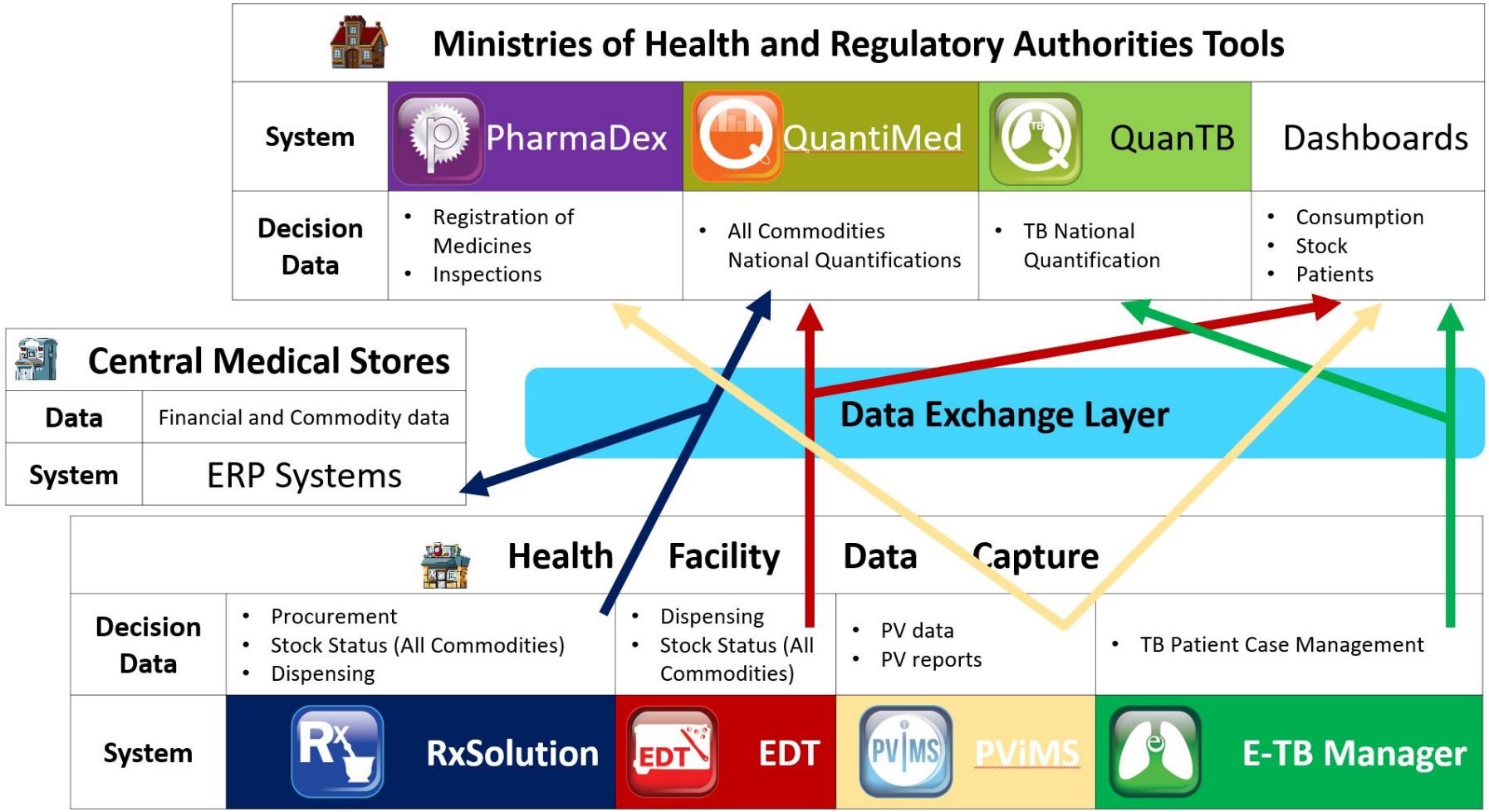
Overview of current MSH tools designed to fit needs in the pharmaceutical system

Pharmadex
medicines registration

PharmacoVigilance Monitoring System
medicines safety monitoring

RxSolution
patient management, dispensing, and inventory management

Overview of available MSH Systems



The WHO Global Benchmarking Tool (GBT) Modules and MIS

1. National Regulatory Systems (RS)
2. **Registration and Marketing Authorization (MA)**
3. **Vigilance (VL)**
4. **Market Surveillance and Control (MC)**
5. *Licensing Establishments (LI)*
6. *Regulatory Inspection (RI)*
7. Laboratory Testing (LT)
8. Clinical Trials Oversight (CT)
9. NRA Lot Release (LR)

Source: https://www.who.int/medicines/regulation/benchmarking_tool_version_vi/en/

GBT M2: Pharmadex module for Medicines Registration

What problem does it solve?
- Complex workflow for many work processes at NMRAs
- Large paper trails leading to long processing time
- Lack of overview of status of applications
- Gap in data analysis e.g. average time for registering a medicine/health product

Global Benchmarking Tool (GBT)
- Module 2 - Registration and Marketing Authorization

System characteristics
- Web-based
- Built to meet standardized workflow (WHO)
- Includes standard codes for INN and ATC

Benefits
- Can ensure more transparent, timely and standardized process for medicines registration

GBT M3: PViMS for Pharmacovigilance

What problem does it solve?

- Complex workflow for many work processes at NMRAs
- Large paper trails leading to long processing time
- Lack of overview of status of applications
- Gap in data analysis e.g. average time for registering a medicine/health product

Global Benchmarking Tool (GBT)

- Module 3 - Vigilance

System characteristics

- Web-based
- Built to meet standardized workflow (WHO)
- Includes standard codes for ICD-10 and more

Benefits

- The system is unique in performing active surveillance along with spontaneous reporting

GBT M4: Pharmadex module for Medicines Import

What problem does it solve?

- Issuing of Import Licenses
- Large paper trails leading to long processing time
- Lack of overview of status of applications
- Gap in data analysis

Global Benchmarking Tool (GBT)

- Module 4 - Market Surveillance and Control

System characteristics

- Web-based
- Built to meet standardized workflow (WHO)

Benefits

- Can ensure more transparent and standardized import of medicines/health products. Should be linked to Supply Chain to monitor e.g. international narcotics quotas

GBT M5&6: Pharmadex module for Licensing & Inspection

What problem does it solve?

- Ensuring standards are met at provider level ex. no hands are used to count tablets at dispensing point
- Large paper trails leading to long processing time
- Lack of overview of status of applications

Global Benchmarking Tool (GBT)

- Module 6 - Regulatory Inspection

System characteristics

- Web-based
- Built to meet standardized workflow (WHO)

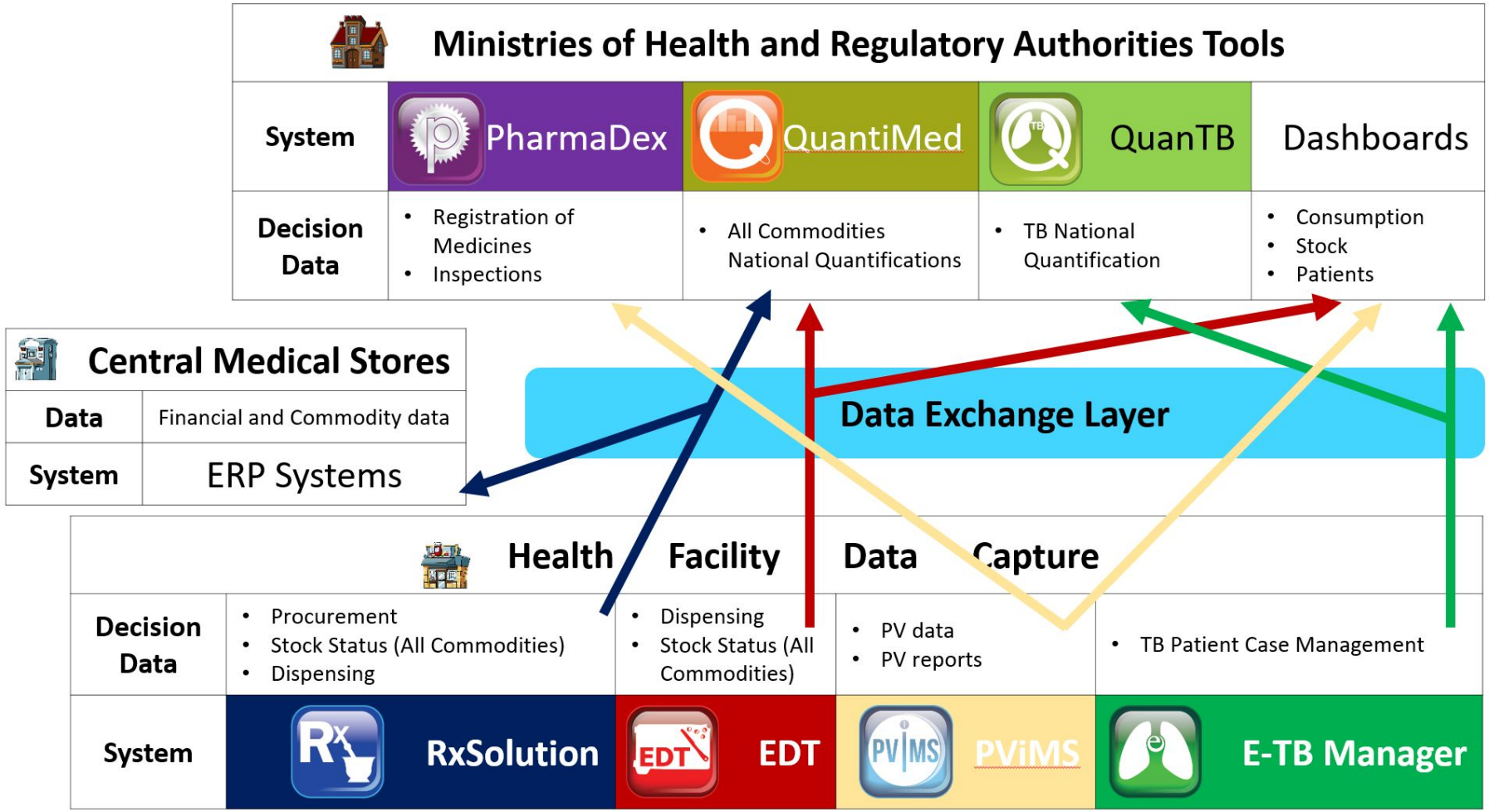
Benefits

- Can ensure safer and higher quality service for patients at the service points

Challenges

- Needs strong processes, workflows and SOPs for the functions that the MIS support
- Needs good conversations with NMRAs to find the right balance between Cloud and On-Premise

Overview of available MSH Systems



RxSolution : Introduction

What problem does it solve?

- Supports areas with poor infrastructure - no or limited internet
- Enterprise level supply chain management - @ country level
- Enterprise level patient dispensing

How?

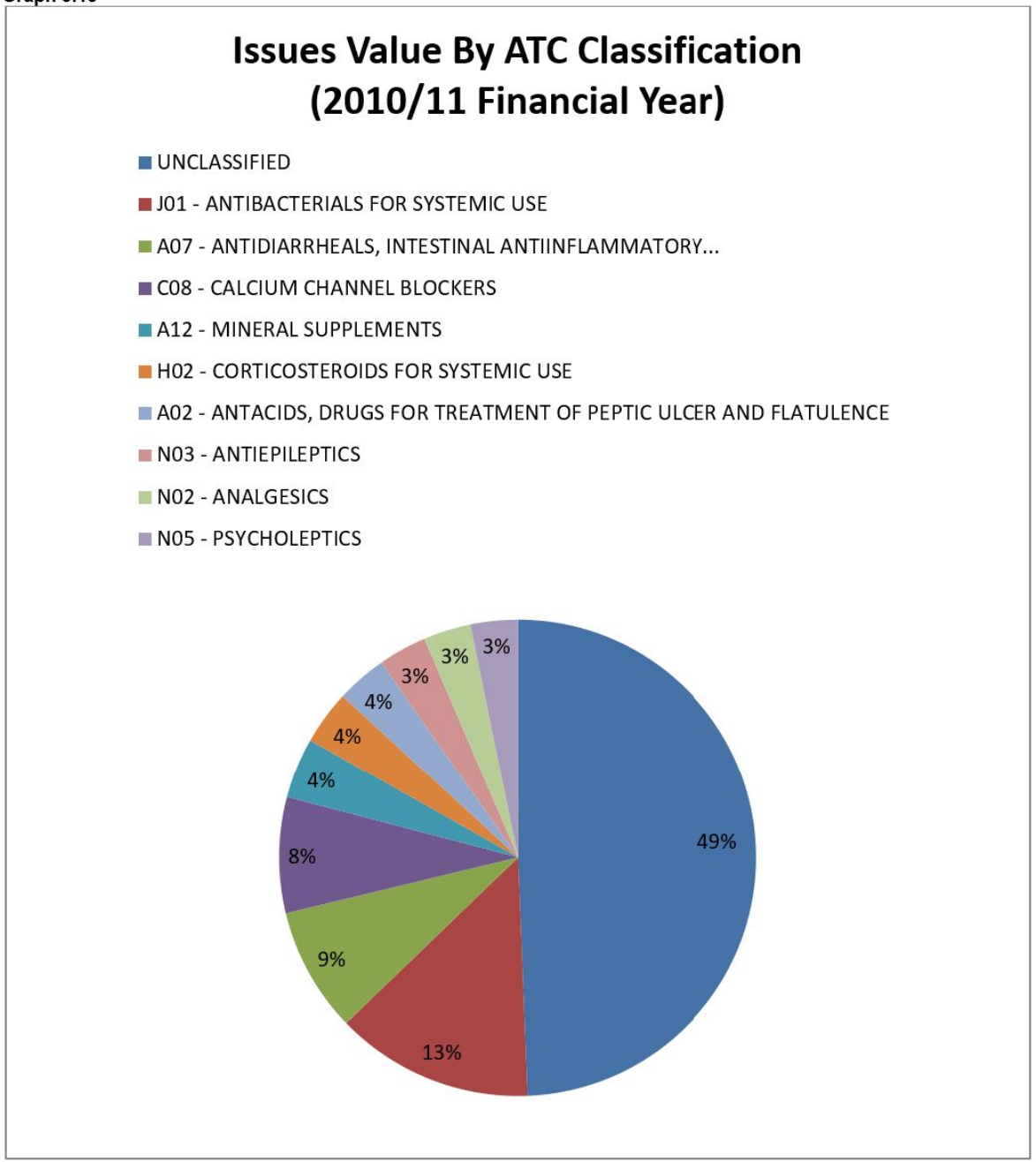
- Manages medicine & medicine supplies from supplier to the patient
- Submits data to central repository when connected

RxSolution: Supply chain facilities

- Procurement, Inventory, Distribution, Dispensing and Down Referral Management.
- Automatic calculation of stock levels.
- Recommended order quantities.
- Keep track of outstanding orders.
- Expiry date register and reports.
- Integrate with other systems.
- Stocktaking.
- Forecasting.
- Monitor Expenses vs. Allocated Budget.

RxSolution: Issues

Graph 3.13

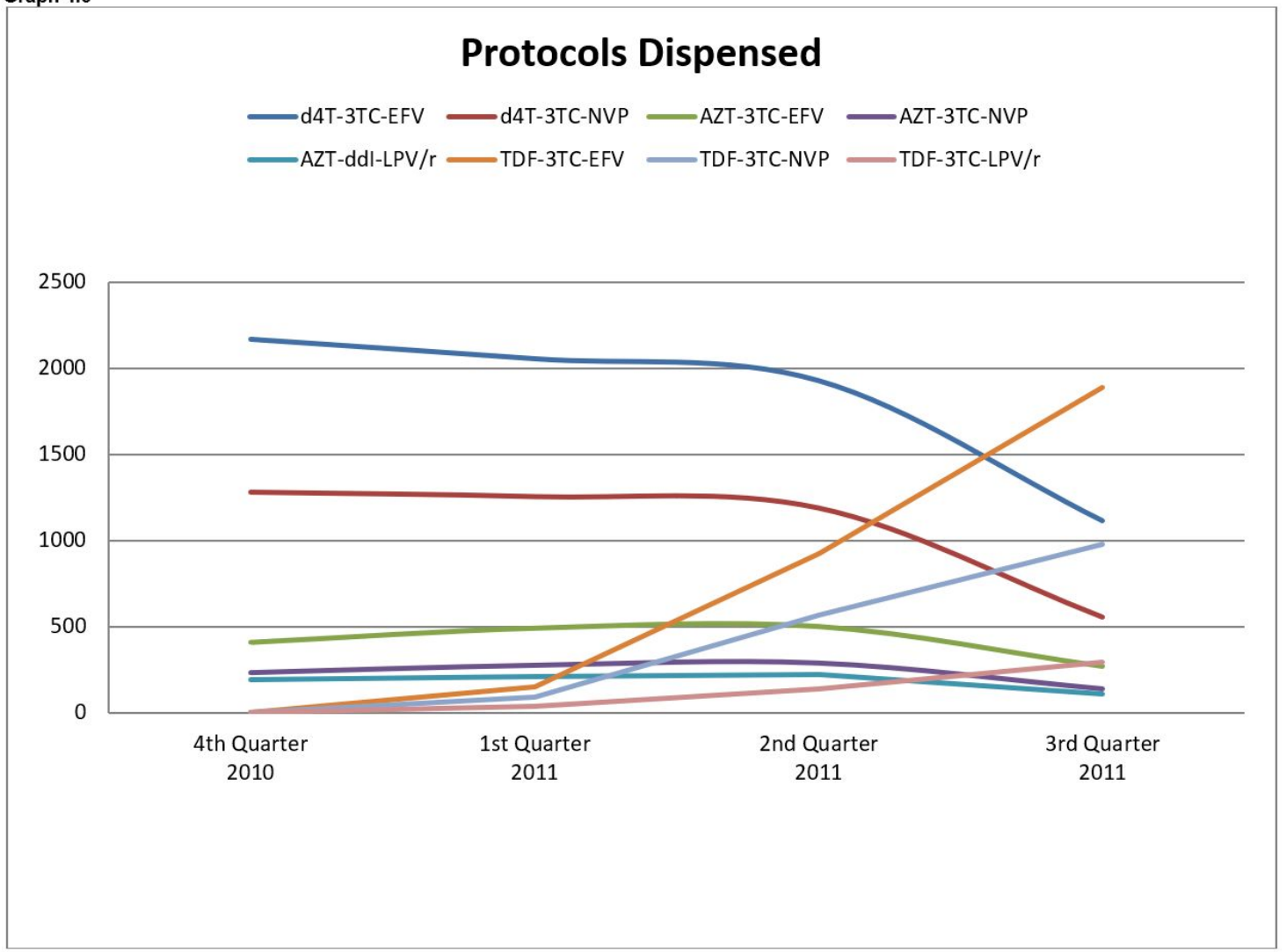


RxSolution: Dispensing capabilities

- Setup and Configure products
- Capture and document Patient Information
- Capture and document Prescriptions
- Access to product consumption information
- Access to prescriber trends
- Chronic Pre-Dispensing
- Customised labels
- Dispense Reports

RxSolution: Standard Treatment Guideline Tracking

Graph 4.6



RxSolution: Sustainability

- Developed by MSH in Eastern Cape funded by USAID/PEPFAR
- Established and sustainable (has no MSH/USAID support currently) in two African countries (Uganda & South Africa)
- 700+ sites, and primary public sector system in South Africa where it processes +/- $1 Billion in medicines and medical supplies each year
- 300+ sites in Uganda
- Been through many security and financial audits
- Data warehouse
- Public sector innovation award - 2013 RSA

Future Plans

- Focus on **international** versions
- Build on **global standards -** pharmaceutical as well as software
- **Integrate** where possible and sensible
- Focus on **Sustainability** and **Handover**
- MSH approach: Tools are **Open Source -** https://github.com/MSH

Q&A

Contact Us!

We can be reached on Digital@msh.org

Thank you again for attending the Webinar!