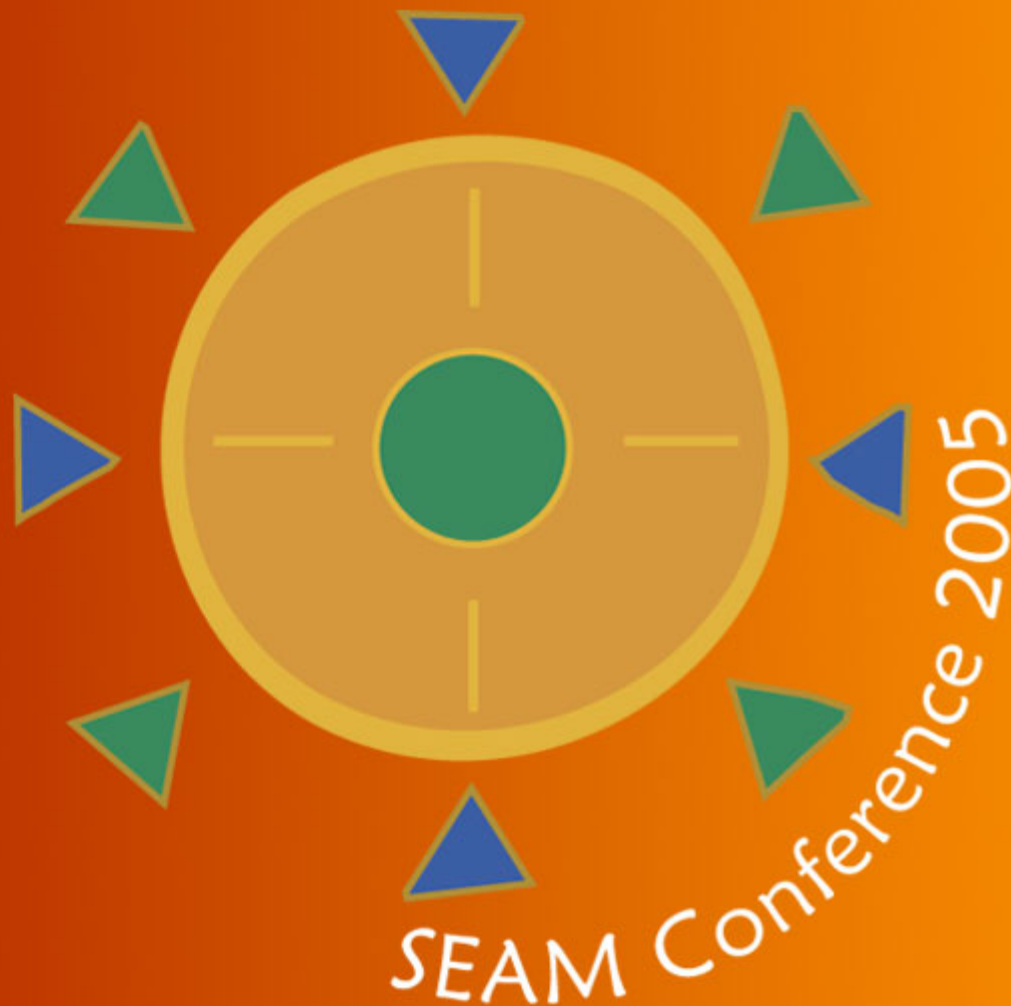


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Targeting Improved Access



MANAGEMENT SCIENCES for **HEALTH**

SEAM | Strategies for Enhancing Access to Medicines

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The Use of Personal Digital Assistants to Facilitate Inspections, Data Transfer and Data Analysis: The Tanzanian Experience

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Background

- ❖ In 2002, MSH/SEAM and the Tanzania Food and Drugs Authority (TFDA) initiated a quality assurance (QA) program to ensure that:
 - ❖ drugs in market meet required standards
 - ❖ pharmaceutical supply systems operate in accordance with requirements

TFDA/MSH QA program Implementation

- ❖ Structured inspection activities: SOPs, Forms/Checklists developed
- ❖ Inspectors permanently stationed at country's major ports of entry (POEs)
 - ❖ Inspection of all incoming pharmaceutical consignments
 - ❖ Screening of targeted drugs
- ❖ Increased frequency and coverage on inspections of drug dispensing outlets
 - ❖ Dispensing, legality of products
 - ❖ PMS and screening of target drugs



QA implementation: Observation

As a result of program implementation

Increase in:

- ❖ number of Inspections both at POE and PMS
- ❖ number of targeted drugs Minilab screened

But also

- ❖ Increase on the Inspection data received resulting into difficulty in data management

...Data Overload!

- ❖ The sheer number of forms returned made analysis of inspection data tedious and resulted in lengthy report preparation time
- ❖ Storage space for the forms
- ❖ Data retrieval difficult
- ❖ Validation of inspectors' work difficult

Other data related problems

Inspection Data

- ❖ Searching through a printed list of approvals by inspectors was tedious and inefficient - slowing inspectors work
- ❖ Inconsistent data entry (e.g. varying spellings: Roche, Hoffman la Roche)



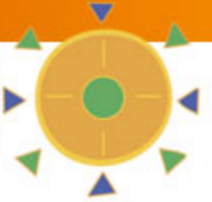
Paper handling Problems

Paper overload

- ❖ Inspectors had to carry numerous copies of inspection forms
 - ❖ Photocopy costs

Data Maintenance

- ❖ Very difficult to file and retain forms in orderly fashion
- ❖ Manual preparation of weekly/monthly summaries of data



❖ What could be done?

- ❖ Pilot a PDA based Inspection data management



Objectives of using PDA as inspection tool

- ❖ To address problems resulting from the success achieved by the QA program implementation
 - ❖ Data over load and data quality
 - ❖ Paper handling
 - ❖ Inspectors workload
 - ❖ Validation of inspectors work



PDA as Data Collection Tool

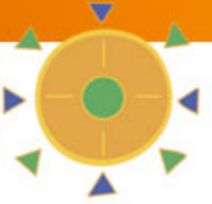
- Capable of storing large amounts of survey data
- Portable, used in field, need not to be plugged into power source, once daily battery charge
- Data easily transferable to into Access data base
- Cheap alternative (power/dollar)



PDA as Inspection Tool

- ❖ Data collected could be downloaded into computer for review/analysis
- ❖ Information of currently approvals-drugs/premises-uploaded into PDA providing on site information to inspectors
- ❖ TFDA/MSH/SATELLIFE adapted inspection forms for PDA





Development of the PDA based Inspection Program:

Alpha (α) version



Alpha (α) version Planning

- ❖ Idea discussed and managerial support obtained
- ❖ Mapped out flow of inspection activities and noted adaptations needed for use of PDAs
- ❖ Converted inspection forms into PDA-compatible format.
- ❖ Training on PDAs and field-testing of the forms with the TFDA inspectors and administrators.
- ❖ α version deployment of PDAs



α version PDA data review

- ❖ After 3 months:
 - ❖ Data quality evaluated
 - ❖ Inspectors interviewed and performance monitored

- ❖ Problems noted:
 - ❖ Loss of data
 - ❖ Design flaws
 - ❖ Download problems

α Version Problems

Data Loss

- ❖ Linkage between sub-forms and main forms made filling of the forms tedious and sometimes resulted in un-intentional non-entry of data



α Version Problems (cont'd.)

Form Design

- ❖ One inspection form designed to be used for all types of drug dispensing outlets
 - ❖ making some questions redundant and unnecessary
 - ❖ resulted into inconsistent data entry,
 - ❖ made the work more tedious.

- ❖ Lack of appropriate safeguards in design allowed inspectors to skip questions or enter data incorrectly.



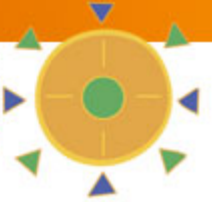
α Version Problems (cont'd.)

Download Process

Download from expansion cards involved numerous steps

- ❖ Possibility of accidental erasure of data
- ❖ Upload of new data more difficult than thought
 - ❖ Insufficient information technology (IT) staff available to aid in managing download process and database maintenance

Data accumulated in the PDA with time making the inspection process slow



α Version Problems: Way forward

TFDA/MSH managerial decision - February
2004

- ❖ Stop α version usage
- ❖ Critically review α version - modify forms and prepare for beta (β) version

β version Action plan

- ❖ Extensive review of the user defined requirements
 - ❖ Review of the forms; problems from alpha version
- ❖ Design qualification
 - ❖ Intensive consultations with PDA form designer
- ❖ Installation qualification
 - ❖ Increased “dummy” data tests
- ❖ Performance qualification
 - ❖ Re-training and testing of small, pilot group of inspectors
 - ❖ Paper/PDA data validation
- ❖ Deployment and monitoring performance (October 2004 – May 2005)
 - ❖ Perform data quality audits

β version: Successes

- Data quality improved through design controls, eliminating possibility of field skipping
- User friendly: specific forms for each type of Inspection activity.
- Potential for accidental data loss minimized as data download process is single step.
- No data accumulation in the PDA

Problems noted

- ❖ TFDA databases not regularly updated
 - ❖ Makes it very difficult for inspectors conducting premises inspections

- ❖ PDA forms are very structured and rigid hence cannot deal with unusual circumstances during inspections

- ❖ Resistance to change

PDA as Inspection Tool: Advantages

To the inspector

- ❖ Provide dictionary of approvals for use in field situation
- ❖ Convenient notebook to carry, provides an impromptu availability of all forms
- ❖ Reduction in workload
- ❖ SOTA tool (Inspector recognition and prestige)



PDA as Inspection tool: advantages

❖ To managers

- ❖ Enforces a disciplined process of inspection (improved consistency among inspectors)
- ❖ Easier to review inspection reports compared to paper forms
- ❖ Data can be retrieved/analyzed and processed with greater ease
- ❖ Reduced cost versus paper forms

Lessons Learned

Before embarking on PDA program ensure:

- ❖ Adequate and dedicated central IT resource is in place
 - ❖ Maintain database
 - ❖ Manage upload/download of data
 - ❖ Create reports as needed by management

- ❖ Existing structured inspection process is available
 - ❖ Laws and regulation, decision tree, flow charts and forms guiding the process

- ❖ Intensive validation of the electronic vs. paper surveys results— before deployment



Lessons Learned (cont'd.)

- ❖ Availability of relevant output data at different levels (minimum data)
 - ❖ Inspectors need data to make fail/pass decision
 - ❖ Managers need information for planning and compliance decisions/actions

- ❖ Make the technology user friendly
 - ❖ Ensure menu options minimize number of steps
 - ❖ Pop-up lists display in order of frequency and not necessarily alphabetical
 - ❖ Maximize number of fields appearing on screen

- ❖ Incorporation of change concepts



Summary

PDA's can be useful as a tool for collection of inspection data which can later be transferred into database and analyzed.

Reminder

- ❖ Need to improve IT/IMS resources as support background – without this, value of PDA's is diminished substantially
- ❖ Structured inspection procedures in place
- ❖ Well defined user needs
- ❖ Careful implementation plan
- ❖ Adopt change concepts during implementation



Access to Medicines initiatives through public-private partnership has proven to play a significant role in the provision of good quality pharmaceutical services, particularly in rural and semi-urban areas where there are no pharmacies.

- ❖ Stakeholders consensus is important to success, need to involve all the key players in the process from the initial design of the intervention
- ❖ Government (MoH) leadership, commitment and support is very important for the private sector to participate in public health interventions
- ❖ Private drug shops play an important role in providing access to essential medicines and other health commodities to the underserved population
- ❖ With the right incentives, the market system works



- ❖ Training and continuing education for dispensers or sellers is an important component in ensuring provision of good quality services
- ❖ Evidence from Tanzania shows that chemical seller type shops can manage antibiotics and other prescription drugs responsibly
- ❖ Close supervision and monitoring is necessary to maintain good dispensing practice
- ❖ Effective drug regulation is an important tool in ensuring the quality of pharmaceutical services.
- ❖ To achieve effectiveness, may entail implementing innovative regulatory systems e.g. decentralization of regulation.

Challenges:

- ❖ Sustainability in terms of cost and institutionalization of training and continuing education, supervision and monitoring, strengthening regulatory capacities given scarce resources available
- ❖ Acceptance of the initiatives by professionals such as pharmacists.