Changing demands on Pharmacy

Lessons learnt

Melanie Maclachlan
Desmond Tutu HIV Centre
Introduction

• Where we come from and where we are now:
  • Tablet studies e.g. HPTN 067
  • LA Injections e.g. HPTN 076
  • Infusions e.g. HPTN 081
  • Tablets and LA Injections e.g. HPTN083/084
Tablets e.g. HPTN 067

• Easy to dispense
• Can often be open label
• Often quicker from a time and preparation perspective
• Unique to this study—using wisepill devices and not dispensing in the original container
• More time available for counselling
• Fewer resources and pharmacy equipment requirements
• Participants had an idea of which arm they wanted to be on prior to randomization
• Managing ppt expectations and ensuring they understood the arm they had been assigned to
LA Injections

- More complex to prepare
- Aseptic preparations and this requires additional resources and pharmacy supplies
- Biggest learning point – timeframes needed to get all resources in place at site
- Blinding especially with saline placebos
- Overlays and tape
LA Injections

• Preparation times for placebo and active injections can vary significantly
• Mock/practise runs to have an estimate of time required especially if first assignment is placebo
• Administration required un-blinded administrators
LA Injections

• Expiry times
• Expiry times require close coordination with administration staff to ensure that prepared injections given within timeframes
• Counselling ppts about injections
  – Main concern was administration and pain
Infusions

• Longest preparation times
• Aseptic/Sterile environment
• Additional pharmacy supplies needed for preparation
• Paperwork heavy
• Limited expiry timeframes
• Weight based dosing
Infusions

• Main lessons learnt:
  – Again close coordination with clinic staff to ensure equilibration of prepared infusion bags prior to infusion
  – Difficulty in contacting ppts prior to visits
  – Prescriptions received prior to infusion visits
  – Wastage prevention requires a coordinated approach
  – Participant education
Tablets and LA Injections

• Tablets are easy to prepare
• Blinded pill bottles require careful selection and double-checking
  – Blinded and Un-blinded labels - Remove un-blinded label
• Injection prep
• Aseptic, BMI based
Tablets and LA Injections

- Use of non-saline placebos to maintain blinding of injections is easier
- No requirement for un-blinded administrators
- Preparation times for placebos – Mock/practise runs to have an estimate of time required especially if first assignment is placebo
Tablets and LA Injections

- Expiry times require close coordination with administration staff to ensure that prepared injections given within timeframes
- Ppt main concern is the injection
Summary

• What are the key takeaways
  – Tablet studies require less time and fewer pharmacy resources
  – Injection and Infusion studies require more time and significantly more pharmacy resources
"This doesn't look good. I'm afraid you've developed an immunity to placebos."

"Take them until further testing shows they really aren't effective."