



# EDP: STGs & EDL Audits

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# Outline of Presentation

- **Definition of Rational drug Use (RDU)**
- **Purpose of compliance tests**
- **Description**
- **Results & Analyses**
- **Reports & Recommendations**
- **Follow-up after an audit**
- **Continual Monitoring, training and planning**

# Rational Drug Use

Is defined as the practice of using drugs:

- Appropriately for a clinical condition,
- In the correct
  - Formulation
  - Doses that meet the patient's individual requirements
  - Frequency
- For an adequate period of time
- And at the lowest cost.

# NDP–EDP: EDL Drug selection

- Must meet the health needs of the majority.
- Sufficient proven scientific data for inclusion.
- Substantial safety and risk / benefit ratio
- As a rule, single ingredient
- Convenience of dosage regimen
- When all equivalent, then only are costs considered.
- All drugs must be used within standard treatment guidelines.

**Efficacy: Safety: Dosing Convenience: Costs**

# Purpose of an Audit

- For the facility to note their strengths & weaknesses i.t.o following the EDP
- To do a turnaround of problem working in partnerships with all departments → for positive growth & interventions using a monitoring, training and planning approach.
- To promote self-auditing using the tools employed in the auditing exercise or alternate measures
- To measure progress over time
- To re-evaluate after reasonable intervals to promote further change or to detect new problems

# Tools Used in KZN

**“Adherence of KZN Facilities to the  
Essential Drug Programme”**

**Adapted by Mariam Cassimjee from: -  
WHO's “How to investigate drug use in  
health facilities”**

**Piloted in the Ugu District by K  
Ramasir & M Cassimjee**

**On the 19 & 20 August 2003  
& 03 & 04 March 2004**

# Other Tools Used

For correct prescribing of top budget items: -

1. ABC analysis → A = top 20% consuming ± 75% of budget p.a.

B = 15% of budget, &

C = 5% of budget.

2. Drug Order Reviews → follow on from ABC analysis → determines orders for specific drug/s from PMSC for specific facilities

3. Prescriber indicator analysis for STG compliance → DUR

(1) and (2) are used provincially → to determine whether the facility needs to be audited for STG compliance i.r.o. the drug being investigated → Drug Utilisation Review (DUR)

For a facility's self auditing: ABC analysis can be sourced & DURs conducted internally.

# Description of “Adherence to EDP-STG” Tool

1. **Questionnaire** : assesses knowledge, attitude, application of the EDP & a STG for a prevalent condition in the community (e.g. hypertension) to enable interventions in practice
2. **Assessments against WHO prescriber indicators**: of retrospectively randomised prescriptions within a time frame to determine the degree to which the health facility conforms to the EDP: STGs & EDL.
3. **Investigation of an Identified Drug**: Using WHO indicators for STG compliance to determine RDU.
4. **Assessment of the availability of key EDL items**: Uses a sample of 20 EDL drugs for spot checks.

## Form: Prescribing Indicators for STGs & EDL

No	Date	Age in Yrs	Drugs	No of Drugs Prescribed Generically	Anti-Biotic (0/1)*	Injection (0/1)*	As per STG (0/1)*	Diagnosis
1	3.6.06	45	Hydrochlorothiazide 12.5mg; Atenolol 50mg; Brufen 200mg; Ventolin Inhaler (4)	2	0	0	0	HPT; Chronic Asthma
2	7.8.06	58	Hydrochlorothiazide 12.5mg; Enalapril 10mg b.d.; Salbutamol Inhaler prn; Budesonide Inhaler (4)	4	0	0	1	HPT; Asthma
3	3.8.06	59	Actraphane 40u mane. 20 u nocte; Erythromycin 500mg qid (2)	2	1	1	0	Diabetes & Flu
4	5.3.06	1/4	Sorbitol 70%; Fosenema; Dulcolax suppository (3)	1	0	0	0	??
30 = (A)								
<b>Total No of Drugs</b>			(B)	(D)	(F)	(H)	(J)	
<b>Average</b>			(C) = B/A					
<b>Percentage</b>				(E)	(G)	(I)	(L)	

# Problem Drug Investigation e.g. Amlodipine 5 mg:

Location: Xixo Hospital

Investigator: M Cassimjee Date: 30.09.06

No #	Date	Age in Yrs	Dept/ Clinic	Drug Name/s as Prescribed	Prescribed Generically (0/1)*	As per STG (0/1)*	Diagnosis
1	3.6.06	36	OPD	Norvasc 5mg	0	0	HPT
	8.9.06	45	MOPD	Amlodpine 5mg	1	1	ISH
30							
Total							
Percentage							

# Results & Analyses

- **Calculations**
- **Interpretations against STGs**
- **Analysis for reports**

## Results of Pilot Sites: Baseline (8/2003) & Post (3/2004) Study

Indicators Used	PHC Clinic		District Hosp		Regional Hosp	
	Base	Post	Base	Post	Base	Post
Understanding & promoting core concepts of the EDP- Percentage score: (Pharmacy or facility Manager)	90	85	40	70	25	45
Average No. of drugs per encounter	2.3	1.7	3	3.8	3.6	3.2
Percentage drugs prescribed generically	55	80	35	23	0	16
Percentage encounters with an antibiotic	55	43	37	9	6.7	17
Percentage injections prescribed per encounters of sample	6.7	27	30	23	6.7	23
Percentage drugs prescribed according to the EDP - STGs	15	80	14	50	6.4	60
Problem areas: %age for the correct prescribing of antibiotic/statin/NSAID injection (A=Amoxycillin) (I = Diclophenac sod) (S= Atorvastatin /Simvastatin)	50 (A)	60 (A)	0 (I)	80 (I)	3.9 (S)	83 (S)
Percentage for the availability of EML Items	95	100	100	100	100	100

■ = Marked Improvement after intervention (DURs, Compliance Tests & Recommendations)

## Questionnaire Result – Pharmacy Manager

<b>Indicator</b>	<b>Result</b>	<b>Comments</b>
<b>Understanding &amp; promoting core concepts of the EMP- Percentage score: (Pharmacy or facility Manager)</b>	<b>97.5</b>	<b>Well done! Understanding the concepts makes application easier and promotable within the department and the facility.</b>

# Average No of Items

## Example 1

Indicator	Result	Comments
Average No. of drugs per encounter	4.8	Were read against the STGs as indicator for correct usage. The norm for a district facility is 3. A value of 4.8 → ?? RDU.

# Av No. of Drugs Per Encounter

Hosp 1	Hosp 2	Comments
4.3	5.8	<p>Norm → 3.0 for hospitals</p> <p>Some consideration is made for prescriptions with multiple chronic diseases.</p> <p>But there is strong evidence of polypharmacy!</p>



## Polypharmacy: Safety Issues w.r.t. Drug Interactions

No	Rx	Comment
1	Asthavent	<p><b>Polypharmacy demands monitoring as-</b></p> <ul style="list-style-type: none"> <li>• <b>Cimetidine ↑ theophylline conc → ↑ 70% SEs → possible cardiac arrhythmias, tachycardia, convulsions. (Mech → inhibition of CYP450 enzymes resp for theophylline metabolism.)</b></li> <li>• <b>Cimetidine ↑ conc of TCAs to toxic levels in some pts. (Mech → inhibition of CYP450 metabolism of TCAs. MANAGEMENT: Close monitoring for clinical response &amp; tolerance recommended whenever cimetidine is +ed or discontinued from a TCA regimen.</b></li> <li>• <b>Co-administration with inhibitors of CYP450 3A4 → ↑ plasma conc &amp; systemic effects of budesonide (metabolized by the isoenzyme). Acc to budesonide labelling, potent 3A4 inhibitors → ↑ plasma levels of budesonide severalfold e.g. 8 fold ↑ systemic exposure (AUC) of oral budesonide observed when co-administered with ketoconazole → leading to Cushing's syndrome with impaired adrenal function</b></li> </ul> <p><b>MANAGEMENT: The possibility of ↑ systemic pharmacologic effects of budesonide sh be considered during concomitant therapy with CYP450 3A4 inhibitors,</b></p>
2	Inflammid	
3	Nuelin SA i b.d.	
4	Cimetidine 200mg b. d. (Sh be 400mg nocte for 2 wks only → for investigation thereafter)	
5	CTM 4mg b.d.	
6	Premarin 0.625mg	
7	Berotec 1.25 mcg (10)	
8	Ca Hexal ..... (dose details - not clear)	
9	Steroid V b.d.	
10	Advantan ointment	
11	Alendronate 10mg daily	
12	Amitriptyline 10 b.d.	

# More Harm than Good!

No	Rx	Comment
1	Indocid supps i nocte	
2	ASA ½ daily	
3	Tenormin 100mg o.d.	Should never be prescribed for an asthmatic – induces an episode. A beta agonist and a beta blocker on the same prescription!
4	Renitec 10 mg b.d.	
5	Norvasc 10 mg daily	
6	Isordil 10 mg t.d.s.	
7	Daonil 5 mg b.d.	
8	Asthavent	

# Prevention vs Relief

No	Rx	Comment
1	HCT ½ daily	<p>No inhaled steroid in an asthmatic!</p> <p>Relievers are the mainstay of this prescription in contrast to the STGs.</p> <p>The preventer (inhaled steroid) would eliminate the need for the theophyllin (Nuelin) and would afford quality of care.</p>
2	Asthavent	
3	Theodur 200mg b d	
4	Buscopan 20mg t d s	
5	Paracod ii prn	
6	Tinaderm Ointment	

# Theophylline: Prescriber Level 3

- PL 3 → restricted to specialists & to respiratory clinics.
- Rational prescribing not determined on price but on optimising the care of the patient.
- Omission of the inhaled steroid in confirmed asthmatic → viewed as compromised care!

# Drugs Prescribed According to EDP - STGs

Indicator - STG	Result	Comments
<u>Percentage</u> of drugs prescribed according to the EDP - STGs	9.8	Only 14/143 drugs prescribed in the sampling were acc to the STGs. Concerns are raised w.r.t. this aspect and needs urgent attention.

# Generic Prescribing

<b>Indicator</b>	<b>Result</b>	<b>Comments</b>
<b>Percentage of drugs prescribed generically</b>	<b>6.3</b>	<b>In promoting compliance, pts needs to know their medicines. Prescribers &amp; pharmacists need to write &amp; talk “generics” esp when counseling. In state facilities, brand names change with the tenders &amp; brand promotions have to be avoided.</b>

# Generic Prescribing

1. **In state facilities, brands change with the tenders.**
2. **Can patients know their chronic meds & names when Drs talk brand names and pharmacists dispense and counsel on generics? (Compliance?)**
3. **Internationally → there are significantly fewer generic names than brand names**
4. **Generic names are international: Brand names may vary between countries**
5. **Exclusive use of generic names for all prescribers: simplifies learning, teaching and reduces confusion**
6. **Generic names indicate chemical class → drug's pharmacology and classification**
7. **Generic nomenclature used routinely in medical & scientific publications → info more accessible if generic names are consistently used.**

# Antibiotic Use / Misuse

Indicator	Result	Comments
Percentage of encounters with an antibiotic	23	<b>Good!</b> 5 out of 7 Rxs with an antibiotic were acc to STGs = <u>71% correct!</u> One of the other 2 Rxs used cotrimox for a UTI with no data on sensitivities for justification.

# Percentage of Encounter With an Antibiotic

Hosp 1	Hosp 2	Comments
33%	6%	<p><b>Hosp 1:</b> Most were rationally prescribed except use of the more expensive erythromycin in place of amoxicillin!</p> <p><b>Hosp 2:</b> Overall small value but for erythromycin usage</p>

# Injection Use

Hosp 1	Hosp 2	Comments
30%	8.7%	<p><b>Hosp 1:</b> Most were non-compliant → use of diclophenac inj (separate audit conducted)</p> <p><b>Hosp2:</b> Most were judiciously prescribed as insulin for DM except for diclophenac 75mg injection (separate audit)</p>

# Percentage: Correct Use of Diclophenac Sod 75mg Inj.

Hosp 1	Hosp 2	Comments
13.3	3	Hosp 1: translates to 86.7% injudicious use Hosp 2: translates to 97% injudicious use

Used for the following: -

"HPT – FFD"; "body pain with flu", "tender thigh", "in pain but comfortable", "mild swelling", "PVD & UTI", "arthralgia with ibuprofen" & "Asthma with HPT" → all not severe to warrant diclophenac injection.

STGs are for safety of Pt → Inj reserved for IP, Orthopaedics & Casualty with restrictions for conditions where it would not be warranted.

# Percentage Drugs Prescribed According to the EDP - STGs

Hosp 1	Hosp 2	Comments
87 %	54%	Hosp 1: Very Good!  Hosp 2: Translates to a non-compliance of 46%

# Prices of Anti-HPT Agents: PMSC's catalogue of Nov 2006

Tablet Preparations for HPT	Price	Price per Tablet	Rating per Price
Amlodipine besylate tab eq to amlodipine base 5mg; 30's	R 20.10	67 c	6
Atenolol tablets patient ready pack; 100mg; 28's	R 6.75	24c	5
Atenolol tablets 50mg; 28's	R 3.56	13c	4
Enalapril maleate tablets patient ready pack; 5mg; 28's	R 2.31	8c	2
Enalapril maleate tablets 10mg; 28's	R 2.56	9c	3
Hydrochlorothiazide tablets patient ready pack; 25mg; 14's	78c	6c	1

Should the usage not follow the STGs for cost effectiveness?

BP > 140/90 mmHg on lifestyle modification

### UNCOMPLICATED HYPERTENSION

Low dose thiazide diuretic  
12.5mg hydrochlorothiazide

i.e.

**STEP 1: INITIAL DRUG CHOICE**  
Start with low dose of a long acting drug  
Titrate dose at 2 monthly intervals

#### COMPELLING INDICATION FOR SPECIFIC CLASS EXISTS

- Diabetes mellitus with proteinuria: ACE inhibitor
- Evidence of CHD/Stroke/PVD/OR diabetes OR 1 major risk factor: ACE inhibitors
- Heart failure - diuretics and ACE inhibitors
- Isolated systolic hypertension – thiazide + long acting calcium channel blocker
- Myocardial infarction - beta-blockers/ACE inhibitors
- Pregnancy - methyldopa

**STEP 2: DRUG THERAPY**  
If not at goal BP after 2 months OR  
If troublesome side effects

- Low dose diuretic or 1 of the following
- (Reserpine deleted from EDL).
- beta-blocker
- ACE inhibitor
- Long acting calcium channel blocker \*\*
- (Fixed dose combination (Not on EDL))

**STEP 3: DRUG THERAPY**  
IF NOT AT GOAL BP AFTER 2 MONTHS

- Add another drug from step 2 above or
- hydralazine or
- alpha-blocker

REFER IF NOT AT GOAL BP AFTER 2 MONTHS

## Hypertension Algorithm

SAMJ, March 2004, Vol 94, No 3

# Ca++ Channel Blocker: Compelling Indication for Specific Class – SA HPT Society 2004 & EDP

- Diabetes mellitus with proteinuria: ACE inhibitor
- Evidence of CHD/Stroke/PVD/OR diabetes OR 1 major risk factor: ACE inhibitors
- Heart failure - diuretics and ACE inhibitors
- Isolated systolic hypertension - thiazide/long acting calcium channel blocker
- MI - beta-blockers/ACE inhibitors
- Pregnancy - methyldopa

# Problem Drugs: Ca<sup>++</sup> Channel Blockers % age for Correct Prescribing

Hosp 1	Hosp 2	Comments
22%	30%	<p>Expensive prescribing!</p> <p><b>Hosp 1:</b> 88% non-compliance</p> <p><b>Hosp 2:</b> 70% non-compliance!</p>

# Calcium Channel Blocker Usage

## Hosp 1

Review Period	Drug	Units Used	Unit Cost	Costs over 9 Mths	Comment
11.11.04 to 19.08.05	Nifedipine 30mg XL	23 220	R26.47	R 614 633	(Data for 9 months)
01.10.05 to 31.12.05	Amlodipine 5mg	12 900	R20.10 N.B. ↓ in unit costs	R259 290	R 1 037 160 Projected annual expenditure

## Hosp 2

11.11.04 to 19.08.05	Nifedipine 30mg XL	72,720	R26.47	R1,924,898.40	(Data for 9 months) Highest use in KZN!
01.10.05 to 31.12.05	Amlodipine 5mg	18,640	R20.10 N.B. ↓ in unit costs	R374,664.00	R1,498,656.00 Projected annual usage Highest user in province!

# Problem Drug: Nifedipine 30mg XL (2004)

Indicator	Result	Comments
Problem areas: Percentage for the <u>correct</u> prescribing of Nifedipine 30 mg XL	30	Translates to 70% incorrect usage! Considering Nifedipine is the most expensive of the HPT agents at 95c per tab → HCT - 7c, atenolol 50mg – 12c, atenolol 100mg 22c, enalapril 5mg – 11c & enalapril 10mg – 13c, should the usage not be judicious?

Facility's annual usage = R 521,009.01 (20/10/2003 to (19/10/2004).

# Cost Implications of Incorrect Usage of Ca<sup>++</sup> Channel Blockers

With use of ACE-I (at highest dose of 10mg b.d.) acc to STGs → big cost savings!

**Hosp 1: 88% non-compliance**

$0.88 * 12\ 900/3 * 12 = 45\ 408$  units annually → R912 700.8

**Possible savings using ACE-I = R680 211.84**  
(= R912 700.8 – R232 488.96 )

**Hosp 2: 70% non-compliance**

$0.7 * 180\ 640/3 * 12 = 52\ 192$  units annually → R1 049 059.20

**Possible savings using ACE-I = R781 836.16**  
( R1 049 059.20 – R232 488.96)

# Problem Drug 2004: Captopril 25mg

Indicators Used	Score	Comments												
<p><b>%age for <u>correct</u> prescribing of Captopril 25mg</b></p>	<p><b>0</b></p>	<p><b>Captopril →reserved for Paeds &amp; emergency HPT on the STGs. Should these prescription be dispensed? Data below is worth considering for better patient compliance and BP control.</b></p> <p><b>References: Opie L H, Angiotensin Converting Enzyme Inhibitors; Shionoiri et al 1986</b></p> <table border="1" data-bbox="827 938 1982 1521"> <thead> <tr> <th data-bbox="827 938 1131 1187"></th> <th data-bbox="1131 938 1415 1187"><math>t_{1/2}</math> - hrs</th> <th data-bbox="1415 938 1673 1187"><math>t_{max}</math> - hrs</th> <th data-bbox="1673 938 1982 1187">Dosing frequency</th> </tr> </thead> <tbody> <tr> <td data-bbox="827 1187 1131 1354"><b>Captopril</b></td> <td data-bbox="1131 1187 1415 1354"><b>1.2</b></td> <td data-bbox="1415 1187 1673 1354"><b>1.5</b></td> <td data-bbox="1673 1187 1982 1354"><b>t.d.s.</b></td> </tr> <tr> <td data-bbox="827 1354 1131 1521"><b>Enalapril</b></td> <td data-bbox="1131 1354 1415 1521"><b>6</b></td> <td data-bbox="1415 1354 1673 1521"><b>6</b></td> <td data-bbox="1673 1354 1982 1521"><b>b.d.</b></td> </tr> </tbody> </table>		$t_{1/2}$ - hrs	$t_{max}$ - hrs	Dosing frequency	<b>Captopril</b>	<b>1.2</b>	<b>1.5</b>	<b>t.d.s.</b>	<b>Enalapril</b>	<b>6</b>	<b>6</b>	<b>b.d.</b>
	$t_{1/2}$ - hrs	$t_{max}$ - hrs	Dosing frequency											
<b>Captopril</b>	<b>1.2</b>	<b>1.5</b>	<b>t.d.s.</b>											
<b>Enalapril</b>	<b>6</b>	<b>6</b>	<b>b.d.</b>											

# Availability of EDL Items

Indicator	Score	Comments
Percentage for the availability of EML Items	85	<p>A 100% is the expected norm. Concerns → 3 items: -</p> <ol style="list-style-type: none"><li>1. TB continuation phase packs for <u>adults &amp; children</u> were not stocked. Management of TB in-pts + TTOs?</li><li>2. O/s Ferrous sulph: a supply problem; been arriving intermittently from PMSC since Aug 2004.</li></ol>

# Problem Prescription: Quality of Care

27 October 2004

- Polypharmacy - 15 items (Rx not included in the retrospective sample)
- Transcribed by nurse and signed by MO!
- Diagnosis on prescription - HPT, diabetes, arthritis and coughing!

HCT 25mg

Lasix 40mg

} 2 diuretics?

Daonil ii – i

Glucophage 1G tds

Reserpine 0,25mg (No longer on STGs)

Isordil 10mg tds

Disprin ½ D

Asthavent refill

ABS Nebs Solution

Inflammid 200µg bd

Neulin SA 250mg bd

Premarin 0.625mg daily

Benylin 10ml tds – Necessity?

CTM 4mg tds

Amoxil 500mg tds

} \* 2 Aha

~~~~~  
Questions: -

- Review for correct inhaler usage , technique & need for cough mixture?
- Dosage & frequency adjustments → Nebs, Salbutamol & Budesonide?
- K<sup>+</sup> levels → Frusemide + HCT + Salbutamol
- Compromise of quality of care → drug related problems?
- Scope of practice of nurse practitioner → MO signing a transcription with pharmacist dispensing the Rx!

# Problem Rx – Referral

Transcribed from poorly compiled referral without necessary concise details.

27 Oct 2004 – 12 items

1. Diamicon 80mg tds
2. Glucophage 500mg tds
3. Ismo 20mg bd
4. TNT 1 prn
5. Aspirin ½ daily
6. Lasix 40mg bd
7. Slow K 1 bd
8. Enalapril 5mg tds
9. Zocor 10mg nocte
10. Tenormin 50mg bd
11. Dolorol F 1-2 prn
12. Fybogel 1 nocte

# Comments & Recommendation

- Areas of positiveness (knowledge of pharmacy manager & antibiotic usage!)
- Need to workshop STGs for improvement
- Self audits (facility & personal practices) → will spearhead success
- Liaison with all prescribers for change.
- Written evidence of the pharmacists' interventions is a legal requirement → need retrievable documentation for correlations & communication between the varying prescribers and pharmacists → holistic practices and care.

# Other Areas of Concern

- **Optimisation for Pt & prescriber: All Rxs → written & signed by prescriber → not within the scope of practice of nurse practitioner to write up script for doctor.**
- **Transcriptions: Need addressing for safety of pt. → correctness, legal cover of prescriber.**
- **Referrals: How should these be handled? Mere transcriptions without concise details → to enable checks and afford legal cover?**

# Follow-up after an Audit

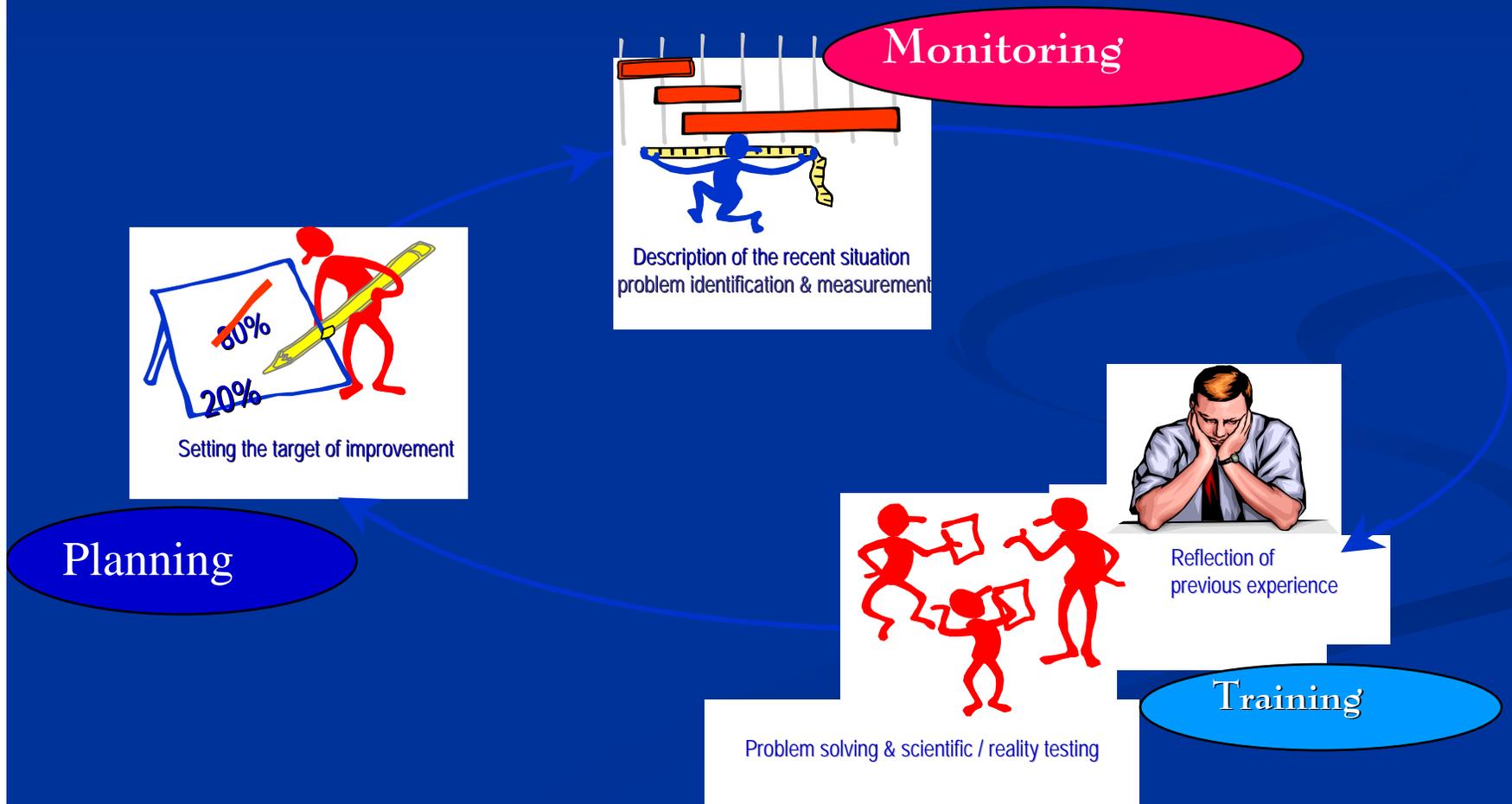
- Baseline can be followed up by post tests after reasonable period to allow for improvements ( $\pm$  6 months later)
- Facility: self audits enabling  $\rightarrow$  same tools



Advocate monitoring, training, and planning for continued success  $\rightarrow$  (MTP)  $\rightarrow$  in-house CE formats

# Continual "Monitoring, Training & Planning"

Can be self-initiated, self-planned, self-executed, and self-evaluated by the hospital team



# Recommendations for RDU

1. Rank or rate problems to prioritise corrections.
2. Which needs attention upfront or can problems be rectified concurrently?
  - Polypharmacy
  - Prescribing according to the EDP – STGs
  - Generic prescribing
  - Use of long acting Ca<sup>++</sup> channel blockers (Amlodipine 5mg) - HPT STGs
  - Antibiotic use – STG or injection use (diclophenac sod 75mg)

| <b>Criterion</b>              | <b>Poly-pharmacy</b> | <b>STG Adherence</b> | <b>Generic Prescribing</b> | <b>Antibiotic Use</b> |
|-------------------------------|----------------------|----------------------|----------------------------|-----------------------|
| <b>Scale of Problem</b>       |                      |                      |                            |                       |
| <b>Seriousness of effects</b> |                      |                      |                            |                       |
| <b>Costs</b>                  |                      |                      |                            |                       |
| <b>Appropriateness</b>        |                      |                      |                            |                       |
| <b>Total Rate or Rank</b>     |                      |                      |                            |                       |

# To Succeed: Need

- **An accountable management team to perform audits and feedback (to include antimicrobial resistance data – infection control)**
- **Motivated management and staff with commitment**

# Acknowledgements

- K Ramasir (District Pharmacy Manager): Piloting compliance tools in the UGU District, KZN.
- WHO Publication: "How to investigate drug use in health facilities"
- "Innovative Strategies to Improve Prescribing: The Pleasant Journey from Field-test to Institutional Program"; Dr Sri Suryawati; ICIUM 2004