How adoption of combination polypharmacy can impact national health systems

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TEPS: a randomized controlled Trial to assess Effectiveness of Polypill in Seychelles at PHC level (district health centers)

- Randomize all patients aged 45 & HBP to polycap FD vs. usual care
- 4 health centers, then all in country
- Outcome: control of risk factors

1. **Is polypill as effective as UC at PHC level ?** (mainly primary prevention)?
2. **Acceptability** by patients and doctors
3. **Directs costs** of polypill vs. UC (context of national HS)
4. Linkage with morbidity and mortality data)
5. Step to **further policy change in HS** (task shifting, etc)

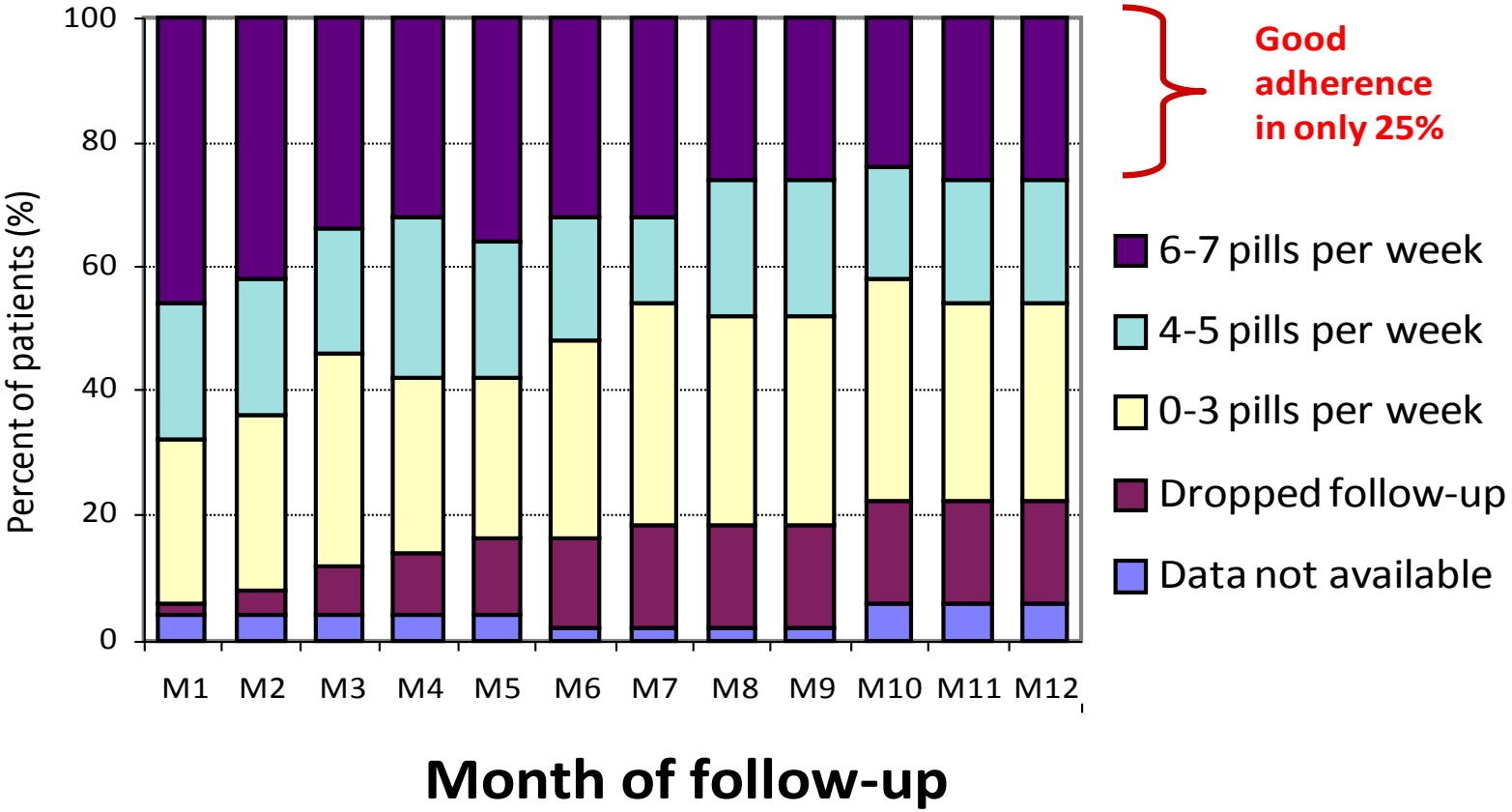
Health services in Seychelles

- Upper MIC (GDP ~8000$ per cap) – little international assistance - sustainability
- Expenditure for health: $370/capita (OOP is minimal)
- Free health care to all residents (national health system)
- Major medications given at PHC level (e.g. statin, CCB, ACEI, ARB, etc)
- Rx relies on doctors but “NCD nurses” have been trained
- Good information system (e.g. register of patients, vital statistics)

- ➢ Good situation for treatment of chronic conditions (among MICs)
- ➢ High expectation for health care by population and policy makers

Low adherence to a combination one-pill per day for HBP (MEMS)

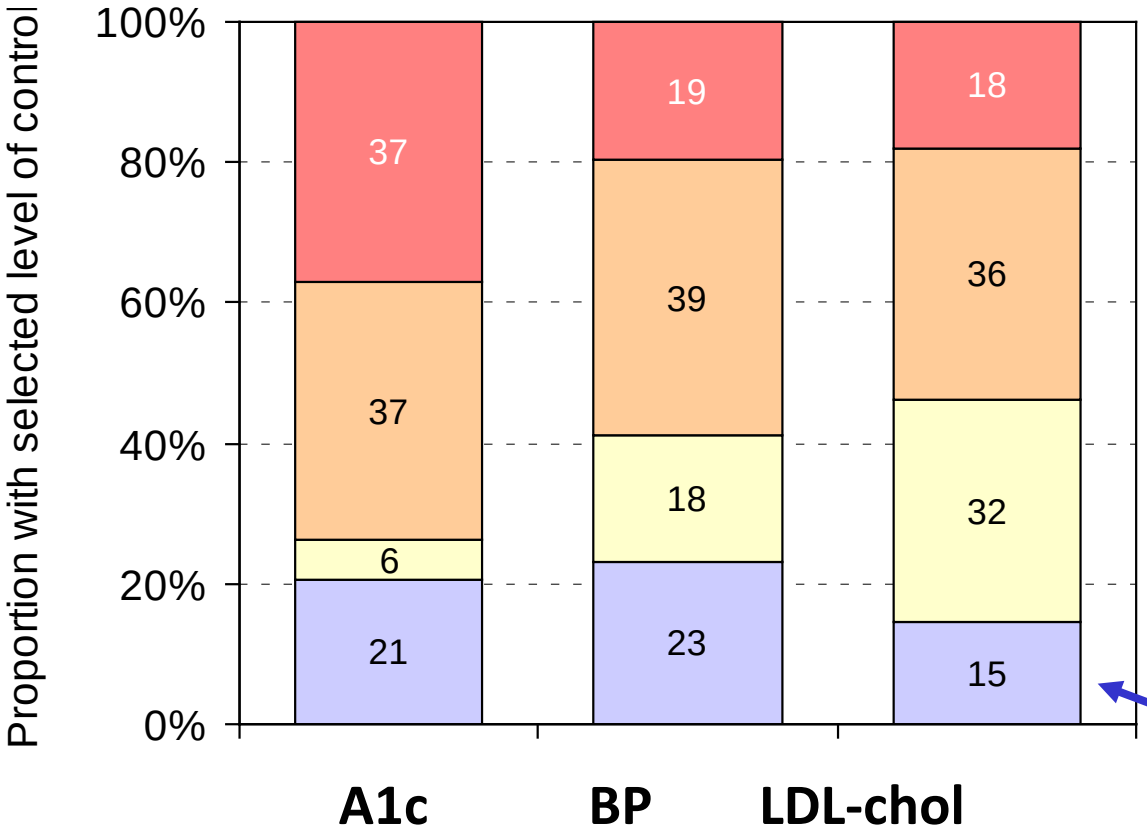
(despite free HC & adequate medications)



Bovet P et al. Monitoring one-year compliance to antihypertension medication in the Seychelles. Bull WHO 2002;80:33-9

Good control of glucose, BP or cholesterol in <25% of diabetic patients

(despite free health care and adequate medications)



Control level	A1c (gluc)	LDL-C	BP
Poor	10+	5+	160/100+
Weak	8-9.9	3.5-4.9	140-59/90-99
Borderline	7-7.9	2.6-3.4	130-9/80-9
Target	<7	<2.6	<130/80

Well controlled

Faeh D et al. Prevalence, awareness and control of diabetes in the Seychelles. *BMC Public Health* 2007;7:163(e).

Marked decrease in age-adjusted mortality of stroke and MI between 1989 and 2010: role of population strategies

Stringhini S et al. Declining stroke and myocardial infarction mortality between 1989 and 2010 in a country of the African region. *Stroke* 2012;43:2283-88.

Issues for implementing polypill in national health system (1)

National health system provides a favorable overall situation

- Low resistance from doctors (on fixed salary)
- Facilitated implementation of standard guidelines at country level
  - "Manual of procedures for PHC"
- Centralized health information system facilitates evaluation
  - Register of all patients at PHC, linkage with other data

Issues for implementing polypill in national health system (2)

Can polypill reduce expenditures? Improve cost effectiveness?

- Lower cost of polypill, simpler procurement, simpler health care
  - But difference in medication costs is small in Seychelles
  - Better adherence and better outcomes? “treat better for same cost” ?
- Task shifting (economic and organizational issues)
  - Many doctors are expatriates
  - “NCD nurses”
  - Need to define role and responsibility of different actors
  - Need for new national guidelines and training

Issues for implementing polypill in national health system (3)

High expectations for health care

- Currently adequate "individual" health care in PHC in Seychelles (~MICs)
  - All needed medications, Dr, lab, free health care
- Need to show that polypill is a technical advancement (not just a "good buy")
  - Political issue
- Need to convince patients/drs about benefit of "one fits all" vs. customized Rx
- Need to anticipate new optimal health care model in PHC

Issues for implementing polypill in national health system (4)

Need to make the case to government (≠ trial)

- Good scientific evidence
  - ± available
- Authoritative "global" policy recommendations for policy makers
  - WHO "best buy" for "multidrug therapy" is helpful, but vague
- **Technical guidelines of use of polypill** from credible agencies
  - Support for ethics/procurement/technical committees
    - Composition/dosage, indications, contraindications, collateral issues
  - Elaboration is beyond capacity of (small) country

Issues for implementing polypill in national health system (5)

How to define high risk patients?

- Apply medical high-risk strategy to the mass? beyond “health sector”?
  - Could reduce pressure on health services and have large benefit
- CVD risk prediction scores?
  - WHO Africa score = theoretical model, not validated
- Simple customized high risk algorithms ?
  - Seychelles - TEPS : age >45 & HBP

Some conclusions

- NHS provide optimal context for implementing polypill
- Good information systems is an asset for monitoring (registers PHC)
- Opportunity for task shifting but need to define new roles/responsabilities
- How to accommodate “one fits all” *vs.* tailored individual management in PHC?
- Need for technical documents to assist LMICs in making the case of polypill
- Pending issues: which risk approach? composition/dosage? Indications? etc

Thank you !

Recruitment from 4 district health centers in Mahe (pilot), later extended to all health centers in the country

Eligibility
- Age ≥45 years & SBP/DBP ≥140/90 or BP treatment
- Exclusion: renal/liver disease, acute gout, known intolerance to medication
- Informed consent

RANDOMIZATION

Switch to polypill
N=300

FU every 3 months up to 12 months

Baseline measurements
- Demographics
- Lifestyle behaviors
- BP & BMI, waist, glucose, lipids, creatinine, GGT, CK, SUA

Measurements and intervention
- BP, weight, risk behaviors,
- Waist, blood at 12 months
- Adherence to Rx, side effects
- Event reporting
- *Lifestyle counseling*

Continued usual care
N=300

FU every 3 months up to 12 months

Update list of all patients with HBP/DM in all health centers

Interim analysis at 12 months (non inferiority of polypill vs usual care)

Extention to other all heath centers and 12-months

Primary outcomes: **change from baseline in BP, lipids, and calculated CVD risk**

Secondary outcomes: **adherence, tolerance, costs (and hard CVD outcomes)**