HIV Treatment Optimization

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Bill & Melinda Gates Foundation HIV Strategy

- Vaccines
- ARV-Based Prevention
- Efficiency & Effectiveness (E2)
- Diagnostics
- Male circumcision
- Prevention Implementation
- TB - HIV
Effectiveness and efficiency portfolio

- Modeling
- Treatment Optimization
- Prevention Effectiveness
- Management
Treatment optimization

- Cost and Cost-Effectiveness Analyses
- Drug Optimization
- Laboratory Optimization
- Systems of Delivery
Treatment optimization

Cost and Cost-Effectiveness Analyses

Drug Optimization

Laboratory Optimization

Systems of Delivery

Facility costing; Cost utility and effectiveness to inform impact
Treatment optimization

- Cost and Cost-Effectiveness Analyses
- Drug Optimization
- Laboratory Optimization
- Systems of Delivery

Process chemistry;
Formulation chemistry;
Dose optimization;
Regimen optimization
Treatment optimization

- Cost and Cost-Effectiveness Analyses
- Drug Optimization
- Laboratory Optimization
- Systems of Delivery

POC diagnostics; Platform optimization; Monitoring and care algorithms
Treatment optimization

- Cost and Cost-Effectiveness Analyses
- Drug Optimization
- Laboratory Optimization
- Systems of Delivery

Decentralization; Integration; HR and task shifting; Management
Treatment optimization assumptions

- Flat funding for global HIV; huge unmet treatment needs

- Need to optimize within existing treatment dollars; do so while preserving quality of care

- Policy agnostic; develop evidence to inform policy

- But will not alone permit achievement of 15 x 15
  - In some cases will need to spend money to save money

- ARV pipeline is no longer robust

- No amount of treatment will obviate the need for primary prevention
Drug optimization

- Reduction of commodity costs – near-term approaches
  - Process chemistry (TDF, EFV, ATV, DRV)
  - Reformulation (TDF, ATV)
  - Dose optimization
    - Clinical studies
      ◊ ZDV – 200mg bd v. 300mg bd
      ◊ d4T – 20mg bd v. TDF
      ◊ EFV – 400mg qd v. 600mg qd
    - PK studies (completed)
      ◊ 3TC
      ◊ Lopinavir/ritonavir

- Paradigm approaches – medium/long-term approaches
  - Manufacturing – flow v. batch approaches
  - Clinical - induction – maintenance using long-acting injection products
Laboratory optimization

- Rapid tests – esp to gain insight into field-level performance
- CD4 (POC)
- Viral load (POC)
- Prequalification processes
- Platform technology approaches
- Paradigm approaches for clinical monitoring
Systems of care optimization

- Decentralization and integration
- Testing, linkage and retention in care strategies
- Task shifting strategies
Optimization to impact – understanding timeframes

- Beyond any area of treatment optimization is the understanding of the downstream processes that permit delivery and uptake – a global end-to-end approach is required.

- Normative agencies, funders and implementers will need to speed the process of evaluation to allow timely adoption of treatment optimized drugs, diagnostics or systems of delivery.

Treatment optimization end-to-end

- Completion of optimization effort: 6 - 48 mos
- Regulatory and/or normative approval: 6 - 18 mos
- Product/practice uptake and impact: 6 – 36 mos
Summary

- Need to define and realize optimization opportunities within existing treatment dollars – goal is to expand treatment rolls; but TO approaches alone will not be sufficient to achieve treatment goals.

- Apply modern biopharmaceutical approaches; leverage technology and maximize effective management and operational techniques.

- Remain policy agnostic - allow evidence to inform policy.

- Expand partnerships and approaches beyond ‘usual public health suspects’.

- We believe that this is work that the BMGF has both an opportunity and obligation to pursue.