

Rethinking Approaches to Expanded Access Programs: The Academic View

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Academic Medical Centers: Environment

HIV Medical Care

- Provides primary and specialty care to patients seen in the “teaching” affiliates
- Serves as a resource for the surrounding community
- Patient population
 - Presents with advanced disease
 - Substantial socio-economic challenges
 - Referred for management of complex medical problems

Academic Medical Centers: Environment

Research Culture

- Clinical research in general expected and strongly encouraged
- Funding in large part derived from extramural support
- Infrastructure supported by and charged proportionally to specific project
- Un or “under”-funded projects
 - Little institutional support
 - No base for effort reporting

Academic Medical Centers: Expanded Access Programs

Pros

- Expands scope of services provided to Center patients
- Provides resource to referral clinicians and surrounding community
- In sync with educational and training missions

Academic Medical Centers: Expanded Access Programs

Cons

- Negative financial impact
 - Scant to no compensation for implementation of expanded access program
 - Fixed costs (IRB fees, staff time, supplies, etc)
- Negative impact on training and research missions
 - Time drain
 - Little opportunity for meaningful career development