Expanded Access Programs

The Viewpoint from a Private Practice

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Dupont Circle Physicians Group

- Large private practice in Washington DC
  - 2 physicians, 1 PA, 1 NP
  - > 750 active HIV patients
    - mostly gay men
  - Also do general internal medicine
- "Academic" atmosphere
  - Full time research coordinator
  - Multiple "pharma" protocols
  - *HOPS* database site

EAP's at DCPG

- Have participated in every EAP
  - from ddI (1989)
  - to Tipranavir (2004)
- Frequently very high enrolling
  - 50 - >100 patients enrolled in some programs

Abacavir EAP

Abacavir EAP

68 CRF Binders

Efavirenz and Adefovir binders stored elsewhere in the office

Why do we participate in EAP's?

- "Expanded access mechanisms are designed to make promising products available as early in the drug evaluation process as possible to patients without therapeutic options, either because they have exhausted or are intolerant of approved therapies".[1]

1. FDA Website

Why do we participate in EAP's?

- In the history of HIV treatment, many patients have exhausted their therapeutic options and have desperately needed new treatment options.
  - Many patients in my practice owe their lives to EAP's
  - These patients are less common and less desperate today, but they still exist
- Toxicity is overlooked as a reason for needing EAP drugs

Additional Advantages of EAP's

- Gives us experience with new agents
  - Increased use immediately after approval
- Gives manufacturer experience and safety data with new agent
  - Increased toxicity with no clinical benefit of 40 mg d4T (vs 20 mg) identified in EAP program

Problems with EAP's…

Complexity:

- In the past:
  - Eligibility was simple: investigator simply verified that patient was "failing or intolerant of currently available agents"
  - Paperwork was simple:
    - d4T required 3 check marks and 5 lab values
  - Programs could be administered by office staff

Problems with EAP's…

- Today:
  - Stringent inclusion/exclusion criteria
  - Data entry complicated
    - Electronic CRF's
    - Queries!
    - Administered like a protocol
  - Requires trained research staff
  - Programs with limited sites require accepting "outside" patients
    - Problems with treatment history, compliance, etc.
  - Concurrent programs are a significant drain on resources
    - MK-0518, Maraviroc, TMC-125
    - But: multiple new agents are advantageous

In the future…

- EAP's will continue to be advantageous to patients
- Providing access to drugs should be bureaucratically simple
  - Any practitioner should be able to participate
- "Safety data" protocols should be run as protocols
  - Example: "POWER 3"
  - Re-imbursement to sites