

Post-Exposure Chemoprophylaxis (PEP) for Bioterrorism-Related Anthrax: Adherence and Adverse Events

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Anthrax Post -Exposure Chemoprophylaxis(PEP)

- About 10,000 individuals offered 60 days PEP
- Initiated October 8 – November 25, 2001
- 6 sites (FL, DC -postal, DC -Capitol, NJ, NY, CT)
- Primarily occupational exposure (AMT employees, postal workers, congressional staffers)

Outline of PEP

- Denominators and demographics
- Adherence promotion
- Adherence monitoring
- Adverse events monitoring

PEP Denominators

	Recommended	Potentially higherrisk
FL	1149	369
NJ	1529	1529
DC-postal	2510	2510
DC-CapitolHill	1200	75
NY	3714	1200
CT	1200	pending

PEP Demographics

	FL (n=435)	NJ (n=437)	DC- postal (n=1234)	DC- Capitol (n=171)	NY (n=3714)
Male	53%	66%	57%	61%	57%
For women, pregnant	1%	1%	1%	0%	1%
Black	n/a	27%	74%	10%	n/a
Age <18yrs	5%	1%	3%	1%	1%
18-64yrs	90%	94%	84%	95%	86%
≥65yrs	3%	5%	2%	0%	3%

Adherence Promotion Activities

- Distribution of educational materials
- Telephone calls to individuals who did not return for refill medications
- Small group and focus group meetings
- Health fairs
- Individual counseling

PEP Adherence Monitoring Methods

- Counting individuals returning for refills
- Cross-sectional evaluations
 - 7-14 days and 30 days
 - Standardized questionnaires
 - Self-, nurse -, or telephone -administered
 - Participation 50 -100%
 - Data collection and analysis ongoing

PEP Adherence Currently Taking Antibiotics

	10-14d	30d
FL(n=1000,435)	70%	45%*
NJ(n=1529)	74%	67%
DC-postal(n=2437,1347)	98%	88%
DC-Capitol Hill(n=369)	--	88%^
NY(n=1786)	48%	40%

*Adherence among high risk group=70%

^Of 38 of 39 Daschle workers for whom information is available, all report taking PEP



30-day Adherence Evaluation NJ and DC -Postal

	NJ (n=980)	DC- postal (n=1347)
Currently taking antibiotics	88%	88%
Took all antibiotics yesterday	78%	70%
Taking antibiotic everyday	70%	61%

30-day Evaluation, NJ and DC -Postal, Ciprofloxacin vs Doxycycline

	Ciprofloxacin (n=157)	Doxycycline (n=1722)
Took all antibiotics yesterday	74%	75%
Took all antibiotics day before yesterday	74%	75%
Taking antibiotic everyday	68%	65%

PEP Adverse Events Monitoring Methods

- **Passive surveillance**
- **Active surveillance**
 - 7 – 14 day and 30 day evaluations
 - Screening questionnaire
 - All potentially severe event evaluated
 - **patient and healthcare provider interviews**
 - **medical chart review**
 - **categorized by FDA criteria**

PEP Adverse Events, Self-reported, 10 -14 days, All Sites

	Ciprofloxacin (n=3856)	Doxycycline (n=232)
Severe gastrointestinal symptoms	19%	13%
Fainting, light-headedness, dizziness	13%	7%
Heartburn or acid reflux	6%	8%
Rash, hives, itchy skin	6%	5%
Required follow-up for adverse events	2%	5%
Required hospitalization	0	0
Discontinued antibiotics because of adverse events	3%	3%

PEP Adverse Events, Self-reported, 30 days

	Ciprofloxacin (n=668)	Doxycycline (n=1876)
Severe gastrointestinal symptoms	33%	45%
Fainting, light-headedness, dizziness	21%	18%
Heartburn or acid reflux	12%	13%
Rash, hives, itchy skin	14%	14%
Required follow-up for adverse events	13%	12%
Required hospitalization	pending	pending
Missed doses or discontinued antibiotics because of side effects	6%	12%

Future Plans

- End of therapy/60 day program evaluation
 - Adherence and adverse events assessed
- Adherence promotion activities and evaluation
- Surveillance for anthrax and adverse events associated with PEP among all exposed groups