

Results from the ASHP Gene Therapy Survey

Susan Goodin, Pharm.D., FCCP, BCOP Associate Director, Clinical Trials and Therapeutics The Cancer Institute of New Jersey Professor of Medicine UMDNJ-Robert Wood Johnson Medical School

Survey Methods

- Administered via email invitation, linking participants to an online survey instrument
- Sent to 3,543 members recorded in by ASHP as Pharmacy Directors
- Launched November 19, 2008; closed
 December 5, 2008 (one reminder)
- 327 responses; 9% response rate
- Margin of error is <u>+</u> 5% at the 95%
 confidence level



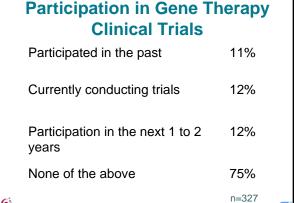
Respondent Characteristics

- Majority (73%) were Pharmacy Directors at institutions caring for both adult and pediatric patients (77%)
- Community Hospitals represented 58% of respondents; university hospitals represented 11%
- Size (# of beds) of the institution varied: 400 + (25%), 300-399 (10%), 200-299 (16%), 100-199 (16%), does not apply (10%)

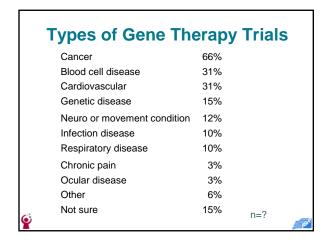


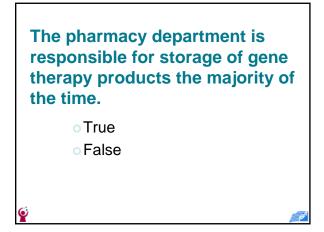
Gene Therapy Trials are not infrequent and not increasing?

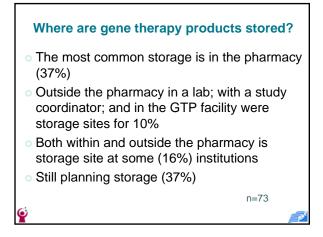
- True
- False

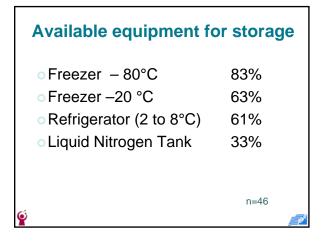


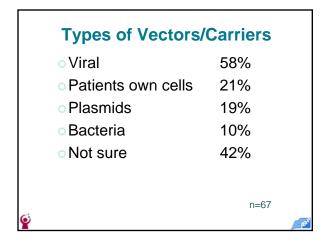
Estimate	of Gene Th	nerapy Trials	
Trials	Past 18 months	Next 1 to 2 years	
None	42%	11%	
1-3	36%	44%	
4-6	7%	13%	
7-10	3%	4%	
11 or more	3%	7%	
Not Sure	9%	21%	
 Responses	67	71	
		Í	P







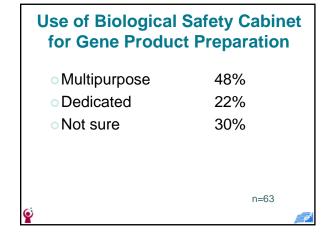




Pharmacy Involve	ement
IRB process	75%
Product storage	64%
Product Preparation	65%
Product Disposal/Return	55%
Patient education	22%
Protocol development	30%
Other	13%
None	6%
~	

Most pharmacy departments participating in gene therapy trials have dedicated biologic safety cabinets for preparation.

- True
- False



Pharmacy Department

	Yes	No
Provides staff training on gene therapy (n=62)	40%	60%
Has gene therapy policies and procedures (n=63)	33%	67%
Is planning to develop policies and procedures within the next 12-24 months (n=41)	63%	37%

Who prepares gene therapy?

- Staff with specific training48%
- Any staff with hazardous training 25%
- o IDS pharmacist
- Not sure 22%

n=60

5%

Challenges preventing participation in gene therapy trials

- Lack of training and staff education
- Lack of personnel
- Lack of capital equipment
- Lack of policies and procedures
- Staff fear of handling gene therapy

n=290

ASHP Gene Therapy Survey Conclusions

- Participation in gene therapy trials is increasing
- Cancer, blood diseases, and cardiovascular disease are the most common areas of gene therapy research reported at responding institutions
- Storage of gene therapy products frequently occurs in the pharmacy and most have appropriate equipment
- Staff training and policies are lacking related to gene therapy
- Patient education is not a frequent role for the
 pharmacy department in gene therapy clinical trials