



*Patient Notification and
Assessment of Patient Willingness To
Be Contacted About Participation in
Research*

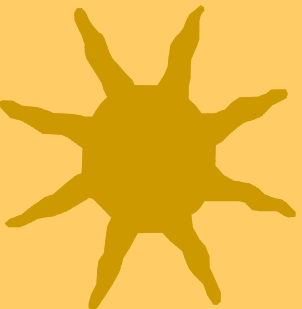
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Presentation Objectives



★ History and intention of Patient Notification Law

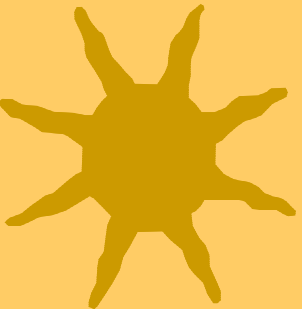


★ Registry implementation

★ Patient responses

– Descriptive statistics

– Anecdotes



★ Stumbling blocks



OSCaR



★ Created 1995

★ Reference date January 1, 1996

★ NAACCR Certified

– Every year of complete data

★ 19,000+ cases annually

★ 10 FTE

★ Patient Notification

– Legal requirement





Registry Purpose

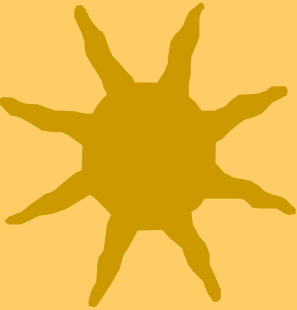


“ The reason for collecting, analyzing, and disseminating information on a disease is to control that disease. Collection and analysis should not be allowed to consume resources if action does not follow.”

– Foege, Hoga, Newton, *IJE*, 1976;5:29-37



Patient Notification



- ★ Legal requirement

- Oregon Administrative Rule 333-010-0035

- ★ Notify patient of inclusion in central registry

- Time requirements (one month)
- Responsibility (OSCaR)



- ★ Patient “Right to Know”

- Patient letter
- Purpose of Registry
- Confidentiality protection





Patient Notification Letter



★ Letter Content

- Purpose of a state-wide cancer registry
- Personal identifiers and cancer characteristics have been reported
- Confidentiality protections
- Additional enclosures
 - OSCaR Brochure, ACS Brochure



★ Research Preference Reply Form

- Indicate preference for researcher contact





Patient Notification



- ★ Research contact preference
 - Patient control over healthcare decisions
 - Advocated by breast ca survivor group
 - Breast cancer survivors
- ★ Research requiring patient consent
 - Public health authority is exempt
 - Research without patient contact is exempt
- ★ “Preconsent”



Research Reply Form



- ★ Direct
 - Contact patient directly



- ★ No Contact
 - No participation



- ★ Physician
 - Contact patient after first consulting with physician
- ★ **Does not** supercede patient consent for individual studies

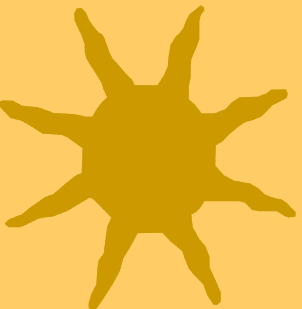


Process/Procedures



★ Monthly activity

- Selection
 - Exclude minors, deceased, federal hospital
 - Include on Oregon residents
- Performed after linking with state death records
 - Automated program
- Letter generation
- Returned letters investigated for good address



★ Patient Response

- Reply forms (mail, fax, email), phone calls
- “Talking Points”



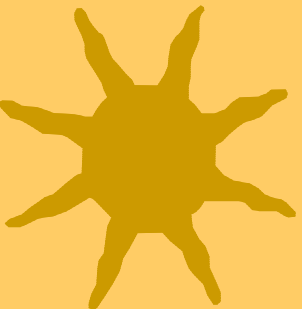


Resources



★ Personnel (approx 370 staff hours annually)

- Generating letters
 - Includes death linkage
- Handling responses
- Managerial support
- **\$10,000+ annual cost**



★ Printing/Postage

- **\$15,000+ annual cost**
 - Postage (Outgoing letters and incoming Reply Forms)
 - Materials



★ Minimum \$25,000 a year



Patients Who Respond



★ Patient Notification

- Why?
- Confidentiality
- Deceased, Moved
- Legal Action
- Physician never disclosed cancer status



★ Research Contact Options

- Confusion with form
- Why type of research?





Attitudes by Response



★ Direct



★ No Contact

– Disabled

- Cancer related

- Age related

– Very Upset/Angry 10-15 per year



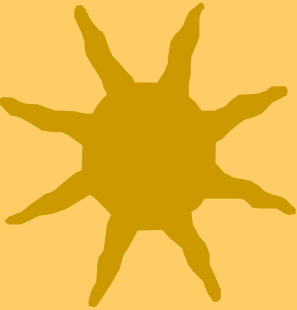
★ Physician

– Update contact info

– Update MD info



Responses



1996

- ★ Letters Sent
 - 9,500
- ★ Responded
 - 30%
- ★ Contact Directly
 - 25%
- ★ Never Contact
 - 5%
- ★ Returned by Post Office
 - 8%



2002

- ★ Letters Sent
 - 14,397
- ★ Responded
 - 40%
- ★ Contact Directly
 - 22%
- ★ Never Contact
 - 7%
- ★ Returned by Post Office
 - 2% (<1% after manual review in DMV)





Responses by Demographics



★ Sex

- More women Direct Contact
- More men Never Contact



★ Age

- Responses increase with age
- No contact increases with age



★ Race

- More Whites responded
- Fewer African Americans responded
- American Indians want Direct Contact
- Asian/PI want No Contact

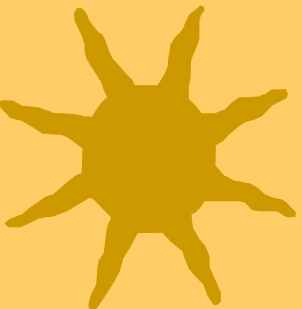


Responses by Cancer Characteristics



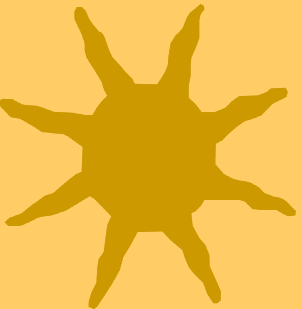
★ Stage

- Early stage more responses
- Early stage more Direct Contact



★ Site

- M/I dependant
 - Melanomas most response and direct contact
 - Pancreas least response and no contact





Customer Service Challenges



★ Timing

- Holidays, deceased



★ Clarity of materials

★ Inconsistent response from Registry personnel

- Telephone Talking Points



★ Confidentiality

- Regular mail
- Patient access to information



Operational Challenges



★ Priority Changes

- Retroactive notification
- Patient intent
- Research usability
 - Physician identifiers
 - Current address



★ Process changes

- Software
- Personnel
 - Manual to automated
 - Documentation





Future Focus



★ Responsibility

- Who pays?
- Notify by Physician/Hospital?
 - Roll into hospital HIPAA implementation?



★ Public Opinion

- Public Health
- Other disease reporting
- Cancer research





Contact Information



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