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
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.”

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 cancer 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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