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Dissemination of Research Results

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DISSEMINATION OF RESEARCH RESULTS

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Case 1:

- 10 year old, ongoing study of Hirschsprung Disease
- Family history, Medical questionnaire, and DNA samples
- 5 years ago, new evidence showed Hirschsprung Disease associated with second mutation RET gene, which causes a highly penetrant, dominant, adult-onset thyroid cancer.
  - No therapy, but prophylactic thyroidectomy often recommended
- Your study starts screening participant DNA for RET mutation as well.
- You find two participants with RET mutation, one a minor (one year old girl) and another a 35-year old man.
  - What are the considerations?
  - What are your options?
  - Should you return these results?
Case 2

- Jane is 33 years old, accountant, mother of two.
- Presented to doctor with breast mass and no family history
- Tests show metastasized cancer
- She was in a study at age 14 for Hodgkin’s disease and received experimental radiation therapy.
- Long-term follow-up showed 30-fold increase in breast carcinoma for those who received experimental radiation therapy and suggests regular mammography for women 8-10 years after this treatment.
- Jane didn’t know this and is very upset.
- What could/should have been done?
- What could/should be done now?
Difference between two cases?

• Individual vs. aggregate results
• Actionable vs. unactionable results
• Adult vs. minor
• Reliability of results
• Feasibility of action
• Others?
Research results are “public”. How?

• Published in journals
• Clinicaltrials.gov
• Academic conferences
• CME to health professionals
• Lay media (sometimes)
But what about the actual participants?
Why? [Ethically speaking]

• Respect for persons
• Beneficence
• Justice
Respect for persons

• Most people want it
  • Review of studies by Shalowitz and Miller (2008) found a median of 90% of people wanted either individual or aggregate results (more than half were involved in cancer or genetic studies)
Beneficence

• Individual
  • “You may get better, stay the same, or get worse from being in this study.”
  • “You have little to no chance of benefit from being in this study.”

• Society
  • Generalizable knowledge
  • Future medical advances
Beneficence of returning results

- Objective criteria usually used
  - Analytic validity
  - Clinical validity
  - Clinical utility
- But also, subjectively helpful
  - Behavior change
  - Life planning
  - Reproductive planning
  - Etc.
Is there a third type of benefit?

- Disseminating aggregate results to participant community.
- What good could this do?
  - Health benefits (like Jane)
  - Feelings of self-worth
  - Comfort from loss (family of lost Phase I oncology participants)
  - Avoid anger at learning results from media as opposed to medical providers (Goodare 1995, Rich 1999)
Other benefits (besides ethics)?

- Facilitating communication between clinicians and patients
- Increase satisfaction with study participation → more study participation
- Increase health and research literacy
Potential harms

• Cost
• Time
• Lack of expertise (participants misunderstand and misuse information)
• Causing distress (if study didn’t yield positive results, or found out afterwards in an inferior treatment group)
• Compromising future follow-ups
Best practices (When and how)
Timing

• Choices:
  • Results-to-date
  • At time active participation ends
  • At time of publication

• Best option: Time of publication
  • Least likely to lead to confusion or misunderstanding
  • Least economically and administratively burdensome
  • BUT: also a good idea to give updates of trial progress if time lag is long.
Method

• Options
  • Given by research team, face-to-face
  • Given by clinicians, face-to-face
  • Group meeting
  • Mailed
  • Emailed
  • Letter notifying results are available, directed to call if they want results
  • Letter notifying results are available, given link to web address
  • Others?

• Best option
  • Depends on particular situation and resources, but. . .
Some lessons...

• Incorporate plan into trial design
• Being directed to web or telephone solves the problem of consent
• Internet, although not always preferred by patients, has been shown to increase uptake
• Negative aggregate results have been well-received as well as positive
• Negative individual results should be given in person
• Information about inferior treatments should be given in person
• Just before or simultaneous with media
Cases revisited. . .

- What should we do about Hirschsprung Disease study?
- What should we do about Jane?
Thank you.