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Anne Cambon Thomsen: "The experiences and views of health care professionals, researchers and patient associations regarding information and feedback of results in the context of next generation sequencing in oncology"



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THE EXPERIENCES AND VIEWS OF HEALTH CARE PROFESSIONALS, RESEARCHERS AND PATIENT REPRESENTATIVES REGARDING THE FEEDBACK OF RESULTS IN THE CONTEXT OF NEXT GENERATION SEQUENCING IN ONCOLOGY



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Context

- European projects, ELSI WP
- Targeted therapy in Renal cell cancer: GENetic and Tumour related biomarkers for response and toxicity"
- genomic approaches to identify biomarkers of most common form of clear-cell renal carcinoma, the most common form of renal cell cancer (RCC)



What and Why?

A- Quantitative Questionnaire Study with “experts”

B- Qualitative Interview Study with patient representatives and experts

Provide empirical data of experiences and values to enlighten the preparation of recommendations and guidelines.

A- METHODS

Questionnaire distributed at 3 scientific meetings:

1- Workshop genomic epidemiology and P3G Privacy Summit on Data Sharing & Cloud Computing, Paris, May 2013

2- ESHG, Paris, France, June 2013

3- Eurotarget annual meeting, Reykjavik, Sept. 2013

METHODS

10 questions: mostly closed-ended, request for comments

- 5 basic info
- **Use of NGS in work**
- **Information given with NGS**
- **Special Measures/limitations** for sharing NGS data
- **requests** for NGS/omics results
- **return of results** NGS/omics
- Return of **IF**

B- INTERVIEW STUDY

9 Semi-structured interviews

- experts and patient representatives, oncology

Main focus was NGS and return of results:

1. provision of information at the informed consent step
2. communication of research results to participants
3. disclosure of Incidental findings,
4. sharing of data and findings with the research community.

RESULTS

n = 95 (77-93)

Characteristics	Data % (n)
Main professional activities (could choose more than 1)	Research = 62% (58) Clinical = 55% (51) Administrative = 5% (5) Other = 5% (5)
Female	57% (51)
Average Age	41 (max 68, min 20)
Does work activity relate to oncology?	Yes = 88% (81)
Is NGS used in some aspect of their work?	Yes = 52% (47)

Countries represented



Information given in NGS

Question	% (n)
If you collect or work with human samples, is specific information about NGS provided to participants?	Yes = 56% (45) No= 38% (31) NA = 6 (5)

Qualitative input

1. provision of information at the informed consent step

e- extra information, time, cost

pr- Lack of understanding, debatable how much they want to know, more info about NGS

Special measures or limitations for sharing NGS data?

Do you think specific measures/limitations should apply for sharing NGS results with colleagues from the scientific community as compared to other research results?

- Yes = 53% (45)
- No = 39% (33)
- No opinion= 8% (7)

Qualitative input

2. sharing of data and findings with the research community.

e- responsibilities, not with commercial inst.,
protected access

pr- important, efficient, max use

Few Requests for results

Question	% (n)
Have you received requests from research PARTICIPANTS or PATIENTS about interpretation of NGS data related to health or medical conditions?	Yes: 13% (11)
Have you received requests from PHYSICIANS or patients for access to NGS data to INFORM TREATMENT DECISIONS ?	Yes: 17% (14)

Yes to Feedback of individual Research Results

Do you think results of NGS research studies should be provided to individual participants?

Yes = 54% (47)

No = 29% (25)

No opinion = 17% (15)

No dif. Clinician/researcher

Feedback of Research Results

CONSENT

“if requested by participant”

“depends on informed consent”

“patients must have consented to being informed.”

VALIDATION

“Must be validated by diagnostic lab”

“If confirmed by Sanger Sequencing”

Feedback of Research Results

USE/ACTIONABLE

“if clinically applicable”

“focused on results with clinical value”

“I think only results with direct clinical impact on the patient should be provided, and this should only cover information whose pathological significance is well-established”

Qualitative input

communication of research results to participants

pr: always aggregated vs indiv., rights to results,
TIME to discuss

Disclosure of Incidental Findings

Do you think clinically actionable incidental findings (unexpected findings discovered during research but beyond the aims of the study) should be disclosed to research participants?

Yes = 72% (62)

No = 20% (17)

No opinion = 8% (7)

No dif. Clinician/researcher

Disclosure of Incidental Findings

CONSENT

“if the patient wants it”

“at request only”

“Depends what has been agreed on with patient”

USE, Consequence

“it depends on positive effect to disclose it (treatment ...)”

Disclosure of Incidental Findings

COMPLEXITY, need for guidance

“Detection of incidental findings is not trivial and automated (yet). Do researchers have an obligation to screen for such findings? ACMG has published a list of genes that must be checked. Without such list the obligation could be extended to all relevant genes. Too much!”

Qualitative input

disclosure of Incidental findings,

e- informed consent, use, affects family members

pr- use, utility for patient, explain before and let patient choose

Discussion- Questionnaire

IF results are on the low end of spectrum in the literature

80% Hays et al. 2011, 97% Strong et al. 2014, 96% Lemke et al. 2013, 95% Klitzman et al. 2013

Small n, specific population

Perhaps oncology specific? Hays et al.: judgments about IF can be influenced by the researcher's disease community (autism, CF)

Define your terms, still some confusion here that makes comparisons between studies difficult.

- Downing et al. 2013 inconsistent definition of IF,
- Parens et al. 2013

Discussion-- General

Discussion-- General

Surveys/questionnaires = engagement light

Interviews are more in depth but difficult to present in
biomedicine

Short questionnaire requested at meetings worked relatively
well.

Awareness of our work

Reflect on their work and the topic at hand

Received a lot of comments

What to do with results beyond a publication???

THANK YOU!

Thank you to those who took the time to fill out our questionnaire

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