ICPerMed
INTERNATIONAL CONSORTIUM

Which are the Ethical, Legal and Social Implications (ELSI) of Personalised Medicine (PM) research and implementation?

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Three questions to debate in this working group

- **1. The handling of incidental/ additional findings originating from molecular analysis.**
- **2. Informing the patient adequately; the issue of the tension between data-provision and the protection of a person's privacy.**
- **3. Tension between principles of evidence-based medicine and fast translation.**

Level of Recommendation

I. Researchers / PI s in PM projects

II. Researchers on Implementation / Health Service Research

III. Health Sytems / Authorities / Funders

1. The handling of incidental/ additional findings originating from molecular analysis.

Consensus

1. Harmonize and clarify the definition of IF (Level I, II, III)
2. There should be a policy in place that speaks to incidental findings and included in IC documents with criteria to report (Level I and III)
3. The option not to receive IF should be guaranteed (Level I and II)
4. The policy should include a process of return (e.g. validation, communication via MD, pre-test and post-test counselling)
5. A blanket no return policy might interfere with the participants right to access their data (I ,II)
6. Context specific policies are needed: Children, newborn, relatives affected by genetic results, impaired adults , vulnerable populations and persons
7. Returning results needs resources – return of results should be integrated in cost calculations

1. The handling of incidental/ additional findings originating from molecular analysis.

Additional Research needed

1. Research on what kind of return categories are meaningful (Level II)
2. Research on the long term effects of returning IF of different categories (certain, uncertain significance) Level II
3. Implementation Research on positive gene lists (eg ACMG List) (Level II)
4. Conceptual research on context specific policies
5. Collect Experiences with the handling of incidental findings through
   - Additional requirements by ethics review boards and funding agencies
   - cases of incidental findings that were not reported and than a law cases filed
   - cases of incidental findings with benefit to the individual
2. Data on follow up costs (For informing patients / follow up diagnostics / benefits)

2. Informing the patient adequately; the issue of the tension between data-provision and the protection of a person's privacy.

Consensus:

1. Information needs to include: benefits (individual or collective), privacy, risk (level I)
2. Information process should make research transparent, in a respectful manner to the needs of participants and should be offered on a continual basis (I and II)
3. Getting patients/ participants involved in designing consent forms and information
4. Organizing information at group and population level
5. Multistate research should account in advance for different information requirements in different countries (level I)
6. Social debate and deliberation about the legitimacy of massive data collection and processing for PM
7. Establish guidelines for participation of persons with impaired decision making capacity

2. Informing the patient adequately; the issue of the tension between data-provision and the protection of a person's privacy.

More research needed :

1. **Including participants in designing information and consents**
2. **Including participants with impaired decision making capacity**
3. **Collect Experiences with different consent models**
4. **Collective discussion and deliberation on massive data processing/collection**
5. **Influences on participant expectations on PM (direct to consumer, media)**

3. Tension between principles of evidence-based medicine and fast translation.

Consensus

Since, in PM we treat patients without robust evidence for efficacy → risk for side effects/ costs

1. **Collect real world evidence about benefit/ risks and access (Level II,III)**
   - **Needs adequate data collection (in a way to be evaluated)**
   - **Data collection interoperable across countries and regions (FAIR principles)**
2. **Guidelines for validation and quality control of new diagnostic tools (eg IVD Regulation Requirements)**
3. **Guidelines on the declaration on conflicts of interest**