**Lay comments on subject of Feedback of Incidental Findings**

These generally fitted with two quotes from the Special Article from Genetics in Medicine

**1) Kohane et al 2007**

Offering discoveries back to individual research participants allows them to be "partners in research rather than passive, disenfranchised purveyors of biomaterials and data"

**2) CIOMS 1990's**

International Ethical Guidelines for biomedical research involving human subjects has provided that "individual subjects will be informed of any finding that relates to their particular health status"

The report from the Wellcome Trust has now been published and this showed overwhelming interest in feedback of incidental findings.

Most of ICPV members who responded to my request for comments felt it was their right to be offered feedback and ethically wrong to withhold this. This was not a decision which researchers should be taking on their behalf – this was seen as patronising or paternalistic.

However, the majority qualified this by saying that some advice/counselling would be needed alongside receiving the findings - together with appropriate referral for further investigations and/or treatment. Some said they were not so sure that they would want to know they were at high risk of developing dementia but others said this would be important to enable them to make proper provision whilst they were able to do this effectively.

**COMMENTS RECEIVED**

- Research participants should be given option to receive feedback
- All knowledge should be disclosed – even if possibility of serious condition is found – because it may give opportunity to adapt life style to mitigate effects of condition or, to have more frequent screening/check-ups as well as raising self-awareness.
- Disclosure of genetic conditions could help prevent or reduce incidence in future generations – Maybe this should overcome an opt-out choice re receipt of information.
- Conditions which lead to decreased quality of life – knowledge enables forward planning for likely needs eg bringing forward plans for activities which may become impossible later.
- We need dialogue and maybe legislation re insurance companies and employment
- Discrepant diagnoses and pathological findings must be disclosed as they may indicate need to change treatment – may be legal issues?
- GP must be informed – Follow-up, referral, monitoring, treating etc.

- Treatments may need to be changed, further investigations may be needed, it may impact on current treatments for known diagnosis.
- There is real need for some "joined up thinking" in this area. It is a difficult topic for all concerned and donors of tissue/blood will need counselling to ensure they are prepared for results.
- There is a cost implication – the extra time needed will add to costs of research but may also cause delay in research.
- If I am taking part in your research by donating tissue then I am entitled to be informed of any findings which could have implications for me or for my family.
- It could be devastating news
- It has knock-on implications for wider family – who informs them and how do we ensure the accuracy of information which is passed on? Who refers other members of family for testing – and where to?
- I don't think "Joe Public" really understands the implications of disclosure of incidental findings – but I still think they have the right to decide for themselves if they wish to receive any findings.
- Much more publicity is needed – it would increase public knowledge but also raise awareness of the need for donated tissues.
- Intellectual understanding is not enough – people need to be able to cope with all the implications for them and for their families.
- What about those whose lower ability to comprehend the information will require much more time and skill? They should still have the right to decide.

**Further Comments by Maggie Wilcox**

**1. UK Biobank**

Started in 2007 with target of 500,000 – reached halfway stage by 2009. It will be amazing facility for Health Research.

1 in 10 people invited accepted the invitation – this is good but it means 9 in 10 did not take part. It would be good to explore why?

Good that there is a requirement for researchers to share their findings for public benefit.

The provisional time and date for the assessment appointment which can be changed means that this is not coercive and people can make contact with queries before making decision.

There is insufficient real PPI at all levels and not enough interest/skill in meeting requests for information about PPI in the organisation. The interest only extends to participation in terms of donating.

**2. Wellcome Trust Report**

Overwhelming support for feedback of health related findings to research participants – particularly when serious and treatable.

Consent process viewed as critical – particularly for potential participants to receive information on health related findings before agreeing to take part.

Respondents valued the role of Health Professionals, or those with whom they had an existing relationship, in the feedback process and it was seen as important that those receiving feedback have sufficient information and access to follow-up.

Study showed public understanding is weak - this needs attention before the policy on feedback is changed? Further research is needed – eg whether more detailed examination of potential harms / disadvantages of feedback has impact on attitudes.
Those affected by medical conditions had more advanced understanding of research and what it involved. Also, their motivation is less individualistic and more focused on contributing to scientific advances.
General perception was that the benefits outweighed the harms, not only to individual but also to family. This perception was not altered by consideration and further information on the potential harms and benefits.
Clinical relevance and accuracy of findings are complex and play a large part in the disadvantages of providing feedback and participants found these difficult to understand.
Discussion about receiving feedback should be part of the consent process and it is essential that it is presented in language and manner to ensure understanding.
80% thought they should be given choice – need to ensure we protect the rights of the 20% not to receive feedback?
Most felt that it may be acceptable to override individual choice not to receive feedback eg if condition could impact on others.
There was preference for face-to-face receipt of feedback from person with medical knowledge and expertise with appropriate follow-up.
Those participating in this survey must have had some interest but even in this group there was poor understanding of medical research and who conducted it. There was also poor understanding of risk.
Those who saw the advantages as outweighing the disadvantages were slightly higher in those who had participated in research and this applied in those with children compared to those without.

The greatest divergence was where the condition was severe but not treatable or manageable.

**Maggie Wilcox, ICPV, July 2012**