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ICO request for information on profiling and automated decision-making: response from PHG Foundation

PHG Foundation consider it possible in the next few years that healthcare and public health programmes could utilise profiling and automated decision-making for various applications, particularly in the context of personalised prevention.

The PHG Foundation is a non-profit health policy think tank. We work to achieve the prompt, effective and responsible application of biomedical and digital technologies within health systems

When, how and why does your organisation carry out profiling? Do you agree that there has to be a predictive element, or some degree of inference for the processing to be considered profiling?

As a health policy think tank our organisation does not, itself, carry out profiling but we were involved in a multi-centre EU project funded by Horizon 2020, that explored ethical, legal and regulatory issues arising from risk stratification, and in particular, the impacts of including genetic and genomic data in risk stratification tools for detecting various cancers (Collaborative Oncological Gene-Environment Study COGS at www.cogseu.org). These tools are becoming more widely used in public health settings, and within the next few years we consider it possible that healthcare and public health programmes could utilise profiling and automated decision-making for various applications, particularly in the context of personalised prevention.

We envisage that depending on context and application, carrying out risk stratification on an automated basis might be justified on the basis of public interest.

On a population level, personalised prevention is likely to involve stratifying 'at-risk' populations using multiple sources of data, to identify sub-populations at different levels of risk who can be offered tailored interventions. Whilst risk-stratification has been an established part of public health practice for many years, the prospect of carrying out such risk-stratification on an automated basis is novel. Yet such an approach could have considerable health benefits. We envisage that depending on context and application, such an activity might be justified on the basis of public interest. A requirement for individual consent for these activities as an alternate legal ground would in our view result in some groups being systematically excluded from health benefits that risk stratification might bring. This would be inequitable and would result in some groups being marginalised from screening that has potential clinical utility.

Another application where automated decision-making might play an increasing role in the future is as part of patient or citizen held devices that are used to monitor or improve the health of an individual...
In contrast to public health example cited, we envisage that such a system would be predicted on obtaining the consent of the data subject.

Another application where automated decision-making might play an increasing role in the future is as part of patient or citizen held devices that are used to monitor or improve the health of an individual. This could be in the context of a digital sensor that is worn by an individual to monitor blood pressure, heart rate etc. It seems possible that such data could be sent to a central repository for automated analysis, or an alert system might notify the data subject if these data fell outside normal clinical ranges. It could also be used to alert a third party clinician or, if fully automated, their designated decision support system. In contrast to the public health example described above, we envisage that such a system would be predicted on obtaining the consent of the data subject. The validity of any consent secured in such an application would rely upon the data subject understanding the reliability of the risk predictions, the extent of uncertainty, (i.e. the scientific validity and utility and the (if any) clinical validity and utility) of the device and its usual functioning. Consent would also need to address data sharing aspects, such as if personal identifiable data is sent to a central repository for analysis.

How will you ensure that the profiling you carry out is fair, not discriminatory, and does not have an unjustified impact on individuals' rights?

Transparency (about scientific and clinical validity and utility) will be key. For certain applications, any algorithms or software used might be classed as *in vitro* diagnostic devices, and as such, part of the accreditation process of CE marking will have involved providing appropriate evidence of clinical performance under the revised EU *In Vitro* Diagnostic Devices Regulation.

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Have you considered what your legal basis would be for carrying out profiling on personal data? How would you demonstrate, for example, that profiling is necessary to achieve a particular business objective?

We envisage that the risk stratification activities described above for disease prevention on a population basis might be justified in the public interest and therefore might depend on how 'suitable' measures to safeguard the data subject's rights and freedoms and legitimate interests are in place in accordance with Article 22(4). Where profiling is undertaken of an individual to monitor a variable which might be relevant to health (such as blood pressure, pulse or blood sugar etc.) it is more difficult to think of an example where the lawful ground for this should not be consent. In such cases, there would need to be mechanisms for those who lack capacity to consent to benefit from such interventions which could improve their health.

How do you propose handling the requirement to provide relevant and timely fair processing information, including "meaningful" information on the logic involved in profiling and automated decision-making? What, if any, challenges do you foresee?

"Meaningful" information does not necessarily mean that the information provided should be comprehensive or exhaustive. What is required is a succinct summary of information that is accessible to all recipients, which may be more challenging. Information should be provided in plain English. Age appropriate information might be needed if children are involved; those who lack capacity should nevertheless be supported to give a legal consent through provision of supporting materials (such as under the UK Mental Capacity Act 2005). If the variables/elements change frequently, the challenge might be to ensure that fair processing information is provided on a timely basis and that recipients don't become fatigued by frequent updates to the terms of their consent agreements.

If someone objects to profiling, what factors do you consider would constitute "compelling legitimate grounds" for the profiling to override the "interests, rights and freedoms" of the individual?

The factors constituting "compelling legitimate grounds" are likely to be similar to those already utilised when delivering healthcare, where individual autonomous decisions are overridden on the basis of the data subjects vital interests (e.g. to avoid foreseeable harm to self or another) or public interest (e.g. quarantining for infectious diseases).

It would be important to ensure that any data uses particularly involving the generation and disclosure of predictive risk information from childrens' genomic data, are consistent with well-developed ethical rules.

Do you consider that "solely" in Article 22(1) excludes any human involvement whatsoever, or only actions by a human that influence or affect the outcome? What mechanisms do you have for human involvement and at what stage of the process?

We would support the ICO's interpretation of the word "solely".

What mechanisms or measures do you think would meet the GDPR requirements to test the effectiveness and fairness of the systems you use in automated decision-making or profiling?

For some applications, as noted above, there might be requirements for the algorithms or software to comply with the relevant annexes of the EU *In Vitro* Diagnostic Devices Regulations. There may therefore be provisions around evidence, validation of changes, information to be provided and labelling which could apply across both sets of Regulations. It would be helpful if these requirements were as congruent as possible with each other. This might be a sector/application where codes of conduct developed pursuant to GDPR Article 40 might be a useful source of guidance for the sector.

Will your organisation be affected by the GDPR provisions on profiling involving children's personal data? If so, how?

We envisage that risk stratification tools could involve the use of childrens' personal data. It would be important to ensure that any data uses particularly involving the generation and disclosure of predictive risk information from childrens' genomic data, are consistent with well-developed ethical rules. For example, these advise against genomic data being generated that relate to a child's risk of developing an adult-onset condition unless there is a clear medical need to generate such information. This is on the basis that a decision should be delayed until that child is competent to make their own decision about whether or not to have a predictive genetic test. Please also see the response submitted above.