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INTERNATIONAL CONSORTIUM

Action Item Group 4:
Health economics and Market Access

Focus on actions from the ICPermed action plan that promote personalised medicine approaches to become available to the patient in a health economically sustainable way

PEGASUS: Personalized Genomics for Prenatal Aneuploidy Screening Using Maternal Blood

https://www.genomecanada.ca/en/pegasus-personalized-genomics- prenatal-aneuploidy-screening-using-

GenomeCanada

Every year in Canada, about 10,000 pregnant women undergo amniocentesis to screen for genetic abnormalities such as Down syndrome. This procedure represents a non-negligible risk and tragically, 70 healthy fetuses are lost due to complications from the procedure. Recently, however, scientists have discovered that fetal DNA present in the mother's blood can be used to test for genetic abnormalities, and this through a simple blood test.

Drs. François Rousseau, Sylvie Langlois and team will compare different genomic technologies for their effectiveness to successfully detect genetic abnormalities using the mother's blood. The goal of the study is to implement the most suitable technology into the Canadian health care system to eventually offer, in the context of standard clinical care, non-invasive prenatal screening to all Canadian women.

PRECISE: A health economic approach to evaluate uncertain evidence in personalised medicine

A project under the Nordic Permed call, initiated in 2018 with participants from Norway, Sweden and UK, funded by Nordic funding agencies. For further info contact project coordinator prof Eline Aas, Univ Oslo, eline.aas@medisin.uio.no

PRECISE will contribute to improved healthcare decisions that facilitate the implementation of cost-effective interventions for personalised medicine in clinical practice. PRECISE will improve decision making by developing novel health economic methods to handle uncertain evidence and heterogeneity when evaluating the benefits and costs of personalised medicine. PRECISE will generate new health economicevidence based on real case studies that address important healthcare decisions. A close collaboration with Nordic healthcare decision makers provides a platform for improving national pharmacoeconomic guidelines and achieving policy impact.

The PRECISE consortium comprises an international team of world-leading experts in health economics, statistics, clinical medicine, and high-level governmental decision makers.

NICE technology appraisal guidance

https://www.nice.org.uk/about/what-we-do/our-programmes/nice-guidance/nice-technology-appraisal-guidance

HTA agencies' experience of precision medicine has primarily been with diagnostic and companion diagnostic tests, the latter referring to those that identify biomarkers correlated with treatment response such as the HER2 receptor protein for breast cancer pharmacotherapies. Several countries have accommodated the additional complexities of evaluating these tests through new procedures, such as the Diagnostic Assessment Programme at the National Institute for Health and Care Excellence (NICE) in UK. Recommendations of NICE are based on a review of clinical and economic evidence:

- Clinical evidence shows how well the medicine, diagnostic or treatment works
- Economic evidence shows how well the medicine, diagnostic or treatment works in relation to how much it costs - does it represent value for money?

Current activities :

- ◊ **Selection and dissemination of best practice examples**
- ◊ **Interactions with relevant networks and experts to further promote, develop and disseminate the field**
- ◊ **Planning of communication and dissemination activities & events**
- ◊ **Mapping of personalised medicine initiatives related to Action Item Group 4**

The following organisations contribute to Action Item Group 4:

Ankara University (Turkey), Canadian Institutes of Health Research, Innovation Fund Denmark, Italian Ministry of Health, Foundation for Science and Technology (Portugal), Inserm (France), Israel Ministry of Health, Fondazione Telethon (Italy), Health Institutes of Turkey, Health Technology Assessment Agency (ISCIII, Spain), Teheran University of Medical Sciences

New contributors are more than welcome!

ICPerMed Workshop, Madrid, November 2019

ICPerMed AIG4

ICPermed Action Item Group 4 items:

A.16 Support research in and development of health economics models and pharmacoeconomics models for personalised medicine

Research is needed to investigate whether a patient-centred, personalised medicine approach requires refinement of or even new health economics and pharmaco economics models, including prevention

A.17 Support research in post-marketing surveillance methodologies aimed at accessing patient outcomes

Personalised medicine development requires post-marketing surveillance methodologies. This raises legal, social and ethical challenges as well as need for new ways to handle big data. Research in this area can outline what needs to be done to facilitate the use of data across nations and cultures

A.18 Support health economics research and assessments of available as well as newly developed personalised medicine approaches

Such research will provide important evidence to support effective and sustainable healthcare systems, now and in the future

B.5 Support strategies to identify financial and risk-sharing instruments to develop personalised medicine approaches

Based on risk evaluations for PM approaches and products from all relevant perspectives, different scenarios could be build and analyzed, thereby supporting improvement of regulatory and economic frameworks

B.6 Support research to analyse, compare and optimise national and regional health systems in the light of personalised medicine implementation

Research projects to be conducted to analyze and compare selected health systems with focus on personalised medicine aspects, thus developing suggestions to optimize health systems

Contact information:

Please contact the AIG 4 lead or ICPerMed Secretariat for all questions concerning AIG 4 and its activities.

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