

## **Imaging asymptomatic people: a framework addressing clinical governance improvement and regulatory compliance**

J. Brodersen<sup>1</sup>, S. Ebdon-Jackson<sup>2</sup>, J. Griebel<sup>3</sup>, J. Malone<sup>4</sup>, F. Martiny<sup>1</sup> and M. Perez<sup>5</sup>

<sup>1</sup> University of Copenhagen, Denmark

<sup>2</sup> Public Health England (PHE), UK

<sup>3</sup> Federal Office of Radiation Protection (BfS), Germany

<sup>4</sup> Trinity College, Ireland

<sup>5</sup> World Health Organization (WHO), Switzerland

The role of medical imaging is recognized universally when considering the provision of high quality and safe healthcare. For a diagnostic imaging procedure to be justified, a net benefit must be ensured by assessing the total benefit for the individual against the individual detriment that the exposure might cause. Computed tomography (CT) is increasingly utilized for individual health assessment (IHA) of asymptomatic people in a number of areas such as coronary artery calcium scoring, investigation of coronary artery plaques, early detection of lung and colon cancers, and whole-body CT surveys. When CT is performed in asymptomatic people as part of opportunistic screening, such as in the case of IHA practices, consideration should be given to both radiological and non-radiological components of the benefit-to-harm balance. The latter includes overdiagnosis, false positives, false negatives, indeterminate and incidental findings, health economics and ethical dilemmas, among others. Screening has an intuitive appeal as it relies on the assumption that early detection will result in better treatment options and thereby improve the prognosis for the screening participants. On the other hand, harms and misconceptions about screening, like overdiagnosis or lead-time bias, are counterintuitive and unfamiliar concepts to many people. These may result in people placing a one-sided emphasis on the benefit of screening while downplaying the harms and physicians being unable to evaluate if a screening procedure is beneficial, harmful or inappropriate. There is a need to implement a robust clinical governance framework of IHA practice using CT, including a comprehensive regulatory dimension to ensure that these procedures are performed as part of good medical practice. WHO is developing a guidance document proposing a framework for enhancing justification and improving the clinical governance of these IHA practices. The objective of this symposium is to present a draft WHO guidance document proposing a framework for enhancing justification and improving the clinical governance of IHA practices using CT and to collect feedback from the audience. The scope and purpose of the project will be described, the key elements of a framework for justification and clinical governance of IHA practice using CT will be summarized, and the content/ format of the document will be presented. The audience's feedback collected during this symposium will be taken during the development of the proposed guidance material. The expected outcome will be a better-informed WHO policy guidance document more relevant to an increased range of stakeholders.