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Editorial

The issues of individualized medicine and pharmacovigilance: A consideration of COVID-19 and vaccination

Some background

A medicine is generally approved for use by the general public on the basis of controlled clinical trials for efficacy. Relatively small numbers of individuals are involved in those studies and they are selected for being as free as possible from any abnormality that is likely to interfere with the results of the trials and their interpretation. The reasoning is fine to form an idea of whether a particular medicinal product works at all, and is free of frequent, major adverse effects. That is a vital and acceptable logic as a starting point.

A definition of individualised medicine is, '*Made for or directed or adjusted to a particular individual*' and individual is defined and explained as, '*The word individual is all about being a single entity that cannot be divided. It can mean person or even personal. A team is made up of individuals, and each individual has individual strengths and weaknesses.*'

What does it all mean in terms of medical care in general? The size of the global population is 7.8 US billion - 7.800,000,000 (March 2020) and the growth 81 million - 81,000,000 per year, so that is a huge number of individuals spread literally all around the world.

The World Drug Report 2019 tells us that 35 million people worldwide suffer from drug use disorders though only 1 in 7 people receive treatment, this presumably refers to allopathic medicines.

Everyone's individuality is determined, in the least, by hugely complex interactions between their genomics, their biomics, their environment and other aspects of their life's context and experience over time - their phenomenology. There can only be limited generalisation that can be used to predict individual response concerning medical care: statistical norms and averages might provide a start, but they can never entirely give us all the practical help we need for the individual clinical management of the myriads of the people on Earth.

Post marketing 'real-life' studies take us forward in our knowledge by including many more varied people who are exposed to a drug or other treatment. There are however still many challenges to be overcome. The size of the sample may still be too small, and different biases (selection, information and confounding) are problematic, and suitable controls may be difficult to acquire. There are many ways in which these issues can be mitigated by restrictions and selection (not really desirable), matching, propensity scoring, stratification, cross-overs, instrumental variable use and more. However, nothing is more important than collecting sufficient, relevant data which is quality assured and fitting the study definitions set out in advance. This is not an easy task in observational studies using retrospective data.

Vaccination against SARS-COV-2

Vaccination against COVID-19 is a current challenge with mass exposure to new agents which will be used in some that have some disposition that may either mean the vaccines may not be as effective as found in relatively small numbers in the studies so far, or those with some unrecognized vulnerability or disease that makes individuals prone to an adverse effect. These small but unknown risks must be considered against the dangers from COVID-19: Globally, as of 12:26pm CEST, 5 October 2020, there have been 35,027,546 confirmed cases of COVID-19, including 1,034,837 deaths, reported to the WHO.

We must emphasise that the likely effectiveness of the various vaccines are probably great compared with the slight risk of adverse effects caused by them, but it seems to us that, when so many of the global population will be exposed, collecting adequate data from those that believe they have been harmed, or not protected from COVID-19, will be essential for the management of any problems that might occur, and for the prevention of harm in those individuals that have similar susceptibilities.

Everyone will have a part to play in this pandemic. Health professionals, scientists and politicians must play their part in careful evaluations and interpretation. The public, however, have the primary responsibility of reporting sensibly to health authorities and responding to requests for further information. The media must be responsible in providing understandable, complete, accurate and balanced coverage. There must be no place for sensationalism during such a global challenge as this.

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