CHARTER FOR OLDER PEOPLE IN CLINCAL TRIALS

Preamble

Older people are the fastest growing section of the population in Europe and the more developed countries. Most long term conditions increase in prevalence with age and it is therefore not surprising that older people also take more medications than other groups. The discovery of new classes of drugs for conditions that were previously untreatable, the use of multiple drugs to treat one condition, the coexistence of multiple pathologies together with better access to healthcare have all contributed to this rise in prescriptions.

Older people also have the highest risk of adverse drug events, mainly due to the consumption of multiple drugs. Older people also benefit from evidence based non-pharmacological interventions. Although both national and international regulators now require that older people are included in clinical trials, it is of great concern that this happens infrequently. As a consequence both prescribers and patients are placed in unnecessarily difficult positions. Prescribers have to decide whether to prescribe a drug even though they might have only limited knowledge of its effects and side effects in older people. The patient who wants to know about the treatments' effects in older people will be denied that opportunity.

Health care systems are developing evidence-based treatment guidance. While this has the potential of greatly improving clinical practice, older people are often treated with therapies that, although shown to be effective in younger adults, lack specific evidence of efficacy and safety in later life. This is an example of age discrimination, which is not acceptable in modern society.

The PREDICT project was established "to help identify, address and resolve the issues related to the exclusion of older people from clinical trials using the full range of scientific and clinical disciplines". This has been achieved through a series of Work Packages (WP):

Work Package 1: Systematic Reviews
Work Package 2: Health professionals' Views
Work Package 3: Patients' Views
Work Package 4: Patient Charter

The PREDICT partners are based in the Czech Republic, Israel, Italy, Lithuania, the Netherlands, Poland, Romania, Spain and the United Kingdom and co-ordinated from Medical Economics & Research Centre Sheffield, UK.
The key findings of PREDICT are:

Work Package 1 Older people are unjustifiably excluded from clinical trials including those currently being undertaken. This exclusion applies to trials investigating both pharmacological and non-pharmacological treatments for conditions that are extremely common in older age, such as heart failure, depression, dementia and cardiovascular diseases.

Work Package 2 Health professionals believe that older people are being disadvantaged because of this under-representation in clinical trials and that change is required to reverse this situation.
Work Package 3 Patients and their carers believe that older people have the right to be invited to take part in clinical trials and that relevant information from clinical trials should be available in order that they can be fully informed before deciding to accept new drugs or other treatments. In addition, they felt that assessment of efficacy in clinical trials of new drugs should also measure any improvements in quality of life.

The findings of Work Packages 1, 2 and 3 have been incorporated into this charter by a process that has involved a wide range of health professionals, ethicists, patients and their carers in all nine countries of the PREDICT partnership.

More information on the charter is available on the PREDICT web site:
www.predictEU.org/

1. OLDER PEOPLE HAVE THE RIGHT TO ACCESS EVIDENCE-BASED TREATMENTS

1.1 Older people have the right to be offered evidence-based treatments.
1.1.1 Older people should expect to be offered drugs and other treatments that have been properly evaluated in clinical trials and demonstrated to be effective in patients of their age.

2. PROMOTING THE INCLUSION OF OLDER PEOPLE IN CLINICAL TRIALS AND PREVENTING DISCRIMINATION.

2.1 Older people should not be discriminated against in the recruitment for clinical trials
2.1.1 Older people should be informed about and invited to participate in clinical trials of treatments that are intended for use in older people.
2.1.2 National and International Regulators should ensure that older people are included in clinical trials without discrimination on grounds of age, gender, ethnicity or social class.
2.1.3 Research Ethics Committees, Sponsors and Regulators should review all studies critically for unjustified exclusions based on age, other illnesses, disability and existing drug treatment. All such exclusions must be justified.
2.2 The participation in clinical trials of patients with multiple morbidities should be encouraged
2.2.1 National and International Regulators should require that trials with drugs or other treatments intended for use in older people include patients with multiple morbidities that are common in later life.
2.2.2 National and International Regulators should require that trials with drugs or other treatments intended for use in later life include older people who are taking commonly prescribed medications

3. CLINICAL TRIALS SHOULD BE MADE AS PRACTICABLE AS POSSIBLE FOR OLDER PEOPLE

3.1 Clinical trials should be designed so that older people can participate easily
3.1.1 Older people should receive information about clinical trials that helps them make an informed decision about participation.
Informed consent procedure should be adapted to the specific needs of older people, taking into account their level of literacy, any sensory deficits, and involving their family or caregiver if needed.
3.1.2 Specific training is needed in order to perform clinical trials in older people.

Researchers should be trained to conduct clinical trials in patients with communication, sensory, mobility or cognitive problems.
3.1.3 Researchers should be prepared to spend additional time with older patients participating in a clinical trial in order to support their participation and adherence.
3.1.4 Trial Sponsors should recognise that older people may need extra support to take part in trials.
Trial sponsors should provide support to enhance the inclusion and adherence of older patients, especially those patients with mobility and communication problems and those patients who also have responsibilities caring for others.
3.1.5 National and international regulators should encourage clinical trials that are designed to make the participation of older people easier.

4. CLINICAL TRIALS IN OLDER PEOPLE SHOULD BE SAFE
4.1 Clinical trials in older people should be safe.
4.1.1 Researchers should assess the benefits and risks of older people's participation in clinical trials.

5. OUTCOME MEASURES SHOULD BE RELEVANT FOR OLDER PEOPLE
5.1 Clinical trials for common conditions in older people should employ outcome measures that are relevant for older people.
5.1.1 Researchers, trial sponsors and regulators should ensure that clinical trials for common conditions in older people use outcome measures that are relevant for older people, including quality of life measurements.
5.1.2 Clinical trial sponsors should involve patients and carers in the design of clinical trials and in the choice of outcome measures for clinical trials of diseases of later life.

6 THE VALUES OF OLDER PEOPLE PARTICIPATING IN CLINICAL TRIALS SHOULD BE RESPECTED.
6.1 The individual values of each older person participating in clinical trials should be respected.
6.1.1 Researchers should respect the values of each older person as an individual.
6.1.2 Older people should be able to withdraw from clinical trials without detriment to other treatments and their overall care.