Eugenia Hong, Clin Exp Pharmacol 2012, 2:3
http://dx.doi.org/10.4172/2161-1459.S1.005

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Pharmacovigilance & Clinical Trials

October 1-3, 2012 DoubleTree by Hilton Chicago-North Shore, USA

The effects of clinical trials pharmacist counseling on participant compliance in clinical trials

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Participant compliance with treatment in clinical trials is critical to the successful interpretation of safety and efficacy of the regimens studied. It has been calculated that a 20% reduction in drug compliance may result in the need for a greater than 50% increase in sample size. Patient education and counseling are important responsibilities for pharmacists in all practice settings including clinical trials. The effect of counseling by clinical trials pharmacist on participant compliance was assessed. Data from 12 participants were reviewed. Six participants, 2 participants each from 3 studies where active counseling by pharmacists was provided were chosen in random and their compliance was compared to that of 6 participants, 2 participants each from 3 studies with no pharmacist counseling. Pill count was chosen to measure compliance for participants as it is the easiest, least expensive and widely used method in clinical trials. The compliance rate for participants on studies where counseling from pharmacists was provided was 99% compared to 89% in patients without the pharmacist's counseling ($p<0.05$). Pharmacists can contribute to positive outcomes by counseling study participants and educate them on the correct administration of the study drug as specified in the study protocol. This study showed that treatment compliance is improved when the participant has been counseled and educated on the correct administration of the study treatment by the clinical trials pharmacist. Clinical trials pharmacist should accept the responsibility for providing counseling to study participants in the context of best pharmaceutical care.

Biography

Eugenia Hong and Emma Michael are senior pharmacists in charge of clinical trials pharmacy at the Royal Melbourne Hospital, Australia. They lead clinical trials pharmacy which provides a comprehensive clinical research service including protocol review, assistance in protocol development, investigational drug management, preparation and dispensing, drug information, patient randomization, emergency 24-hour services and educating patients on clinical trials medications for over 300 studies conducted at RMH. Eugenia Hong is a committee member of The Society of Hospital Pharmacists of Australia and Emma Michael is a member of Human Research Ethics Committee of Melbourne Health.

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