Letters to the Editor
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Can 'Medication by Post' improve medication compliance?

Corresponding Author:

Bernice Lim
Email: bernicelim@ms.pmc.edu.my

Dear Editor,

Poor compliance to medications is a major worldwide problem causing immense financial and health burdens. In the United States of America it is estimated that the total healthcare costs resulting from non-compliance is US $300 billion.[1] In order to decrease waiting times at the counter, ensure medication continuity and increase compliance, the Malaysian government started a pharmacy home delivery service programme called 'Medication by Post'[2] (MBP) in January 2011.

An ethically approved study was conducted among patients with chronic illness on medication from government health clinics and hospitals in a village in Penang, Malaysia. The objective of the study was to explore the problems of non-compliance to medication and the awareness of MBP among this group of people.

Among the 30 participants, eight gave a history of poor compliance. Almost half of the respondents claimed that the average waiting time for their medication was more than 20 minutes and most (47%) were dissatisfied with the waiting period. They were more likely to collect their medication refills on time if the waiting time was 10 minutes or less. The most common reason for non-compliance was forgetfulness. Only four individuals had a problem accessing pharmacies, mostly due to time constraints because the operating hours coincided with their working hours. Satisfaction of pharmacy services was not a factor in increasing compliance. This could be because their expectations of the pharmacy services were low or they were unaware of the services. Half of those who were non-compliant to medication believed that they were not entirely responsible for their own health. How do we help patients achieve full compliance when they feel that it is up to the healthcare providers to be responsible for their health?

Only four respondents had heard of the MBP service. The participants were informed of the MBP services and 14 were interested in subscribing to this service. Most of those who were interested were already compliant to treatment. Half of those who were not compliant believed that the service would not increase their compliance to treatment. Most of them were not willing to pay the RM5 (US $1.43) postal charges for the service and the majority (86.7%) were worried about the risk of tampering even after being informed that procedures were in place to ensure the parcels would not be tampered with. Some also raised concerns about the changes in their illness prior to receiving the next batch of medications.

Table 1.1 Factors that influence compliance to medication

		Not Compliant (n=8)	Compliant (n=22)
Waiting time	≤10 minutes	1	9
	> 10 minutes	7	13
Interested in the service	Yes	5	9
	No	3	11
	Unsure	0	2
Willing to pay fee of RM5	Yes	3	10
	No	5	12
Believe the service will improve compliance	Yes	4	10
	No	4	9
	Unsure	0	3
Consider health as own responsibility		4	9
Do not consider health as own responsibility		4	13

Some questions beg to be answered. Are we confident that patients who receive refills by post will take them on

time and deal with the unexpected adverse effects knowledgeably? Can patients be entrusted with the task of calibrating their medication dose? Approximately 80% of the participants were counselled by the pharmacist when they collected their medication. This important contact between the patient and the pharmacist which provides an opportunity for counselling will be lost. However we agree that if done right, it can enhance productivity as well as improve efficiency by reducing the waiting time. Alongside the service, we believe education is the key in changing the patient's behaviour and empowering them to take charge of their own health.

MBP indeed sounds very promising but besides a single trial run conducted in the federal capital there have been no other reported trials. Larger studies among different groups of patients in different settings, both rural as well as urban, should be conducted to establish the pros and cons of this service.

Sincerely,

Bernice Lim, Abdul Rashid Khan, Nur Amanda Abidin and Siti Umairah Ismail
Penang Medical College, Malaysia.

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What role do research ethics committees play in Bulgarian clinical trial research?

Corresponding Author:

Dr Yordanka Krastev
Email: y.krastev@unsw.edu.au

Dear Editor,

Like other countries in Central and Eastern Europe, Bulgaria has experienced a major transition in its healthcare system in the last 20 years. One change that was significantly influenced by Western countries was the growth of multicentre clinical research conducted by large pharmaceutical companies. This led to the establishment of research ethics committees, called local ethics committees (LECs) at the beginning of the 1990s, with the purpose of providing ethics reviews of research protocols for clinical trials involving humans and ensuring the safety and well-being of participants.

An Ethics Working Party of the European Forum for Good Clinical Practice (EFGCP) explored over 30 aspects of the ethical review of protocols for clinical trials in 33 European countries and published country-specific reports in 2006.1 Since then there have been annual updates of the information. It is surprising that the last Bulgarian report dated April 20112 was not entirely updated.

The aim of this letter is to clarify some of the missing information about the ethical review of clinical trials in Bulgaria and the role of LECs.

Laws and regulations for the conduct of clinical trials cited in the last report refer to old documents that were replaced in 2007 by the Bulgarian Law on Medicinal Products for Human Use3 and Regulation 31 for determining good clinical practice of the Ministry of Health. 4

Moreover, all LECs are guided by the principles of the Declaration of Helsinki. 5 Currently the ethical review of a clinical trial protocol is conducted by a competent LEC (for single-site clinical trials) or by the Multicentre-Ethics Committee (for multicentre clinical trials).

Currently there are 153 registered ethics committees that can provide opinion about single site clinical trials and one for multicentre clinical trials conducted in Bulgaria. Membership of a LEC is determined by the manager of the relevant hospital and consists of an average of nine members, including representatives of

both genders, physicians with different specialties, at least two members with a non-medical degree (e.g. a lawyer, a psychologist) and at least one external lay person (e.g. a philosopher, an administrative person).6 Training of ethics committee members was in the past inadequate, and this role of the LEC was poorly performed due to a lack of training requirements. Between June 2004 and June 2005 the author conducted a questionnaire survey of 205 LEC members as part of a PhD study, and found that 43% of the respondents had received no training related to their committee duties.6 Now, however, there is compulsory preliminary ethics training, and continuing education of ethics committee members ais part of the standard operating procedures of each LEC.

The Bulgarian Drug Agency and the Specialised Committee for Authorisation of Performance of Clinical Trials are the two bodies that give the final approval for clinical trials to begin, after receiving a positive recommendation from the ethics committee. The time frame for regulatory approval of a clinical trial is up to 60 days, including the ethics committee review and resolution with an opinion (30 days). Unlike other countries, such as Australia, the authority of Bulgarian ethics committees is restricted to provision of an opinion rather than approval or rejection. This limits their role in the clinical trial approval process and their authority in the research community.

The EFGCP report for Bulgaria on the ethical review of clinical trials and the role of ethics committees is a good source of information.1,2 With e-updates on the latest changes in the process, it can be used as a guide for international organisations and researchers who may consider conducting their clinical trials research there.

Sincerely,

Yordanka Krastev, Research Fellow,
Centre for Primary Health Care and Equity, University of New South Wales, Sydney, Australia

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