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Motivations and Obstacles for Adverse Drug Reactions Reporting among Healthcare Professionals from the Perspective of Lewin's Force Field Analysis Theory: Analytic Approach

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Abstract

Spontaneous Adverse Drug Reactions (ADRs) reporting system is considered the back-bone for any pharmacovigilance system. Within this context, active Involvement of healthcare professionals is very crucial to improve the rate and quality of ADRs reporting. Despite the various techniques that have been adopted in order to improve the rate and quality of ADR reporting, there is a decline in the rate of ADRs notification. Under-reporting of ADRs is well-recognized phenomena associated with the almost all of pharmacovigilance systems around the world. Many logistic and personal barriers to ADRs reporting among healthcare professionals including resistance to change have been reported. This commentary focuses on the problem of resistance to change towards ADR reporting and the possibility of applying theory of Force Field Analysis (FFA) to overcome the problem of under-reporting among these professionals.

Keywords: Pharmacovigilance; Adverse Drug Reactions Reporting; Resistance to Change; Kurt Lewin; Malaysia

Problem Background

The unanimous view that all healthcare professionals including pharmacists, physicians and the other health care providers, consider adverse drug reactions (ADR) reporting an integral part of their role is extensively supported by studies of Belton et al. in 1995 [1] and Bates et al. in the same year [2]. This has been reinforced by many studies carried out in developed and developing countries [1,3], which have encompassed attitudes, perceptions and barriers towards ADR reporting. However, ADR reporting is considered an important component of the drug safety monitoring framework [4]. Despite the recognition of ADR reporting as an essential element in today's transformed era of medication safety, it seems that there is a decline in the number of ADR reports submitted by healthcare professionals to their respective pharmacovigilance centers [5,6]. This trend is also evident in developed nations, who believe that they have ideal pharmacovigilance systems in place and where the culture of ADR reporting has existed for more than four decades; it was reported in the UK that the number of ADR reports from GPs fell by 58% between 1994 and 2005 [7]. Similarly, it has also been noted that in most developing countries, the number of ADR reports received by pharmacovigilance centers did not reach the level stipulated by the WHO collaborating center for international drug monitoring, the "Uppsala Monitoring Center" [4,8].

An extensive literature review on studies focusing on the knowledge, attitude and practice towards ADR reporting among healthcare professionals using electronic databases such as MEDLINE, SpringerLink, ScienceDirect and EBSCOhost revealed that several different interventions and approaches [educational or other] aimed at improving the rate and quality of ADR reporting have been proposed. Despite the positive and promising outcomes, the vast majority of these studies have been carried out with limited objectives and short follow-up periods. In addition, the majority of these studies was suffering from a limited number of participants, as they were mainly regional surveys and lacked the representation of all healthcare providers on the national level [9-13]. This leads us to raise an important question: Do healthcare professionals suffer from the problem of resistance to change and what are the possible strategies that could be adapted to mitigate this problem? If this hypothesis is true, application of models which aim at combating resistance to change, such as "Lewin's Force Field Analysis" [14,15], may be warranted.

The clear understanding of these obstacles and planning strategies to work through these barriers may be the key to implementing a successful pharmacovigilance system in complex and diverse healthcare systems. Lewin's theory of change provides a structure for understanding healthcare professional's behavior during times of change and possible approaches to enhance this behavior when establishing change in the actual practice setting [14]. However, this model features the fundamental role of the concept of motivation and intention in understanding the behavior of individuals and groups. Healthcare providers are encouraged to use Lewin's change model as guidance when developing plans to implement patient care services [16]. As change becomes an increasingly common occurrence in the healthcare environment, equipping healthcare professionals with advanced clinical knowledge and familiarizing them with changing processes is necessary [17].

Lewin in his model identified two opposed forces that have an impact on the change process in an environment. The first is driving forces which move toward a positive region and encourage the occurring of change. The second is restraining forces; it is the Static

forces that endeavor to maintain the current status. Lewin described his change process model in three components includes unfreezing the current level, changing or moving to the new level, and freezing [refreezing] at the new level [18]. The driving force might be the outcome of external forces urges for changing or internal forces such as the desire for change and break the monotony or improve the situation. On the contrary, the restraining forces can hinder and prevent the change from occurring by creating barriers [19]. The fail of changes in practice has been attributed to that healthcare providers are not sustained and empowered to adjust emotionally to the new ways of practicing environment, in addition to the past negative experience with unsuccessful change or fear of losing the current state of contentment [18,20]. For achieving the desired and successful change the driving forces must be strengthened in favor for change.

Underreporting of ADRs is a well-recognized problem associated with spontaneous ADR reporting systems around the world [2]. Different obstacles to detecting and reporting ADRs were proposed by Inman in the mid-eighties [3] and have since been mentioned in numerous studies [1]. Fear of litigation and fear of appearing ridiculous were reported as two of these barriers. This could be one of the aspects of resistance to change among these professions. Fear of litigation is impeding efforts to improve the involvement of healthcare professionals in ADR notifying. Healthcare professionals may be reluctant to report ADR and participate in the pharmacovigilance activities because they fear being dragged into lawsuits, even if they have done nothing wrong. The need for a confidential reporting system for healthcare providers to share information regarding ADR without fear of litigation is encouraged.

Uncertainty regarding the causal relationship between the event and the suspected drug, in addition to the skepticism regarding the triviality of ADR notification, were reported as barriers for ADR reporting [11]; these may hinder healthcare professional involvement in ADR reporting in particular and pharmacovigilance activities in general.

In view of all that has been mentioned so far, no studies have been conducted aiming at adoption and explore the possibility of the implementation of Lewin's theory in the field of pharmacovigilance. Obviously, pharmacovigilance activities consisted of behavioral aspects in addition to the cognitive skills which healthcare professional should have. From our previous studies in the field of pharmacovigilance we can say that the positive force towards improve rate and quality of ADRs reporting includes; familiarity with ADRs reporting system, familiarity with ADRs reporting process, feedback and acknowledgement from the regulatory authorities, availability of ADRs report form. Furthermore, there is debating about some components of the force, such as incentives. Healthcare professional form different disciplines and regional locations have different views regarding this component. With regard to the construing forces: Unsuccessful involvement into previous activities may result into negative reaction towards the proposed change. Individual skills and level of knowledge of the healthcare providers may have impact on their perception and attitudes towards ADRs reporting and their competent to detect and report ADR.

A correlation between positive attitudes towards ADRs reporting and increasing year of experience [pharmacist practicing] has been reported. However, pharmacists with high level of education with more years of experience were correlated positively with attitude towards pharmacovigilance activities in general and ADRs reporting in particular [21]. Gavaza P et al. found that the number of hours worked and practice setting were associated positively with the pharmacists' attitudes towards ADRs reporting [22].

The final stage in the Force Field Analysis theory (FFA) is the process of refreezing (freezing) the changed practice occurs. Once the changes have been achieved stability and evaluation process will be established. Petrescu indicated that changing process is very slow thus continuous support of healthcare providers should be sustained until the change is deemed effectively complete and they become comfortable with their new routine status [23]. Holbeche reported that the most failure of changes in practice occurs due to lack of continuous cognitive and behavioral support to the healthcare professionals [20].

The regulatory authorities and the other stakeholders relevant to pharmacovigilance activities should plane thoughtfully and adopt the above identified facilitators to integrate the professional services into the different disciplines of pharmacy practices. Involving of pharmacists and their staff, policy makers, academicians/instructors, and researchers is of paramount importance in the moving/transforming from the static status (freezing) to the refreezing stage (change). Further research is needed to determine the actual factors affecting the competence of pharmacists to implement change.

Conclusion and Suggestions

To minimize the resistance to change, the competence of the healthcare professionals in the field of ADR reporting must be reevaluated. This assessment should include the skills and knowledge of pharmacovigilance activities and the ADR reporting process in light of the local pharmacovigilance guidelines [17,24]. Relevant authorities must encourage and adopt comprehensive policies at a national level aimed at spreading the culture of ADR reporting and urging consumers and patients alike to engage in these activities, especially as there have been successful projects focusing on the involvement of patients in ADR reporting and pharmacovigilance activities [24]. Such successful projects have indicated the numerous benefits that can be achieved from involving all stakeholders in the community in the process of ADR reporting. This objective can be achieved through the coordination of national pharmacovigilance centers and collaboration with the WHO Collaborating Centre for International Drug Monitoring, the Uppsala Monitoring Centre.

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