Chapter: 4

Summary and Conclusion

Adverse Events are important problems in any health care settings most often caused by the care or intervention of the health care provider. Health care systems across the world are attempting to identify these events appropriately so as to prevent recurrence of such events. But due to the complicated nature of the events, it is hard to differentiate between the complications of disease process and the events caused by care process. Thus various types of AE monitoring systems are in practice each with its own advantages and limitations. The trigger tool methodology pioneered by Classen et al provides an alternative approach to handle this problem. Surgery department is a department with potential to have AEs in the patients they treat and therefore they need to develop specific methods to identify and prevent AEs. In India studies reported on adverse drug reactions detected using various approaches. But use of triggers as a method to identify adverse drug reactions was attempted by Thiyagu et al, 2010 was the only study in this country. Use of triggers tools is a newer concept in our country and no study was conducted using this approach in a surgical setting.

The present study was aimed to develop, validate and implement a trigger tool methodology to identify AEs in a surgery department of a tertiary care teaching hospital. Two units of surgery units participated in this study. The development phase involved identification of suitable items for the trigger tool from different sources like published literature, IHI global trigger tool kit. At this stage the number of items was more and this list was subjected to review by a panel of experts. This panel of experts reviewed tool item wise and recommended on additions and deletions. At the end of this
process 76 items were finalized and submitted for the review by Delphi panel for further revision.

Delphi panel conducted three rounds of review and at each round number of items were added and removed. The final tool had 77 items. These items were classified under three major categories namely: critical, surgical and medical care module. This tool was piloted in 120 patient records collected over a period of six months. After the pilot stage, trigger tool was used to review the case records for a period of two and half years with 20 cases randomly selected for each month.

A total of 526 patient records were reviewed at the end of the study period. 679 triggers were indentified in 236 case records. Out of total triggers 621 were found to be true positive with identification of AEs. When the resulting harm were categorized according to NCCMERP index, category E was the most commonest and category G was the least commonly occurred type.

Critical care module included 14 items were there and 8 of them were found to be significantly better in identifying AEs. Transfusion of blood products, Infection of any kind and readmission within 30 days were prominent triggers in this category. In surgical care module, 9 out of 18 were found to be significantly better in identifying AEs. Occurrence of any post-operative complications, return to surgery and change in procedure were prominent ones in this category. In the medical module 21 out of 45 items were effective in picking up AEs. Use of laxative/constipation, repeated lab assessment and pyrexia were important triggers in this category.
Most important five AEs identified were bleeding, lab value abnormality, constipation, breathing difficulty and pyrexia. These events are mostly associated with complications of surgery and highlight the need for specific preventive measures to minimize or avoid these incidents. A total of 89 case records had only one trigger when reviewed whereas 9 case records had more than 10 triggers. It was found that higher the number of triggers present, higher the chances of occurrence of AEs. The average trigger per record was 2.88±2.92.

At the end of the review process, the perception of surgeons on the trigger tool methodology for identifying AEs was assessed. Their opinion was sought specifically on the level of AEs in daily practice, impact of AE on outcome of patient, need to monitor, need for hospital based AE monitoring and prevention system and effectiveness of electronic patient record in AE. Surgeons were of the opinion that AEs are a problem in their practice and there is a need to monitor and prevent them and the present trigger tool system appears to be effective in monitoring AEs and electronic records will enhance the ability to monitor AEs.

The present study was planned to develop, validate and implement a trigger tool system in the surgery department of the study hospital to detect AEs. At the end of this study all these objectives were met. Developed trigger tool had 77 items under three different modules. The developed tool was effective for the task. Higher the number of triggers in a case record, it was found that higher chances for occurrence of AEs. The identified AEs were almost similar in all aspects like category and severity to the reports from other parts of the world. This showed that this problem is common across different health care settings. The trigger tool methodology is equally effective in the current
study setting like other settings where it has been already implemented. The surgeons of the department gave positive feedback about the system and thereby making its implementation in routine practice possible. The developed trigger tool system was found to be an effective, practical and relevant approach for ensuring appropriate monitoring of AEs in the surgery department of the study hospital.