

# Prescribing Errors involved Splitting of Tablets: A Two-Hospital Case Analysis

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## ABSTRACT

**Objectives:** To decide on whether tablet splitting scenarios represent prescribing error situations or not by a panel of expert judges composed of thirty members and to analyze splitting of tablets orders in two teaching hospitals.

**Methods:** A questionnaire containing scenarios was submitted to each member of the panel of expert judges, and a two round Delphi technique was followed to obtain consensus. Based on the Delphi rounds results, 902 and 316 medication orders were screened from Services hospital and Punjab Institute of Cardiology, respectively.

**Results:** Two scenarios were considered prescribing error situations, one was excluded and one was partially agreed upon. In Services Hospital 42 errors were detected, out of which 20 errors involved splitting of modified release tablets while 22 errors involved splitting of coated tablets. In Punjab Institute of Cardiology 41 errors were detected, out of which 23 errors involved splitting of modified release tablets while 18 errors involved splitting of coated tablets.

**Conclusion:** It was concluded that programs are needed to increase the current awareness regarding unsuitability of splitting all tablet types.

**Key words:** Splitting, prescribing error, Delphi technique, Services Hospital, Punjab Institute of Cardiology.

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## INTRODUCTION

Splitting of tablets is a common practice, prescribers instruct their patients, nurses or other healthcare providers to split scored as well as non-scored tablets. Practitioners justify their practice by many advantages such as overcoming swallowing difficulties, adjusting dose for pediatric and geriatric patients, and long term therapy cost reduction<sup>1, 2</sup>. Some literature defended the rationale behind this practice and concluded the insignificant difference between whole and split tablets in terms of stability and efficacy<sup>3, 4</sup>. While others called for more research to generalize this approach in order to cut costs and ensure safety and efficacy<sup>5</sup>. Some researchers have gone beyond that studying the forces required to break a tablet, tensile and fracture strengths, relationship with tablet thickness defending scored and crushable tablets as rational dosage forms<sup>6, 7</sup>. Apart of its advantages, the practice is confronted with many disadvantages such as; breaking inaccuracy, dose inconsistency, weight variability, contamination, loss of pharmaceutical elegance and consumer acceptability<sup>8-10</sup>. Though the practice could be argued for conventional-release and scored tablets, but it is still controversial for modified-release,

coated and unscored tablets, since questions regarding dose dumping possibility, stability and efficacy needed to be answered<sup>11,12</sup>.

No consensus was reached on splitting tablets whether consist a prescribing error or not. Also little is known about current splitting practice in Pakistan hospitals, since to the best of our knowledge no such study was conducted in Pakistan before. In this study, we investigated splitting tablets as prescribing error with special focus on modified-release, unscored, and coated tablets.

## METHODOLOGY

### Definition of Prescribing Errors

Splitting a tablet (including modified-release and coated tablets) for any advantage may increase the risk of dose dumping and regimen failure, therefore it lies in the definition of prescribing errors developed by Dean et al and Ghaleb et al., which states that "A clinically meaningful prescribing error occurs when, as a result of a prescribing decision or prescription writing process, there is an unintentional significant (1) reduction in the probability of treatment being timely and effective or (2) increase in the risk of harm when compared with generally accepted practice"<sup>13,14</sup>.

### Panel of Expert Judges

To agree upon the above assumption, a panel of expert judges composed of thirty members was

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carefully selected from cross-sectional multidisciplinary medical and healthcare professionals. The panel was composed of 9 pharmacists, 14 doctors, 3 nurses, 2 pharmacologists, and 2 risk manager, the demographic details of the panel is presented in Table 1. The selection criteria were based on their expertise and active involvement in medical practice and research. All the judges agreed to participate without any incentives.

### Scenarios, Delphi Technique and Questionnaire

The study focuses on splitting un-scored, modified-release and coated tablets. Four scenarios representing ordering to split a tablet were developed, the scenarios were:

- Ordering to split a conventional tablet for economical purposes while an alternative dose is commercially available at higher prices.
- Ordering to split a conventional tablet for economical purposes while commercial alternative are available at equivalent savings.
- Ordering to split a modified-release system which would cause dose dumping and delivery system failure, while alternative doses are commercially available.
- Ordering to split a coated tablet (including enteric coated) which may be contradictory to the coating rationale, while alternative doses are commercially available.

The scenarios were compiled in a questionnaire and delivered hand by hand to each member of the panel and Delphi Technique was followed to reach consensus on the above definition of prescribing errors and the mentioned scenarios, as Delphi Technique is one of the widely accepted and followed techniques to reach consensus in clinical practice and research. A scale of nine was given against each scenario; each expert had to indicate his agreement with each scenario, a sufficient space was left under each scenario to add further comments and suggestions<sup>15, 16</sup>.

Prior to pursuing the Delphi rounds with the panel of expert judges, a pilot study was conducted by piloting the questionnaire with an independent *ten-membered* panel resembling the panel of expert judges; the results indicated the acceptability and understandability of the questionnaire.

### First and Second Round Delphi

A first stage Delphi was conducted and responses were obtained from 24 judges (85% response was obtained). In the second stage Delphi responses were obtained from 30 judges (100% response was obtained). The results were analyzed and consensus were achieved.

### Identifying Potential Prescribing Errors in Hospitals

In order to quantify orders to split tablets and identify potential prescribing errors, two major teaching hospitals namely; Services Hospital and Punjab Institute of Cardiology, Lahore (Pakistan) were selected for the study. The study involved inpatient profiles containing the patient's clinical history and medications prescribed; the same document was used by nursing staff to determine the doses due at each medication round and to record their administration. From Services Hospital fifteen inpatient profiles were scanned from the following wards: Medical Emergency Ward, ENT Ward, Gynecology Ward, Medical Ward One, Medical Ward Two, Medical Ward Four, Pediatrics Ward, Psychiatry Ward, and only six inpatient profiles were taken from Pulmonary Unit, using a digital camera (Orite 6.6 mega pixel); the near snaps option was selected producing images similar to digital scans when viewed on computer.

Similarly, fifteen inpatient profiles were scanned using the same digital camera, from the following wards of the Punjab Institute of Cardiology: Cardiology Ward, Chronic Care Unit, and Jilani Ward. The data were collected during an internship, in order to keep the usual prescribing behavior, the ward doctors weren't informed about the nature of the study.

### Data Analysis

In Delphi Technique, guidelines to reach consensus on clinical issue can be developed according to the needs of the study<sup>17-19</sup>. In the present study disagreement on prescribing error was considered when the median of the scores lied between 1-3; partial agreement (equivocal) occurred when scoring lied between 4-6; while agreement was considered when the median lied between 7-9. The scanned inpatient profiles snaps made by the (Orite camera 6.6 mega pixels) were transferred to a computer, where they looked like digital scans that can be enlarged and viewed clearly, then the scans were viewed and screened for potential prescribing errors regarding "ordering to split tablets"<sup>13, 17, 20</sup>.

## RESULTS & DISCUSSION

### Consensus on Scenarios

After the 1<sup>st</sup> and 2<sup>nd</sup> Delphi rounds consensus was achieved to include two scenarios as prescribing errors, exclude one scenario considering it justifiable as commonly practiced, and partially agreed (equivocal) on another scenario to be considered an error or not depending on the individual case and possibility of justification, these scenarios are given in

Table 2. When asked, the majority (90%) of the practitioners agreed that ordering to split tablets was commonly practiced, and they agreed that most of the practitioners were unaware of the pharmaceutical formulation design of the dosage forms they instruct their patients to split (including unscored, modified release and coated tablets). The panel justified the practice if it didn't affect the dose flexibility, weight variability, safety, stability and efficacy of the crushed dosage form. The panel found no justification if the practice led to dose dumping, failure of the regimen or contradiction with coating rationale.

#### **Prescribing Practice and Error Analysis in Services Hospital**

The analysis for potential prescribing errors was based on the scenarios the panel reached consensus to consider them as prescribing errors displayed in Table 2. Results analyzed from each ward of Services Hospital are presented in Table 3. It was found that ENT Ward had the lowest error percentage, followed by the Gynecology Ward. The highest error percentage was found in the Psychiatry Ward. Ordering to split coated tablets counted more than ordering to split sustained release tablets errors.

#### **Prescribing Practice and Error Analysis in Punjab Institute of Cardiology**

While for Punjab Institute of Cardiology; the lowest error percentage was found in the Chronic Care Ward and the highest error percentage was found in the Cardiology Ward. Ordering to split modified release tablets counted more than ordering to split coated tablets, the results are displayed in Table 4.

Generally the incidence of ordering to split tablets was more in the Punjab Institute of Cardiology than in the Services Hospital.

Even though formulators and institutions such as Institute for Safe Medication Practices published warnings and cautions regarding un-crushable tablets, it seems that splitting still being malpracticed and generalized for all tablet designs<sup>21-23</sup>. It seems that awareness of the prescribers with un-crushability of certain tablets is at alarming stage. Development of tutorials and instructive programs to increase awareness of prescribers are crucially needed, also labeling of un-crushable tablets needs revision. Promotional aids should stress more on this issue. Large-scale awareness has to be established through promotional messages; advertorials might also help in this regard.

Insight research exploring the reasons leading to such practice is still deficient as well as multi-centre quantitative research identifying the incidence of such errors. The present paper calls for further investigation on this issue.

## **CONCLUSION**

Crushing or splitting of tablets cannot be generalized for all tablet formulation designs; it can be justified for conventional release tablets and scored tablets that were designed to be crushed into halves for certain advantages, also can be justified for crushable tablets to which sufficient stability and efficacy testing have been conducted. While modified-release, coated (including enteric coated) and unscored tablets shouldn't be crushed unless sufficient research on stability of split tablets has been established.

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Table 1: Demographic Details of the 50 Expert Judges

Profession	Grade	Specialty	Employer
Pharmacist	Senior	Clinical Service	Children Hospital
Pharmacist	Lecturer	Quality Control	University
Pharmacist	Lecturer	Bioavailability	University
Pharmacist	Scholar	Pharmaceutical Technology	University
Pharmacist	Lecturer	Bioequivalence	University
Pharmacist	Junior	Retail & Marketing	Retail Pharmacy
Pharmacist	Senior	Hospital Pharmacist	General Hospital
Pharmacist	Assistant Professor	Pharmaceutics	University
Pharmacist	Senior	Pharmacologist	Cardiac Hospital
pharmacologist	Assistant Professor	Pharmacology	University
Risk manager	Lecturer	Risk Management	University
Risk manager	Lecturer	Health Safety	University
Nurse	Senior	Public Health Nursing	Nursing School
Nurse	Senior	Cardiology Nursing	Nursing School
Nurse	Senior	Community Health	Nursing School
Doctor	Assistant Professor	Diabetes Medicine	Teaching Hospital
Pharmacologist	Associate Professor	Clinical Pharmacology	Medical College.
Doctor	Junior	Cardiology	Cardiac Hospital
Doctor	Senior Registrar	Medicine/ Cardiology	Cardiac Hospital
Doctor	Professor	Pediatrics	Teaching Hospital
Doctor	Assistant Professor	ENT	Teaching Hospital
Doctor	Consultant	Gynecology	Teaching Hospital
Doctor	Head of Department	Psychiatry	Teaching Hospital
Doctor	Senior	Urology	Teaching Hospital
Doctor	Head of Department	Gynecology	Teaching Hospital
Doctor	Assistant Professor	Medicine	Teaching Hospital
Doctor	Senior Registrar	Surgery	Teaching Hospital
Doctor	Assistant Professor	Anesthesia	Medical College
Doctor	Lecturer	GP/ Lecturer	University
Doctor	Senior Registrar	Pulmonology	Teaching Hospital

Table 2: Scenarios Presented to Panel of Expert Judges, Results for 1<sup>st</sup> & 2<sup>nd</sup> Rounds Delphi

Scenario	Round One	Round Two	Median	Decision
Ordering to split a modified release system which would cause dose dumping and delivery system failure, while alternative doses are commercially available.	8.2	8.1	8.15	*Con, **In
Ordering to split a coated tablet (including enteric coated) which may be contradictory to the coating rationale, while alternative doses are commercially available.	7.8	8.0	7.9	Con, In
Ordering to split a conventional tablet for economical purposes while commercial alternative are available at equivalent savings.	5.1	5.6	5.35	Equivocal
Ordering to split a conventional tablet for economical purposes while an alternative dose is commercially available at higher prices.	1.7	2.0	1.85	*Con, *Ex

\*Con=consensus, \*\*In=Included, \*Ex= Excluded

Table 3: Analysis of Prescribing Practice in Services Hospital

Ward	No. of Profiles	No. of Medication Orders	No. of Orders to split a tablet	No. of Orders to split a modified release tablet	No. of Orders to split a coated tablet	Error %age
Medical Emergency	15	72	2	1	1	2.77
ENT	15	88	1	0	1	1.13
Gynecology	15	94	1	0	1	1.06
Psychiatry	15	84	9	5	4	10.71
Pediatrics	15	112	8	2	6	7.14
Medical One	15	136	10	6	4	7.35
Medical Two	15	153	7	3	4	5.18
Medical Four	15	110	2	2	0	1.8
Pulmonary Unit	6	53	2	1	1	3.77
Total	126	902	42	20	22	4.65

Table 4: Analysis of Prescribing Practice in Punjab Institute of Cardiology

Ward	No. of Profiles	No. of Medication Orders	No. of Orders to split a tablet	No. of Orders to split a modified release tablet	No. of Orders to split a coated tablet	Error Percentage %
Cardiology	15	102	15	10	5	14.7
Chronic Care Unit	15	109	12	7	5	11.0
Jilani	15	105	14	6	8	13.33
Total	45	316	41	23	18	12.97