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ANALYSIS AND CONTROL OF ISSUES THAT DELAY PHARMACEUTICAL PROJECTS

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Abstract. Every project will have certain objectives and service levels to be achieved. The success of a project depends on several dimensions like time, cost/budget, quality, etc. and managing a project involves completing the project within time, within budget and with quality to satisfy the users. Because of the significance of health, pharmaceutical companies realized the importance of project management methods and techniques to make available the life saving drugs in time to the needy patients and hospitals. In literature, there is meager information about pharmaceutical project management oriented towards analysis of issues and factors that contribute to the failure or success of projects. This study attempts to analyse different issues that contribute to time delays in pharmaceutical product-based projects, group them under a finite set of prominent factors and identify remedial measures to control those delays. The feedback of project people of some big pharmaceutical firms of Indian sub-continent was collected for this purpose. Exploratory factor analysis (EFA) has been used to reduce the reasons for time delays to a limited number of prominent factors and the EFA model has been further examined by confirmatory factor analysis (CFA) for its validation. Remedial measures under each factor of time delays have been gathered and a framework designed to mitigate the time delays in pharmaceutical projects. The derived factors that delay the pharmaceutical projects include resource, monitoring & control, scheduling and planning problems. Important remedial measures like blended resource approach, estimation and forecast of shortage of labour and skills, regular quality training, etc. have been recommended.

Keywords: project analysis, time delays, project management, health care industry, factor analysis, delay controls.

JEL Classification: C38, I11, O22.

Introduction

Usually any project ends up with either success or failure in achieving all the objectives in a satisfactory way. According to Papke-Shields *et al.* (2010), project management evolved over the past two decades as both researchers and practitioners have attempted to identify the causes of project failure and the various factors that lead to success. Meredith and Mantel (2012) reported that there are three major forces involved for the development of new methods in project management – (i) the exponential expansion of human knowledge; (ii) the growing demand for a broad range of complex, sophisticated customized goods and services; and (iii) the evolution of worldwide competitive markets for the production and consumption of goods and services. Project success aspects included achieving client satisfaction and achieving business objectives, which mean the agreed service levels. The key project management responsibilities include managing the triple constraints for projects – cost, time, and scope. According to Chen and Huang (2013), completeness of requirements may contribute significantly to the success of building projects in terms of schedule success, cost success, quality performance and overall benefit. Over the last two decades, research on project management (Tishler *et al.* 1996; Tukel, Rom 1998; Roger 1999;

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Hammer, Champy 2003; Zhang *et al.* 2003; Evans 2005; Ward 2014; Mejillano *et al.* 2007) demonstrated that most of the projects fail either in meeting time and budget goals or in satisfying customer and/or company expectations. According to Tukel and Rom (1998), completion of a project by scheduled due date was treated as one of the most frequently used measurements of project success. Time delays will be so severe that they can reap up in any task/activity/phase of a project and reinforce in the connected stages. Hence considerable attention is needed for their control and this is becoming one of the big challenges for project people. This study focuses on time delays in projects.

Since health needs have top most importance in human society, both public and private pharmaceutical companies have taken up the challenge of providing affordable medicines to more people around the world at lower costs. Despite aggressive application of good tools, methods and techniques, many pharmaceutical companies have been struggling to make their projects more economical and schedule-oriented to achieve maximum service levels. Most of the major and big pharmaceutical companies are committed to provide affordable and innovative medicines by focusing on customer requirements and delivering the products at right time. Currently, these companies have been aggressively using project management techniques to complete the projects in time and within budget and maintain their competitive advantage by meeting the market demands. The very nature of drug development cycle or product development through its different stages and the competition prevailing amongst the pharmaceutical companies by ensuring an early product launch to capture the market are just a few reasons for the growing importance of project management in pharmaceutical industry.

The pharmaceutical industry is unique in its procedures and methods of manufacture since the integrity of its products must be ensured by three main functions – current good manufacturing practices, quality assurance, and quality control (Cole 1998). According to Hwang *et al.* (2008), pharmaceutical projects often demand a tailored benchmarking approach because of their intensive qualification and validation procedures. They developed and validated a benchmarking framework for pharmaceutical capital projects by taking into consideration three major drivers – schedule, cost and dimensional performance. In pharmaceutical industry, competitive advantage and increased sales revenue would be achieved by reduced time-to-market (Nalewaik 2005). In the management of pharmaceutical projects, there has been a growing interest in finding ways and means to control delays in making drugs and taking to market in time. For example, Yang and Yau (2013) developed a computer-based method that integrates two process-based schedule delay analysis methods simultaneously based on information flow analysis. The present study took the support of statistical factor analysis and applied both exploratoratory and confirmatory factor analyses on the collected data to analyse time delays in pharmaceutical projects.

Statistical factor analysis is a multivariate statistical method used to identify common underlying variables called factors within a larger set of measures. There are two statistical approaches, namely, exploratory factor analysis (EFA) and confirmatory factor analysis (CFA) that are used to examine the internal reliability of a measure. EFA is helpful in the initial stages of analysis to explore interrelationships among sets of variables and reduce them to a few factors so as to arrive to a measurement model. CFA is used in the later part of analysis to test the model derived from EFA, by testing its "goodness of fit" and conformity of the factors. Several researchers applied statistical factor analysis to several fields including project management for analysis of data collected on different issues. Bryson and Bromiley (1993) used factor analysis to identify major factors from various variables describing the context of the projects, their planning and implementation processes and project outcomes. They reported that a number of contextual variables strongly influence project planning and implementation process, and indirectly influence the outcomes through planning and implementation process. They added that both process and contextual variables affect project outcomes directly. Shi and Wright (2001) used both exploratory and confirmatory factor analyses to examine and validate factor structures of international business negotiator's profile. They used the commonly accepted goodness-of-fit indices as reported by Jöreskog and Sörbom (1993) to assess the overall fit of the measurement model. Sureshchandar *et al.* (2002) identified the critical factors of service quality from the customer perspective, developed an instrument to measure customer-perceived service quality based on those factors and with the help of CFA, they empirically tested and validated the instrument. Wang and Ahmed (2004) developed an organizational innovativeness construct and assessed its validity and reliability using confirmatory factor analysis. This study, after identifying the prominent factors that delay the pharmaceutical projects from EFA, attempted to test the "goodness of fit" of the model and validate it further using CFA.

Chan and Tam (2000) examined the underlying factors affecting the quality of building project and found that project management action by the project team was the most powerful predictor of client's satisfaction with quality. Li *et al.* (2005) investigated into the relative importance of various potential critical success factors for construction projects in UK with public-private partnerships (PPPs) and private finance initiative (PFI) and identified the three most important factors out of them. Doloi (2009) applied factor analysis to identify the prominent factors that influence

contractors' performance in construction projects. Aubry *et al.* (2010) made a survey on transitions of project management offices (PMOs), which are dynamic organizational entities and found that the transition of a PMO from one configuration to the next is not a question of being right or wrong. Nwachukwu and Emoh (2010) analysed materials as an integral part of direct and indirect factors that hinder project management success of public and private sector construction in Nigeria. They used factor analysis to derive potential factors. Jou *et al.* (2010) used factor analysis to identify the key elements that affect new product development (NPD) in a semiconductor equipment manufacturing firm, whereas Thomas and Vilakshan (2011) used for software project risk management. Much of the literature concerned with projects in various fields except pharmaceutical industry. Hence this study attempted to examine and validate important time-delay factors in pharmaceutical projects and as a first step the study focused on product based projects only.

The objective of this work is to come out with a framework to control time delays in pharmaceutical product projects in order to help the project people to meet the planned service levels. It has been attempted to analyse in depth the various issues that contribute to time delays. By performing surveys in pharmaceutical companies and interacting with experienced project people, the study explored several issues that hamper achievement of service levels in terms of time in pharmaceutical projects. To derive the major factors from the feedback data, exploratory factor analysis was used and to validate the constructs thus derived, confirmatory factor analysis was used. Taking the results to the notice of experienced pharmaceutical project managers, valuable information on different remedies to control time delays was collected. Finally, a framework was developed to give an overall picture of time delays and remedial measures to control them in pharmaceutical projects.

1. Research methodology

Industries like pharmaceutical, bio-tech, life sciences and R&D are quality and schedule driven sectors marked by strong competition to launch their product first in the market and capture high marginal profits for their survival and future growth. In the light of treating reduced time-to-market as one of the important factors to achieve competitive advantage and increased sales revenue in pharmaceutical projects (Nalewaik 2005), this study was initiated to examine the reasons behind not achieving service levels in pharmaceutical projects in terms of time dimension.

To study the importance of time dimension in achieving the service levels of pharmaceutical projects, a simple questionnaire was distributed to managers at different levels dealing with projects in four big pharmaceutical companies – A, B, C and D (to maintain confidentiality, the names of the companies are suppressed) in India. They were requested to express their perception on importance of time dimension in achieving the service levels of projects on a scale of 0–5, '0' representing 'not important' and the remaining scores representing importance of time proportionately with '5' the highest importance. A total of 137 managers responded and the weighted average was found to be around 3.5, with no one opting for zero importance. This result provided good support for the fact that time is an important dimension in the success of pharmaceutical projects. In continuation of this, another survey was taken up simultaneously in the companies to check the status of different projects during the financial year 2006–07 in terms of time. Four categories of status of 91 projects were considered – completed in time, completed with delays, work-in-progress projects as per schedule, and work-in-progress projects with delays. It was observed that about 70% of the projects were completed in time and remaining ones completed with delays in all the four quarters. Most of the work-in-progress projects were moving as per schedule in the first two quarters, and in the remaining two quarters, the percentage was coming down with more delays.

The above two preliminary studies motivated the present research work by establishing a strong base to proceed further for a detailed analysis of the reasons behind time delays and thereby finding remedies to mitigate them in improving the service levels of pharmaceutical projects. For this, a detailed survey was conducted in the four pharmaceutical companies to collect useful feedback about the reasons behind time delays in the projects.

1.1. Survey instrument

As a first step, face-to-face interviews were conducted with several pharmaceutical project managers, who directly involved in managing the projects. This attempt led to preparation of a draft list of reasons behind success and failure of projects in terms of time. The list is further refined by interactions with a group of selected senior project managers having long experience with pharmaceutical projects. Based on these interactions, a final list consisting of a total of 13 reasons behind time delays in pharmaceutical projects was prepared. To get the feedback of people on the significance of each of these 13 reasons for time delays, a questionnaire was developed and circulated to different people who are working in those four companies and are all internal project stakeholders only. They were requested to fill the questionnaire by assigning a significance level to each reason on a Likert scale of 1–5, which ranges from 'not at all significant' (assigning a score of 1) to 'most significant' (score of 5) and the remaining ones representing the relative significance. All the reasons are listed in Table 1 and the questionnaire is given in Table AI of Appendix.

To analyse the feedback data, statistical factor analysis, both exploratory and confirmatory, has been used. For exploratory factor analysis of survey data, the method of principal component analysis is used along with Varimax rotation method to reduce the variables to a minimum number of factors. To check the adequacy of the sample, KMO and Bartlett tests are conducted. Based on eigenvalues and proper loadings of the variables, a finite set of factors has been selected. Using the feasible value of Cronbach's α (alpha), the reliability of each factor is checked. The conformity of the factors thus extracted from factor analysis is further examined with the help of confirmatory factor analysis. Thus, both EFA and CFA are used to extract reliable and well validated factors from the feedback data collected on various reasons related to time delays in pharmaceutical projects.

1.2. Data collection

Out of a total of 170 questionnaires distributed, 150 employees from the four big pharmaceutical companies responded with proper and clear feedback. Hence the response rate was above 88%, which is reasonably very good. 17% of respondents were senior project managers, 11% project managers, 11% senior managers, 18% managers, 22% deputy managers and remaining 21% were assistant managers. Regarding length of experience, 21% of the respondents had above 10 years, 26% had 6–10 years, 30% had 2–5 years of experience, and remaining 23% had about 2 years of experience. Regarding company-wise responses, 24% contribution was from company A, 29% from B, 28 % from C and the remaining 19% of respondents from company D. All these demographic details are given in Table 2.

2. Data analysis

2.1. Factor extraction

Keiser-Meyer-Olkin (KMO) measure of sampling adequacy was found to be 0.593, which is very close to the required merging of 0.6 (Alhaji *et al.* 2011) and also matching the requirements reported by Hair *et al.* (1995) and Tabachnick and Fidell (2007). In addition, the Bartlett's Test of Sphericity produced a χ^2 (Chi-square) of 1937.934, degrees of freedom of 78 and a significance level of 0.000, which is less than 0.05. These results indicate the significance of the sample. Using the latent root (eigenvalue) criterion, five factors were identified with eigenvalues greater than 1.0. It is found that all the five factors altogether account for about 83.8% of the total variance, with first factor (F1) of 22.6%, second factor (F2) 21.8%, third factor (F3) 15.8%, fourth factor (F4) 13.8 % and fifth factor (F5) of 9.8% of variance. After rotating of the factors by Varimax method, the degree of association (correlation) of each variable with each factor was identified. A cut-off for all loadings followed here was above 0.40 (Conway, Huffcutt 2003; Mathur *et al.* 2007). Each of Factor 1 and Factor 2 has three variables, whereas Factor 3 and Factor 4 have two variables with significant loadings greater than 0.9. Factor 5 has 3 variables with loadings of 0.646, 0.411 and 0.800 respectively.

Table 1. List of variables considered for statistical factor analysis on time delays

Item Number	Reason for Time delay
1	Improper Planning (IP)
2	Improper Schedules (IS)
3	Wrong selection of Consultants (WC)
4	Improper Resource mapping (IR)
5	Improper Designs (ID)
6	Non-availability of Skilled Labour (NSL)
7	Improper Vendor Selection (IVS)
8	Improper Service Contracts (ISC)
9	Project Scope creep (PSC)
10	Delays in Order processing (DOP)
11	Improper Follow-ups (IF)
12	Delays in drawing Approvals (DA)
13	Non-availability of funds (NF)

Table 2. Demographic data of respondents

Category	Total number of respondents	Percentage (%)
Designation-wise:		
Senior Manager (Projects)	26	17
Project Manager	16	11
Senior manager	17	11
Manager	27	18
Deputy Manager	33	22
Assistant Manager	31	21
Age-wise:		
<2 years	34	23
2–5 Years	45	30
6–10 Years	39	26
Above 10 Years	32	21
Company-wise:		
A	36	24
B	43	29
C	42	28
D	29	19

2.2. Factor reliability

The internal consistency of a measuring instrument is established by using a reliability coefficient, Cronbach's α (Cronbach 1951). Nunnally (1988) considered Cronbach's α value of 0.6 and 0.7 or above as the criteria to demonstrate internal consistency of new scales and established scales respectively. In the most reliable form, the coefficients should be as close to 1.00 as possible (Reinard 2006). In the present work, the Cronbach's α was derived for each of the five factors as 0.977, 0.966, 0.974, 0.718 and 0.273. Table 3 lists the communalities and factor loadings of all the 13 reasons, whereas Table 4 gives the eigen values, percentage of variance explained and reliability in terms of Cronbach's α of all the five factors extracted.

Table 3. Factor analysis for the reasons of time delays

Variable	Communalities		Factor loading
	Initial	Extraction	
IP	1.000	0.832	0.905 (F3)
2. IS	1.000	0.967	0.982 (F2)
3. WC	1.000	0.950	0.971 (F2)
4. IR	1.000	0.957	0.975 (F1)
5. ID	1.000	0.927	0.951 (F2)
6. NSL	1.000	0.922	0.956 (F1)
7. IVS	1.000	0.538	0.646 (F5)
8. ISC	1.000	0.415	0.411 (F5)
9. PSC	1.000	0.844	0.907 (F3)
10. DOP	1.000	0.967	0.982 (F2)
11. IF	1.000	0.944	0.968 (F2)
12. DA	1.000	0.972	0.985 (F1)
13. NF	1.000	0.663	0.800 (F5)

Table 4. Eigen values, variance and reliability of factors extracted

Factor extracted	Eigen value	Percentage of variance explained	Reliability, Cronbach's α
F1	3.076	22.6	0.977
F2	2.865	21.8	0.966
F3	2.048	15.8	0.974
F4	1.816	13.8	0.718
F5	1.091	9.8	0.273

Table 5. Names of the factors and the time delay issues grouped

Factor	Variables grouped
F1: Resource problems	IR: Improper Resource mapping NSL: Non-availability of Skilled Labour DA: Delays in drawing Approvals
F2: Monitoring & Control problems	WC: Wrong selection of Consultants ID: Improper Designs IF: Improper Follow-ups
F3: Scheduling problems	IS: Improper Schedules DOP: Delays in Order processing
F4: Planning problems	IP: Improper Planning PSC: Project scope creep

It is found that the fifth factor (F5) attributed very low value for both percentage of variance explained (9.8%) and Cronbach's α (0.273) and hence it cannot be treated as a prominent and reliable factor. Therefore, the first four factors have been treated as significant factors, based on their reasonably and relatively high values of percentage of variance explained and reliability. In addition, all these four factors attained a cumulative percentage of total variance explained as 75.76, implying a satisfactory degree of construct validity. In addition, these factors have variables loaded with higher values, greater than 0.9.

Depending on the type of variables grouped under each of the four factors, proper naming has been done for them. Factor 1 is named as 'Resource problems', Factor 2 as 'Monitoring & Control problems', Factor 3 as 'Scheduling problems' and finally Factor 4 is named as 'Planning problems'. The factor of resource problems has contribution from the issues of improper resource mapping, non-availability of skilled labour and delays in drawing approvals. Similarly, 'Monitoring & Control problems' has contribution from wrong selection of consultants, improper designs and improper follow-ups. Improper schedules and delays in order processing contribute to the factor of scheduling problems. Planning problems is loaded with the issues of improper planning and project scope creep. Table 5 lists all the four named factors along with the associated time delay issues (variables).

2.3. Confirmatory factor analysis

Exploratory factor analysis (EFA) is concerned with the question of how many factors are necessary to explain the relations among a set of indicators and with the estimation of the factor loadings, whereas confirmatory factor analysis (CFA) is concerned with parameter estimation and tests of hypotheses regarding, for example, the number of factors underlying the relations among a set of indicators (Pedhazur, Schmelkin 1991). CFA is a type of factor analysis conducted to test hypotheses or confirm theories about the factors one expects to find and it is a subtype of structural equation modeling (Vogt *et al.* 2008) and is the initial step of a complete test of a structural model (Hair *et al.* 2006). According to Schumacker and Lomax (2004), CFA is commonly used to confirm that the indicators sort themselves

into factors corresponding to how the research has linked the indicators to the latent variables. While analyzing the measurement for self-directed learning, Harvey *et al.* (2006) used CFA to check the reliability of the results of exploratory factor analysis (EFA) and the responses in the case of students' self-directed learning. Since EFA resulted in a finite number of significant factors that are required to explain the inter-correlations among the measured variables, and CFA is more appropriate than EFA (Bentler 1995), the present study applied CFA to confirm the results of EFA.

In CFA, a model is built based on a priori information about the data structure in the form of knowledge derived from previous studies with extensive data. The confirmatory factor models will be displayed as path diagrams, where squares represent the observed variables, ellipses represent latent concepts (constructs or factors) and circles represent any errors in correlating variables to the respective constructs. Single-headed arrows show the direction of assumed causal influence and the curved double-headed (bidirectional) arrows represent covariance between two latent variables, that is, correlation among the paired dimensions. Each indicator reflects (has a loading on) one factor only and the errors are said to be not correlated (Pedhazur, Schmelkin 1991). Taking into account the four factors derived from EFA, the path diagram of time delays in pharmaceutical projects is developed as shown in the Figure 1. In the path diagram, e1 to e10 represent the errors in correlating variables to the respective factors.

To support the results of EFA, there are several classes of model fit indexes in CFA and Marsh *et al.* (1996) recommended that individuals utilize a range of fit indices. These classes of fit indices include discrepancy functions (chi-square test, relative chi-square, and RMS); comparing the target model with the null model (CFI, NFI, TFI, and IFI); information theory goodness of fit measures (AIC, BCC, BIC and CAIC); and non-centrality fit measures (NCP). According to Jaccard and Wan (1996), usage of indices from different classes would overcome the limitations of each index. Various authors (Bentler, Bonett 1980; Hoelter 1983; Jöreskog, Sörbom 1993; Bollen 1989; Steiger 1990; Browne, Cudeck 1993; Byrne 1994; Hu, Bentler 1999; Schumacker, Lomax 2004; etc.) proposed different fit indices and recommended the cutoff values to them to assess the acceptance of model.

According to Child (2006), three common measures of overall goodness of fit are a chi-square (χ^2) measure, goodness of fit index (GFI) and root mean square residual (RMR). Carmines and Zeller (1990) suggested the ratio of χ^2 to df (degrees of freedom) of 2 or 3 as criterion of fit. This relative χ^2 should be less than 2 or 3 (Kline 1998; Ullman 2001). According to Hair *et al.* (2006), the recommended values for relative χ^2 is 3.0 or below. In this study, the χ^2 value is derived as 82.271 and df as 29 and hence the relative χ^2 is found as 2.837, which is within the acceptable range as specified in the literature reports. RMR and GFI fall between 0 and 1 with GFI to be as near to one as possible, whereas RMR as near to zero as possible (Child 2006). According to Byrne (1994) and Hair *et al.* (2006), GFI value should exceed 0.90, the adjusted goodness of fit index (AGFI) should be 0.8 or above (Hair *et al*. 2006) and Normed fit index (NFI) should be greater than 0.90 (Byrne 1994) or 0.95 (Hu, Bentler 1999; Schumacker, Lomax 2004) and both GFI and AGFI may range from 0 to 1 (Pedhazur, Schmelkin 1991). Cole (1987) stated that values greater than 0.9 and 0.8 for GFI and AGFI

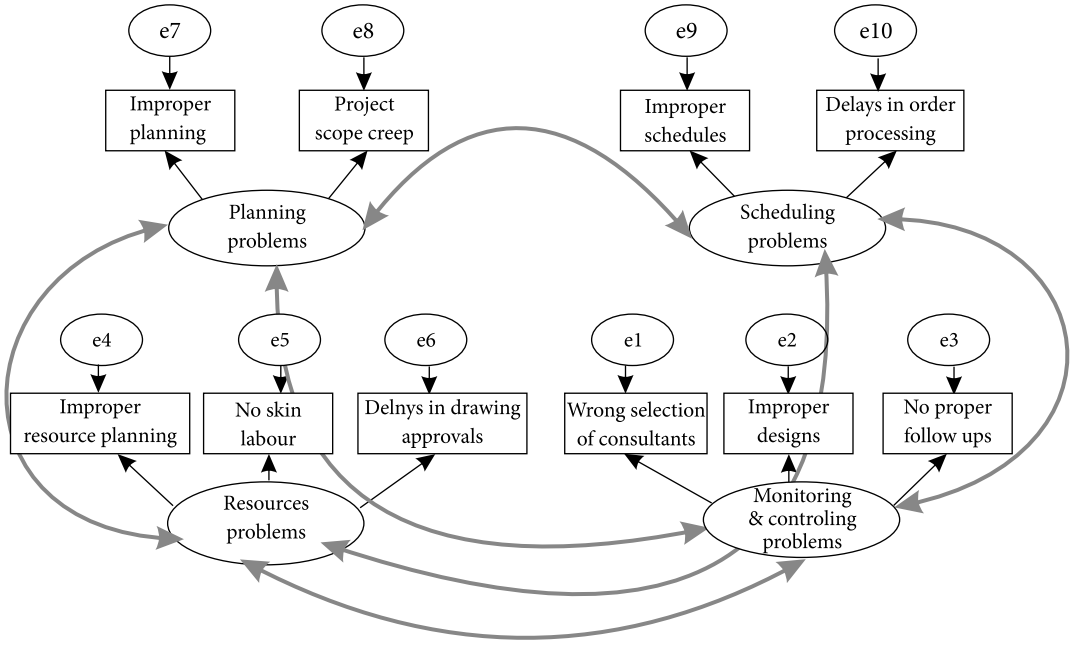

Fig. 1. Path diagram for confirmatory factor analysis of time delays

respectively, usually indicate good fit. In the present study, the derived values for RMR, GFI and AGFI are 0.047, 0.911 and 0.832 respectively, which are all within the acceptable ranges. Hence overall goodness of fit has been established for the model.

The unidimensionality of the measure represents the existence of a single construct underlying a set of measures. According to Anderson and Gerbing (1991), the unidimensionality of the measure is a highly mandatory condition for checking construct validity and reliability. According to Bollen (1989), a comparative fit index (CFI) value of 0.85 represents progress and should be acceptable. CFI of 0.90 or above represents strong evidence of unidimensionality for a model (Byrne 1994; Hair *et al.* 2006). In this study, the derived value for CFI is 0.972, which strongly supports the unidimensionality of the measurement model.

Table 6 lists all the derived values of measures of goodness of fit and unidimensionality and these results well confirm the goodness of model fit and validate the unidimensionality of the model. Hence CFA provided significant support for the grouping of reasons behind time delays in pharmaceutical projects under the said four major factors.

Table 6. Model fit indexes for time delays

Model fit index	Recommended value or cut-offs	Measurement model
Chi-square (χ^2) to degree of freedom ratio (CMIN/df)	3.000 or below	2.837
Goodness of fit index (GFI)	0.900 or above	0.911
Adjusted goodness of fit index (AGFI)	0.800 or above	0.832
Root mean square residual (RMR)	Nearer to 0.0 or below 0.05	0.047
Comparative fit index (CFI)	0.900 or above	0.972

2.4. Interpreting results

All the extracted and validated factors are described below in the light of grouped reasons:

1. *Resource Problems:* In pharmaceutical projects, people work for multiple projects at a time, and this situation leads to keeping same people on more than one project. Such multi-tasking by single resource keeps lot of pressure on that resource. When sufficient labour with skill set matching the requirements of projects is not available, many tasks will be kept pending and those completed tasks would have poor quality. In such case, rework by other skilled labour will be awaited leading to time delays. While doing detailed engineering in projects, external consultants would send execution drawings for approvals of project team members who spread across many functional departments or divisions. The issues of multi-tasking, integration failure among the project team members, etc. lead to delays in approving the drawings.
2. *Monitoring* & *Control problems:* Selection of low profile consultants due to cost cutting procedures and improper negotiations by project team needs lot of follow-ups to get the drawings, detailed Bill of Quantities (BOQ), etc. in time from the consultants. When such follow-ups are absent, lot of time delays happen. And at the same time, improper designs of equipment, for example selection of MOC (Material of construction), design parameters, etc. lead to time delays in projects. This is because of re-ordering with proper designs. Similarly, when important activities like delivery of long lead equipment by the vendors, services from external agencies, etc. are not properly tracked and controlled, the project or the concerned project tasks may be delayed.
3. *Scheduling problems:* When micro-level (individual) and macro-level (combined) activities are not properly scheduled according to the inter-connections and concurrence among different functional departments, projects would face delays. Due to lot of procedural requirements in ordering process, like preparation of user requirement specifications (URS), collection of quotations from multiple vendors, technical bid analysis (TBA) and final negotiations, etc., the procurement cycle period would be enhanced and becomes a source of time delays.
4. *Planning problems:* Improper planning of manpower, equipment, resources, etc. in projects contributes to time delays. In most of the pharmaceutical projects, continuous change requests from users would be common. They enhance the scope of the project further and further. Such scope creep would require additional time to accomplish all the added requirements.

Another round of personal interactions and brain-storming exercise with experienced project managers and study of various projects in the four big Indian pharmaceutical companies helped to prepare a list of remedies to control time delays. These remedies stood as great support to design the framework to improve service levels. The remedies thus collected are discussed in the following sections.

3. Remedies to control time delays

Based on the derived factors and their loaded reasons that contribute to time delays, a list of remedies to control time delays was prepared with the help of personal interactions established with the experienced and senior project

managers working in the five big pharmaceutical companies. Figure 2 provides a framework that shows the contributions and remedies to time delays in pharmaceutical projects and the following paras describe those remedies.

- *Blended resource approach:* It is a pool of talented people from different disciplines of projects working for multiple projects as per the individual project requirement which will be useful for optimum utilization of resources.
- *Estimation and forecast of shortage:* Estimation and forecast of skilled labour at regular intervals will be used to maintain required strength at any point of time and thereby avoiding any shortages of required skills and skilled labour.
- *Regular quality training:* Regular quality training programmes in special areas improve the skill set of the people, who can show better performance in complex project activities.
- *Common talent pool:* Maintaining a pool of talented people across the organization, can be useful for developing the required resources on multiple projects wherever necessary.
- *Co-ordination among departments:* Consultants submit the project related drawings for approval of multiple departments, which have stake in the concerned projects. In such cases, instead of individual study of the drawings by each department, it would be better to form a team among departments to study

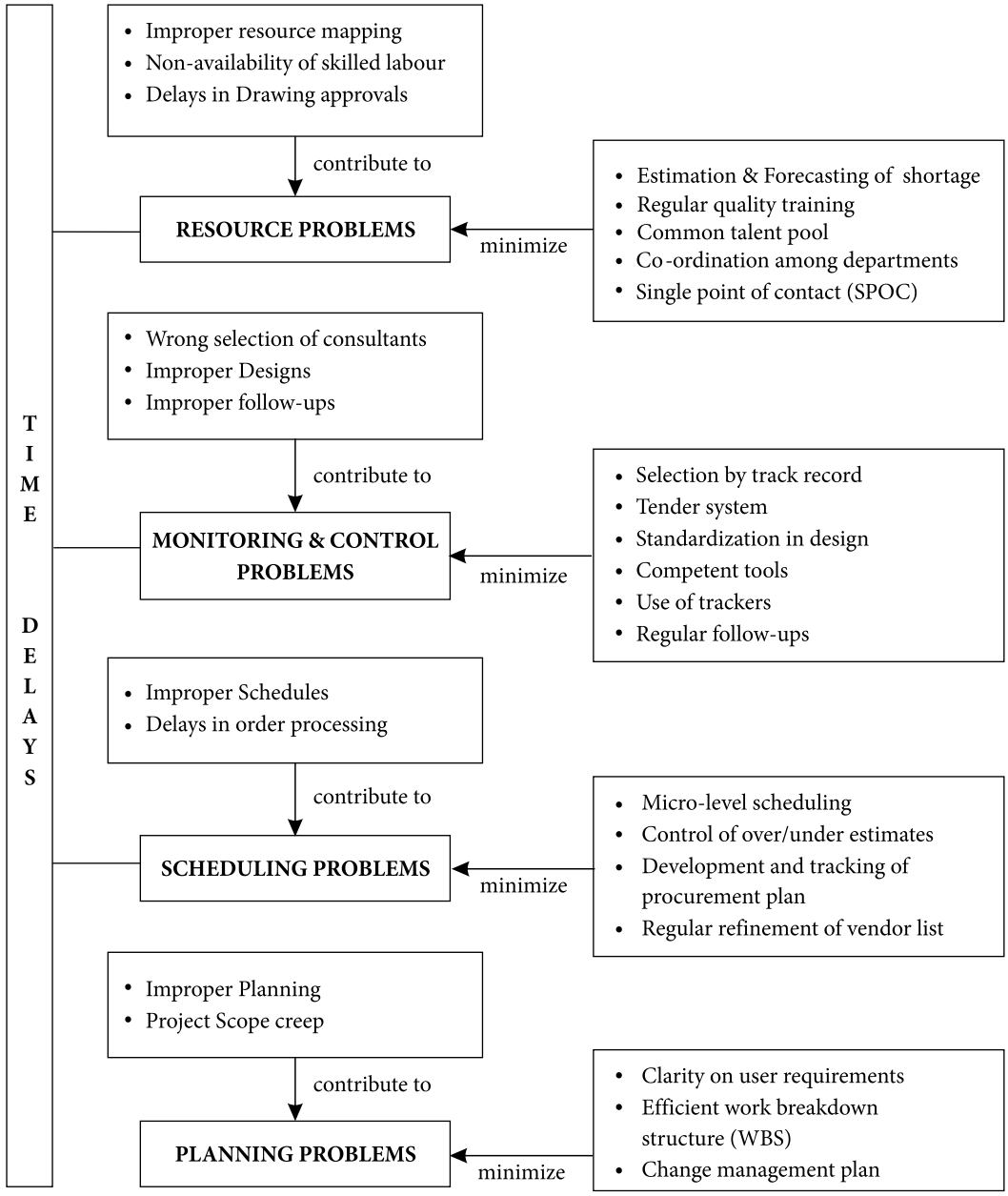

Fig. 2. Framework showing contributions and remedies for time delays in pharmaceutical projects

and approve the drawing, by this way time delays will be reduced considerably.

- *Single point of contact (SPOC):* Instead of multiple people, one person from a project team may continuously coordinate with direct and in direct project stakeholders, this can help in maintaining and tracking projects to get things done quickly.
- *Selection by track record:* For selection of good consultants to the project, it would be better to collect the feedback on consultants' performance and their track record from project teams of other companies. This would help project teams in getting right drawings and required inputs from consultants at right time.
- *Tender system:* Transparent and un-biased tender system would lead to selection of qualified consultants for complex and mega project, right choice of qualified consultants benefits project teams from beginning to end of the project by avoiding delays in getting right drawings approvals and right inputs at right time from the consultants.
- *Standardization in design:* Standardization of designs in projects will be useful to swap the equipment from one project to other and also reduce the inventory on spares.
- *Application of competent tools:* Use of proper competent tools helps project team to have proper design of equipment, right selection of material of construction (MOC), easy maintenance, user friendliness, adoption of new technologies, improvisation in automation, etc.
- *Use of trackers:* Utilization of *p*roject trackers helps in identifying the critical activities like delivery delays of equipment, resource requirements, etc. of the projects.
- *Regular follow ups from the initial stage:* Regular follow ups from the beginning of the project would help to minimize the problems faced at eleventh hour situations.
- *Micro level scheduling:* A micro level schedule with sufficient details can be used as a predictive model of the project. Micro level schedules help project team members forecast project performance, facilitate quality decision making, shorten project feedback loops and accelerate team learning.
- *Control of over/under estimates:* An inaccurate or superficial estimate of resources, time or budget may convince the project stake holders initially, but slowly throws challenges to project success; hence such inaccurate estimations should be avoided and controlled, as to have optimal schedule performance.
- *Development and tracking of procurement plan:* It would be better to have good procurement plan from p2p (procurement-to-pay) in projects, which helps to minimize delivery delays or failures for long-lead delivery equipment / materials.
- *Regular refinement of vendor list:* Development of new list of alternative vendors at regular intervals leads to better control on cost at the time of bulk order of equipment or materials, and split of orders on multiple vendors to minimize the order delays.
- *Clarity on user requirements:* During the planning stage itself, it is important to classify the key success factors that coincide with the user requirements. Collection of entire requirements from all the end-users during planning phase helps to have better project planning to optimize the project time lines.
- *Efficient WBS:* Detailed and efficient work breakdown structure (WBS) provides a structured view of various components of a project, which are planned in sequentially lower tiers of details.
- *Establishment of change management plan:* A proper change management plan with a positive approach could be adopted by involving all the project stake holders and incorporating their needs thorough out the project life cycle. To avoid any project disputes, it is important to always seek approval of changes from users and communicate them to concerned team members in a timely manner.

Conclusions

There are several factors that contribute to the success or failure of a project and every project will be evaluated on the basis of some important dimensions, including time, cost, and quality. All these issues should be properly analysed and handled while managing the projects. Like other industries, pharmaceutical industry realized the importance of project management to meet the agreed service levels and many big pharmaceutical companies have been aggressively adopting various project management methods, tools and techniques. Meager research has been done in the direction of project management in pharmaceutical industry. In order to fill the research gap in literature on pharmaceutical project management and to have an in-depth analysis of the reasons that delay the projects, this study took the help of statistical factor analysis including both exploratory and confirmatory factor analyses. Four big pharmaceutical companies in the Indian sub-continent were selected for survey and feedback data of the internal project people was collected. The measurement model based on the extraction of four reliable factors from the exploratory factor analysis has been examined for its goodness of fit and further validation by confirmatory factor analysis. The results are quite satisfactory. The time-delay factors include resource, monitoring & control, scheduling and planning problems and each factor groups certain reasons. Interactions with

the senior project managers of pharmaceutical projects helped to collect useful information on various possible remedial measures to mitigate the time delays in projects. Based on the results of factor analysis and interaction with senior project people, a framework has been designed to control time delays in pharmaceutical projects. These findings provide valuable support to the pharmaceutical industry to control the time delays.

This study focussed on time dimension in meeting the service levels of product-based pharmaceutical projects. In addition to time dimension, there will be many other dimensions that can further improve the service levels of pharmaceutical projects. The data and information required for the present study was collected from four big pharmaceutical companies in Indian sub-continent only. Future research would cover more number of big companies to improve the sample size and scope of analysis. In addition to product-based projects, other types of projects like capital projects in pharmaceutical industry would also be surveyed. Next, other dimensions like cost and client satisfaction would also be considered so as to enhance the analysis useful to improve the service levels of pharmaceutical projects.

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APPENDIX

Table AI. Survey questionnaire for statistical factor analysis of time delays

Name of the Employee: Company: Designation: Experience:						
Reasons for TIME delays in pharmaceutical projects	Significance level					Your suggestions to resolve the issue
	1	2	3	4	5	
1. Improper Planning						
2. Improper Schedules						
3. Wrong selection of Consultants						
4. Improper resource mapping						
5. Improper Designs						
6. Non-availability of skilled labour						
7. Improper Vendor Selection						
8. Improper Service Contractors						
9. Project Scope Creep						
10. Delays in Order Processing						
11. Improper Follow Ups						
12. Delays in Drawing approvals						
13. Non-availability of funds						
Others, if any (your views) 14. 15.						

Note: Please tick in the respective box to specify the significance level of each issue that affects TIME delays in pharmaceutical projects. The values 1 to 5 mean 'Least' to 'High' significance in ascending order.

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