

Summer Training Report

By

Vaishali Mittal

MBA (Hospital and Health Management)

2019-21



ACKNOWLEDGEMENT

It is my pleasure to express with deep sense of gratitude to Dr. Sheenu Jain, Associate Professor, Marketing and Chair, Centre for Innovation, Incubation, and Entrepreneurship, Indian Institute of Health Management and Research, for her constant guidance, continual encouragement, understanding; more than all, she taught me patience in my endeavor. My association with her is not confined to academics only, but it is a great opportunity on my part to work with an intellectual and expert in the field of research and development.

I would like to express my gratitude to Prof. (Dr.) Pankaj Gupta, President and Dr. P.R. Sodani, Pro President & Dean, MBA-Health and Hospital Management, IIHMR University, for providing with an environment to work in and for his inspiration during the tenure of the course.

In jubilant mood I express ingeniously my whole-hearted thanks to all teaching staff and members working as limbs of our university for their not-self-centered enthusiasm coupled with timely encouragements showered on me with zeal, which prompted the acquirement of the requisite knowledge to finalize my research study successfully. I would like to thank my parents for their support.

It is indeed a pleasure to thank my friends who persuaded and encouraged me to take up and complete this task. At last but not least, I express my gratitude and appreciation to all those who have helped me directly or indirectly toward the successful completion of this project.

Place: Jaipur

Date: July 24, 2020

Vaishali Mittal

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Abbreviations

CER	Comparative Effectiveness Research
CONSORT	Consolidated Standards of Reporting Trials
DCP	Data Collection Plan
DMAIC	Define, Measure, Analyze, Improve and Control
ECRI	Emergency Care Research Institute
EMBASE	Excerpta Medica Database
ICU	Intensive Care Unit
LSS	Lean Six Sigma
MEDLINE	Medical Literature Analysis and Retrieval System Online
MOOS	Meta-analysis of Observational Studies in Epidemiology
NPT	Non Productive Time
OR	Operating Room
OT	Operation Theatre
PICO	Participants Interventions Comparisons Outcomes
PRISMA	Preferred Reporting Items for Systematic Reviews and Meta- Analyses
QI	Quality Improvement
RCT	Randomized Controlled Trial
SIPOC	Supplier, Input, Process, Output, Customer
STROBE	Strengthening the Reporting of Observational studies in Epidemiology
VOC	Voice of Customer
VSM	Value Stream Mapping

PART-1

Identifying the Most Common Reason for the Cancellation of Scheduled Cases on the Day of Surgery in Operation Theatre of Tertiary and Government Hospitals in India- A Systematic Review

Abstract

Rationale

There have been various researches conducted all over the world in context of operation theatre efficiency. The reason underlying these researches is that operation theatre (OT) forms one of the most important components of a hospital that requires significant amount of investment and forms the main source of revenue generation. Therefore, it becomes necessary that operation theatres are used optimally with efficient utilization of resources and time. Delay and cancellation of scheduled cases on the day of surgery have often been seen to cause inefficient utilization of operation theatres. It also leads to emotional and psychological distress to the patients and their family. Hence, we must know the reasons underlying on-the-day cancellation of scheduled surgeries to improve operation theatre efficiency. Systematic reviews help in delivering evidence-based health care to the people, and hence, this study.

Objective

To systematically review the research papers to identify the most common reason for the cancellation of scheduled cases on the day of surgery in the operation theatres of tertiary care and government hospitals in India.

Methodology

MEDLINE/PubMED, Research Gate, Google Scholar, Embase, and Cochrane Library were searched from 20 April 2020 to 1 July 2020, with manual searches and systematic snowballing of reference lists. Two investigators screened the observational and interventional studies on operation theatre efficiency independently. Only those studies that were observational and aimed to analyse operation theatre efficiency along with identifying reasons for on-the-day cancellation of scheduled surgeries in the operation theatres of tertiary care and government hospitals of India were included in our systematic review. The rest were excluded. Double data

extraction was used for abstracting data from the included studies. Blinding of the assessor was done to prevent bias in our systematic review.

Key Findings

Qualitative analysis of the studies in the systematic review revealed that the most common reason for the cancellation of scheduled cases on the day of surgery was lack of availability of OT time. Other common reasons were medical reason of the patient and the patient not turning up on the day of scheduled surgery.

Conclusion

Sufficient evidence supports that the lack of operation theatre time was the most common reason for on-the-day cancellation of scheduled surgeries which is a potentially avoidable reason. Reasons for operation theatre time constraints may be non-availability of senior surgeons and preparation of operation theatre list by inexperienced or junior surgeons among various other cited reasons.

Keywords

Operation theatre, efficiency, OT time, cancellations, optimization

Identifying the Most Common Reason for the Cancellation of Scheduled Cases on the Day of Surgery in Operation Theatre of Tertiary and Government Hospitals in India- A Systematic Review

1. Introduction

Operation theatre (OT) forms one of the most important components of a hospital that requires huge investment of resources and constitutes the primary area of revenue generation. This place therefore requires optimum utilization to ensure the resources are utilized efficiently and generate targeted cost benefits. Researches in various countries including India have shown that delay and cancellation of scheduled cases on the day of surgery is a frequent problem faced by majority of hospitals which is an obstacle to achieving efficient and optimum operating room utilization. This causes considerable loss to patients and hospitals both in terms of financial and opportunity costs. With increased lengths of inpatient hospital stays, cancellation of scheduled surgeries causes unnecessary wastage of hospital resources. It also causes emotional distress to the patient and family who had prepared themselves for the operation. Both the patient and his/her family incur loss in terms of working days lost and disturbance in family life. Therefore, it becomes necessary to identify the reasons of cancellation of scheduled cases on the day of surgery in operating rooms of hospitals in India. It is a matter of great concern for a hospital administrator to optimize the utilization of operating rooms to maximize cost benefits for the hospital. This study was conducted as the systematic reviews help in generating evidence based decisions and health care for the people concerned.

2. Objective

This study aims to systematically review the research papers to identify the most common reason for the cancellation of scheduled cases on the day of surgery in the operation theatres of tertiary care and government hospitals in India. The primary outcome of interest in the study is the optimal utilization and improved efficiency of the operation theatres. Patient and staff satisfaction are the other outcomes of interest.

3. Methodology

Research papers that studied OT efficiency were specifically sought.

3.1 Data Sources and Searches

We reviewed all the included studies (1-6). We searched MEDLINE/PubMED, Research Gate, Google Scholar, Embase, and Cochrane Library from 20 April 2020 to 1 July 2020 to identify researches on OT efficiency. We also searched the references of relevant research papers by manual searching and systematic snowballing.

3.2 Study Selection

Two investigators screened the observational and interventional studies on operation theatre efficiency independently. Each study's abstract was then reviewed against prespecified inclusion criteria. To minimize the risk of bias, the assessor was blinded to the author and his/her qualifications, publication journal and the outcome during the process of study selection.

3.2.1 Inclusion Criteria

Only those studies that were- 1) observational, 2) aimed to analyse operation theatre efficiency along with identifying reasons for on-the-day cancellation of scheduled surgeries in the operation theatres of tertiary care and government hospitals of India, and 3) observed all or general elective surgeries rather than specialized elective surgeries, were included in our systematic review.

3.2.2 Exclusion Criteria

The rest of the studies were excluded as they did not satisfy the inclusion criteria. That is, the studies that were- 1) interventional, 2) had an objective other than identifying or analysing reasons for on-the-day cancellation of scheduled surgeries in the operation theatres, 3) were conducted in a setting other than tertiary care and government hospitals, 4) were conducted in countries other than India, and, 5) observed only specialized elective cases rather than all or general elective cases, were excluded from our systematic review.

3.3 Data Extraction

One investigator abstracted information about study purpose, study design, time frame of the study, setting in which study was conducted, methodology, number of scheduled surgeries, total number of on-the-day cancellations, reasons for the cancellations and their respective frequency of occurrence in percentage. The second investigator checked if the data was accurate. Double data extraction and verification was thus used for the process. Any disagreements were resolved through discussion

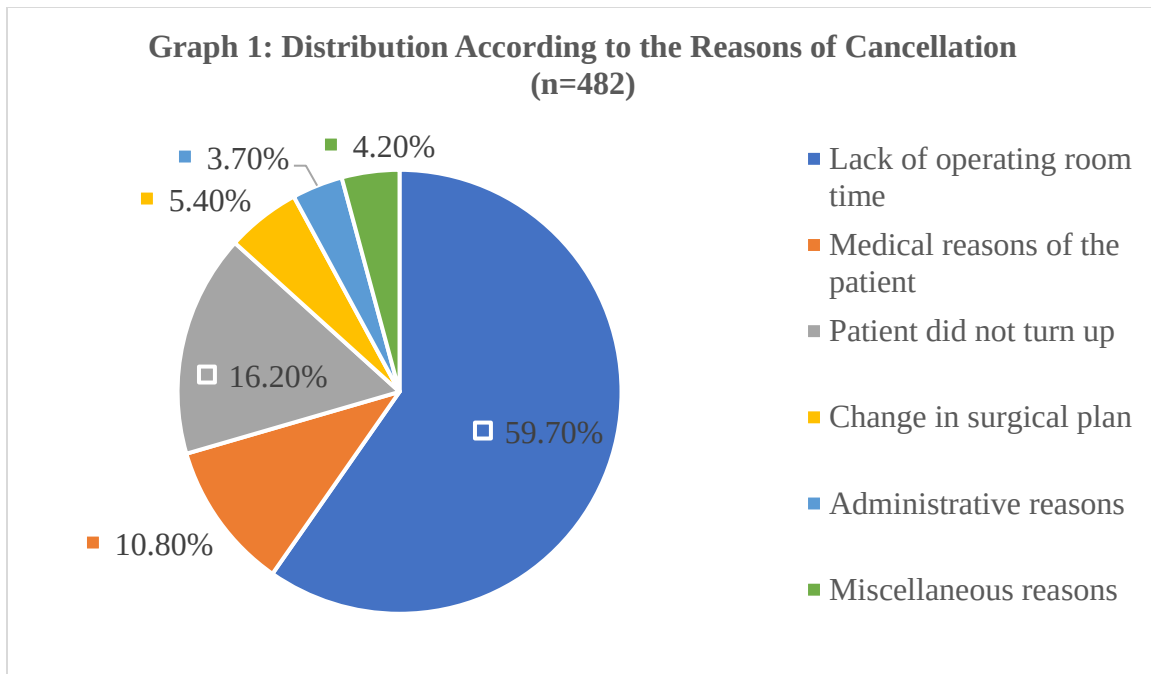
3.4 Data Synthesis and Analysis

The evidence was qualitatively described and summarized.

4. Results

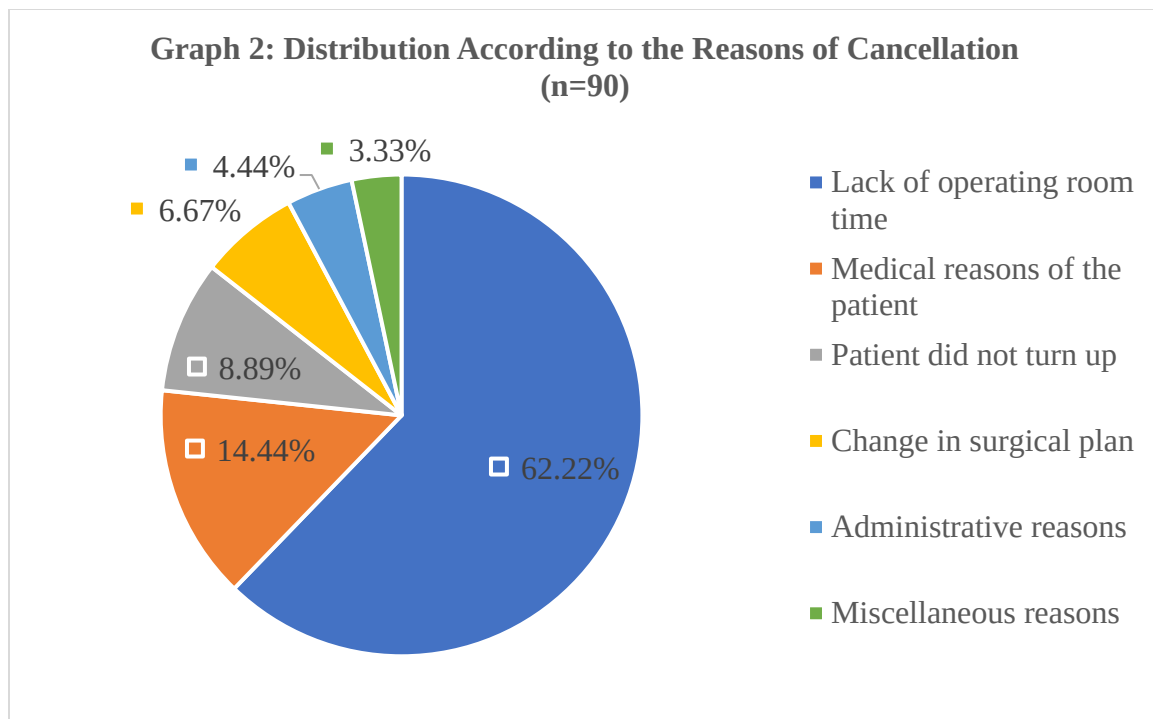
We screened and reviewed 20 studies that included both the full-text articles as well as abstracts. Six studies were included for our systematic review based on the pre-specified inclusion criteria.

In a study by Garg et al. [1], the most common reason for the cancellation of scheduled cases on the day of surgery was found to be lack of availability of theatre time. It was a prospective study that was conducted in a government hospital in New Delhi with an aim, “to find out the causes of cancellation of cases scheduled on the day of surgery and to suggest measures for optimum utilization of operating room (OR) time.” It was observed that over a study period of 6 months, 482 (30.3%) out of 1590 cases were cancelled on the day of surgery with 288 out of 482 (59.7%) being cancelled due to lack of availability of theatre time, 52 out of 482 (10.8%) being cancelled due to medical reasons and 78 out of 482 (16.2%) being cancelled as the patients did not turn up on the day of surgery. 26 out of 482 (5.4%) surgeries were cancelled by surgeons due to change in the surgical plan, 18 out of 482 (3.7%) were cancelled due to administrative reasons (autoclaved instruments, linens not available and instruments not available) while 20 out of 482 (4.2%) were cancelled due to miscellaneous reasons (non-availability of senior surgeon for the case, ICU bed/ventilator, adequate blood products and refusal of consent by patient). [Graph 1]



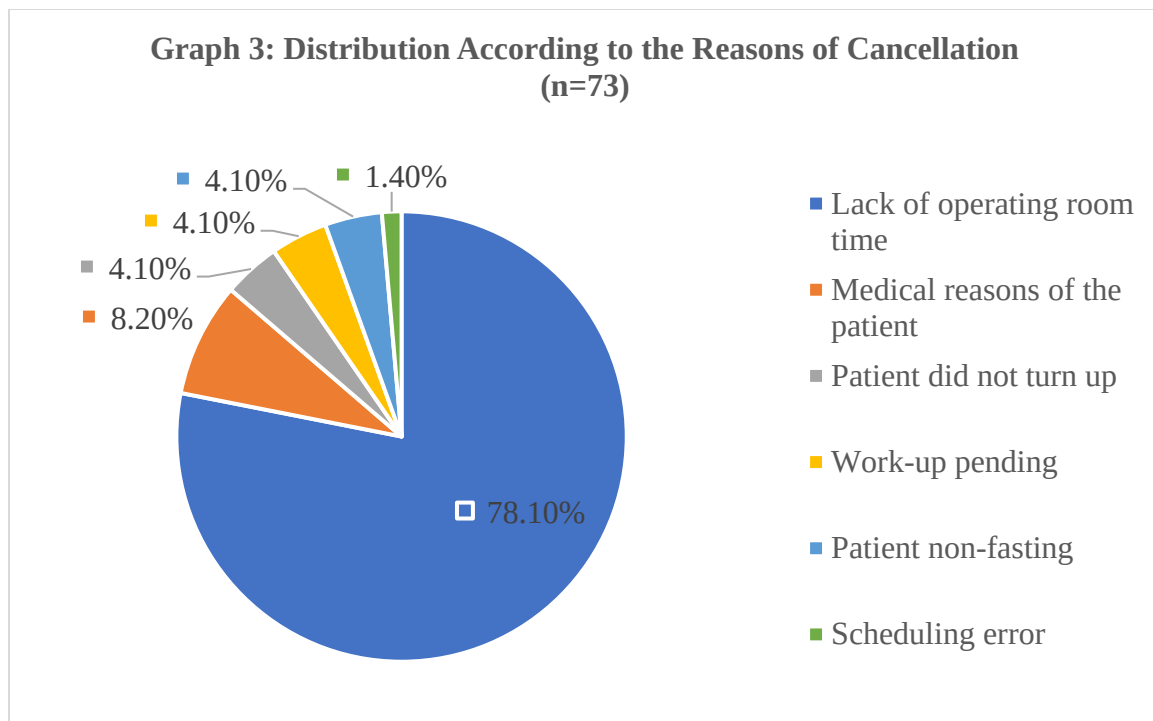
Source: Study by Garg et al. [1]

Naik et al. [2], in a study showed that the most common reason for the cancellation of scheduled cases on the day of surgery is lack of operating room time. It was a prospective study conducted in a tertiary care teaching hospital in western rural Maharashtra over a period of 2 months with an aim “to study the OT utilization time and most common causes of cancellations and rescheduling of surgeries.” It was observed that 62.22% cases were cancelled due to lack of operating room time, 14.44% cases were cancelled due to medical reasons, 8.89% cases were cancelled as patients did not turn up, 6.67% cases were cancelled due to change in surgical plans, 4.44% cases were cancelled due to administrative reasons (autoclaved instruments/linens not available, instrument not available) while 3.33% cases were cancelled due to miscellaneous reasons (non availability of senior surgeon for the case, ICU bed/ventilator, adequate blood products and refusal of consent by patient). [Graph 2]



Source: Study by Naik et al. [2]

Another study by Talati et al. [3] showed that the most common reason for the cancellation of scheduled cases on the day of surgery is lack of time resulting from improper scheduling that consequently left no time to provide anaesthesia. It was a prospective study that was conducted in a tertiary care teaching institute of North India over a period of 96 days with an aim “to analyze the time utilization and to assess the stated causes of cancellations of scheduled cases in the OT complex of a tertiary care teaching institute.” Results showed that 73 (22.5%) out of 325 total scheduled surgeries were cancelled over a period of 96 days due to various reasons. 57 out of 73 (78.1%) surgeries were cancelled due to lack of time resulting from improper scheduling that led to no time left for providing anaesthesia. 8.2% cancelled surgeries were due to unfavourable medical condition of the patient, 4.1% cases were cancelled as the patients did not turn up on the day of surgery while another 4.1% cases were cancelled as the patients did not complete the work-up advised to them before the day of surgery. Another 4.1% cases were cancelled as the outdoor patients reported in a non-fasting state due to inadequate counselling. The remaining 1.4% cases were cancelled as the case was scheduled after the list had been generated which consequently led to no pre-anaesthesia work-up and hence lack of readiness for surgery. [Graph 3]



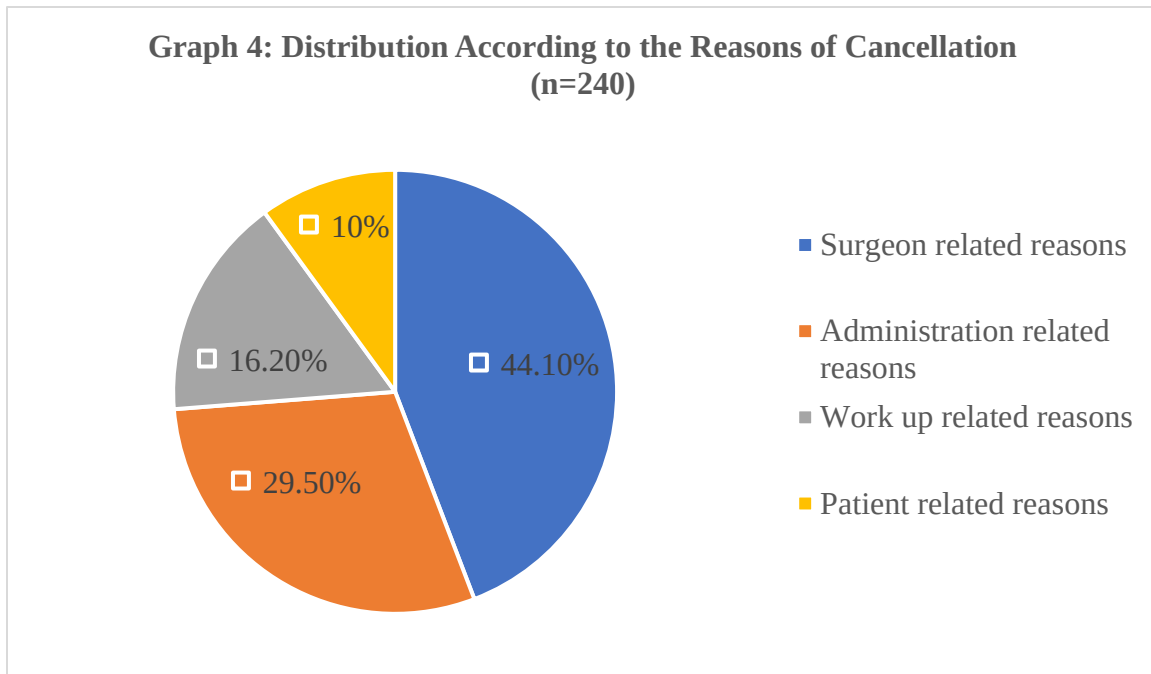
Source: Study by Talati et al. [3]

Farhanul Huda [4], reported the most common reason for the cancellation of scheduled cases on the day of surgery as the lack of availability of theatre time which resulted due to overrun of previous surgery and intentional overbooking of the OR list. It was a retrospective study that was conducted at Teerthanker Mahaveer Medical College and Research Centre, India for a period of eleven months with an aim to analyse the reasons for cancellation of elective surgery in a teaching hospital. They excluded the procedures that did not require an anaesthetist and those that were cancelled from the ward. Results showed that 246 surgeries (6.8%) were cancelled out of a total of 3618 scheduled surgeries. There was no detailed reason found for 6 patients in the medical records out of 246 cancelled cases. They categorised the reasons for cancellations into patient related, surgeon related, work-up related and administrative related. It was seen that the surgeon related category was the most common that is 106 (44.1%), which was followed by 71 (29.5%) administrative, 39 (16.2%) work-up related and 24 (10%) patient related. They observed that overall it was the lack of availability of theatre time which formed the most common reason which in turn was a consequence of overrun of previous surgery and intentional overbooking of the OR list. [Table 1, Graph 4]

Table 1: Reasons of Cancellation of Surgical Cases (n=240)

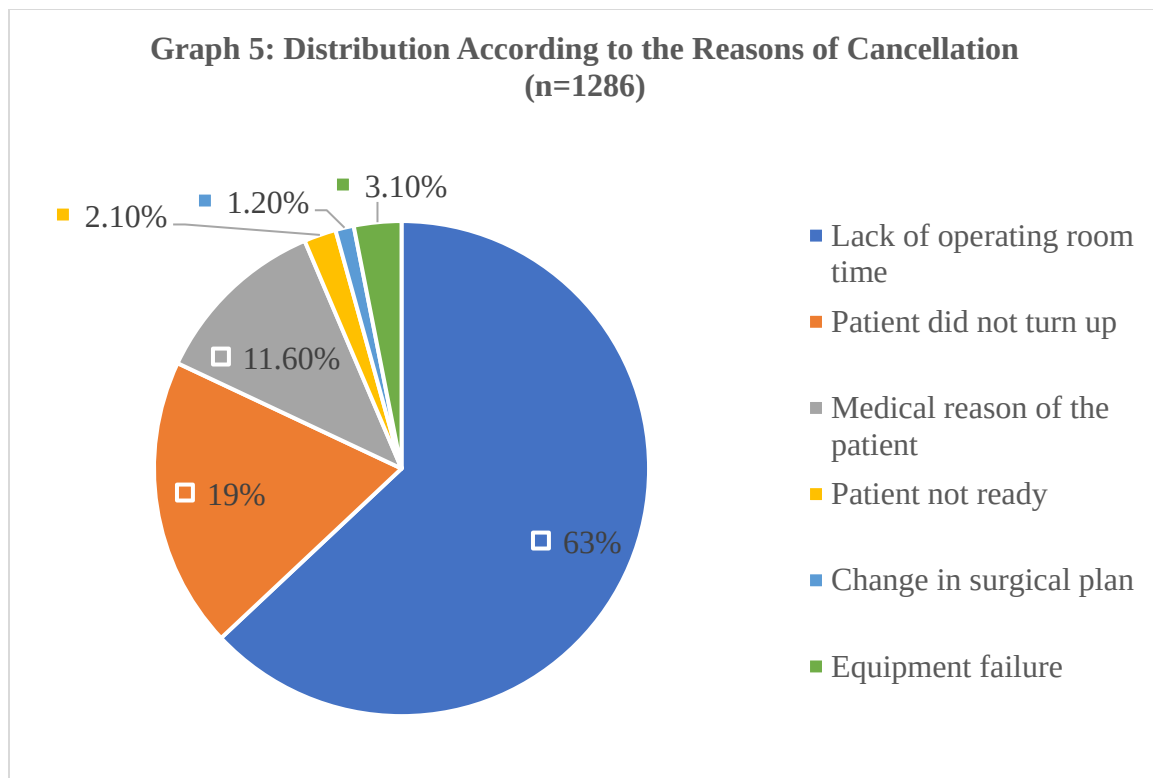
Categories	Cancellation reasons	No. (n)
Surgeon	Time constraints	74
	No senior surgeon available	14
	Surgical team involved in a different emergency	07
	Change in surgical plan	06
	Wrong diagnosis/decision	05
	Subtotal	106 (44.1%)
Administrative	Shortage of autoclaved surgical equipments/linen	20
	Lack of OT staff	09
	Blood not arranged by attendants	19
	Surgical equipment failure	07
	Acute disruption of water/electric supply	08
	Subtotal	71 (29.5%)
Work up	Acute change in medical status	24
	Abnormal laboratory tests	10
	Medical work up incomplete	05
	Subtotal	39 (16.2%)
Patient related	Patient refused consent	09
	Patient did not turn up	07
	Pre-operative instructions not followed	08
	Subtotal	24 (10%)

Source: Study by Farhanul Huda [4]



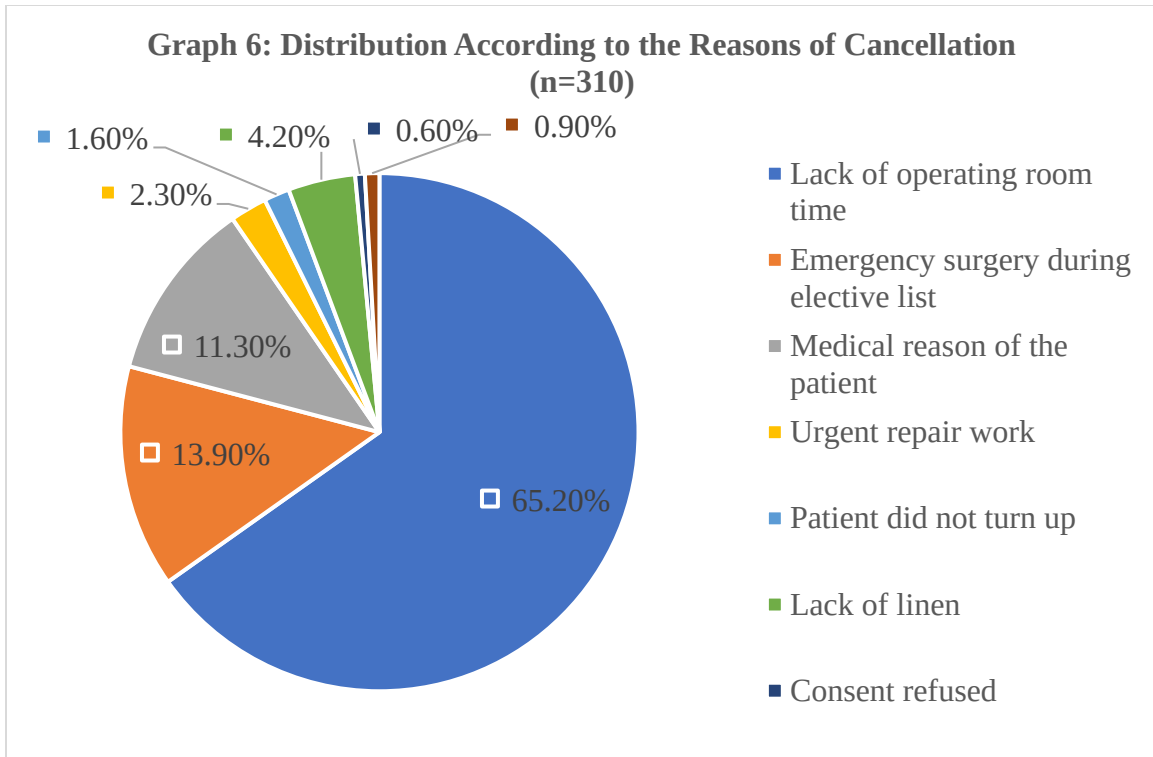
Source: Study by Farhanul Huda [4]

Kumar et al. [5] cited the most common reason for the cancellation of scheduled cases on the day of surgery to be lack of availability of OT time. It was a prospective study that was conducted in a multidisciplinary 500 bedded government hospital of India over a period of 12 months with an aim “to evaluate reasons for cancellation of elective surgical operation on the day of surgery”. A total of 1286 scheduled surgeries were cancelled out of 7272 cases that had been scheduled for elective surgical procedures during 12 month study period. Results showed that out of 1286 cancelled cases, 809 (63%) scheduled surgeries were cancelled due to lack of availability of OT time , 244 (19%) cases were cancelled as the patients did not turn up, 149 (11.6%) were cancelled due to medical reasons, 16 (1.2%) scheduled surgeries were cancelled by the surgeon due to change in surgical plan, 28 (2.1%) cases were cancelled as the patient was not ready (patient not adequately prepared; or necessary tests or referral not undertaken) while 40 (3.1%) cases were cancelled because of equipment failure. [Graph 5]



Source: Study by Kumar et al. [5]

Vinukondaiah et al. [6] reported the most common reason for the cancellation of scheduled cases on the day of surgery as the lack of operating time. It was a prospective study that was conducted over a period of 12 months in Jawaharlal Institute of Postgraduate Medical Education and Research, Pondicherry. The aim of the study was to find out how efficiently operating time was utilized in a major teaching hospital and to identify areas, if any, where improvements are feasible. Results from the study showed that out of a total of 2083 scheduled surgeries during the study period, 310 scheduled cases of surgery were cancelled. Out of these 310 cancelled scheduled cases, 35 (65.2%) cancelled cases were due to lack of operating time, 43(13.9%) cancelled cases were due to emergency surgery during the elective list while 35(11.3%) scheduled cases were cancelled due to preoperative lack of fitness. Additionally, it was observed that “absence of monitoring equipment and non-availability of additional qualified anaesthetists necessitated induction of anaesthesia in the main operating room and accounted for 11% of the total operating time”. [Graph 6]



Source: Study by Vinukondaiah et al. [6]

Table 2: Combined Findings of Included Studies

Study	Study Purpose	Time Frame	Study Setting	Study Design	No. of Scheduled Cases	No. of Cancellations	Cancellations (%)	Most Common Reason of Cancellation and Frequency of Cancellation due to it (%)
Garg, R., Bhalotra, A. R., Bhadoria, P., Gupta, N., & Anand, R. (2009). Reasons for cancellation of cases on the day of surgery-a prospective study. <i>Indian Journal of Anaesthesia</i> , 53(1), 35-39.	To find out the causes of cancellation of cases scheduled on the day of surgery and to suggest measures for optimum utilization of operating room (OR) time	6 months	Government Hospital New Delhi, India	Prospective Observational type	1590	482	30.3%	Lack of OT time (59.7%)
Naik, S.V., Dhulked, V. K., & Shinde, R. H. (2018). A	To study the OT utilization time and	2 months	Tertiary Hospital, Western Rural Maharas	Prospective Observational type	n/a	90	n/a	Lack of OT time (62.22%)

prospective study on operation theatre utilization time and most common causes of delays and cancellations of scheduled surgeries in a 1000-bedded tertiary care rural hospital with a view to optimize the utilization of operation theater. <i>Anesthesia Essays and Researches</i>, 12(4), 797-802.	most common causes of cancellations and rescheduling of surgeries		htra, India					
Talati, S., Gupta, A. K., Kumar, A., Malhotra, S. K., & Jain, A. (2015). An analysis of time utilization and cancellations of scheduled	To analyze the time utilization and to assess the stated causes of cancellations of scheduled cases	3 months	Tertiary Hospital, North India	Prospective Observational type	325	73	22.5%	Lack of OT time (78.1%)

cases in the main operation theatre complex of a tertiary care teaching institute of North India. <i>Journal of Postgraduate Medicine</i> , 61(1), 3-8.	in the OT complex of a tertiary care teaching institute							
Huda, F. (2014). A retrospective analysis of reasons for cancellation of elective surgery in a teaching hospital. <i>International Journal of Scientific Study</i> , 2(2), 28-30.	To analyse the reasons for cancellation of elective surgery in a teaching hospital	11 months	Tertiary Hospital, Uttar Pradesh, India	Retrospective Observational type	3618	246	6.8%	Lack of OT time (30.8%)

Kumar, R., & Gandhi, R. (2012). Reasons for cancellation of operation on the day of intended surgery in a multidisciplinary 500 bedded hospital. <i>Journal of Anaesthesiology Clinical Pharmacology</i> , 28(1), 66-69.	To evaluate reasons for cancellation of elective surgical operation on the day of surgery	12 months	Government Hospital, India	Prospective Observational type	7272	1286	17.7%	Lack of OT time (63%)
Vinukondiah, K., Ananthakrishnan, N., & Ravishankar, M. (2000). Audit of operation theatre utilization in general surgery. <i>National</i>	To find out how efficiently operating time was utilized in a major teaching hospital and to identify areas, if any, where improvements are feasible	12 months	Tertiary Hospital, Pondicherry, India	Prospective Observational type	2083	310	14.3%	Lack of OT time (65.2%)

<i>Medical Journal of India,</i> 13(3), 118- 121.								
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From the analysis of the studies in our systematic review, the most common reason of on-the-day cancellation of scheduled surgeries in the operating theatres of tertiary care and government hospitals in India was observed to be lack of availability of OT time [Graphs 1, 2, 3, 5 and 6 and Table 1]. In comparison to some other common reasons of cancellation, time constraint is an avoidable reason. From Graphs 1, 2, 3, 5 and 6 and Table 1, it can be deduced that the occurrence of lack of availability of time as a reason for the cancellation of scheduled surgeries is significantly higher in all the included studies in comparison to other reasons, many of which are non-avoidable such as patient not turning up and the medical condition of the patient. Hence, for the better management of OTs with improved time utilization and resource optimization, it becomes important to manage OT time efficiently in order to minimize on-the-day cancellation of scheduled surgeries.

5. Discussion

Reduced frequency of cancellation of scheduled operations ensures an efficient and cost effective use of surgical facilities. Efficient utilization of theatre time and personnel, thus, becomes important. Cancellation of scheduled surgeries leads to underutilization of operating theatres which in turn endangers the efficiency followed by lengthy waiting lists resulting in increased costs of health services delivered to the people. When resources are not efficiently utilized or are underutilized, the cost of the services rises which is passed on to the patients. India being a developing country, majority of population especially people with lower income rely on government or public healthcare facilities and services. Therefore, these groups suffer the most due to increased costs of health services. Cancellation of scheduled cases causes not only financial distress but it also results in emotional and psychological harm to the patients and their family who took leave from their work and had prepared their minds for the surgery.

Therefore, efforts should be made to minimize if not avoid the cancellation of scheduled surgeries as it would prevent both the financial burden as well as the anxiety and frustration in the patients and their families.

Our systematic review included six studies (5 prospective observational and 1 retrospective observational) that examined the reasons of on-the-day cancellation of scheduled surgeries in the operation theatres of tertiary care and government hospitals in India. We found consistent evidence showing that the most common reason for the cancellation of scheduled cases on the day of surgery is lack of availability of operating room time. Studies cited that the time constraint is a potentially avoidable reason. Cancellation on the day of surgery was defined by the included studies as any operation that was either scheduled on the final OT list for that day (generated at 14:00 on the previous day) or was subsequently added to the list and that was not performed on that day. Lack of operating room time can be attributed to several reasons according to the studies. Underestimation of surgery time and overrating of the operations' list by the surgeons to avoid more surgeries on waiting list has been observed as one of the main reasons of time constraints or non-availability of operating time. Other reasons may include non-availability of senior surgeons, surgeries performed by junior or inexperienced surgeons or interns, unplanned admissions, long operation theatre lists prepared by junior surgeons and anticipation of unexpected cancellations leading to scheduling errors. Improper coordination and collaboration or the presence of conflicts among the OT staff is often seen as yet another reason of lack of OT time.

To minimize bias in our systematic review, a comprehensive research was done to include all the available studies that aimed to identify and analyse OT efficiency and time utilization along with the reasons for the cancellation of on the day surgeries in India.

Scarcity of researches on OT efficiency and the analysis of reasons for on-the-day cancellations of scheduled surgeries in India remains the limitation to our systematic review. Also, inaccessibility to the authors for missing data in one of the studies [2] is the weakness of this systematic review. However, the strength of our systematic review is the comprehensive search that was done to build the quality of the study. Included studies have been conducted across different parts of India through the past twenty years which adds yet another strength to our study.

6. Recommendations and Conclusion

Looking at the higher frequency of on-the day cancelled scheduled surgeries due to lack of availability of operating room time, it is clearly evident that OT efficiency can be significantly improved with optimized time utilization. Since, time constraint is a controllable factor, hospitals can work on it for effective and efficient management. This can be achieved by a proper team approach under the supervision of OT in charge with sufficient coordination and better conflict management techniques like collaboration, accommodation and negotiation. Proper time estimation of operations and planned admissions, preparation of OT list by experienced surgeon, effective coordination and cooperation among anaesthesiologists and surgeons and reducing time to clean and prepare the resources for surgery are other ways to manage time constraints. Various models can also be applied to better manage the problem of on-the day cancellations of scheduled surgeries and to improve the OT efficiency.

A study by Rohini et al. [11], applied the DMAIC Six Sigma approach of Define, Measure, Analyse, Improve and Control to improve the process in the operation theatre of a corporate multi specialty hospital in Bangalore, India. A six-sigma team defined the problem statement and the goals. A data collection plan (DCP) was made. Analysis of process was done to identify cycle time, rework and other steps that do not add value to the customer. Data was analysed to find patterns and other differences that can support or reject factors related to the causes of defects at service or production. A fish bone diagram was used to show the reasons for delay and cancellation of cases. A protocol was designed for smooth functioning of OT addressing major issues like scheduling cases. Under the control phase, various supervisory activities were designed for all the team members and the top management. Cost of error per year due to cancellations before implementation phase was 4,98,60,000 Rs. After the implementation phase, the cost of error per year due to cancellations was found to be 64,80,000 Rs. Thus, the result of this interventional study was that the OT utilization was increased and an annual financial savings due to reduction in number of cancellations amounted to 4,33,80,000 Rs. 87% reduction in cost of error per year due to cancellations was therefore, achieved. The sigma status of cancellations reached from baseline sigma value of 2.11 to current sigma value of 3.4. The results of this study hence showed a significant improvement in OT time utilization and efficiency.

Another study by Singh et al. [12], used one of the quality improvement (QI) tools, Lean Six Sigma (LSS) in their study setting with the objective of increasing the efficiency of the OT utilization in order to avoid the non-productive time (NPT) in OT, improve efficiency and reduce related financial loss. Voice of customer (VOC) was done. Supplier, Input, Process, Output, Customer (SIPOC) was used and a project charter with the detailing of DMAIC phase was prepared in the study. Value stream mapping (VSM) was used to map value-add, nonvalue add and operational value-add activities. It was done to work toward reducing or removing nonvalue added activities. Fishbone diagram and the cause and effect diagram were prepared to represent the controllable causes and the list of solutions with their causes respectively. The final results of the study through the implementation of LSS in OT showed that total NPT was reduced from 60 to 28 minutes. Results showed that there was a considerable benefit in terms of cost savings over the period of 6 months by making the system more efficient and performing more surgical cases. Though the lack of information on baseline cost and final cost incurred due to cancellations remains the limitation to this study.

Sufahani et al. [16], pretested a procedure to optimize the utilization of operating theatre by minimizing the total deviation from the weekly target hours and relative amount of under-allocation of rooms to different departments. An integer linear programming technique with a small data set was used to find the optimal operating theatre schedule in one-week period with open scheduling strategy. Integer solution was used as it shows better results than real number solutions by producing a better and logical use of the available rooms. Results of the study showed that the integer linear programming technique managed to obtain the optimal schedule that meets the objectives of the study and also the related constraints. It was shown that with this method, extra treatment on surgery, ophthalmology, oral surgery, otolaryngology and emergency could be provided if needed based on the availability of the rooms. The scheduling procedure proved to be efficient where it was managed to meet all the requirements and to give a major impact on the productivity of the hospital treatment. It greatly outperformed older manual scheduling methods and optimized real-time workloads.

Several other techniques like heuristic algorithm and hybrid genetic algorithms can be used to reduce the constraints and solve the non-productive scheduling problems.

A paucity of studies on OT efficiency in India serves a future scope for conducting more such studies and updating the systematic review regularly. This would guide the hospitals in a direction towards efficient and effective management of the OTs with improved time utilization. It would, thus, help in optimizing resources invested in the building and running of operation theatres in the government and tertiary care hospitals in India. Consequently, the costs of the services delivered to the patients would be contained and the quality of health care delivered to them would be improved appreciably.

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PART-2

INTRODUCTION TO SYSTEMATIC REVIEW AND META-ANALYSIS

1. Why this Course?

This course from Coursera was taken in order to enhance my secondary research skills. The primary intention underlying the course selection was to gain useful learning in adopting well-planned and scientific approach for conducting review of research studies systematically with the help of secondary data.

2. Course Description

The course explains methods that are used to conduct systematic reviews and gives a deeper understanding about the process of meta-analysis of clinical trials. It describes the formulation of a research question that can be answered, defining the criteria of inclusion and exclusion, finding the evidence, extraction of data, assessment of the risk of bias in the included studies, and the process of meta-analysis.

3. Objectives of the Course

- i. To describe the steps that are to be followed in order to conduct a systematic review
- ii. To give a deeper insight into the process of meta-analysis
- iii. To formulate an answerable research question with the use of standard PICO format, that is, “Participants Interventions Comparisons Outcomes”
- iv. To explain the process that is deployed for the collection and extraction of data from the studies of clinical trials
- v. To explain the methods that are used for the critical assessment of the risk of bias of clinical trials
- vi. To describe and interpret the results of qualitative synthesis in a systematic review

4. Course Contents

- i. Introduction
- ii. Framing the question
- iii. Finding the evidence- searching principles
- iv. Assessing the risk of bias in clinical trials
- v. Minimizing meta-bias
- vi. Qualitative synthesis and interpreting results

5. Learning Methodology Used in the Course

Lectures, PPT, Assignments, Reading Material

6. Key Learnings From the Course

Beginning with the understanding of the process of systematic review, the primary key learning from the course is that the systematic reviews are integrative synthesis where we systematically collect, critically evaluate, and formulate the results of primary researches addressing a specific issue or problem. There are two components of systematic review- qualitative and quantitative. Qualitative synthesis describes the nature of the evidence in the literature, interpret the possible effect of the many differences among studies, evaluate the strengths and weaknesses in the evidence base and conclude about if those studies could be combined quantitatively. A quantitative synthesis, also called meta-analysis uses statistical methods to combine the results of various studies that are independent and are considered capable of being combined by the analyst. It is not always a sensible step and is only as good as the qualitative synthesis that precedes it. These key learnings are further elaborated in detail point by point in the report that follows below.

7. Understanding Systematic Review

Systematic review deploys the use of methods that are explicit, pre-planned and scientific in order to identify, select, evaluate and summarize studies that are similar but separate. It targets a specific question.

7.1. Understanding Protocol for Performing Systematic Review

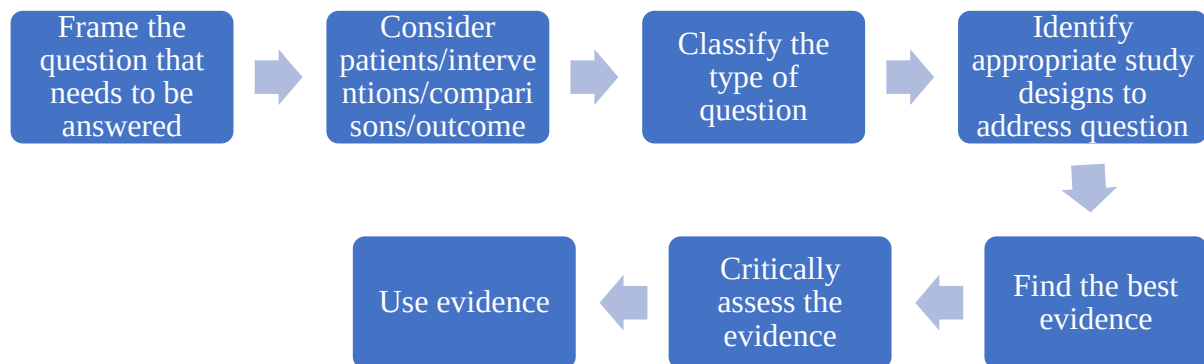
Figure:1 Flowchart Depicting the Protocol for Conducting Systematic Review



7.2. Evidence Based Health Care

This practice uses the best evidence available in the process of decision making for providing health care services to the people. The best evidence is available from the updated, reliable and valid researches that evaluate the effectiveness and efficiency of the health services and interventions.

Figure 2: Steps in the Practice of Evidence-based Health Care



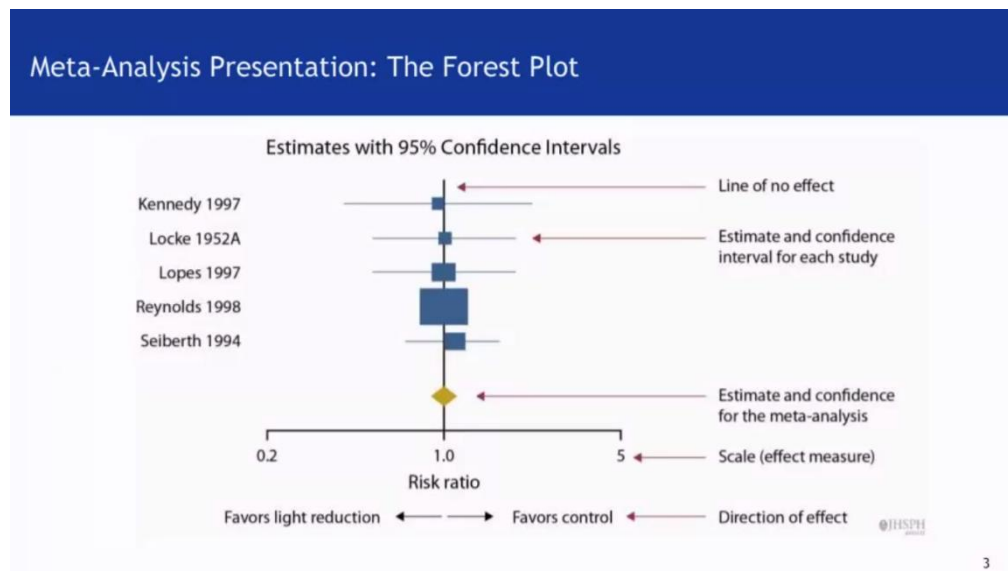
7.3. Comparative Effectiveness Research (CER)

CER is used to compare effectiveness of various methods for managing a clinical condition or for the improvement of health care by searching and formulating best evidence. It compares benefits and harms of using alternative interventions or health care delivery methods to the patients or concerned people.

7.4. Understanding Meta-Analysis

Meta-analysis uses statistical methods to analyse results from individual studies for integrating the findings. Systematic reviews may or may not include meta-analysis as an essential component. Meta-analysis can be conducted when a treatment effect or association has been estimated by more than one study, when the treatment effect is unlikely to be affected by the differences in the characteristics of the study or when there exist similar ways that have measured and reported the treatment effect. They are conducted by independent authors, Cochrane collaboration, businesses like ECRI and groups that are interested in policy such as governments and professional societies. They are used by the decision makers like individual doctors, researchers, patients, consumers, guideline producers and policy makers including payers, purchasers and regulatory authorities.

Figure 3: Meta-analysis Presentation: The Forest Plot



Source: Lecture 1B: Introduction to Meta-analysis; Introduction to Systematic Review and Meta-analysis; Coursera

Meta-analysis deploys statistical methods to show the direction of effect (association), the size of effect, if the effect is consistent across studies and the strength of evidence for the effect. It also assists in the assessment of the strength of evidence.

7.5. Features of a Systematic Review

Systematic reviews efficiently integrate the information for rational decision making. They offer a process that is both clear as well as transparent. The areas in which the health care effects are consistent and the areas in which they vary are very well demonstrated with the help of systematic reviews. They also ensure that the chances of bias or systematic errors along with chance effects are not only reduced but also minimized. When compared to individual studies, meta-analysis tend to show estimates with increased precision. These studies have an advantage in that they can be updated readily as needed. The decisions are allowed on the basis of the totality of the available evidence.

7.6. Framing Question

Every research study that is focused and clearly defined including systematic review starts with a well framed question. But first, we need to decide a topic to frame a review question which can be done by confirming the need for a new review. The review question must follow the standard PICO format, that is, it must specify types of population, types of interventions (and

comparisons), and the types of outcomes that are of interest. Depending on our decision, the questions that we frame may be broad or narrow. Questions may be related to incidence, prevalence, therapy, screening, diagnostic accuracy, prognosis, harm, etiology or prevention. There are different study designs for studying different types of questions like cohort studies, case control studies, surveys and clinical trials. The type of study design to be used depends on the type of question.

7.7. Finding the Evidence: Searching Principles

There are a few key sources for searching such as key electronic databases, controlled vocabulary (indexing), indexing of randomized controlled trials (RCTs) and observational studies and other sources like trials registers, gray literature searching and personal contacts. There are major Bibliographic Databases for RCTs and observational studies such as MEDLINE/PubMED, EMBASE and others. Use of all of these databases may be necessary to identify all reports. Systematic snowballing is another feature which means by using the reference list of the paper, we can begin from one reference followed by selecting other relevant references from the list or move forward to the citing articles in order to identify additional papers.

7.8. Documenting Your Search and Conclusions

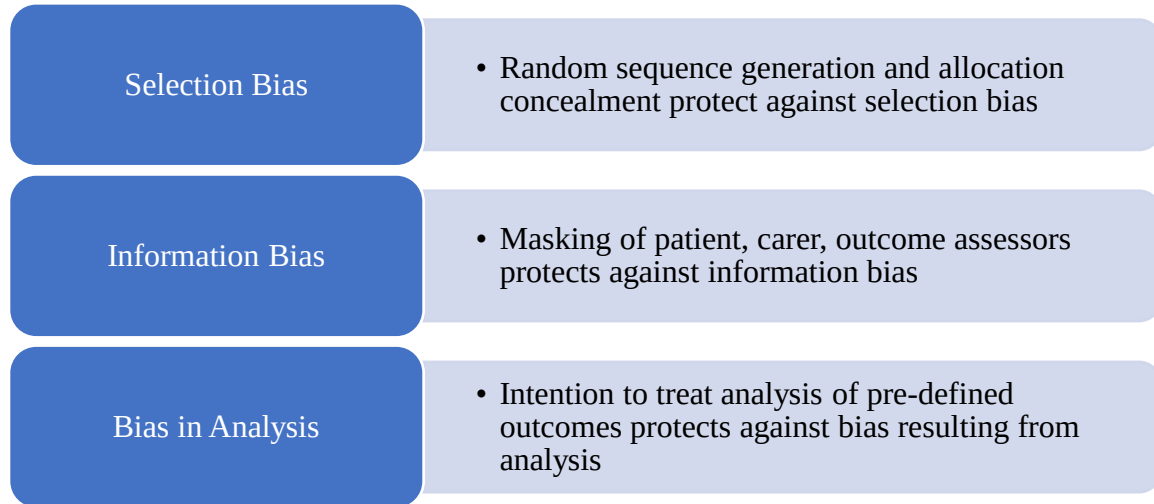
We can use Endnote as our database of records of all the citations that we collect from the various sources for the purpose of documenting our search with conclusions.

7.9. Assessing Risk of Bias in the Methods Used in the Included Studies and Defining Study Quality

Presence of bias in the methods that are used by the studies included in the systematic review of meta analysis is an undesirable phenomenon. Therefore, we attempt to lower the risk of bias. “Quality” refers to the methods used to conduct a study -the way the study was actually done. Though it is not possible to find out how well the study was done one can always find how well it was reported. Reporting guidelines such as the CONSORT statement for reporting clinical trials and the STROBE statement for reporting observational studies are recommended for use so as to ensure that the study is reported well. So, some of the elements of the study

quality that can be assessed by reading study report are internal validity, external validity, relevance, originality and ethics.

Figure 4: Sources of Bias in RCT and Methods to Minimize them



7.10. Minimizing Meta-Bias: Bias in the Methods Used in the Systematic Review

Reporting bias is the most important way in which selection bias manifests itself. Another type of selection bias is what we call as inclusion bias. A comprehensive search for all published or unpublished studies is therefore recommended by various standards to minimize these meta-bias. In terms of information bias, we are concerned about the accuracy of our quality assessment. Knowledge of study investigators or outcomes might affect selection of studies to be included in systematic review and data abstraction from those studies. Single data extraction plus verification and double data extraction are a few other methods to minimise such meta-bias. It is not always possible to minimize the meta-bias in the systematic reviews and meta-analyses that exists in the literature and while sometimes, this may be related to bias in the analysis, at other times, it may be related to selection bias and information bias.

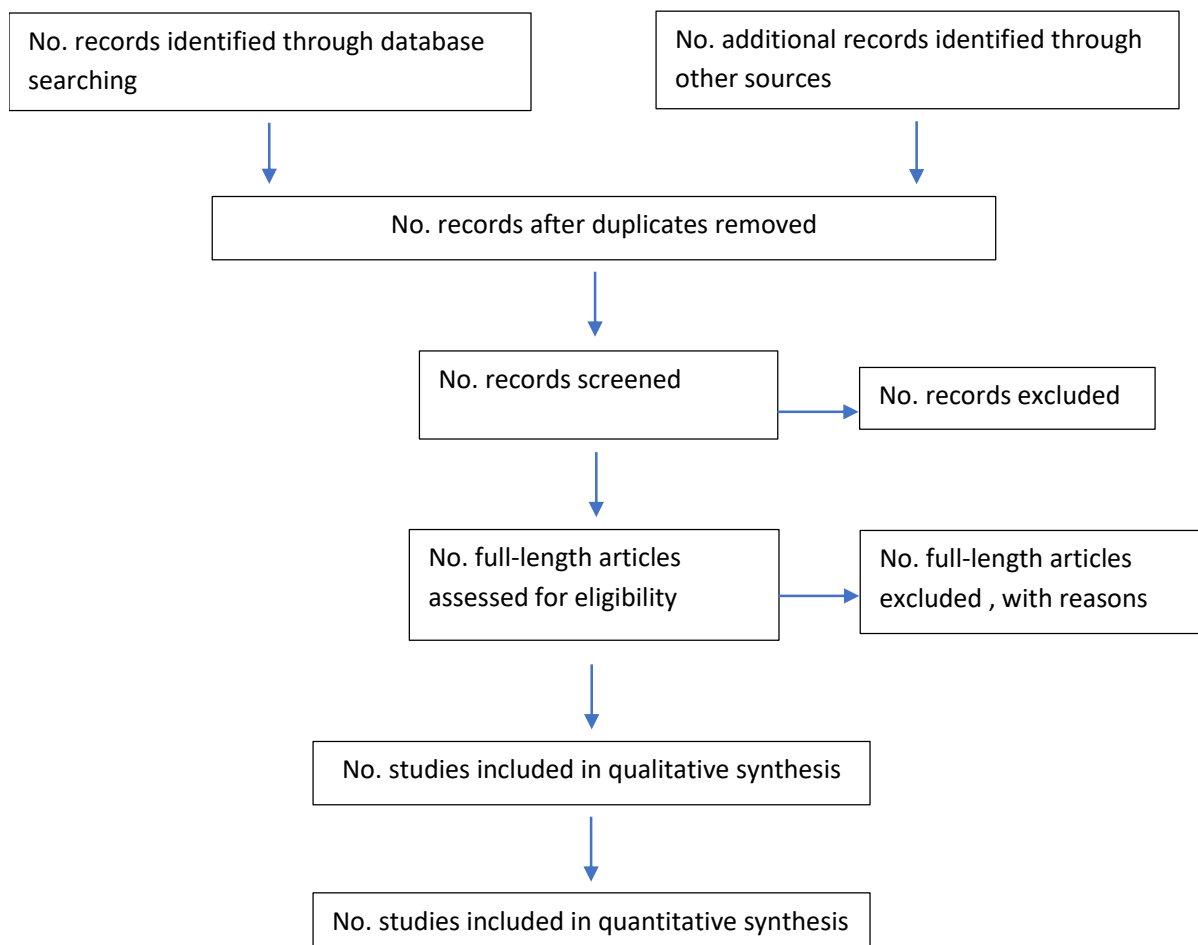
7.11. Reporting Transparently

There are reporting guidelines for systematic reviews and meta-analyses just like there are reporting guidelines for clinical trials like CONSORT and STROBE for observational studies. PRISMA is known to be the reporting guideline for systematic reviews of clinical trials while

MOOSE despite being a little outdated is known to be a useful, reporting guideline for systematic reviews of observational studies. An updated MOOSE is being worked on.

PRISMA is a standard for transparent reporting of systematic reviews and meta-analysis. It's a helpful tool that we can use to sort of get an overview of what is required to do a high quality rigorous review.

Figure 5: PRISMA Flow of Information



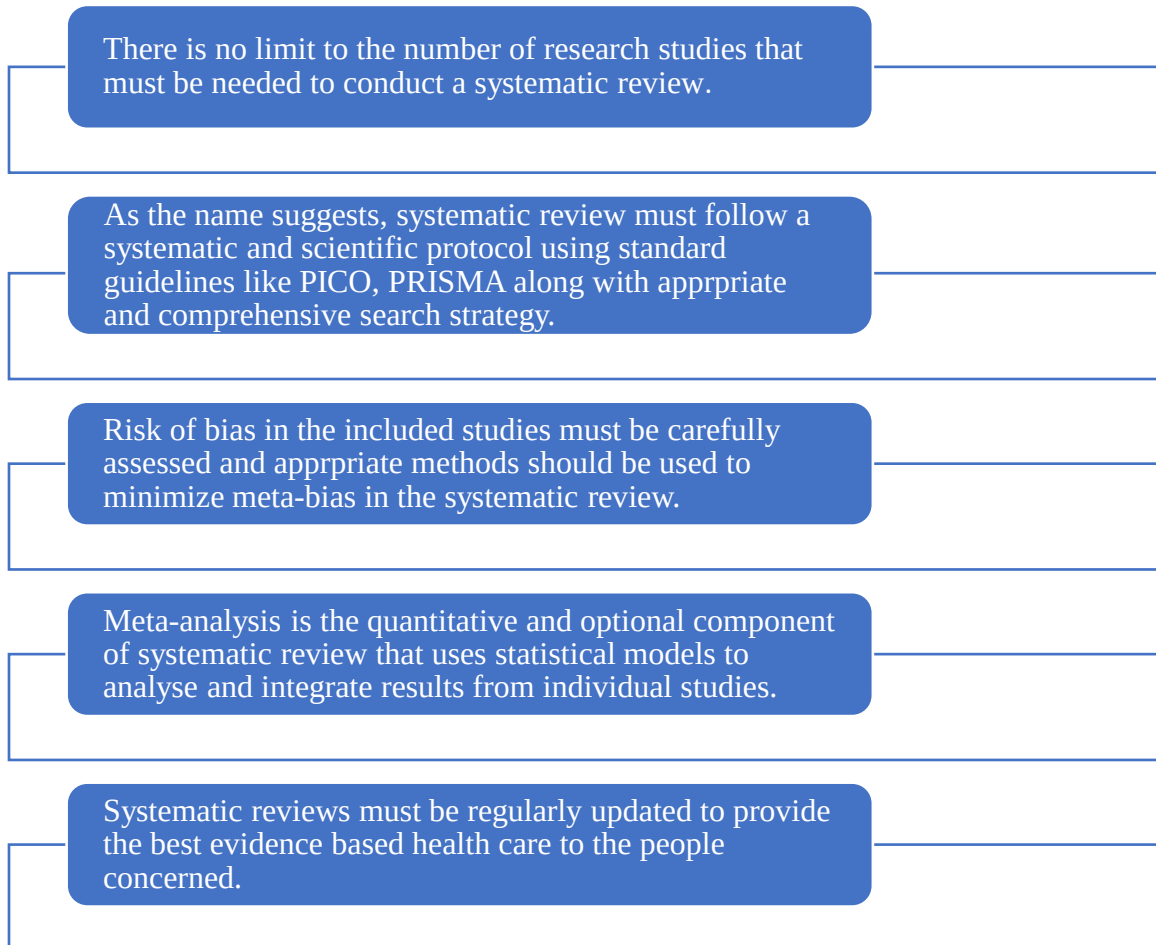
(Source: Google)

7.12. Qualitative Synthesis and Interpreting Results

When the results of all the studies are brought together without the numbers, it is known as qualitative synthesis. In qualitative synthesis, we evaluate the body of evidence which is beyond factual description. It describes in detail the number of studies examined, reason of excluding the studies, the range of sizes of study and comparison of treatments. The objective of the qualitative synthesis is to formulate and provide a deeper insight into the effectiveness of the intervention or into the existence of a true association. The idea of doing the qualitative synthesis is to guide the reader in the direction of the clinical background. The purpose is to explain the studies, fate of the participants over the course of the studies, about the interventions, the comparators and the outcomes. The whole idea of a qualitative synthesis is to amalgamate what has been found and to catch attention towards specific groups, interventions, outcomes and the way the studies were conducted so that the readers of the systematic review are able to elucidate both its findings and the strength as well as richness of the meta-analytic results.

8. Lessons Drawn and Final Outcome

Figure 6: Chart Depicting the Lessons Drawn



This course serves as a useful learning tool that would guide me in conducting a systematic, scientific and well-planned evidence-based research in the form of systematic review for my upcoming academic research study.