



## **SOCIOTECHNICAL NETWORKS IN ROBOTIC SURGERY: AN ACTOR-NETWORK THEORY ANALYSIS OF INNOVATION AND REGULATION IN INDIA**

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### **RESEARCH ARTICLE**



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#### **Abstract**

Robotic-assisted surgeries have attracted significant attention from both medical professionals and patients, influencing the interplay between technology, disease, and society. Robotic-assisted surgeries involve a diverse array of human and non-human actors and are reshaping and impacting social, cultural, economic, and political aspects of human lives. Through the framework of science and technology studies, this research employs actor-network theory to investigate the dynamic relationship between science and society. This study demonstrates that technology and society mutually influence each other during robotic-assisted surgery. The study categorises the actor-networks involved in robotic-assisted surgery into tiers and reveals that, as new actor-networks emerge, the obligatory point of passage shifts. This network becomes 'black-boxed' and develops into an established hospital practice once the number of patients treated with robotic-assisted surgeries increases. This study also stresses the need for dedicated legislation on medical devices in India. This research advances understanding of robotic-assisted surgeries, their interactions with society, and related regulations in India.

**Keywords:** *Robotic-Assisted Surgery, Robotic-Assisted Surgical Device, Actor-Network Theory, Science and Technology Studies, Healthcare Innovation, India, Medical Technology Regulation, Sociotechnical Networks, Hospital Practice, Technology Adoption*

### **Introduction**

Science enhances our understanding of human health, while medicines play a crucial role in translating scientific advancements into societal benefits (Lambert & Rose, 2003). India, with a population of 1,438 million, has witnessed substantial growth in its healthcare sector, primarily due to an expanding middle class, higher incomes, and improved access to healthcare services (Paddock, 2010). Today, worldwide non-communicable diseases (NCDs) are the most common cause of morbidity and premature mortality (Muley, Mamtani, Mistry, Kantharia, & Chandrakar, 2019). NCDs killed 43 million people in 2021, equivalent to 75% of non-pandemic-related deaths globally and among this 73% deaths are in low- and middle-income countries. In India, about 49.1% of all deaths occur due to NCDs (Noncommunicable diseases, 2025) and are expected to increase due to factors like ageing, sedentary lifestyles and increasing incidence of obesity and diabetes. Chronic kidney disease (CKD) is one among these NCDs, which affects 8% to 16% of the population worldwide. If the kidney disease progresses, it can lead to end-stage kidney disease (ESKD), where kidney transplantation is considered the optimal therapy with a living donor kidney (Chen, Knicely, & Grams, 2019). Kidney disease accounts 12.15% of deaths in India (Noncommunicable diseases, 2025). CKD patients are evaluated on a risk-based approach and treated based on symptoms. The treatments include conservative management, hemodialysis and kidney replacement therapy.

In Gujarat, over the past few decades, the state government has been facing a staffing shortage in government hospitals. Between 2016 and March 2022, 23% of the doctors (including Specialist Doctors), 6% of nurses, and 23% of paramedics in the cadre were vacant (Government of Gujarat, 2024). There is a severe dearth of super-specialist doctors at government hospitals, including urologists and uro-surgeons. The state government is promoting medical tourism. According to the World Health Organisation (WHO), in India, 325.5 million (295 million to 355.9 million) additional people are expected to be protected from health emergencies by 2025 compared to 2018 (Noncommunicable diseases, 2025). Considering this, it becomes vital to have advanced medical technologies and experts at its hospitals to attract patients from across the world. As a step forward, hospitals were encouraged to procure robotic-assisted surgical devices (RASDs).

The robotic-assisted surgical device (RASD) provides high precision and dexterity necessary during complex, MIS (minimally invasive surgical) procedures to surgeons (Chaudhary, Atal, & Kumar, 2014). The number of robotic surgeries performed worldwide nearly tripled from 80,000 to 205,000 surgeries between 2007 and 2010 (Barbash & GI, 2010). The global surgical

robots market, valued at US\$11.98 billion in 2024, reached US\$13.69 billion in 2025 and is projected to advance at a resilient CAGR of 14.7% from 2024 to 2030, culminating in a forecasted valuation of US\$27.14 billion by the end of the period (Surgical Robots Market Size, Growth, Share & Trend Analysis, 2025). The introduction of robotics has facilitated the adoption of minimally invasive surgery among surgeons and their capacity to undertake advanced and complex reconstructive procedures (Palep, 2009). The rapid dissemination and aggressive marketing of RASD has today captured the imagination of doctors and patients alike.

In India, 90% of medical devices and disposables are imported. The absence of specific guidelines or standards for manufacturing, importing, and using medical devices in the country raises concerns about the safety, proper calibration, and reliability of these devices. Without established regulations, it becomes challenging to ensure that medical devices meet consistent quality and safety benchmarks, potentially putting patients at risk and undermining trust in the healthcare system. A study on RASD, consisting of a shared network of human and non-human actors, serves as a valuable research site for analysing the social construction of this technology. Enhances understanding of robotic surgeries and provides insights into medical device regulations in India. During data collection, various studies on RASDs emphasise the benefits and applications of RASD; however, no studies have evaluated robotic surgeries through an actor-network perspective. In contrast, this study examines RASD from the perspective of Science and Technology Studies (STS). In this study, Actor-Network Theory (ANT) is used to examine power dynamics, organisational influence, actor-networks, and government policies in the context of robotic surgery.

### **Emergence of robotic-assisted surgical devices: some observations**

In RASDs or robotic surgery (RS), the word ‘robot’ is derived from the word ‘Robota which is a Czech word that means forced labour (Lanfranco, Castellanos, Desai, & Meyers, 2004). The word ‘Robotics’ was first coined in 1942 by science fiction writer Isaac Asimov. After four decades, the world’s first surgical robot- ‘Arthrobot’ was designed to assist in orthopaedic procedures for the first time in Vancouver, Canada, in 1983 (Yates, Vaessen, & Roup, 2011). In 1985, a Programmable Universal Machine for Assembly (PUMA) 560 robot was used to place a needle for a brain biopsy- neuro-stereotactic surgery. It was the first robot-assisted surgical procedure. In 1992, Integrated Surgical Systems introduced ROBODOC, a robotic system designed to accurately mill the femur for hip replacement procedures in orthopaedic surgery (Otero, Paparel, Atreya, Touijer, & Guillonneau, 2007), to achieve precision and consistency during surgery.

The first robotic arm controlled by a surgeon’s voice commands for manipulating an endoscopic camera: the System for Optimal Positioning (AESOP), was approved for use by the Food and Drug Administration (FDA) in 1994 (Eto & Naito, 2005). Later, several other robotic models were used in human surgeries, including the CyberKnife® in 1994 for neurosurgical applications and the ZEUS® Robotic Surgical System in 1998 for endoscopic surgical procedures, such as fallopian tube re-anastomosis. In the same year, Intuitive Surgical, Inc., Sunnyvale, California, USA, launched the ‘da Vinci’ robot for the surgical procedure-heart bypass surgery (Lanfranco, Castellanos, Desai, & Meyers, 2004). The latest RASD in use today is the ‘da Vinci X System’ manufactured by Integrated Surgical Systems (Intuitive Surgical) in 2017.

The development of RASDs did not follow a linear trajectory; instead, it resulted from a series of innovations over several years. The initial objective of creating RASDs was to support military applications by enabling remote medical care and ensuring the safety of trained physicians away from combat zones. Currently, RASDs are used in a range of procedures, including mitral valve repair and ENT (ear, nose, and throat) surgeries. RASD has emerged from an interdisciplinary network of various social actors, including engineers, physicians, pharmacists, technicians, and patients, each contributing distinct expertise from diverse cultural and social backgrounds.

### **Concerns about robotic-assisted surgical devices- internationally**

The RASDs offer several advantages, but also present significant challenges. The RASD requires additional room space in the operating room (OR), trained staff, prolonged operative times, a steep learning curve for surgeons, high dependency on ancillary equipment, anaesthetic risks related to patient positioning, a higher incidence of local tissue injuries, and concerns among employees about job security, among others. The RASD is highly expensive, with each unit costing around \$114,943. Each robotic arm is to be replaced after every ten procedures, and each robotic arm costs \$6,000 (Gujarat to soon boast of Rs 10-cr da Vinci robot surgeon, 2010). During robotic-assisted surgery (RAS), rather than face-to-face communication (Anne-Sophie & Adélaïde, 2009), the surgeon relies on the OR team’s communication, which contributes to 43 % of adverse events (Gawande, Zinner, Studdert, & Brennan, 2003) during RAS.

### **Regulations on robotic-assisted surgical devices in the international context**

The RASD in the United States of America is currently regulated as Class II 510(k) devices, under the “Endoscope and accessories” regulation (21 CFR 876.1500) (Shayne Jacobson, 2015). However, in India, there are no specific guidelines to regulate RASDs.

## **Methodology**

### **Literature Review**

Science, Technology and Society (STS) studies focus on the dynamic and reciprocal relationship between science and society. Reveals how these two entities mutually shape each other. At the same time, it also emphasises how technology is embedded within a social context. There exist several schools within the domain of STS, specifically the Social Shaping of Technology, the Social Construction of Technology (SCOT) and the ANT.

### **Social Shaping of Technology**

Social Sharpening of Technology (SST) scholars believe that technology is a social product, patterned by the conditions of its creation and use. During its creation there are choices between different technical options, a range of social factors that influence the content of technologies, and their implications (Williams & Edge, 1996). Technologies are an outcome of interdisciplinary research across social, material and other sciences and do not exhibit uniform effects in their application or a linear way of development.

The images of a developing fetus not only identify abnormalities, but also create an emotional bonding towards the fetus on the part of the parents. It establishes a separate identity for the fetus as a person (Petchesky, 1987). The stethoscope, which was initially invented for the detection of heart and respiration sounds, pneumonia, and pulmonary oedema, has today become the marker of the identity of medical personnel- a doctor, in society. The digital power of X-ray, ultrasound, computed tomography (CT), and magnetic resonance imaging (MRI) technology to generate visual or pictorial images of the body is today the description and agreed-upon factor of a person's health or ill-health. This information impacts the work and family life of an individual, regulates individual and social norms, and determines the allocation of resources, material or in-kind, to specific groups. The medical shaping of social identity is thus a significant aspect of medical devices, diagnostic tools, and data dissemination that deserves analysis.

### **Social Construction of Technology (SCOT)**

The SCOT School focuses on the development phase of technology and pinpoints that technology is basically shaped by social processes. It focuses on user practices and forums where users' input is studied. The unit of analysis in SCOT is the social group, with less attention to individual users or the lead users. Some scholars criticise SCOT, stating it neglects power relations and the reciprocal relationship between the relevant social groups and the artefacts, which are hidden but important to understand the organisational dynamics (Bartis, 2007).

### **Social Constructivism**

The social constructivism approach provides three important assumptions about science and technology: First, science and technology are socially important. Second, they are active- the construction metaphor suggests activity, and third, they do not provide a direct route from nature to ideas about nature (Sismondo, 2008). Criticising this approach, Star (1990) states that the technological determinism approach implicitly assumes a specific type of power relations between users and designers in which designers are represented as powerful and users as disempowered relative to experts (Star, 1990). The social constructivist argues that technological development has no natural or logical order of progression. It is not out of human control. Instead, they maintain that society shapes and directs the technology in every phase of its development- from conception to production to use (or even non-use). It is people, not machines, that give meaning to technologies and ultimately decide which ones to adopt and which ones to reject.

### **Actor-network Theory (ANT)**

ANT is distant from the idea that technology impacts humans as an external force; rather, it emerges from social interests (e.g. economic, professional) and has the potential to shape social interactions. It traces associations or relationships between network components (or actors), assuming that non-social phenomena can account for something social consisting of human and non-human actors within the network (Blok & Jensen, 2011). ANT is an engineering process where elements from social, technical, conceptual, and textual domains are assembled and translated into a set of equally diverse scientific products (Law J., 1992). ANT characterises these networks and explores how they come to be patterned to generate effects in organisation, inequality and power. ANT investigates how certain entities (called actants) become related to one another and how, in certain cases, this process leads to the establishment of relatively durable and extended actor-networks- translation. It focuses on hybrid actants and their network rather than on human actors. According to ANT, action is not an attribute of humans alone, but of an association of actants including technical mediators (Latour, 1999).

According to Blok and Torben (2011), there are macro and micro actors. Macro actors represent a network of other actors and serve as spokespersons for the actor-network. They hold influential positions, functioning as black boxes that consolidate complex chains of science and technology, and occupy central, strategic roles within the network (Blok & Jensen, 2011).

According to Larsson (2011), the central concepts of ANT can be summarised as an actor, enrollment and translation, actor-network, inscription, OPP, black box, and episode (Larsson, 2011). Table 1 elaborates the ANT-related concepts.

**Table 1: ANT-related central concepts**

<b>Concept</b>	<b>Definition</b>
Actor	Actors are not only human, but there are also non-human actors, socially connected in networks and dependent on one another (Walsham, 1997).
Enrollment and translation	Enrollment is the process of creating a body of allies. Through this, the translation of the actors' interest is aligned with the rest of the network (Walsham, 1997).
Actor-network	A heterogeneous network of actors with interests aligned. An actor is also always perceived as a network (Walsham, 1997).
Inscription	An embodiment of translated interest, which provides direction on how other actors should act (Hanseth & Monteiro, 1997, as cited in Lango, 2018).

OPP	A defined border, which actors need to pass to be able to go on with the process Callon, 1986, as cited in Lango, 2018).
Black box	When a network is defined as a single actor and acts as a unit, it is black-boxed. However, this is just a relative stability (Hanseth & Monteiro, 1997, as cited in Lango, 2018).
Episode	An episode occurs when the stability of a process is challenged, either by the enrollment of new actors or by an event that might trigger a change (Cho et al., 2008, as cited in Lango, 2018).

Source: (Lango, 2018).

Some scholars criticise ANT, stating that it treats both human and non-human as equal and their network as the only social explanation. ANT excludes technology as a barrier or violence, marginalises and oppresses those who do not get to do science or design technologies or those who cannot access or shape such knowledge or artefacts, but are compelled to feel their effects (Star, 1991, as cited in Law J. , 2007). ANT grants too much power to technology and reinforces rather than rejects the heroic inventor/engineer (Matthewman, 2016).

### **Studies on Medical Devices from an STS Perspective**

According to Yoxen (1993), the shift of ultrasound technology from military use to medical diagnosis was a result of agreements among doctors, engineers, and institutions. When doctors began to trust ultrasound images for clinical decisions and allowed radiographers and other staff to use them, the technology became a black box (Yoxen, 1993). New medical technologies can change the social and economic structure of communities, the environment, institutions, culture, values, and the law (Shah & Robinson, 2007).

Plough (1986) states that the high costs of chronic illnesses, including end-stage renal disease, have led to treatment options being narrowed to dialysis rather than other possible therapeutic options. In most cases, it is due to the intense lobbying by manufacturers of the new technologies (Plough, 1986). According to Alan Prout (1996), the metered dose inhaler (MDI) device was sociotechnically embedded. It reconfigures both human beings and the device, human beings in terms of the competencies it demands and the device itself, with modified versions (Prout 1996).

According to Annemarie Moland Elsmann (1996), the manifestation of atherosclerosis varies with place change. There were different perspectives on a single disease, and each practice generates its own material reality. She argues that “in theory the body may be single, but in practice it is multiple because there are many body practices and therefore many bodies (MoI & Elsmann, 1996). According to MOI and Law (1994), the difference in haemoglobin count varies from one region to another. As haemoglobin meter devices and techniques move from the centre to the periphery, the truths become progressively less reliable. Like blood, anaemia too flows like fluid and generates invariant transformations (MOI & Law, 1994).

### **Study on Medical Device Regulations in India**

Harmon and Kale (2012) report that 70% of medical devices used in India are imported from developing countries. Although the market is substantial, India has not established effective regulation of medical devices, which is attributed to flawed industrial policy, limited entrepreneurship, and insufficient Government oversight. The authors further observe that when Boston Scientific and Johnson & Johnson (J&J) withdrew their stents globally in 2004, India lacked data on device usage and adverse events. In the absence of standardised quality and certification protocols, clinicians remain hesitant to adopt Indian-manufactured medical devices (Harmon & Kale, 2012). Furthermore, following the recall of the J&J hip implant on August 24, 2010, more than 51% of Indian recipients were unaware of the device’s defects and related health risks. The absence of a comprehensive tracking system prevented the government from reaching over 2,000 of the 4,700 implant users in the country (M, 2018).

### **Rationale and Significance of the Present Study**

During the literature review on medical devices, it was revealed that there are very few studies on robotic surgeries conducted in the Indian context, particularly those examined through the lens of ANT perspectives. The present study aims to address this gap in the Indian context. This study adopts ANT because it enables researchers to identify the complexity and fluidity of reality, aspects that may be overlooked by other research approaches that assume linear and causal relationships. ANT facilitates the conceptualisation of how different realities are experienced and enacted by various actors, resulting in a more nuanced understanding of the dynamic relationships among them without neglecting their interconnectedness. It helps guard against simplistic assumptions regarding the role of objects in shaping social realities—not as passive “black boxes,” but as active participants whose roles are determined by their positions within ever-changing networks. ANT does not strictly separate the material and human worlds; instead, it provides a valuable framework for investigating the complex relationships between human and non-human actors, where boundaries are often blurred.

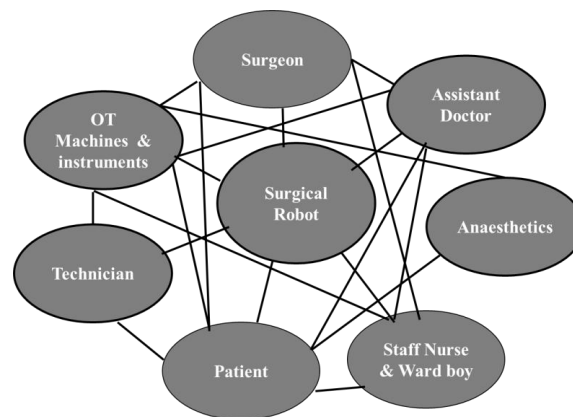
The RASD (a non-human actor) involves diverse actors from various fields and places. Due to its hybrid evolution process and continuous rapid social transformation, ANT is the best available method to apply and explore the connection between the technology and human actors and their dynamics- establishment and changes over time. In this way, ANT provides a whole parliament of things in different forms of social intelligence- scientific, political, moral, and economic, which can be applied simultaneously to the matter of concern. This conceptualisation provides a good tool for investigating complex relationships

between human and non-human actors. In other words, this approach helps describe a social process that cannot be achieved with other approaches.

*Relevant actors and their network involved in robotic surgery:*

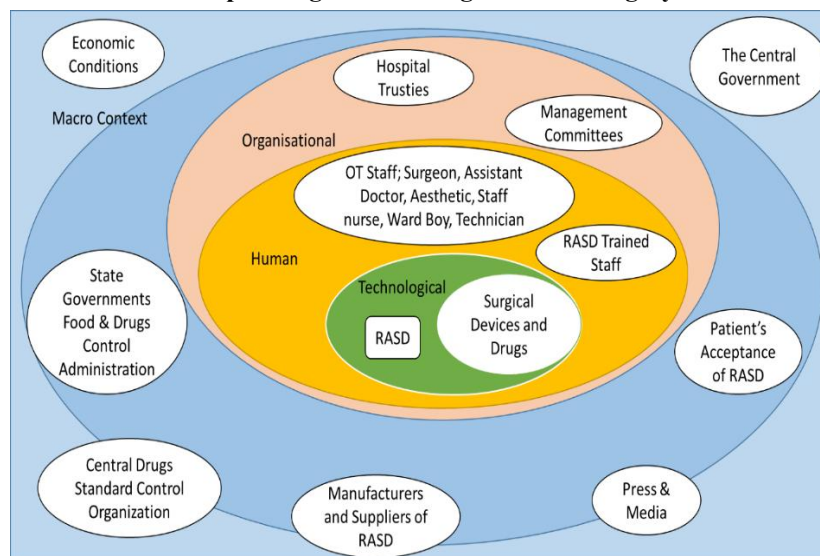
Some of the central actors involved in a robotic surgery were identified through a pilot study. Ethnographic studies were conducted at hospitals performing robotic kidney transplant surgeries. The perception of the actors engaged in robotic surgery (such as purpose and development over time), their role, central events and issues in the process of procuring RASD and implementing RS were gathered. Actors' perception engaged in robotic surgery (purpose and development over time), their role, central events and issues in the process of procuring RASD and implementing RS were gathered. Informant selection was initially carried out by identifying actors playing central roles during an open and robotic surgery in an OR. The central actors involved in robotic surgery identified were the surgeons, ASs, anesthesiologists, the RASD, staff nurses, ward boys, patients, technicians, and the OR equipment and are illustrated in figure- 1. However, it was identified that this network was also connected to several other networks and extended beyond the robotic OR and influenced the actor-network being studied. These actors come from various fields, including the state and central government, RASD suppliers, the press and media, patients, hospital management committees and alike. These actors belonged to various fields, including the state and central government, RASD suppliers, the press and media, patients, hospital management committees and alike. They were part of many other networks, which may or may not overlap with the network being studied. During robotic surgery, the connections among these actors at micro and macro levels (outside the operating theatre) are illustrated in the figure- 2.

**Figure 1: Simplified illustration of potential actor-networks during a robotic surgery in an operating room**



Source: Own compilation.

**Figure 2: Illustration of actor-networks incorporating larger actor-networks beyond the operating room during a robotic surgery**



Source: Own compilation.

## **Data Collection**

Data was collected through participant observation during an open and robotic kidney transplant surgery, in-depth interviews with key informants, including surgeons, OR staff, hospital management, robotic device vendors, patients, and government regulators responsible for regulating medical devices and the formulation of policies. Secondary data was collected through the hospital's website, archival records, publications, newsletters, press releases, journals, news articles, and government reports. In-depth interviews with key informants were conducted between July 2016 and March 2019. Informed oral consent was obtained, and participants were allowed to refuse or withdraw from the study at any time. After each interview, impressions and observations were recorded in the field notes, which were included in the analysis. The interviews were transcribed, and key informants received a description of the research project. Informed oral consent was obtained, including their right to refuse participation and to withdraw from the study at any time. Nine sets of interview schedules, tailored according to the roles of the respondents, were prepared for data collection. The questionnaire was divided into seven categories: history of RASDs, RASD-related issues, education, training and skills, adoption of RASDs, key indications for robotic and open surgery, key processes in robotic surgery, involvement of actors, benefits and risks, and guidelines and policy requirements. Gujarat state was selected for this study since it has the second-highest number of diabetic patients in India (Koria, Kumar, Nayak, & Kedia, 2013), which eventually leads to kidney failure, requiring dialysis or transplantation (Diabetes - A Major Risk Factor for Kidney Disease, 2015). This study is exploratory in nature and utilises a non-probability purposive sampling technique.

## *Sample Description*

The population studied for this research includes individuals associated directly (performing robotic surgeries) or indirectly (involved in procurement, management, or supply of RASDs) with the RASDs. From this broader group, based on selection criteria, thirty-two potential key informants were contacted and invited to participate, either in person or by phone. An abstract of the proposed research was provided to inform their decision. Of the 32 individuals contacted, thirty-one responded and were interviewed. The sample comprised 26 (83.87%) males and 5 (16.13%) females, with an average age of 35.53 years. All participants had worked in the healthcare or a related industry.

## **Kidney transplant surgery**

The section details the processes of open and robotic kidney transplantation surgeries and describes the dynamics within each OR. It also examines the process of implementing RAS in a healthcare institution, detailing the roles of each black-boxed actant and their networks. The analysis outlines the relevant actors and their networks within and beyond the OR. The findings are drawn from a multi-sited ethnographic study that includes live observations of open and robotic kidney transplant surgeries at a leading hospital specialising in robotic kidney transplantation in Gujarat.

## **A case study of robotically-assisted kidney transplant surgery**

The surgeon instructed me to wear a blue apron, cap, mask, and slipper in accordance with protocol before entering the OR. The OR was cool, with focused lighting on the operating table (OT) and subdued lighting elsewhere. It was quiet. The OT was centrally positioned. The patient was covered with a white sheet illuminated by a headlamp attached to the ceiling. A whiteboard hung on the left wall of the OT, displaying information divided into two sections. The first section listed: OT room number, name of the unit head, patient's name, patient's serology report status, gender, case number, operation date, type of surgery, surgeon's name, assistant doctor's name, anaesthetist's name, cross donor's name, and the number of mops and folding towels selected for surgery. The second section included: patient indoor time, incision time, console start and end times, total console time, ward cleaning time, and total operation time. The notice board indicated that the patient lying on the operation table (OT) was male.

The assistant surgeon (AS) standing on the right side of the patient's abdomen, at the OT, instructed the theatre assistant to adjust the table height to monitor readings on the endoscope stack. A staff nurse arranged surgical instruments of various sizes and shapes on a white cloth, which was lined on a nearby trolley sitting on the patient's left side. Next to this tray, a container held ice cubes, which the staff nurse replenished by adding ice and removing excess water. Out of the three lady anaesthetists, two were interns and were standing at the head of the patient. Among them, one was taking readings on a notepad, while others were monitoring the patient's temperature and oxygen flow. A giant RASD stood quietly, with its four arms covered in transparent plastic sheets, near the patient's foot, with only the fingertips of the robotic arms exposed.

One person sat at a computer on the patient's left, behind the robot, taking notes. There were five adjustable screens connected to the RASD- three were ceiling-mounted above the table, one was on the wall, and one was attached to the robot. The ward boy was assisting with shifting, adjusting, and delivering materials as needed from outside the OR. The instrument continuously displayed readings in green, yellow, and red. The surgeon asked the ward boy to help him put on an additional blue apron made of plastic-like material. The surgeon then moved to the console and sat on a nearby stool. The surgeon instructed the ward boy to bring the robot closer to the patient's leg, and after it was positioned, gave a thumbs-up for the robot to be locked in place. The assistant doctor then extended the robotic arms and inserted them into pre-made abdominal cavities. Once the laparoscope arm was inserted, images of the internal organs appeared on the monitors.

The surgeon, sitting in one corner of the room far from the patient, inserted his head into the console to see through the binoculars attached to it and asked the assistant surgeon to adjust the laparoscope's focus on the operation site inside the abdomen. On the screen, clear pictures of the robotic fingers and equipment attached to it appeared. The images were enlarged to 100%–200% of

their original size. The surgeon placed his fingers into a steering-like instrument and both feet on pedal-like instruments attached to the console, moved the handle up and down, sometimes sideways. At the same time, the surgeon pressed and released the foot pedals to control electro-cautery, camera focus, instrument and camera arm clutches, and master control grips that drive the robotic arm at the patient's side. On the screen, each movement of the surgeon's finger and legs at the console was translated into actions of the robotic arms, and the tip (robotic finger) of the robotic arm inside the abdomen was clearly visible.

Initially, some soft tissues were cut, and whatever blood was coming out was sucked outside in a jar through a tube by the AS. Sometimes the surgeon burned the tissues, creating fumes inside the abdomen. In the OT, one can smell the burning of a body part. On the screen, it was clear that the ends of the veins- their tips- were burned to stop the blood flow. Every movement of his finger and leg at the console had an effect on the patient's abdomen- every action of the surgeon had a reaction seen on the screens. Even a small drop of blood coming out due to a cut inside can be seen clearly on the screen as a pool of blood.

Using the microphone attached to the console, the surgeon instructed the staff nurse to retrieve an item from the tray submerged in ice and solution. The staff nurse handed the item to the AS, who was positioned closest to the patient. The AS then placed the item inside the abdominal cavity. The monitor displayed a red-colored section of the kidney. The surgeon made an incision in a blood-filled artery, creating an opening.

At this stage, the operative field became filled with blood. The surgeon instructed the AS to aspirate the blood and irrigate the incision site with saline through a tube to improve visibility. The blood-saline mixture was evacuated, clearing the surgical field. The suction apparatus collected the fluids in a jar positioned near the OT. The kidney, within the abdominal cavity, had two capillaries attached to it. The AS introduced a hook with several centimetres of thread attached through one robotic arm, known as a suture, into the abdomen. The surgeon first straightened the thread and started taking stitches inside, all with the robotic arm. He attached one end of the capillary to the cut, which he had made on the big pipe. He completely attached the end pipe of the kidney without any leakage.

After completing the swing process, the remaining suture material was placed in a designated area within the abdominal cavity. The surgeon then made an additional incision in the primary vessel, positioned slightly below the initial cut, and connected the second end of the renal conduit. The television (TV) screen provided a clear view of the procedure to all the OR staff. Using the robotic arm, the surgeon retrieved the previously placed suture materials from the abdominal cavity and put them on a tray. All surgical steps were performed remotely from the console. During a break between procedures, the surgeon briefly advised a patient regarding medication timing via his mobile phone.

The OR was quiet, and everybody was silently performing their assigned task. The surgeon said that since the patient had already undergone kidney transplant surgery nine years back and it had failed, he first created a space inside the abdomen for the new kidney without disturbing the previous one. The surgeon stated that the previous kidney no longer serves any function. Leaving it as it is will not cause harm to the patient in the future. The new kidney will fulfil the required task. The surgeon inquired about the quantity of urine collected in the urine bag (having various levels of measurement printed), attached to the patient through a catheter, and tied to the OT. Once satisfactory urine output was confirmed, the surgeon declared the operation complete. The AS then withdrew the robotic arms one by one. He removed the tips from the robotic arms for sterilisation. The ward boy moved the robot back to its original position, where it had been placed before the surgery. The person sitting at the computer screen has now stopped taking the reading. The staff nurse began gathering the used instruments into a formalin-filled tub; she counted the blood swabs, mops, and towels before putting them into the dustbin. The AS started taking stitches manually on the cavities that he had made before on the abdomen for the robotic arms. The anaesthetist removed the airway tube and concluded the readings, which she captured during the surgery. The surgeon left the OT and went to another OT where an open kidney transplant surgery was planned- surgery without the robot.

### **Open kidney transplant surgery**

In this case, unlike the previous robotically-assisted kidney transplant surgery, no robot was available to assist the surgeon and his team. The patient was positioned on the OT and covered with a white cloth, with a large abdominal incision measuring approximately 10 to 12 inches. The surgical lamp was directed at the abdomen, providing clear visibility of the surgical field as if inviting all to look inside. This time, even from a distance, the blood and the organs were visible. Here, in the OR, the ward boy handed a bag containing a pair of binoculars to the surgeon. The surgeon wore it on his eyes and adjusted it by focusing on both his thumbnails. Once the view was adjusted, the surgeon went nearer to the patient's abdomen (on the patient's right side). The AS had already opened the abdomen for the kidney transplant. This time, the staff nurse was standing beside the surgeon with the ice tray containing the kidney (to be transplanted), and the AS was on the opposite side of the table in front of the surgeon.

A separate tray, located in front of the ice tray next to the nurse, contained surgical instruments such as scissors, forceps, sutures, needles, swabs, and injections. The instruments were organised in the order of their expected use, reflecting the assistant's understanding of the surgeon's procedural needs. In this setup, the AS was positioned on the patient's left side- a spot typically occupied by the staff nurse during RAS. Conversely, the staff nurse occupied the AS's usual location. The anaesthetist was stationed at the patient's head, and the ward boy managed the transfer of materials from outside the operating theatre.

The notice board contained significantly fewer entries compared to those for robotically-assisted surgeries. Missing information included the assistant doctor's name, the head of department's name, procedure timings, patient admission and incision times, console operation start and end times, total console duration, ward cleaning schedule, and overall operation time. During the

procedure, the surgical team accessed the abdominal cavity using large steel retractors. Following preliminary intra-abdominal assessments, the surgeon requested the kidney from the nurse, who retrieved it from the ice tray. The surgeon then placed the kidney on the patient's chest and carefully separated the two capillaries. These vessels were so narrow that only the surgeon could view their ends with the magnifying glass. The length and circumference of the structure could not be determined. After the pipes were straightened, the surgeon positioned them within the abdominal cavity. In robotic surgeries, the AS positioned the kidney, whereas in conventional procedures, the primary surgeon performed this task.

After the initial incisions, the surgeon instructed the staff nurse to provide a fine, hook-shaped suture needle with attached thread from the surgical tray. The surgeon manually sutured the internal tubing within the abdominal cavity. In contrast, during RAS, the techniques and timing of incisions and sutures are clearly observable by all OR staff. During the procedure, the surgeon's mobile phone rang, and the ward assistant was instructed to answer the call. After suturing was complete, the surgeon asked the AS to measure the patient's urine output in the collection bag attached to the OT. The output was within the expected range. The surgeon then declared the operation successful and instructed the AS to close the abdominal incision and exit the OR.

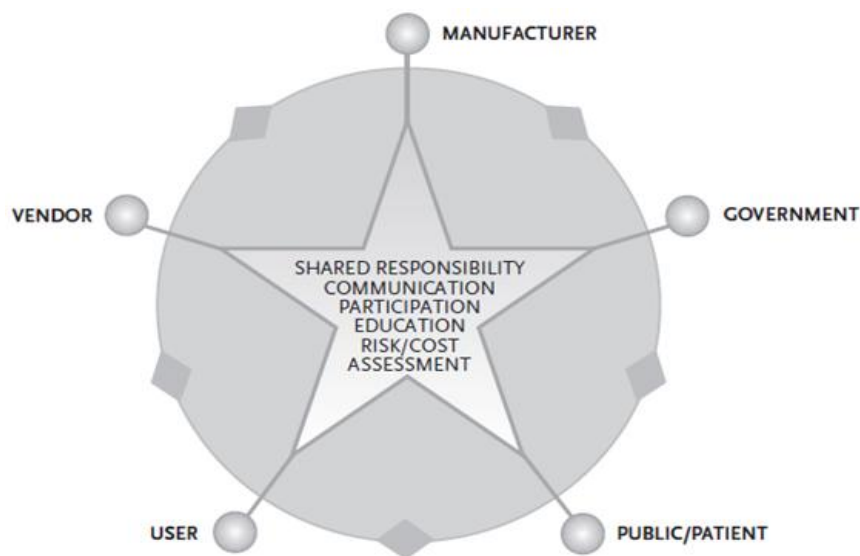
### Results and Discussion

The development of RASDs has a significant social context that continues to influence their integration within healthcare systems. The advancement of RASDs involved extensive research by hundreds of scientists over several decades. The process engaged a diverse range of stakeholders, including healthcare professionals, institutions, industries, and government regulatory bodies- resulting in a dynamic and interconnected network comprising both human and non-human agents. RASDs are developed solely by scientists and used by clinicians and patients. Instead, their evolution is shaped by human behaviours, relationships, and societal factors.

#### Actor-Networks Involved in A Medical Device

The development of a medical device is inherently a process of translation. It aligns the designer's goals with those of the manufacturer, marketer, and end user. From its design phase, it is embedded with a script or set of instructions that determines how the device will function, restricting others from shaping it. They are punctualised and become a point or node that represents a complex network of ordered actors and things that is often not readily visible. They have a designed purpose and are considered clinically effective only when they produce the effect intended by the manufacturer relative to the medical condition. This aspect is considered throughout the lifespan of a medical device. The safety and performance of medical devices are ensured by five key actors: manufacturer, vendor, user, public/patient and government officials/departments. In figure- 3, the circle illustrates the shared responsibilities of the stakeholders, and the diamond handshake symbolises the network (cooperation and two-way communication) between them. The star highlights how the fundamental elements for network functions best when all stakeholders cooperate with each other (World Health Organization, 2003).

**Figure 3: Conditions for Ensuring Safety and Performance of Medical Devices**



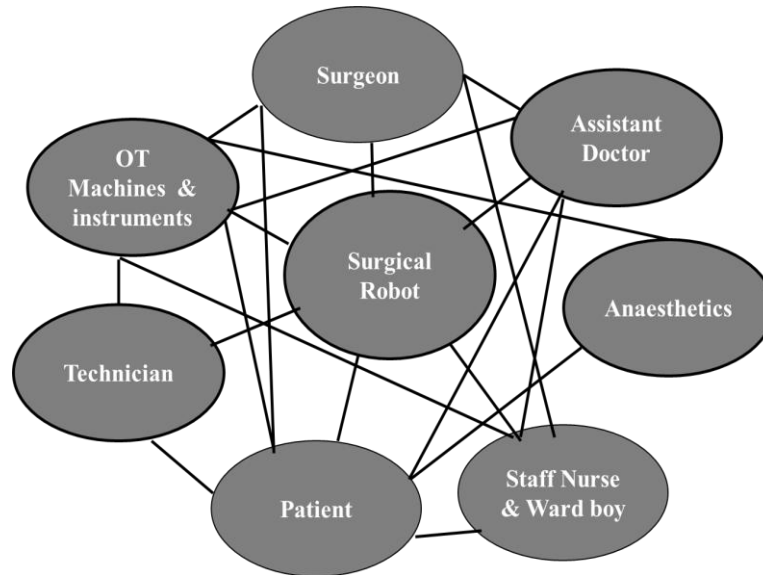
Source: (World Health Organization, 2003).

#### Actor-Networks during Robotic Surgery

The development and adoption of robotic surgery stem from the dynamic interactions within a complex network of diverse actors, including research scientists, universities, patients, the patent system, healthcare professionals, and consumers. These actor-networks are neither uniform nor stable, but are ambivalently changing, coming into and out of existence, and subject to numerous stresses and forces. It becomes essential to study these actor-network and their sub-networks in detail. Entails analysis of all elements from surgeons to patients, hospitals to government regulators and technicians, including their interests, goals, and relations that link these actors together.

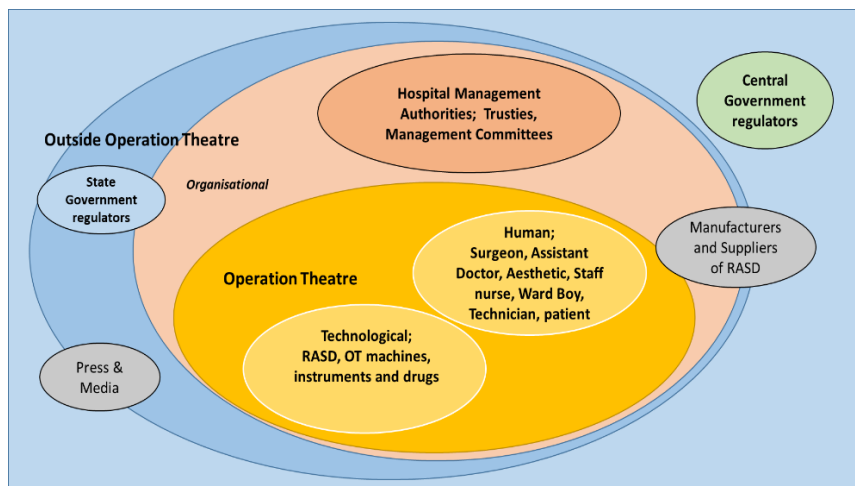
Based on the case studies, the study reveals that the actor-networks can be segregated into three tiers. First- the actor-network inside the robotic OR, second- the actor-network at the hospital level and third- outside the hospital. At the first tier, the key human and non-human actors involved are the surgeon, RASD, surgical equipment and instruments, AS, anaesthetist, staff nurse, technicians, ward boy and patients. In the second tier, the actors outside the robotic operating theatre but within the organisation at the hospital level involved are: the hospital management authority and procurement committee. Outside the hospital, in the third tier, the actors are vendors of RASDs, regulators- government officials responsible for formulating medical device-related policies and ensuring device safety and performance. The actor-network association with robotic surgery in an operating theatre is shown in figure- 4. The three tiers of actor-network associated with the robotic surgery are illustrated in figure- 5.

**Figure 4: Actor-networks within the robotic operating room during a robotic surgery**



Source: Own Compilation

**Figure 5: Tiers of actor-networks associated with the robotic-assisted surgical device during robotic surgery**



Source: Own compilation.

**Tier One: Actor-Networks within a Robotic Operating Room**

*Patient and Disease (Chronic Kidney Disease):*

Through case studies, the study finds that at tier one, the human and non-human actors involved are: human body organs (affected with kidney disease), heavy metals (causing description), blood, urine, water, food, and the diagnostic tests (establishing disease in laboratories).

Various studies on diseases and their causes mention that the toxicity and toxic effects of heavy metals has proven a major threat to the human body. They play a significant role in the traditional functioning of the human body. Its imbalances upset the conventional performance and cause cell toxicity. These heavy metals possess chemical coordination and redox properties that allow them to evade the cell’s control mechanisms. Binds to proteins, displacing essential metals from their natural binding sites, and ultimately causes cellular malfunction. This crossover occurs when heavy metals interact with other metals to form new

alliances, resulting in unusual hybrids that can disrupt normal cellular functions. These hybrids can exceed the cell's threshold capacity, interfere with metabolic processes, and cause toxicity. These metal collectives bind to protein sites, causing cellular malfunction and presenting themselves as an alliance- kidney disease. The displacement of these collectives begins when the patient reaches the hospital, where new actants such as the laboratory, doctors, operating theatre, and RASDs are enrolled, forming a new set of actor-networks. During data collection, one respondent-patient stated that:

“Initially, I went to the hospital nearby. The doctor prescribed me some tests. From my diagnostic reports, he suggested me for a kidney transplant surgery. I heard about kidney disease for the first time. It took away my sleep. At the hospital, I came to know that doctors here do simple surgery [open surgery] and robotic surgeries”.

When body organs are allied, they function well. All actors and their network work in synchronisation, but once an actor, who is an outsider- heavy metals/total dissolved solids (TDS), enters the body and reaches the organ, the conflict arises. In the minority, these metals help organs fulfil their biological functions, but once they align with new actants like oxalate and phosphate, they together break the control mechanisms of organ cells, causing homeostasis. They capture cellular components, including proteins, and render immune agents—previously firmly bound to the kidney and other organs—permeable, fragile, powerless, and prone to breakdown. This new alliance of metals moves collectively through cells, organs, and the body, manifesting as disease and creating an artefact—an inscription—that safeguards the interests of the actors involved.

The heavy metals become the OPP of human cells/organ, allowing them to cause diseases. The organ becomes powerless to prevent all the causes of a disease. Though small in micromilligrams, these heavy metals form a powerful network that crosses and moves through cellular pathways, ultimately translating and infecting organs such as the kidney. This new metal alliance not only enrolls actors, body organs, its cells and others successfully and translates their interest to its companion alliances- an inscription of making the body organ malfunction and creating a black box called CKD, but also decides future actors and their networks- which actors and actants will be and will not be a part of their further network.

#### *Robotic-Assisted Surgical Device and Operating Room Staff:*

When the study looks at the device- a RASD, it ends up with a sociotechnical system. It is an object-virtual (software) and actual (hardware). An association of actants that helps in coding areas of social life and tends to upgrade continually. A collective of mutes that creates to produce and utilise certain effects. In the collective, it is a technique of right knowing and right doing, useless for an unskilled actor. In this regard, the respondent surgeons unanimously stated that to access a robot-assisted surgical device, a surgeon must know about computer hardware and software. One of the respondent surgeons performing robotic surgery stated that:

“It can be understood that if a person is doing a surgery, he must have basic computer knowledge”.

The robotic surgical device is not just a device consisting of hardware and software, but comprises multiple components, practices, knowledge, authorities and organisations. The RASD is the spokesperson speaking about the array of actors, encompassing the manufacturer, patient, instruments, operating theatre, surgeon, OT staff, medical records and reports—as well as their related issues addressed and resolved. It also includes an assemblage of agents and their networks for its proper monitoring and use, providing follow-up, repair or replacement. Robotic surgery not only shapes the actor, but during a robotic surgery, the RASD demonstrates and repeats what others expect it to do- it channels the actions, performs political functions and plays a part in individual and group identity.

The RASD materially alters the associations of actors in the OT from open or laparoscopic surgery to RAS, from manually cutting and sewing the patient's body to mimicking it, establishing new OT, new actor-networks, their associations and institutions. The RASD has its own effects. It mediates between treatment and society, diseases and surgical practices, between matter and meaning.

The robot convinces all actors associated with its networks by channelling surgeon actions according to the surgeon's expectations. Throughout the surgery, this was a two-way process. The robot guides the surgeon as precisely as possible by enlarging the operation site. A separate operating theatre for the robot assured the patient that with the robot, they would have fewer insertions, a shorter hospital stay and early discharge. Patients perceived themselves as distinct from others because they underwent robotic surgery, a procedure accessible primarily to those with the socioeconomic means to afford its high cost. This process involves configuring user groups, determining eligibility for access, and modifying or establishing a new social structure. It also generates a power structure within the network that influences the capacities of both actors and end-users. One respondent from the hospital management authority group, who was directly involved in managing the RASD operating theatre, stated that:

“The reason the surgical robot was brought to this hospital was that, in Western India, ours is the biggest corporate oncology setup. So, if you want to call yourself a cancer centre, without a robot, it would not be complete. If there is anything in the market that pertains to your subject and you claim to be a specialist in that particular subject, then you have to keep up with where the world is running with. You can't lag. Studies have shown that hospitals without a surgical robot (da-Vinci) have experienced a lower number of patients. Robotics has enhanced the rate of surgeries. It has become a brand issue. If you do not have a robot and are not doing robotic surgeries, then that is something a parameter to judge- an added parameter to judge”.

Another respondent a staff nurse:

“If you want to aim at success and to prove credibility in the eyes of referring doctors in the market and patients, the only way somebody would take it seriously is if you are up to the mark (having the latest advanced technology- robotic surgical device)”.

The RASD as technology may have embedded in its scripts notion of autonomy and individual responsibility, the counseling helps patients to understand some of the limitations of robotic surgery (in case if anything will go wrong during surgery, then they will go for open surgery), simultaneously discussing about various concerns of individual and family members with the counselor, patients often decide whether to have or not to have robotic surgery- informed decisions. One of the respondents from the surgeons’ group stated that:

“When we brought this robot, we were explaining to patients that with the use of this technology (RASD), there would be more accuracy in operation. So that people can recognise this hospital”.

With the introduction of RASD, the peers were so profound that they were not simply reshaped, but were turned into new actors in their own right. Socially, the robot made the hospital staff feel proud of having a robotic surgery at their organisation. They received recognition- a separate identity from other staff who were involved in open surgeries. One of the respondents, a staff nurse,

“My salary is fixed. There are no extra incentives for helping with robotic surgeries. Still, I feel proud that my colleagues and family recognise me as a staff nurse who works with the latest technology in surgery”.

One of the respondent, a staff nurse,

“We do get an incentive for doing robotic surgery. Robotic instruments come with limited time use – ‘only 10 times’. So it’s washing, handling, replacement, arrangement according to the operation, supply as per the surgeon’s request, storing, etc., requires extra care since these instruments are very light and too costly and therefore extra incentives are given during a robotic surgery”

A robotic-surgical device consists of many actors from various times and places in a structured network. The name of the manufacturing company on the console and on the robot speaks, acts, and exerts influence on the manufacturing company even when they are not present in the operating theatre. The minerals it is composed of are as old as the world, the software is significantly less, and the time it left the factory is less still. It has crossed the factory, the country where it was manufactured, overcoming the country’s legal formalities and government approvals. Crossing over the sea, arriving at the hospital and finally at the OR. Crossing over the boundaries between the symbols and things and doing the thing that humans would otherwise have to do in the operating theatre.

The robotic operating theatre itself went further. It had developed an immunity that outlasted the attentions of not only hospital staff but also other trainee surgeons, hospitals, and patients from other hospitals and countries. The network, which was previously limited to the four walls of the operating theatre and within the OR staff, now, through a web link, reached the manufacturing company. Crossing over the boundaries of hospital and country, through the online web link through which the robot is always connected to its manufacturer, located in California, USA.

Once the network of heavy metals is established and the disease CKD is being noticed, the surgeon, AS, and staff nurse, whose beliefs, knowledge and skills played an active role. The disease enables surgeons and operating staff to access areas of the body that were previously unreachable in living patients—accessible only during post-mortem examinations. As one respondent surgeon stated that:

“During robotic-assisted onco surgery, the insertion into the body is much less invasive and much more precise. There is a fluorescent effect which shows the affected part in red. As the robot proceeds, we can see the exact extent of disease spread- very precisely and accurately”.

The surgeon, who had inoculated many animals in the laboratory during various robotic surgery practices, stated it as an experimental trial - a hybrid made of knowledge of RAS and knowledge of curing disease. Seizing a diseased kidney from its own terrain to a corner of the body, replacing it with a new actant (kidney) from another actor-network (kidney from a cadaver or live donor) to speak on its behalf. Moving from the operation site of an animal to humans, for a while becoming a veterinary doctor from a human doctor, and back from the laboratory to the operating theatre, from where the surgeon went initially, all scattered in time and place.

Due to the interventions of time, the technique of performing surgery drifted. The surgery, like removal of the gallbladder (cholecystectomy), which was done through open surgery initially drifted to laparoscopy and then to robotic-assisted device-first entered everyday practice and then the horizon widened; from robotic kidney transplant, then removal of a kidney from a cadaver through robots and now kidney transplant from a live donor to another body (recipient).

With the RASD, the allies recruited by the surgeon and his team make the time irreversible. Now, no one could contradict them-robotic surgery no longer remained controversial. Together, these allies make their position impregnable. Robotic surgery is evolving into a fully developed science, with an indisputable long-term plan for its application to other surgical procedures. As one respondent surgeon stated that:

“The surgeon does the robotic surgery. Once the robot is switched off, it can’t move. It is a computer system. Whatever the surgeon does, the robot mimics. The surgeon has two screens in the console. If, during surgery, a surgical instrument

moves out of the screen, it could injure other organs. The robot is an inert thing. It is the surgeon's negligence if such an incident happens".

At the console, the built-in sensors guided the surgeon on when to begin the surgery. It started only when the surgeon was within the console range. If the sensors do not identify the surgeon's face, it refuses to start- it encodes morality. The robotic eyes (polarising glasses) provided a 3D view of the surgical site to the surgeon's vision, a manipulated handle to control surgery, voice command and a tele-monitoring facility to view the surgical site even when sitting far from the patient. The RASD mimicked the surgeon's movements exactly through its arms and connected instruments further to the patient. It also allows the surgeon to add a second surgeon console for training or performing a surgery in combination. One of the respondents- a surgeon shared that:

"The console is equipped with sensors that, once activated, initiate the robot. If my head moves even slightly out of the screen's field of view, the robot locks in its current position, making further movement impossible. Multiple tasks, such as talking on the phone while performing surgery, are not possible; the system requires the surgeon's continuous engagement. The foot pedals at the console are linked to the cautery function. When the pedals are pressed, this action is reflected as motion on the screen. If the left indicator light blinks, it means the pedal has been pressed but the cautery has not been activated. The console has two knobs: bipolar and monopolar. If the bipolar knob is activated by mistake instead of the intended monopolar, a warning light alerts me that the wrong pedal has been pressed. Any instrument attached to the robotic arm by the assistant surgeon is displayed on the console along with its name, such as "penetrating driver" or "needle driver." If a consumable is inserted for the 11th time, the system will display a message instructing to change the instrument, as the da Vinci robot allows consumables to be used only 10 times. Overall, it is a highly sophisticated computerised system".

In this regard a respondent –technician stated that:

"The da Vinci system allows for the attachment of two consoles simultaneously. While this feature is expensive, it is available for use. In India, only a few hospitals have operating rooms equipped with dual consoles. These are primarily used for training purposes or during lengthy surgeries".

### **Tier Two: Actor-networks at the Organisation/ Hospital**

*Hospital Management Authority, Vendors and Robotic-Assisted Surgical Device:*

The OR consists of large networks, a network within a network of humans; the OT staff and non-human actors; screens, patient's cart, console, instruments for measurements, light indicators, electricity, mike, different types of surgical instruments and so on, creating its own environment different from the usual OR. The embedded size and shape of the robot compelled the hospital authority to construct a new OR- a condition set by non-human actors in the creation of a new network in the OR and at the hospital. Displacing technical engineers in the operating theatre, making room for themselves, elaborating a network to a new actor-network; the designing for robotic OR, its designing team, schedules and contracts- a creation and mobilisation of actors in a local network. One of the respondents, a surgeon, stated that:

"It (the surgical robot) is very bulky (around 8 feet in size). The height of the operating theatres is usually about 12 feet. For the robot, we had to develop a new OT with a 15-foot ceiling height. We had to modify the design of the entire OT, and accordingly, the construction".

Another respondent, a staff nurse,

"Robot has changed the entire OT. First, it has changed the electric fittings and boards. Previously, in the OT, there was a single electric plug to which we used to attach an electric board, and through this board, we further attached the cables of other lights, a robotic plug, etc. Due to heavy electric load and fluctuations, the robot stopped. Now, we have separate electric supply and electric points for different lights and robotic parts-vision points, robotic point, console point, etc."

After a few successful robotic surgeries, some actors lost their places; the engineers, hospital management authority (involved during procurement of robot), the mechanics who installed the robot, the builder, the architect who made the robotic OR, all were forgotten, and others new actors gained their place; surgeon, AS, anesthetics, staff nurse and other OT staff. Everyone was displaced, translated. Created a new politics at the hospital, in the operating theatre, due to the arrival of a new and disturbing agent called a RASD on the scene: non-living but visible.

Robotic surgery has become a powerful tool in today's highly competitive medical market, creating tension between patient care and profit among medical practitioners, attracting all stakeholders, patients, doctors, businessmen, and hospitals toward robotic solutions. For hospital authorities, it was a difficult decision to invest heavily in this technology, as robots become central to questions of both patient treatment and financial viability. Drifting its initial purpose to the commercialisation of robotic surgery, seeking to expand its market by relaxing strict access criteria. As one AS shared that:

"Today, misuse of robotic surgery is a major concern. People are performing robotic surgeries in small surgeries, even though it might not be necessary to do so with a robot. Since it is a costly surgery, they may perform it. For example, suppose I want to do a robotic surgery for the appendix (appendectomy), nobody can say no to me, even though there may be no meaning in doing it through a robot".

A preliminary network of local actors, including the surgeon, RASD, and hospital management committee, was successfully in mobilising in creating intermediaries; the procurement committee, OT team, to satisfy global actors; Intuitive Surgical with the help of local network like; satisfying government conditions and formalities of purchasing medical instrument, defining surgeries, its types, package rates and so on. Intermediaries started to flow from the global network: a manufacturer in the USA, to a permanent local network- supplying RASD, its consumables, annual maintenance, and so forth, at the hospital.

### **Tier Three: Actor-networks beyond Organisation/Hospital**

At the hospitals, the enrollment and translation of actors was not an easy process. Initially, there was no consensus among the actors of the hospital management authority and the hospital procurement committee. The hospital procurement committee refused the procurement of an RASD. The reason was its high cost. However, here, since the network between the surgeon, hospital management authority, and the hospital procurement committee was stable, the procurement decision of RASD was cleared after a few negotiations between them. Although the RASD device was weaker at this stage due to its cost, the whole robot was first translated and inscribed in the papers before its procurement. The surgeon, along with his alliance here, successfully enrolls the procurement committee with their inscribed objective associated with the RASD. One of the respondents from the hospital management authority stated that:

“We shared with the committee that the new technology will not only help the postgraduate students at the institute but will also enable them to excel in the field of kidney transplant surgeries”.

The design and creation of a network between the local and global networks was finding difficulties in interacting. The success and shape of the project were now dependent crucially on the creation of two networks- the hospital management committee and the procurement committee, and on the exchange of intermediaries between these two networks. Once the agents of these two networks formed a single alliance, the translation of procuring RASD began. One of the respondent technicians stated that:

“Intuitive Surgical is the only company manufacturing surgical robots. It is based in California, USA. The US FDA has approved the da Vinci robot. In India, the manufacturing company had previously collaborated with a channel partner called Vattikuti Foundation. In May 2018, this partnership was withdrawn, and they opened a new company called Intuitive Surgical India Private Limited. Today, this company is supplying robots in India. Intuitive Surgical India Private Limited is the distributor and supplier of the da Vinci surgical robots in India.”

If this negotiation were not to be successful, the hospital management authority would not have been able to enrol and translate their inscriptions to the procurement committee. The surgeon's skills and his laboratory experiences might have remained ideal, confined to the laboratory, and immovable- the whole thing could have been turned into a fiasco. The committee needed to be convinced that the RASD supplier company agrees to provide the device in instalment payments, and it is indeed capable of producing the expected benefits within this defined budget. With the approval of RASD by the procurement committees, it is no longer open; gallbladder, prostate, liver or kidney surgeries are now an inscription ‘robotic surgery’ - a new surgery for patients, a new experience for operating staff, a pride for hospital management authority, a source of producing new agents- actor-networks.

Although the procurement committee was “punctualized”- an actor that was reduced to a single function of approving the RASD's procurement process, its approval was very important for its commissioning. All decisions of the hospital management committee regarding the procurement of any costly item need support from the procurement committee. With the procurement committee seemingly enrolled in the actor-network, the interests of the hospital management committee got aligned, a new actor-network was created, and within it, a common plan for implementation was inscribed. The government regulators- the FDCA- didn't have any objection to the import of RASDs since these are not included under the notified medical devices list. In this context, a government official stated that:

“There are regulatory provisions under various sections of the Drugs and Cosmetics Act, 1940, to control the selling of drugs to consumers, and the same rules apply to medical devices. However, a robotic-assisted surgical device is the latest technology and has not been notified by the central government. There are no guidelines in this regard with us that mandate any hospital to seek permission from our department before its procurement”.

Here, the OPP moving the project forward was the enrollment of the hospital procurement committee. The committee's objective in joining the network through the procurement of RASD was to solve their students' and patients' problems. The robotic surgery at the hospital was conceived as an instrument of attracting people from within and outside the country, along with several new actor-networks to the hospital's existing network. The hospital management committee successfully enrolled skilled hospital staff, funds and infrastructure for conducting robotic surgery, and thus, reached the OPP.

The Government, specifically the FDCA, also became an actor potentially involved in the procurement process, aiming to align legal requirements with the procedures for RASD procurement. As one government medical device regulator stated:

“In India, medical devices are currently regulated as per the Drugs and Cosmetics Act, 1940. For medical devices, a separate Act is required. A separate regulation for medical devices is in the framework process”.

The robotic surgery at the hospital gained stability as the values inscribed within it were consistently interpreted in a similar way by all actors, and over time, the RASD gets black-boxed.

### **Actor-networks and their social effects**

Robotic surgery (RS) is an outcome of human and social interaction, enacted by the interactions of human and non-human actors. The ANT permitted this study to follow the interactions among these actants during an RS, in a rich, empirical, and understandable way. It has enabled a sustained and ethical critique. It does not exist apart from the social world, but is developed and accessed for various personal and social reasons. By applying the ANT approach in this study, the processes such as enrollment and translation, actor-network formation, inscription, OPP, black box, and episode are not only successfully revealed but also explain the social effects arising from the associations between various actors and their networks in the OR.

#### **a) Enrollment and translation**

In the human body, as long as heavy metals remain in the minority, they help organs perform their natural functions. However, when they combine with new actants (oxalate and phosphate), they disrupt the controlled cellular homeostasis and cell constituents. This crossover in the cell network spreads and infects the organ. Brings in a new actor and shifts their interests to other alliances, causing diseases. This action belongs not to a metal or an organ alone, but to an association of actants, or technical mediators.

The surgeon presented the disease to the hospital management as a problem and proposed a novel technological solution called RAS, convincing them to adopt RASD. He persuaded others to stop using conventional surgical methods in difficult-to-reach areas. He enrolled the colleagues he was trained with in the USA, forming a network based on skills rather than logic or language, and built networks with them to make the system work. With the procurement of an RASD, the final translation happened. A whole new network was created at the hospital. The leading network builder was the RASD. The robot enrolled all actors in the OR, including the surgeon, OT staff, and others who understood the robot and its behaviour. This alliance agreed to follow the script written by the robot- their role, how to act, and when to act. In return, the robot behaved loyally and obediently following the surgeon's instructions in OT- a translation of human and non-human actants exchanging their properties. The actants, the robotic arm, TV screens, the patient, and others, became technical mediators for the alliance to achieve successful RAS. The collective conferred life and meaning upon RASD, generating novel hybrids and altering the direction, scope, and composition of activities through enrollments and the mobilisation of new actants.

During RAS, the creation and distribution of new competencies extend through time and space. All actors present in the OT were configured in terms of a new set of abilities, as one set of competencies implied other actors linked to the network. By performing multiple functions, the robot served as a spokesperson for the collectives absent during open surgery.

The RASD selected the new actors meticulously, only those with appropriate knowledge, training, skills, and the ability to handle it (the robot). The operating protocols of RASD were sufficient to enrol other actors in its alliances. The TV screen encoded the surgeon's ability to create a trade-off between the patient's access and surgical control, enrolled the operating staff through its screens, forced the surgeon to act promptly, on time- translating a non-human source of actions to a human action, performing realities from a different time and space (manufacturing features, instruments, and so on), in the network to make RAS successful.

#### **b) Inscription during robotic-assisted surgery**

To bring RAS to their hospital, the surgeons travelled to the USA for training, repeatedly performed abdominal surgeries on animals using the robot and its arms. He carefully recorded details in his logbook. Upon returning, the surgeon integrated the RASD into his network, blurring the boundaries between material and human skills. RASD's ability to stay connected with its manufacturer through a web link during surgery introduced a new set of actor-networks in the OR. The surgery now extended beyond the OR, hospital, state, and even country, ultimately connecting to California, USA- the headquarters of the RASD manufacturer. This large-scale, human-built, encrypted system worked for disease cure- an act central to societal function. Both human and non-human actors shared responsibility for the patient's outcome, success or failure of surgery, in an environment where disruptions are common. Each instrument used in RAS carried an inscription built by its creator. The headlamp illuminated the surgical site as brightly as possible, the surgical knife was sharpened for maximum precision, anaesthesia was administered with utmost care, and the robotic arm displayed remarkable craftsmanship. All aligned together, translated to achieve a successful surgery. The RAS united human and non-human actors, transforming them so they would not become traitors or deserters, and eliminated all possibilities of failure during the procedure.

#### **c) Obligatory point of passage during robotic-assisted surgery**

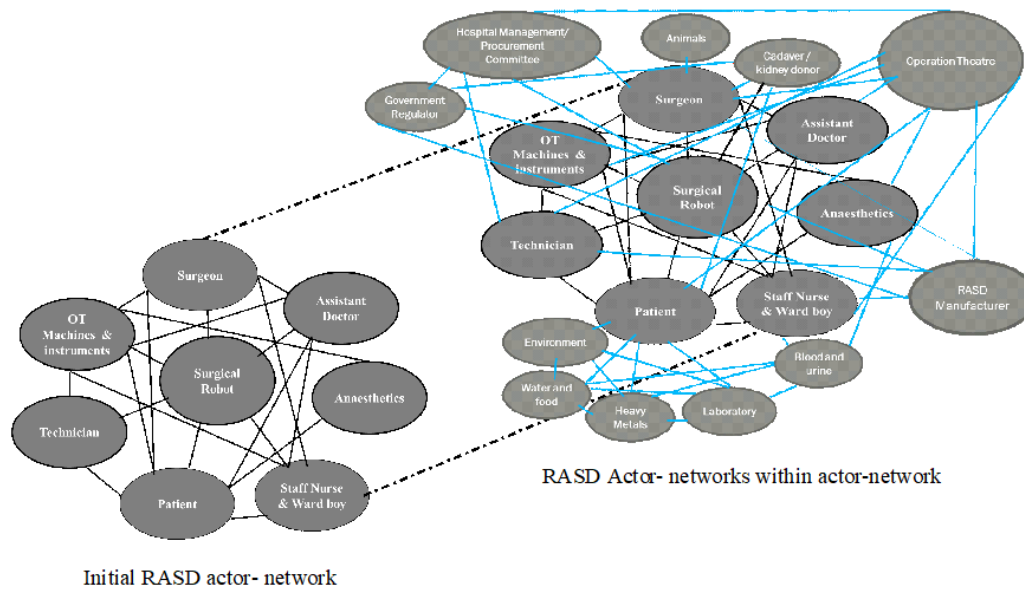
The study finds that during RAS, each new actor-network has an OPP that shifts continuously along with the network. During the study, the heavy metals served as the initial OPP, passing through the body, forming alliances, and causing organ dysfunction that leads to disease. These effects manifest as specific signs and symptoms observed in laboratory and diagnostic tests. Heavy metals also unify the interests of other actors—such as cells, human metabolism, and laboratories—by linking them to their acquired properties. This process establishes heavy metals as a key OPP: as cells pass through this point, they progress to the laboratory, hospital, surgeon, OT, and RASD.

The surgeon became the second OPP at the hospital. He connected the interests of various stakeholders, including OR staff, hospital management, and the RASD manufacturer, to the specialised knowledge he acquired abroad. This positioning enabled him to serve as a central mediator. The surgeon negotiated with the RASD manufacturer and successfully persuaded the procurement committee to purchase the device. He adapted the OR to accommodate the RASD, thereby limiting external

influence from those outside his established network. The technical skills he acquired through animal-based training were imparted to the OR staff through focused instruction, seamlessly integrating them into the RS process.

In the OR, the third OPP was the RASD itself. It comprised both human and technological components. It served as a central hub for all surgical activities. Its TV screens, computer, laparoscope, and console effectively facilitated collaboration among human and non-human actors. Each stakeholder engaged with the RASD for distinct reasons: for the surgeon, it represented a novel treatment approach; for hospital management, it offered opportunities for student training and market recognition; and for the patient, it meant a procedure with reduced hospital stay and blood loss. Once the users became proficient with the RASD, RS became routine. Figure- 6 illustrates the initial actor-network of the RASD and the related networks identified during the study, indicated by light blue lines.

**Figure 6: The actor-networks within actor-networks in a robotic-assisted surgery**



**d) Robotic-assisted surgery- a black box**

The hospital is performing multiple robotic surgeries. Patients from various regions are seeking RS at the hospital, which offers reduced scarring, decreased pain, and shorter hospital stays, making RS procedures a black box.

**e) An episode during robotic-assisted surgery**

The findings reveal that the RASD has had a significant social impact on the medical sector. The high cost of RASD has exacerbated disparities among patients, limiting access based on financial means. The variation in RASD functions and designs complicates the application of existing regulations and necessitates the development of a dedicated legislative framework in India. Future shifts in cost, technological innovation, adverse events, or new government policies could significantly influence the adoption and utilisation of RASDs.

**Conclusion**

The case studies demonstrated that during a robotic surgery in operating theatres, there are assemblies of both human and non-human actors. Among human actors are doctors, staff nurses, technicians, vendors, patients, representatives from government authorities and other stakeholders. RASD, OTs, monitors, light indicators, syringes, needles, threads, instrument trays, swabs, and a notice board were among the non-human actors. The common actors in both open and robotic surgeries were: OT, operation notes, OT lamp, surgeon, patient, anaesthetist, AS, staff nurse, ward boy and vendor.

The actors involved in RS successfully mobilised and stabilised their networks beyond the OR and their organisation to secure the resources and approval needed for their project. They established new relationships between actor-networks, expanding their tier-one network into a tier-two network—transforming a local network into a global one—essential for the successful implementation of robotic-assisted surgeries at their hospitals, ultimately making the RASD a black box.

The RASD demonstrated variable geometry, representing different things to different actors and exhibiting a high degree of interpretive flexibility. The project carved out its own time and space to deploy resources borrowed from outside, achieving a measure of autonomy—a negotiable space. For the government and procurement committee, the RASD was not merely a medical device but a tactical tool for attracting foreign patients to the state and bringing recognition to their hospitals. For the hospital management committee, it signified technological advancement, offering students exposure and serving as a gateway to marketing the hospital’s surgical specialities as the most advanced treatments available. To hospital staff, it provided a new means of patient care. For vendors, it represented a new market in Gujarat. For patients, it meant shorter hospital stays and minimal surgical scarring, rendering most of the artefact’s complexities invisible to these actors.

A series of translations occurred. Some in the form of economic exchange: RASD would provide benefits to the patient. RASD will provide new exposure to students that they cannot get in any other hospital in the country, ultimately translating into RASD. Some translations were political: the government was increasing medical tourism in the state.

In summary, the interviews revealed that most hospitals adopted robotic surgery because it appeared to be an advanced technology that offered greater ease in treating patients, rather than based on clear data demonstrating improved survival rates compared to open or laparoscopic surgeries. The decision to adopt—or not adopt—a surgical robot was not a straightforward yes/no choice, but rather a process involving negotiations among multiple human and non-human actors. Using the actor-network approach, this study makes this complexity visible.

### **Theoretical and practical implications**

The RAS is a sociotechnical system shaped by a range of stakeholders, both human and non-human, and has created a web of actor-networks at the local and global levels. The RASDs have created a highly technical environment where people and machines, each with their own roles and expertise, work in situations that can be uncertain and emotionally charged, becoming a key part of the larger system. It has led to new practices and allied organisations, built a network linking medicine, diagnostics, and business, and distinguished infected from uninfected individuals. All within a broader web of social connections. It has shaped the relationships between technology, disease, and society—determining how the technology is used, who operates it, and which economic groups have access.

In India, RASDs fall outside the current Drug and Cosmetic Act, which shows the need for separate regulations for medical devices. The existing Medical Device Rules 2017 cover only 462 medical devices and 250 in vitro diagnostic devices. It excludes medical devices that incorporate software. There are no guidelines for ensuring the quality and safety. There is no dedicated tracking system for reporting adverse reactions due to RASDs. While it has improved patient outcomes, access to this technology often favours those who can afford it, influencing social identity and highlighting the need for further investigation.

### **Limitations and future directions**

The present study examined robotic surgeries, their selected interactions, and the major actors in an OR from an ANT perspective. The scope of the present study was relatively limited. Identifying all actors and studying their interactions is beyond the scope of this study. Comparative hospital studies on RS, including longitudinal network analysis, detailed examination of regulatory and commercial actors, and a larger sample size, are required for further generalisation in this regard.

### **Abbreviations**

NCDs: non-communicable diseases, CKD: chronic kidney disease, RASDs: robotic-assisted surgical devices, RASD: robotic-assisted surgical device, STS: Science and Technology Studies, ANT: Actor-Network Theory, USA: United States of America, RAS: robotic-assisted surgery, OR: operating room, Assistant Surgeon (AS), OT: operating table, TV: Television, RS: robotic surgery, OPP: obligatory point of passage.

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