HOSPITAL ASSOCIATED INFECTIONS: PREVENTION AND CONTROL

Sectional Editor
P.S. Shankar
Emeritus Professor of Medicine
KBN Institute of Medical Sciences
Gulbarga

Contributors
Gopal R
Professor and Head

Shanmugam J
Professor

PrachiSaban
Mangaiyarkarasi T
Sunil Shivekar
Assistant Professors
Department of Microbiology
Sri ManakulaVinayagar Medical College
Puducherry 605 107

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Introduction

Microbes particularly bacteria and viruses have played havoc with human life since time immemorial. The discovery of antimicrobials had a significant impact on the control of bacterial infections along with prevention of a few dreaded bacterial and viral infections with the invention of vaccines. However, the irrational use of antimicrobials and the lack of newer effective drugs have led to the development of multidrug resistant bacteria leaving fewer therapeutic options for those patients infected with multidrug resistant strains particularly in health care settings which is an ideal niche for breeding of these bugs. It is therefore essential to adopt stringent infection control measures in the health care establishments to prevent the spread of the drug resistant strains and thereby reduce the morbidity and mortality associated with these infections.

Hospital acquired infection (HAI) also called health care associated infection (HCAI) or nosocomial infection is an infection acquired by a person in a hospital and was not present or incubating at the time of admission to the hospital. The disease may be due to the infectious agent or its toxins and usually manifest after 48 hours following admission or after discharge from the hospital.

Risk factors for acquisition of HAI:

1. Prolonged stay in intensive care units (ICUs), burns or trauma care units, etc.
2. Invasive procedures for diagnostic or therapeutic purpose
3. Indwelling devices eg. I.V catheter, urinary catheter, endotracheal tube, etc.

4. Prolonged use of broad spectrum antibiotics, steroids or immunosuppressive agents.

Source of Infection:

1. Contaminated hands of health care workers (HCWs)
2. Inanimate objects in the vicinity
3. Contaminated medications eg. Eye drops, I.V fluids, etc.
4. Contaminated instruments and antiseptic lotions, etc.

Routes of infection:

1. Contact with skin (Percutaneous) or Mucous membrane
2. Inhalation of airborne droplet nuclei.

Common types of HAI:

1. Catheter-associated urinary tract infections (CA-UTIs)
2. Catheter-associated blood stream infections (CA-BSIs)
3. Surgical site infections (SSIs)
4. Ventilator Associated Pneumonia (VAP)

Most common pathogens associated with HAI:

1. Methicillin resistant Staphylococcus aureus (MRSA)
2. Methicillin resistant Staphylococcus epidermidis (MRSE)
3. Vancomycin Resistant Enterococci
4. ESBL Producing Gram-negative bacilli
5. Mycobacterium.tuberculosis
6. Candida species
7. Aspergillus species
8. Human immunodeficiency virus (HIV), Hepatitis B virus (HBV), Hepatitis C virus (HCV)
9. Herpes viruses: H.simplex, Varicella zoster

Standard Precautions

' Standard Precautions ' are safety practices to be followed in all health care settings and is based on the assumption that every patient is potentially infectious that include blood, body fluids, secretions and excretions except sweat. Non intact skin and mucous membranes may

contain transmissible infectious agents. The practice of standard precautions contributes to significant decrease in HCAI. The major components of standard precautions are as follows.

1. Hand Hygiene:

The hands of the health care workers (HCW) are important vehicles for transmission of infectious agents and therefore hand hygiene is of utmost importance in control of HAI. Different types of hand hygiene are practiced as per the situation. These practices remove or reduce the transient and/ or resident bacterial flora of the hands thus reducing the transmission of the potentially infectious agents. A simple 'hand wash' with plain soap and water helps to remove the dirt and organic matter from the hands and is sufficient for routine noninvasive contacts with the otherwise healthy patients before and after contact. 'Surgical hand wash' requires the use of a medicated soap and water for preoperative preparation of the surgeon's hand.

2. Hand rub:

It is the process of disinfection of hands by application of alcohol based compounds for quick and in between two patient contacts as in ICU as a practically convenient method.

3. Personal Protective Equipment (PPE):

The use of PPE protects the HCW and the patient from cross infection. The type of PPE used varies with the situation.

a) Gloves: Clean gloves act as an important mechanical barrier and protect the HCWs hand from being contaminated with potential infectious material. Some of the applications include, use by phlebotomists, dental surgeons for performing an oral cavity examination, surgeons performing per rectal and gyne cologists per vaginal examination.

b) Sterile gloves: These are used for all invasive procedures which come in direct contact with potentially infectious sub stances such as blood, body fluids, tissues, etc. of the patient, e.g. invasive procedures like urinary catheterization, surgical procedures, etc.

c) Gowns / Aprons: These are used whenever contact with blood or body fluid is a possibility as in the operation theatres or other invasive procedures. A non-permeable plastic gown may be necessary in addition to the absorbent gown where huge blood spills are anticipated. Gowns / Aprons should be changed in between two patients or when visibly soaked with blood or body fluids. Donning of surgical gowns for the entry into ICU as a routine is not required.

d) Masks: Face masks are to be worn in operation theatre and in wards / rooms with patients suffering from respiratory tract infections, as in the case of patients with pulmonary tubercu losis or whose respiratory or oropharyngeal secretions are infective.

e) Cap: Mostly used in operation theatres by HCW to protect the patient from being infected.

f) Eye shield: To be worn by the HCW when anticipating a blood or body fluid spill. eg. Dental surgeons during manipula tions in the oral cavity.

Transmission based precautions

These are indicated when standard precautions alone would not suffice for control of the spread of infectious agents.

Airborne precautions:

Airborne infection isolation rooms (AIIRs)

Use of special air handling and ventilation systems is required to contain the spread of airborne infectious agents such as M. tuberculosis, spores of certain fungi, varicella virus etc. from patients that can remain viable over a period of time and distance in the air. Patients should preferably be kept in single isolation rooms under negative pressure and instructed to use disposable face masks while coughing or sneezing. HCWs should use higher level respirator 5masks while entering rooms of patients with highly infectious and virulent pathogens like severe acute respiratory syndrome (SARS), corona virus, H1N1 influenza virus, viral agents of hemorrhagic fevers like Ebola virus. Positive pressure ventilation,

directed room airflow, HEPA filtration of incoming air are some of the measures advocated for patients who have undergone hematopoietic stem cell transplant.

Contact precautions: Indicated for prevention of transmission of infectious agents spread by direct or indirect contact.

Methods

1. Cohorting of patients

2. Maintaining the minimum distance of 3 feet between adjacent patients.

3. Appropriate stringent disinfection of floor and material including the frequent contact points like bed railings, table, toilet, etc

Urinary Tract Infections (UTIs)

Catheter associated UTI (CA-UTI) are the most common type of HAI, UTI are considered as CA- UTI if the patient had an indwelling catheter at the time of or within 48 hours of onset of the event. Approximately 95% of U.T.I in hospitals is catheter associated. The proximity of the urethral meatus to the anal sphincter in females, the passage of the catheter through a natural orifice and location in the bladder, deposition of Tamm-Horsfall proteins around the catheter facilitate the adherence of uro-pathogens and initiation of infection. Some of the important risk factors for CA- UTI are:

- Female patienta
- Prolonged catheterization
- Diabetes mellitus
- Severe underlying diseases
- Elderly patient
- Poor catheter care

Prevention of CA-UTI6

- Aseptic technique of catheterization
- Proper care of the catheter and collection bag
- Use of the narrowest size of catheter as possible
- Ensuring dependent drainage
- Minimizing the duration of catheterization

Use of closed drainage system

Use of silver impregnated or antibiotic catheter as indicated by the duration and risk.

Use of condom catheters in male

Use of systemic antimicrobials

Blood Stream Infections (BSIs)

Vascular catheterization has become an inevitable procedure as a part of patient care particularly in ICUs and is a known risk factor for catheter associated blood stream infections (CA-BSIs). CA-BSI is defined as bacteremia or fungaemia in a patient who has an intravascular device and a positive result of culture of blood samples obtained from peripheral vein with clinical features of infection and no apparent source of infection except the catheter.

Risk factors for CA- BSI

Severe underlying illness

Loss of skin integrity

Plastic catheters

Central catheters

Prolonged catheterization

Inadequate care of catheter site

Common agents of (CA- BSI)

Coagulase negative staphylococci

S.aureus

Candida sp.

Enterococcus sp.

Pseudomonas aeruginosa 7

Serratiamarcescens

Prevention

Hand hygiene plays an important role. Hand washing before and after insertion and subsequent contacts with the insertion site.

Use of 2% chlorhexidine as skin disinfectant

Strict aseptic practices

Avoiding unnecessary manipulations

Proper education and training of HCWs involved in the care of such points.

Use of subclavian site rather than jugular or femoral site in adults for non-tunneled central venous catheter placement.

Use of jugular or femoral veins for hemodialysis and pheresis.

Use of upper extremity instead of lower extremity for peripheral vein and midline catheter insertion.

Use of antimicrobial impregnated catheters viz. chlorhexidine silver sulphadiazine impregnated catheters and/or minocycline - rifampin impregnated catheters, reduces the risk of CA-BSI by nearly 40%

Prophylactic use of anticoagulants reduces the occurrence of thrombosis at the site of catheter insertion which serve as a nidus for colonization with microbes.

'Bundle approach' includes the simultaneous application of selected interventions when applied together drastically reduce the CA-BSI. The essential components include:

1. Hand washing
2. Full barrier precautions
3. Preparation of the skin with antiseptic like chlorhexidine
4. Avoiding femoral site if possible.
5. Removal of catheter as early as possible.

Surgical Site Infections (SSIs)

Surgical site infections constitute about 20% of HAI. SSI is defined as infection of the surgical site that occurs within 30 days of the surgical procedure or within one year of an 8 implant or foreign body such as prosthetic heart valve or joint prosthesis. Most of the S.S.I results from contamination of the surgical wound with patient's own flora or that of the H.C.W. or the environment in the operating room. Infection may manifest during hospitalization or after discharge. The common clinical features of SSIs are localized pain, redness and discharge. Most common bacterial agents of SSI are S.aureus,Esch.coli, Klebsiella, Proteus sp. Pseudomonas sp. Drug resistant pathogens like MRSA and ESBL producing Gram negative bacilli have become more common. Outbreaks have occurred following use of contaminated adhesive dressings. Elastic bandages, contaminated antiseptic lotion SSI can be superficial, deep or organ or space involving any organ or space.

Risk factors

- Very old or very young age
- Poor nutritional status
- Uncontrolled diabetes
- Smoking
- Use of steroids
- Obesity
- Co-existing morbidity
- Colonization of carrier
- Prolonged preoperative stay
- Preoperative shaving within 24 hours of surgery

Prevention

Strict hand hygiene measures and use of proper surgical attire.
Use of appropriate antimicrobial depending on the site and type of surgery
Cefazolin provides adequate coverage for most clean contaminated wounds
Cefoxitin is preferred for surgery on distal intestinal tract
Aztreonam is a suitable alternative for cephalosporin
Metronidazole or clindamycin should also be added for coverage of anaerobes
Maintenance of positive pressure in the operating rooms
Use of high-efficiency particulate air (HEPA) filters
Optimum room temperature of 20° to 22°C
Uni-directional air flow
Use of appropriate drains
Debridement of devitalized tissues
Effective haemostasis
Adequate post-operative care
Periodic surveillance of operation suites

Hospital acquired pneumonia (HAP)

Pneumonia is the second most common HAI and it carries a high morbidity and mortality. Ventilator associated pneumonia (VAP) is the specific type of HAP that occurs 48 hrs after initiation of mechanical ventilation. The most important risk factor for HAP is prolonged

mechanical ventilation. Other risk factors include:

Prolonged administration of broad spectrum antimicrobials
Underlying chronic lung disease
Insertion of nasogastric tube
Surgical procedures involving head, neck, thorax
Co-morbidities

The first step in the pathogenesis of HAP is colonization of oropharynx with resistant pathogens and subsequent translocation to the lower respiratory tract. Most of the HAPs are of bacterial origin. Early onset HAP is usually caused by antimicrobial sensitive pathogens while late onset HAP is usually caused by multidrug resistant pathogens such as Pseudomonas species, Acinetobacter species, and Staphylococcus aureus. About 40% are polymicrobial.

Prevention:

Selective decontamination of digestive tract (SDD) by local administration of antimicrobial agents as polymyxin / colistin, aminoglycosides, quinolones coupled with amphotericin B or nystatin prevents colonization of oropharynx with potential pathogens.

Frequent mouth wash preferably with an antiseptic and brushing of teeth
Semi recumbent position unless contraindicated
Enteral feeding as soon as the patient's condition permits
Appropriate care of devices used in mechanical ventilation
Avoidance of invasive ventilation where feasible
Use of silver coated endotracheal (ET) tubes
Use of orotracheal or orogastric tubes in preference to nasogastric tube
Avoidance of prolonged nasal intubation
Avoidance of frequent re-intubation

Bundle approach to prevention of VAP

Ventilator bundle is defined as a group of preventive interventions that when executed together result in a better outcome than when implemented individually. The four components of the bundle are

1. Elevation of the head end of the bed by 30 - 45 °.
2. Prophylaxis for deep venous thrombosis and peptic ulcer disease.
3. Daily interruption of sedation
4. Daily assessment of feasibility to extubate.

Prompt and appropriate use of antibiotics improves the outcome of VAP; monotherapy may be used in patients with no risk factor for multi-drug resistant (MDR) pathogens, and infections caused by Gram positive bacteria. Combination therapy is to be preferred for Gram negative pathogens and in the presence of risks factors for MDR pathogens.

Prevention of Infection in immuno-compromised (IC) hosts & special situations

Burns wound infections

Isolation in single rooms with filtered air at positive pressure into rooms with exhaust to exterior.

Stringent hand hygiene measures
Donning of appropriate PPE
Scrupulous environmental cleanliness
Prohibiting HCW with skin or throat infections

Dermatology wards

Isolation of patients with sepsis
Isolation of patients with desquamating lesions
Exhaust ventilation in dressing rooms

Dialysis units

Patients are at increased risk of blood borne pathogens
Dialysis fluid carries high risk of bacterial contamination
All patients should be screened for HIV, HBV, and HCV
Standard precautions to be followed during dialysis
Subcutaneousarteriovenous (AV) fistulae to be preferred.
Strict aseptic techniques and environmental disinfection.

Transplant recipients

Screening of patients for various infections before and after transplantation

Appropriate antimicrobial prophylaxis

Standard precautions especially hand washing
Use of well cooked food
Avoiding formation of water aerosols

Immuno compromised patients

I.C patients are at an increased risk of acquiring variety of infections due to impaired humoral and cellular immunity

Prophylactic antimicrobials to be administrated as indicated.
Standard precautions to be practiced
Maintaining environmental hygiene.

Laboratory acquired infections

Laboratory personnel are at an increased risk for? infections due to frequent handling of potentially infectious specimens both by direct contact, inhalation of aerosols or injuries with sharps and spills.
Provide training and education about safety measures to be practiced by the laboratory staff
Covering of open wounds with sterile dressing
Use of PPE like gloves, mask as indicated
Prophylactic vaccination for Hepatitis B
Post exposure prophylaxis for HBV and HIV as indicated
Hand hygiene
Use of appropriate safety cabinets
Proper exhaust ventilation

Biomedical Waste Management

Hospital infection control is also dependent on proper segregation, disinfection and disposal of all biomedical waste generated in the health care setting. Inappropriate management of the hospital waste is a potential threat to the patients, HCW and the community at large. Every institution should formulate a policy for safe disposal of hospital waste. Colour coded bins for each category of waste is to be provided at all points of waste generation. All infectious sharps should be disinfected at the point of generation before discarding into the bins. Appropriate PPE like leather gloves (for handling sharps), masks, gowns. etc. should be worn by the HCW. Plastic and rubber material should not be incinerated. All categories

of waste should be disposed as per the standard protocols and guidelines issued by the health authorities. Disposable items should not be reused.

Purpose of surveillance of nosocomial infections

"Good surveillance does not necessarily ensure the making of the right decisions, but it reduces the chances of wrong ones"

Alexander. D. Langmuir

The purpose of surveillance of nosocomial infections is to reduce the incidence of HAI and thus to reduce the associated morbidity, mortality, and costs. Before beginning surveillance activities it is essential to develop a clear plan. It should address

1) What questions are being asked
2) How infections are to be defined
3) How the data are to be collected, stored, retrieved, summarized and interpreted
4) How to feed the results back to frontline practitioners
5) How to use the information to bring about change

Prevention of nosocomial infections is the responsibility of all individuals and services providing health care. Everyone must work cooperatively to reduce the risk of infection for patients and staff.

A yearly work plan to assess and promote good health care, appropriate isolation, sterilization, and other practices, staff training, and epidemiological surveillance should be developed.

An Infection Control Committee should include wide representation from relevant departments viz. management, physicians, other health care workers, clinical microbiology, pharmacy, central supply, maintenance, housekeeping, training services.

Minimal Requirements for Surveillance

1. Monitor infection patterns (sites, pathogens, risk factors, location within the facility)
2. Detect changes in the patterns that may indicate an infection problem

3. Direct the rapid implementation of control measures
4. Monitor antibiotic use and resistance
5. Provide the staff with exactly the information they need in order to improve infection prevention practices

Operating theatres

Modern operating rooms which meet current air standards are virtually free of particles larger than 0.5 ?m (including bacteria) when no people are in the room. Activity of operating room personnel is the main source of airborne bacteria, which originate primarily from the skin of individuals in the room. The number of airborne bacteria depends on eight factors.

1. Type of surgery
2. Quality of air provided
3. Rate of air exchange
4. Number of persons present in operating theatre
5. Movement of operating room personnel
6. Level of compliance with infection control practices
7. Quality of staff clothing
8. Quality of cleaning process

Conventional operating rooms are ventilated with 20 to 25 changes per hour of high-efficiency filtered air delivered in a vertical flow. High-efficiency particulate air (HEPA) systems remove bacteria larger than 0.5 to 5 ?m in diameter and are used to obtain downstream bacteria-free air. The operating room is usually under positive pressure relative to the surrounding corridors, to minimize inflow of air into the room.

For operating theatres, a unidirectional clean airflow system with a minimum size of 9 m2 (3 m x 3 m) and with an air speed of at least 0.25 m/s protects the operating field and the instrument table. This ensures instrument sterility throughout the procedure. It is possible to reduce the costs of building and maintaining operating theatres by positioning such systems in an open space with several operating teams working together. This is particularly adapted to high-risk surgery such as orthopedics, vascular surgery, or neurosurgery

Need for an infection control programme

To develop and continually update guidelines for recommended health care surveillance, prevention, and practice

Develop a system to monitor selected infections and assess the effectiveness of interventions

Harmonize initial and continuing training programmes for health care professionals

Facilitate access to materials and products essential for hygiene and safety

Encourage health care establishments to monitor health-care associated (nosocomial) infections and to provide feedback to the professionals concerned

Infection control programme

The important components of the infection control programme are:

Basic measures for infection control, i.e. standard and additional precautions

Education and training of health care workers

Protection of health care workers, e.g. immunization

Identification of hazards and minimizing risks

Routine practices? essential to infection control such as aseptic techniques, use of single use devices, reprocessing of instruments and equipment, antibiotic usage, management of blood/body fluid exposure, handling and use of blood and blood products, sound management of medical waste; effective work practices and procedures, such as environmental management practices including management of hospital/ clinical waste, support services (e.g., food, linen), use of:

Therapeutic devices

Surveillance

Incident monitoring

Outbreak investigation

Infection control in specific situations

Research.

In addition to implementing basic measures for infection control,

health care facilities should prioritize their infection control needs and design their programmes accordingly.

Organization of an infection control programme

As with all other functions of a health care facility, the ultimate responsibility for prevention and control of infection rests with the health administrator.

The hospital administrator/head of hospital should:

Establish an infection control committee which will in turn appoint an infection control team; and provide adequate resources for effective functioning of the infection control programme.

Infection control committee

An infection control committee provides a forum for multidisciplinary input and cooperation, and information sharing.

The infection control committee is responsible for the development of policies for the prevention and control of infection and to oversee the implementation of the infection control programme. It should:

Comprise of representatives of various units within the? hospital that have roles to play (medical, nursing, engineering, housekeeping, administrative, pharmacy, sterilizing service and microbiology departments);

Elect one member of the committee as the chairperson (who? should have direct access to the head of the hospital administration);

Appoint an infection control practitioner (health care? worker trained in the principles and practices of infection control, e.g. a physician, microbiologist or registered nurse) as secretary.

Meet regularly. (Ideally monthly, but not less than three times a year)

Develop its own infection control manual(s)

Monitor and evaluate the performance of the infection control programme

The committee must have a reporting relationship directly to either

administration or the medical staff to promote programme visibility and effectiveness

In an emergency (such as an outbreak), this committee must be able to meet promptly.

It has the following tasks:

To review and approve a yearly programme of activity for surveillance and prevention;

To review epidemiological surveillance data and identify areas for intervention;

To assess and promote improved practice at all levels of the health facility;

To ensure appropriate staff training in infection control and safety management, provision of safety materials such as personal protective equipment and products; and

Training of health workers.

Infection control team

The infection control team is responsible for the day-to-day activities of the infection control programme. Health care establishments must have access to specialists in infection control, epidemiology, and infectious disease, including physicians and infection control practitioners; the infection control team has appropriate authority to manage an effective infection control programme. The infection control team is responsible for the day-to-day functions of infection control, as well as preparing the yearly work plan for review by the infection control committee and administration.

These teams have a scientific and technical support role, e.g. surveillance and research, developing and assessing policies and practical supervision, evaluation of material and products, the overseeing of sterilization and disinfection, ensuring sound management of medical waste and the implementation of training programmes.

The infection control team should:

Consist of at least an infection control practitioner who should be trained for the purpose;

Carry out the surveillance programme

Develop and disseminate infection control policies

Monitor and manage critical incidents

Coordinate and conduct training activities

Recommended HIV Post-Exposure Prophylaxis for Percutaneous lnjuries

	Infection Status of Source				
\Exposure Type	HIV-Positive Class 1-	HIV-Positive Class 2'	Source of Unknown HIV Status"	Unknown Sources-	HIV Negative
Less severed	Recom-mend basic 2-drug PEP	Recom-mend expanded ~3-drug PEP	Generally, no PEP warranted; however, consider basic 2-d rug PEP" for source with HIV risk factors'	Generally, no PEP warranted; however, consider basic 2-drug PEP" in settings in which exposure to HIV-infected persons is likely	No PEP warranted
More severe	Recom-mend expanded 3-drug PEP	Recom-mend expanded ~3-drug PEP	Generally, no PEP warranted; however, consider basic 2-d rug PEP" for source with HIV risk factors'	Generally, no PEP warranted; however, consider basic 2-drug PEP" in settings in which exposure to HIV-infected	No PEP warranted

Recommended HIV Post-Exposure Prophylaxis for Mucous Membrane Exposures and Non-Intact SkinExposures

\Exposure Type	Infection Status of Source				
	HIV-Positive Class 1-	HIV-Positive Class 2'	Source of Unknown HIV Status"	Unknown Sources-	HIV Negative
Small volume	Consider Basic 2-drug PEP	Recommend basic 2-drug PEP	Generally, no PEP warranted	Generally, no PEP warranted	No PEP warranted
Large volume	Recom-mend basic 2-drug PEP	Recommend expanded .<::3-drug PEP	Generally, no PEP warranted; however, consider basic 2-drug PEP' for source with HIV risk factors!	Generally, no PEP warranted;however, consider basic 2-drug PEP in settings in which exposure to HIV-infected persons is likely	No PEP warranted

Recommended post - Exposure prophylaxis for exposure to Hepatitis B virus

Vaccination and Anti-body Response Status of Exposed Worker	Treatment		
	Source HBsAgb Positive	Source HBsAgb	Negative Source Unknown or not Available for Testing
Unvaccinated	HBIGx 1 and initiate HB vaccine series	Initiate HB vaccine series	Initiate HB vaccine series

Previously vaccinated

Known responder	No treatment	No treatment	No treatment
Known non-responder	HBIG x 1 and initiate revaccination or HBIG x 2	No treatment	If known high-risk source, treat as if source were HBsAg positive
Antibody response unknown	Test exposed person for anti-Hbs If adequate: no treatment is necessary. If inadequate,' administer HBIG x 1 and vaccine booster	No treatment	Test exposed person for anti-Hbs. If adequate/ no treatment is necessary. If inadequate/ administer vaccine booster and recheck titre in 1-2 months

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SAFEGUARDING AGAINST MEDICO-LEGAL ISSUES

Sectional Editor
Shankar PS
Emeritus Professor of Medicine
KBN Institute of Medical Sciences
Gulbarga

Contents

Contributors

Ananda Reddy
Assistant Professor
Deparatment of Forensic Medicine,
Sri Manakula Vinayagar Medical College & Hospital
Puducherry-605107

Chandrashekar T N
Director, Chamarajanagar Institute of Medical Sciences,
Chamarajanagar
Formerly Professor and Head,
Department of Forensic Medicine,
Mysore Medical College and Research Institute, Mysore

Rajendra N Kagne
Professor and Head
Department of Forensic Medicine
Sri Manakula Vinayagar Medical College
Puducherry 605 107

Rajesh Sangram
Professor and Head,
Department of Forensic Medicine
Raichur Institute of Medical Scicnce
Raichur

PROFESSIONAL NEGLIGENCE (MALPRACTICE)

Rajesh Sangram

Doctor and Society

The responsibility of medical professional has grown due to rising demand from patients for medical help. Patients are better informed about their health and expect their doctors to make decisions with them and not for them.

A doctor is required to make decisions based on an unambiguous estimate of the problem. Patients approach the physician with their ailments, for which he has to provide a diagnosis and undertake treatment. This works well in practice. Often, clinical picture is ambiguous, making it difficult for physician to reach a definitive conclusion. In such a situation, the possibility of a mistake is real and is a common professional hazard. Rather than accepting the ambiguity of certain clinical situations and explaining it to patient, doctors are often pressurised to make a definitive decision in unclear circumstances, situations, which actually demands a probabilistic inference due to incomplete and fragmentary nature of information. They are often discussed in terms of clinical certainty, forcing errors.

No human being is infallible, and in the present state of science even the specialist may be at fault in detecting the true nature of the disease. A practitioner can only be held liable in this respect if diagnosis is so palpably wrong as to prove negligence, i.e., if his mistake is of such a nature as to imply an absence of reasonable skill and care on his part. Reasonable skill is equated with ordinary or average level of skill in the profession.

In medico-legal cases, however, part of the problem lies in the legal connotation of the word "negligence". The failure of a doctor and

hospital to discharge their obligation is a civil wrong, called tort in law, a breach of which attracts judicial intervention by way of awarding damages.

Protection to Doctors

In this era of commercialization of the profession, pontifications about "noble" profession and "sacred" doctor-patient relationship bring under the IPC to doctors for acts which may result in death or hurt for acts done in "good faith". However, "good faith" has been defined in section 52 with "due care and attention".

Medical malpractice is not merely the negligence on the part of the care giver; a conscious decision of the care giver; to offer and/ or force a product, procedure or investigation upon a patient for monetary gain either personally or for the institution comes under the definition under 'malpractice'.

There could always be deficiency of service inherent in every profession and the nature and extent of deficiency or efficiency is governed by the circumstances, qualifications and experience of the dispensing professional as well as the availability of gadgets and convenience at hand to the attending doctor.

The court has observed that the service which medical profession renders is probably the noblest of all and hence there is a need to protect doctors from unjust prosecution. Even a minor lapse on the part of doctor is blown out of proportion, canceling out the enormous amount of good work the doctor might have done silently. Looking at the component of negligence-of-duty and resulting damage, the court has repeatedly observed that it is not necessary for every professional to possess the highest level of expertise in that branch which he practices. In an acceptable standard of conduct; the competence is to be judged by the lowest standard that would be regarded as acceptable. The court has observed that the standard is that of the reasonable average and the law does not require of a professional man that he be a paragon combining the qualities of polymath and prophet.

Bolam test

The classical statement of law in Bolam case (1957) has been widely accepted as decisive of the standard of care required both of

professional men generally and medical practitioners in particular and holds good in its applicability in India.

A medical professional to be prosecuted for negligence under criminal law, there should be evidence that he did something or failed to do something, which a medical professional, "in his ordinary senses and prudence would have done or failed to do". The apex court has observed that "a simple lack of care, an error of judgment or an accident is no proof of negligence". A private complaint against a doctor will be entertained only if the complainant is able to furnish prima facie evidence before the court.

Civil cases of negligence

Civil cases pertain to disputes between two or more persons regarding wrong or inadequate treatment, wrong diagnosis and failure to keep professional secrecy. When a patient sues a doctor in civil courts it is mainly for compensation.

- Due to the injury or death of the patient or as the case may be, caused because of the negligence of the doctor, Or
- When a doctor files a civil suit for realization of his professional fees from the patient or his relatives who refuse the same on the grounds of malpractice.

Examples of civil negligence:

- Unnecessary treatment
- Wrong diagnosis
- Prolonged treatment
- Duty(to warn in possible side-effects) not discharged
- Treatment leading to further complications

A 'causation' means "to bring about". In order to obtain compensation in a case of medical negligence, it is not sufficient to prove that negligence has occurred, but also that the negligence was the cause of the damage. The more proximate the causation (proximate cause) to the damage, the greater is the chance of succeeding in a claim for compensation. The more remote the causation (remote cause), the lesser

is the chance of success in getting compensation.

In order to succeed in a medical negligence case, the claimant must prove, on a balance of probabilities, that the doctor's breach if duty to care, i.e., negligence, caused the damage, and he has to show that:

- The damage would not have occurred, but for the doctor's negligence or
- The doctor's negligence materially contributed to, or materially increased the risk of injury.
- Further, if the claim is that the doctor failed to disclose the risk involved in the treatment or surgery, and the risk actually occur, the claimant can raise a plea that had such risk been disclosed he would not have agreed to such treatment or surgery.

The great problem of alleged medical negligence lies in the continuum of 'standard of care' between actions that are accepted medical practice and those that constitute a l ack of care. At the junction of these two extremes is a grey area of debatable clinical judgment where some doctors would act in one way where as others would act, quite legitimately, in a different way.

Claimants(patients) in clinical negligence actions have to demonstrate first that they owed a duty of care by their health care provider, second that there was a breach of the duty, and third, that they suffered harm as a result.

- Inadequate notes, lost records, failing or muddled memories may all lead to an inability to rebut the claimant's case.
- Keeping up-to-date is another important and related issue.
- Unless basic systems are in place to deal with patient referral, follow up, completion of clinical records, clinical correspondence, reviewing test results and acting appropriately on abnormalities, all sorts of things can and do go wrong with potentially catastrophic effects for patients.

- Operation without consent
- Issuing wrong certificates or reports.

It is important to note that 'damage' in the sense of injury or harm, is quite different from 'damages', which is the financial compensation awarded to a successful litigant (here it is a patient's side).

There is also the problem in putting a proper definition for error, as an acceptable description is yet to be evolved.

What the court says:

Supreme Court held that the Damocles' sword of criminal prosecution should not be hanging constantly over medical practitioner's head by making them liable for every instance of negligence.

- A simple lack of care, error of judgment or accident is not a negligence
- Error must be gross in nature
- Doctor can't be arrested in routine manner
- Complaint won't be entertained when there is credible opinion from another competent doctor, preferably from Government doctor in that branch of medicine.

A Doctor can be prosecuted for causing death due to 'rash and negligent act' (304A) if his patient dies, but the doctor cannot be prosecuted for 'culpable homicide not amounting to murder' (304) IPC, which entails a higher punishment. While punishment for rash and negligence act is two years, a life sentence can be imposed for an offence under culpable homicide not amounting to murder.

Criminal cases of negligence

Criminal cases are related to violation of laws. In such cases, the guilty doctor is awarded with a punishment. It may be fine, imprisonment or even death sentence. In case of serious injury, the doctor may be charged under various sections of IPC;

- Section 304A of IPC: causing death of any person by doing

any rash or negligent act which does not amount to culpable homicide, which is punishable with imprisonment for a term which may extend to 2 years.

- Section 336 of IPC: rash or negligent act endangering human life.
- Section 337 of IPC: causing hurt to any person by doing any rash or negligent act as would endanger human life.
- Section 338 of IPC: causing grievous hurt to any person by doing any rash or negligent act so as to endanger human life.

Examples of criminal negligence

- Injecting anesthetic in a fatal dosage or into wrong tissues.
- Transfusing wrong blood.
- Performing a criminal abortion.
- Leaving instruments or sponges inside the part of the body operated upon.
- Operation on wrong patient or wrong part

There are many loopholes, variations and deficiencies in the knowledge and outcome of a treatment. It is unwise to expect that everything will go well in medicine according to the plan in every case. It is also true that the knowledge in medicine and its application is advancing so fast that every doctor cannot be an expert and be expected to offer the best expertise in every situation.

Medicine is a highly codified body of knowledge and procedures of treatment are meticulously standardized. With this level of procedural consistency, the profession cannot claim that the law does not have the expertise to evaluate its performance. The evaluation consists only in seeing whether the doctor in the dock has gone by the book. The law is as competent to rule on a medical case as in the case of financial irregularity. Most malpractice cases are self-evident anyway, and the principle of res ipsa loquitor (literally, the issue shall speak for itself) may safely be applied. It is usually a case of a surgical oversight- the ubiquitous forceps problem- or the maladministration of anaesthesia. The law does not need technical skills to come to adequately comprehend such matters.

Elements of negligence

The necessary elements of an action founded on negligence are held to be;

- A duty or obligation recognized by law requiring the person to conform to a certain standard of conduct for the profession of others against unreasonable acts.
- A failure on the part of the defendant (doctor) to conform to the standard required.
- A reasonable close casual correction between the conduct and the resulting injury.
- Actual loss or damage resulting to the plaintiff (patient).

Right to life

The only way to resolve the problem of whether an act is truly negligent is by 'peer judgment' and this is the means by which most medical disputes are settled. The facts of the case are placed before experts in that particular specialty and their views sought. It is sufficient in this context to show only that a substantial number of doctors agree with the actions of the defendant (here it is a doctor's side); there is no need for unanimity of either condemnation or support.